Investigation of Olympus TJF-Q180V Scopes at UMC Utrecht regarding contamination found after cleaning and disinfection

Reporting, Conclusions and Suggestions

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Investigation of Olympus TJF-Q180V Scopes at UMC Utrecht

regarding contamination found after cleaning and disinfection

(working title: Investigation of UMC Utrecht ERCP scopes)

Reporting, Conclusions and Suggestions

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1 Background – Contamination 'Scope 170485' and 'Scope 179505'

In 2015, a multi-resistant Klebsiella pneumonia bacteria ("MR Klebsiella") was found in two Olympus video duodenoscopes of the type TJF-Q180V in the Utrecht University Medical Center ("UMC Utrecht") after the culturing of flush samples (sterile physiological saline), which were sent through the suction and biopsy channels. The MDR Klebsiella found in the two scopes were indistinguishable after molecular typing and are therefore considered identical. The MR Klebsiella persisted in both scopes after manual pre-cleaning, manual cleaning and machine cleaning and disinfection in Olympus ETD3 scope disinfection machines. UMC Utrecht took the scopes out of service as of August 13, 2015.

For convenience, the two contaminated scopes are referred to as '*Scope A*' and '*Scope B*' in this report. The identification characteristics of these scopes are listed in Table 1.1.

Table 1.1: Details of contaminated Olympus video duodenoscopes.

Working name	**Olympus Type**	**Olympus serial number**	**UMC Utrecht inventory no.**	**Purchase date**	**Suspected contamination since**
Scope A	TJF-Q180V	2101841	170485	for 16-SEP-2011	13-JAN-2015
Scope B	TJF-Q180V	2304233	179505	for 16-SEP-2013	15-JUN-2015

To try to find the cause of the persistence of the MR Klebsiella, it was decided to examine scope A and scope B via various sampling and disassembly steps, and then perform microbiological and viral testing (in its entirety "*the investigation*").

Olympus Netherlands and the UMC Utrecht together have decided upon and implemented the investigation into the contamination of scope A and scope B. On December 15 and 16 of 2015, a research team (from here "the research team"), consisting of representatives from the UMC Utrecht and Olympus, as well as an independent expert from the Technical University of Delft ("TU Delft"), performed "*the investigation*" at the UMC Utrecht, Heidelberglaan 100, Utrecht, The Netherlands, and at Olympus Nederland B.V., Industrieweg 44, Zoeterwoude, The Netherlands. Observers and support staff from various parties (further specified in chapters 4 and 6) also attended *the investigation*.

2 Purpose and structure of the investigation and this report

The purpose of this report is to reach an objective determination of the cause/causes of the persistence of the multidrug-resistant Klebsiella pneumoniae bacteria in Scope A and Scope B.

To this end, a factual report, including photos and registration/result lists, of the preliminary discussion and execution of *the investigation* is provided first. As a result of the findings from *the investigation*, an opinion was formulated by the independent expert from the TU Delft regarding the possible causes of the persistence of the MR Klebsiella in Scope A and Scope B.

In this report, we refer to sample reference numbers by {00}, in which "00" is the sample number. A list with the description and result of the sample analysis is included in Appendix C.

The investigation is an attempt to identify whether the persistence of the bacteria is caused by:

- incorrect or incomplete performance of cleaning and disinfection guidelines,
- incorrect or incomplete formulation of the cleaning and disinfection guidelines,
- damage or construction defects affecting the endoscopes, or
- other causes.

The investigation was carried out in two parts:

Substudy I - 'Supervised cleaning' was carried out on day one in the UMC Utrecht, in order to start the investigation with scopes that were cleaned and disinfected strictly in accordance with the Olympus guidelines. Both scopes were subjected to the following steps in turn:

- sampling of channels and tip again,
- flow-through test of the channels for suction, water, and air,
- manual pre-cleaning in the scope room in accordance with Olympus' instructions,
- manual cleaning in the cleaning and disinfection room in accordance with Olympus' instructions,
- machine cleaning and disinfection with an Olympus ETD3 scope disinfection machine (serial number 8120237, inventory number 158945) in the Gastroenterology and Hepatology Department of the UMC Utrecht,
- drying in the Van Vliet GV 700 drying cabinet (serial number 709004, inventory number 161267) at the UMC Utrecht,
- package in sterile bags and seal for transport to Olympus Nederland B.V. in Zoeterwoude for the second part of the investigation.

All steps were recorded, in writing, on photos and video, by the independent expert from the TU Delft.

Substudy II - 'Dismantling' was performed on day two at Olympus Nederland B.V. in Zoeterwoude, to determine the underlying factors of the persistence in the design and/or status of the scopes. Both scopes were subjected to the following steps in turn:

- removal from sealed packaging,
- meticulous visual inspection of external parts and channels,
- dry sampling of accessible, relevant, external parts and channels for microbiological tests,
- dismantling from outside in, whereby the components were always treated as follows:
    - external visual inspection,
    - external sampling,
    - disinfection with 70% ethanol,
    - dismantling,
    - sampling of areas freed up by dismantling,
    - packaging in sterile or clean bags or containers for further examination.

All steps were recorded, in writing, on photos and video, by the independent expert from the TU Delft.

3 Disclaimer

Photos used in this report have been visually color-corrected by an experienced photographer for deviations from varying light sources and the use of various cameras. (Overview photos and macro photos were made using a Nikon D800 and borescope photos with borescope used.) However, this does mean that colors may still differ from the actual colors as they would be observed in daylight or under daylight lamps. Variations may be increased due to differences in color representation by different monitors, printers or paper types. Photos may be cropped to remove irrelevant parts from the image. Photos have not been retouched in any way.

Conclusions on observations must in no way be based on color nuances or specific, characteristic, absolute color values on the basis of the photos used.

The conclusions, assessments and suggestions as indicated in Chapter 9 - "Opinion of independent expert" are conclusions, assessments and suggestions based on the events observed during *the investigation*, the knowledge and experience of the independent expert from the TU Delft, Dr. Arjo J. Loeve, and confidential consultation of this independent expert with experienced colleague researchers and the department head Dr. Jenny Dankelman from the BioMechanical Engineering department at the Technical University of Delft, faculty 3mE.

Therefore, conclusions, assessments and suggestions in Chapter 9 "Opinion of independent expert", must be seen as substantiated expert opinions by the independent expert, but in no way as the formal standpoint of the Technical University of Delft or as the opinion of one of the other parties.

The suggestions as provided in Chapter 9 - "Opinion of the independent expert" must be read as stand-alone options to prevent individual potential risk factors and causes in the future. These suggestions are made in an attempt to be able to rule out as many potential causes as possible if this type of case should unexpectedly arise in the future, and so-doing, simplify the search for the causes.

These suggestions therefore should not per se be read as solutions that can be directly implemented in practice, because the formulation of these suggestions do not per se take into consideration the possible increase in design, manufacturing, purchasing, use and maintenance costs, complexities in the usage or cleaning of the scopes possible in the execution of these suggestions.

The names used in this report are used to refer to components of the scopes are not necessarily the same as names as used in the user field or within Olympus. A "seal" for example, can also be known as "bonding joint"/"Cement" or a "cap" as a "cover"/"sleeve"/"housing". This report uses consistent and uniform names to the greatest extent possible.

In case of ambiguity or doubt about which part is indicated with a certain name, please contact the author before attaching conclusions and/or consequences to this report.

4 Preliminary discussion report Substudy I - 'Supervised cleaning'

Part I of *the investigation* was carried out on Tuesday December 15, 2015 at the University Medical Center Utrecht, Heidelberglaan 100, Utrecht. At approximately 13:00 hours, *the research team* gathers there. It is made up of:

	Name	Code	Position	Organization
-	####	P1	Expert Infection prevention	UMC Utrecht
-	####	P2	Microbiologist	UMC Utrecht
-	####	P3	Disinfection staff	UMC Utrecht
-	####	P5	Expert Infection prevention	UMC Utrecht
-	####	P9	Service Engineer Flexible Instruments	Olympus NL B.V.
-	####	P10	Senior CDS Consultant	Olympus NL B.V.
-	####	P12	Researcher	ErasmusMC
-	Arjo Loeve	AL	Researcher BioMechanical Engineering	TU Delft

Names of individual employees of Olympus, UMC Utrecht and ErasmusMC are replaced by a letter code for privacy reasons.

The names of these persons are known to the author and the parties involved.

There is a discussion about the approach to *the investigation*:

1. P2 goes through the action plan with the research team (see appendix A).
2. The instructions from Olympus for cleaning and disinfection will be strictly adhered to for the entire duration of substudy I.
3. The cleaned, disinfected and dried scopes will each be packaged in sterile bags, placed in clean bags and stabilized in Olympus cases. The cases will then be sealed by wrapping with tape, which will thereafter be written on.
4. Sampling will be in duplicate, for Olympus and for UMC Utrecht.
5. The samples for Olympus will be analyzed by the Institute for Hygiene and Public Health, Bonn University, Germany. The results of the analyses will be provided in a timely manner to AL.
6. The samples for UMC Utrecht will be analyzed by UMC Utrecht. The results of the analyses will be provided in a timely manner to AL.

A number of issues regarding the instructions come up specifically:

- MC Senior Endoscopy Nurse, Gastroenterology-Hepatology department UMC Utrecht, will perform the manual cleaning of the scopes in the examination room.
- P3 will perform manual cleaning pursuant to the training checklist for cleaning and disinfection of Olympus TJF-Q180V scopes (see appendix B) and place the scopes in the ETD3.
- VK, disinfection staff at the Gastroenterology-Hepatology department UMC Utrecht, takes the scopes out of the ETD3 after the wash program is complete, places the scopes in a drying cabinet to dry, takes the scopes out of the drying cabinet after the drying time is up, and helps to package the scopes.
- AL will take care of reporting, take photo and video recordings for documentation, objectively and critically observe the process, and if necessary, give directions, and has the final authorization for making decisions about the investigation steps to be taken.
- P10 will perform the sampling and sampling storage for Olympus.
- P1 will perform the sampling and sampling storage for UMC Utrecht.
- P10 and P1 will assist each other in sampling.
- P9 will perform the flow tests on the scopes.
- P5 will not be present for any other part of substudy I.

5 Report Substudy II - 'Supervised cleaning'

13:54 hrs The research team is present in Scopy room 2.

13:58 hrs The fluid for the first cleaning is prepared by MC. At the request of P10, this water will not contain any cleansing agent.

14:08 hrs P9 explains how the flow tests will be performed. P1 reports that on Friday (December 11, 2015), the scope was again sampled by flushing the channels and then was not cleaned again.

5.1 Sampling and flow test Scope B

Entire Section 5.1 only concerns Scope B.

14:14 hrs **Scope B**was taken out of the case by P1 and laid on the scope table (or "trolley"). Start of sampling.

- Forceps elevator and space around it were sampled by P10 with a swab {distal end of endoscope 1}, camera and light surface were not sampled.
- Forceps elevator and space around it were sampled by P1 with a pernasal dry swab {1}, camera and light surface were not sampled.
- Suction and biopsy channel and part of the suction and biopsy channel were sampled by P10 by manual flush with injection syringe with approximately 30 ml of sterile physiological saline {suction/biopsy channel endoscope 1}. Forceps elevator is lowered here.
- Suction and biopsy channel and part of the suction and biopsy channel were sampled by P1 by manual flush with injection syringe with 2 x 10ml of sterile physiological saline {2}. Forceps elevator is lowered here.

Figure 1: (from left to right) Case with packaged Scope B; Scope B Serial Number; Scope B on the table.

Figure 2: (from left to right) Forceps elevator recess sampling using dry cotton swab; Olympus culture dish {distal end endoscope 1}; Forceps elevator recess sampling using pernasal dry swab; Storage of sample at UMC Utrecht {1}.

Figure 3: (from left to right) Sealing of the channels; Flushing of suction/biopsy channel; Detail of flushing of suction/biopsy channel; Collection of flush sample from suction/biopsy channel {2}.

14:49 hrs P10 attaches the hose set for the flushing of the water-air channel.

- Water- air channel was sampled by P10 by manual flush with injection syringe with approximately 30 ml of sterile physiological saline {air/water channel endoscope 1}. Forceps elevator is lowered here.
- Air-water channel were sampled by P1 by manual flush with injection syringe with 2 x 10ml of sterile physiological saline {3}. Forceps elevator is lowered here.

Figure 4: (from left to right) Instruction card for plugging water-air channel; Flushing water-air channel; Flushing water-air channel.

14:56 hrs P9 connects the scope tot he scope towers (Olympus Evis exera III P9-190, serial number 7552896 and Olympus Evis exera III CLV-190, serial number 7504940) and starts the flow measurements. Water flow was measured by flushing the scope for thirty seconds at the highest level and measuring how much water was collected from the tip in the container. Air flow rate is measured with a gas flow meter. Exhaust water flow rate is measured by suspending the scope tip in one liter of water and measuring how much water is removed from the container in 30 seconds. Below are the measured values:

- Water flow rate: 25ml in 30s = 50ml/min
- Air flow: 1600ml/min
- Exhaust water flow rate: 650ml in 30s = 1300ml/min

Olympus indicates that these meet the Olympus standards, but does not want to reveal what these standards are.

Figure 5: (from left to right) Light source used; Collecting water from water flow rate measurement; Flushed water after 30 seconds.

Figure 6: (from left to right) Air flow measurement; Start volume of exhaust water flow rate; Timer with end measurement of exhaust water flow rate; Remaining water volume after 30 seconds of suction.

15:00 hrs **Scope B** is placed in a clean transport container.

5.2 Sampling and flow test Scope A

Entire Section 5.2 only concerns Scope A.

15:00 hrs **Scope A** was taken out of the case by P1 and laid on the scope table. Start of sampling.

- Forceps elevator sampled by P10 with a swab {distal end endoscope 2}, camera and light surface were **also** sampled.
- Forceps elevator and space around it were sampled by P1 with a pernasal dry swab {4}, camera and light surface were **also** sampled.
- Suction and biopsy channel and part of the suction and biopsy channel were sampled by P10 by manual flush with injection syringe with approximately 30 ml of sterile physiological saline {suction/biopsy channel endoscope 2}. Forceps elevator is lowered here.
- Suction and biopsy channel and part of the suction and biopsy channel were sampled by P1 by manual flush with injection syringe with 2 x 10ml of sterile physiological saline {5}. Forceps elevator is lowered here.

Figure 7: (from left to right) Serial Number Scope A still in the case; Sampling of forceps elevator recess of Scope A using dry swab; Olympus culture dish [distal end Endoscope 2}.

Figure 8: (from left to right) Sampling forceps elevator recess using pernasal dry swab; Sealing of the channels; Flushing suction/biopsy channel; Storage of flush sample Olympus {suction/biopsy channel endoscope 2}.

Figure 9: (from left to right) Flushing of suction/biopsy channel; Detail of flushing of suction/biopsy channel with 10ml physiological saline; Collection of flush sample from suction/biopsy channel {5}.

P10 attaches the hose set for the flushing of the water-air channel.

- Water- air channel was sampled by P10 by manual flush with injection syringe with approximately 30 ml of sterile physiological saline {air/water channel endoscope 2}. Forceps elevator is lowered here.
- Air-water channel were sampled by P1 by manual flush with injection syringe with 2 x 10ml of sterile physiological saline {6}. Forceps elevator is lowered here.

Figure 10: (from left to right) Flushing water-air channel using 30ml physiological saline {air-water channel endoscope 2}; Scope A with tube set connected; Flushing of water-air channel using 10ml physiological saline {6}.

15:18 hrs P9 connects the scope tot he scope towers (Olympus Evis exera III P9-190, serial number 7552896 and Olympus Evis exera III CLV-190, serial number 7504940) and starts the flow measurements. Water flow was measured by flushing the scope for thirty seconds at the highest level and measuring how much water was collected from the tip in the container. Air flow rate is measured with a gas flow meter. Exhaust water flow rate is measured by suspending the scope tip in one liter of water and measuring how much water is removed from the container in 30 seconds. Below are the measured values:

- Water flow rate: 23ml in 30s = 46ml/min
- Air flow: 1600ml/min
- Exhaust water flow rate: 650ml in 30s = 1300ml/min

Olympus indicates that these meet the Olympus standards, but does not want to reveal what these standards are.

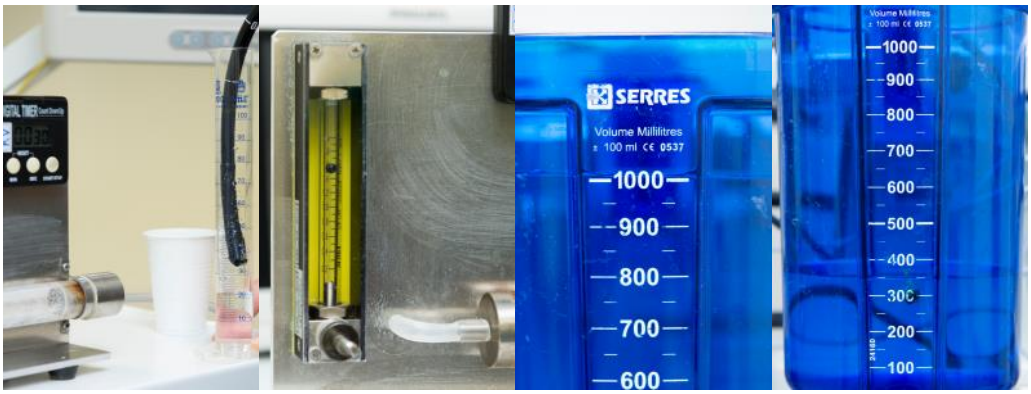


Figure 11: (from left to right) Water flow rate measurement after 30 seconds; Air flow measurement; Start volume of exhaust water flow rate; Remaining water volume after 30 seconds of suction.

15:24 hrs **Completion of flow measurements of Scope A.** Scope remains connected to tower.

5.3 Manual pre-cleaning of scope A

Entire Section 5.3 only concerns Scope A.

15:30 hrs Maney takes **scope A** from P9 and performs the cleaning steps which must be performed directly after use in the scope room:

- Wipes the insertion section of scope using wet gauze cloths.
- Places the forceps elevator in the lowest position.
- Aspirates water through the scope for 30 seconds and then air for 10 seconds.
- Raising and lowering the forceps elevator three times was forgotten here.
- Flushes air-water channel for 30 seconds with water and then for 10 seconds with air.
- Removes valves and supply tubes and removes the scope from the tower.

15:36 hrs MC puts **scope A** in a clean transport bin.

Figure 12: (from left to right) Wiping Scope A with gauze; Flushing Scope A with water; Aspirating Scope A with air; Scope A in the clean transport container.

5.4 Manual pre-cleaning of scope B

Entire Section 5.4 only concerns Scope B.

15:37 hrs MC takes **scope** B from the clean transport bin and performs the cleaning steps which must be performed directly after use in the scope room:

- Wipes the insertion section of scope using wet gauze cloths.
- Places the forceps elevator in the lowest position.
- Aspirates water through the scope for 30 seconds and then air for 10 seconds.
- Raises and lowers the forceps elevator three times during aspiration of water.
- Flushes air-water channel for 30 seconds with water and then for 10 seconds with air.
- Removes valves and supply tubes.

15:36 hrs MC puts **scope B** back in a clean transport bin. *The research team* moves to the cleaning and disinfection room of the GE&L department at the UMC Utrecht, taking Scope A and Scope B, each in their own containers.

5.5 Manual cleaning of scope A

Entire Section 5.5 only concerns Scope A.

15:51 hrs *The research team* is present in the cleaning and disinfection room. P3 joined them and starts the manual cleaning of **scope A**, assisted by P10 strictly according to the current Olympus instructions as listed in appendix B through step 3.12. This process is displayed chronologically below using photos. Some deviations and noteworthy facts occurred when following the steps from the checklist:

- **Step 1.4:** raising and lowering of the forceps elevator three times during aspiration was forgotten.
- **Step 1.7:** not applicable.
- **Step 2.2:** Scope A is immersed in water with a detergent at **16:01 hrs**
- **Step 3.1** UMC Utrecht uses "Dr. Weigert Neodisher MediClean Forte 0.5 – 3%" as detergent and not the detergent delivered by Olympus. P10 said that this may be incompatible with the cleaning with the EDT3 as another rinsing agent is used in the ETD3.
- **Step 3.6:** because the suction pump was not available, the channels were manually flushed with 400 ml of detergent by filling a 50 ml syringe 8 times.
- **Step 3.12:** aspirating the channels is not only done using water, but also air. Scope A is immersed in water with a detergent at **16:18 hrs**

16:23 hrs Manual pre-cleaning of Scope A has been completed. **Scope A** is placed in the ETD3.

Figure 13: (from left to right) Dr. Weigert Neodisher MediClean Forte 0.5 – 3% detergent; Scope A connected to the leak tester; Scope A submerged in water with detergent.

Figure 14: (from left to right) Wiping insertion tube; Brushing tip; Brushing suction/biopsy channel from control section side; Brushing suction/biopsy channel from connector side, brush emerges from the channel input by the connector.

Figure 15: (from left to right) Brush emerging from the tip when brushing suction/biopsy channel from control section side; Brushing channel inputs; Channels sealed by flushing adapters; manually aspirating detergent through suction/biopsy channel by flushing eight times using a 50ml syringe.

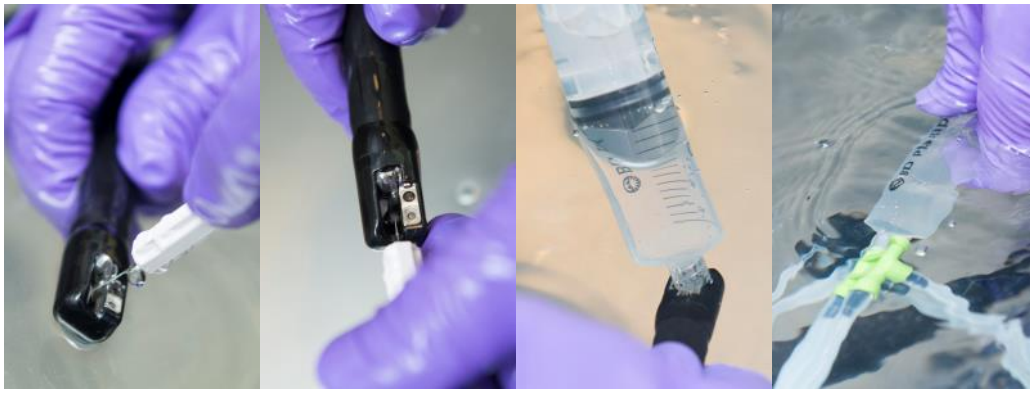


Figure 16: (from left to right) Brushing around forceps elevator using MAJ-1888 brush; Brushing under forceps elevator using MAJ-1888 brush; Flushing forceps elevator recess; Manually flushing air-water channels using three times 30ml.

Figure 17: (from left to right) Aspirating channels using water (3x30ml) and air; Scope A in the ETD3; Scope A in the ETD3 with the forceps elevator at 45 degrees; Scope A plugged at the connector in the ETD3.

Figure 18: Scope A connected to the control section side in the ETD3.

5.6 Manual cleaning of scope B

Entire Section 5.6 only concerns Scope B.

15:25 hrs P3 starts the manual cleaning of **Scope B**, assisted by P10 strictly following the current Olympus instructions as listed in appendix B through step 3.12. This process is displayed chronologically below using photos. Some deviations and noteworthy facts occurred when following the steps from the checklist:

- **Step 1.7:** not applicable.
- **Step 2.2:** Scope B is immersed in water with a detergent at **16:36 hrs**.
- **Step 3.1** UMC Utrecht uses "Dr. Weigert Neodisher MediClean Forte 0.5 – 3%" as detergent and not the detergent delivered by Olympus. P10 indicates that this may be incompatible with the cleaning with the EDT3 as another rinsing agent is used in the ETD3.
- **Step 3.6:** because the suction pump was not available, the channels were manually flushed with 400 ml of detergent by filling a 50 ml syringe 8 times.
- **Step 3.12:** aspirating the channels is not only done using water, but also air. Scope B is removed from the water with detergent at **16:44 hrs**

16:47 hrs Manual pre-cleaning of Scope B has been completed. **Scope B** is placed in the same ETD3 as Scope A.

Figure 19: (from left to right) Scope B ready to be cleaned; Scope B immersed in water with detergent; Wiping insertion tube; Brushing tip.

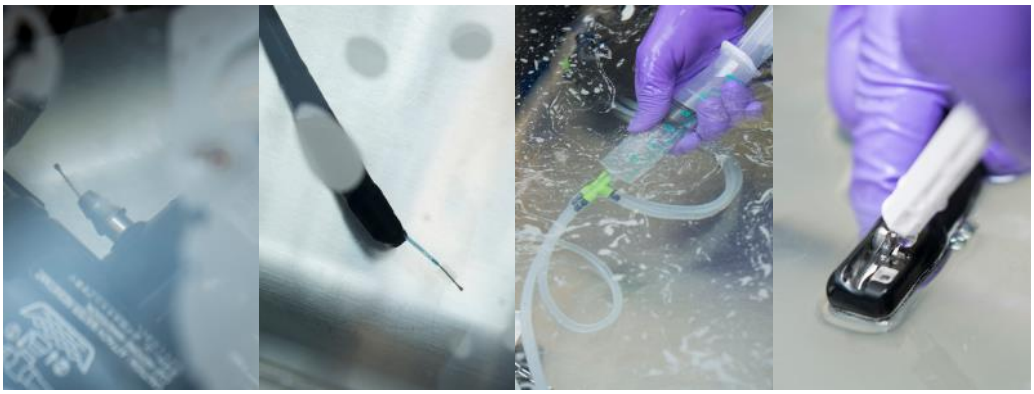


Figure 20: (from left to right) Brushing suction/biopsy channel to connector side; Brush emerging from the tip when brushing suction/biopsy channel from control section side; Manually aspirating detergent through suction/biopsy channel by flushing eight times using a 50ml syringe; Brushing around the forceps elevator using a MAJ-1888 brush.

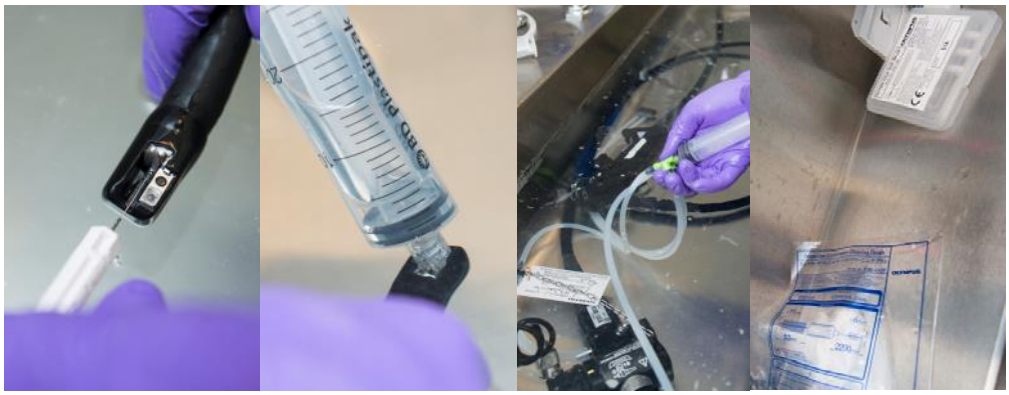


Figure 21: (from left to right) Brushing under the forceps elevator using a MAJ-1888 brush. Flushing forceps elevator recess; Manually flushing air-water channels using three times 30ml; Packaging of the used brushes.

Figure 22: (from left to right) Scope B with plugged connector in the ETD3; Forceps elevator of Scope B at 45 degrees; Scope B connected to control section side in ETD3; ETD3 containing Scope A and Scope B, ready to start the machine disinfection process.

5.7 Machine cleaning, disinfection and drying, packaging and sealing

16:49 hrs — P3 turns on the ETD3 containing **Scope A** and **Scope B**. The *research team* waits until the ETD3 indicates successful completion of the leakage test and flow test.

16:54 — Leakage test and flow test OK. The *research team* leaves.

17:40 — The research team is back in the cleaning and disinfection room and dressed in clean protective clothing, including gloves. P3 is replaced by his colleague VK from the night shift. The ETD3 containing Scope A and Scope B is opened and the scopes are hung one by one in the drying cabinet (Van Vliet GV 700, serial number 709004, inventory number 161267) to dry for 2 hours.

17:47 — Scope B is suspended in position 1 and Scope A is suspended in position 6 in the drying cabinet. The drying cabinet is closed and the *research team* leaves.

19:47 — *The research team* is back in the cleaning and disinfection room and once again dressed in clean protective clothing, including gloves. VK opens the drying cabinet and takes out the clean, dry Scope B from position 1. Scope B is packaged by P1, P2 and VK in a sterile plastic bag, a clean plastic bag is placed around it and the packaged Scope B is stabilized in an endoscope case with clean cloths. The endoscope case is wrapped in tape and labeled with the inventory number of Scope B and the signature of AL so that it will be visible when this seal is opened.

19:59 — VK opens the drying cabinet and takes out the clean, dry Scope A from position 6. Scope A is packaged by P1, P2 and VK in a sterile plastic bag, a clean plastic bag is placed around it and the packaged Scope B is stabilized in an endoscope case with clean cloths. The endoscope case is wrapped in tape and labeled with the inventory number of Scope A and the signature of AL so that it will be visible when this seal is opened.

20:10 — The research team leaves the cleaning and disinfection room with the two sealed cases. P2 takes the two cases home and will take them the following day to Olympus Nederland B.V. in Zoeterwoude.

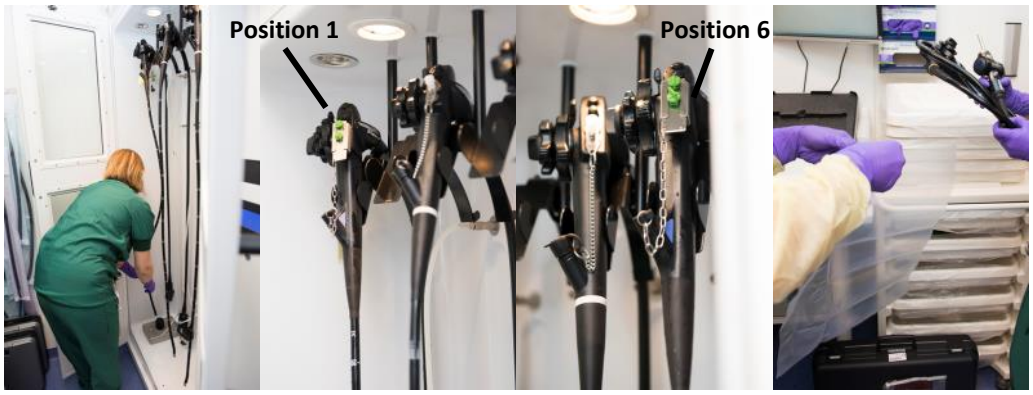


Figure 23: (from left to right) Cleaned and disinfected scopes are placed in the drying cabinet; Scope B at position 1 of the drying cabinet; Scope A at position 6 in the drying cabinet; Packaging of Scope B after two hours of drying time.

Figure 24: (from left to right) Packaging Scope B; Scope B in the sterile bag; Scope B in the sterile bag in the clean bag and swaddled in protective cloths in the case.

Figure 25: (from left to right) Removing Scope A from the drying cabinet after two hours of drying time; Scope A packaged in the sterile bag; Scope A in the sterile bag in the clean bag and swaddled in protective cloths in the case.

Figure 26: The two sealed cases containing Scope A (170485) en Scope B (179505).

6 Preliminary discussion report Substudy II - 'Dismantling'

Part II of *the investigation* was carried out on Wednesday December 16, 2015 at the Olympus Nederland B.V., Industrieweg 44, Zoeterwoude. At approximately 08:00 hours, *the research team* gathers there. It is made up of:

	Name	Code	Position	Organization
-	####	P1	Expert Infection prevention	UMC Utrecht
-	####	P2	Microbiologist	UMC Utrecht
-	####	P3	Disinfection staff	UMC Utrecht
-	####	P4	Instrument technician	UMC Utrecht
-	####	P5	Expert Infection prevention	UMC Utrecht
-	####	P6	RA/QA Expert	Olympus Europa SE & CO. KG
-	####	P7	Senior R&D liaison	Olympus Europa SE & CO. KG
-	####	P8	Production Support Specialist	Olympus Europa SE & CO. KG
-	####	P9	Service Engineer Flexible Instruments	Olympus NL B.V.
-	####	P10	Senior CDS Consultant	Olympus NL B.V.
-	####	P11	Service Manager	Olympus NL B.V.
-	####	P12	Researcher	ErasmusMC
-	####	P13	Student BioMechanical Engineering	TU Delft
-	Arjo Loeve	AL	Researcher BioMechanical Engineering	TU Delft

A number of issues regarding the instructions come up specifically:

- P11 leads the meeting and indicates that he will not be present at any further time during *the investigation.*
- AL gives a summary report of the actions in Substudy I. All of those present will wear a clean, white overcoat from Olympus. Anyone coming into close proximity of the scopes that are to be dismantled will also wear latex gloves, a hairnet and surgical mask.
- AL, as independent expert from the TU Delft, will take care of reporting, take photo and video recordings for documentation, objectively and critically observe the process, and if necessary, give directions, and has the final authorization for making decisions about the investigation steps to be taken. AL wears latex gloves, a hair net and a mouth-nose mask.
- P8 takes care of the scope assembly and wears latex gloves, a hair net and a mouth-nose mask.
- P1 performs the sampling and wears latex gloves, a hair net and a mouth-nose mask.
- P5 takes care of the labeling and storage of the sample materials and wears latex gloves and a hair net.
- P2 supports P1 and P5 and wears latex gloves and a hair net.
- P9 provides and operates any additional equipment and tools.
- P12 and P13 will video record *the investigation.*
- P10,P7, P6, P4 and P3 observe the process and will gather and provide information as needed and will take extra photos.
- P6 indicates that Olympus, to the best of its ability, tries to prevent environmental contamination during the disassembly of the scopes, but that this is no guarantee because this approach is not validated. The UMC Utrecht takes samples and in the analysis of the samples looks for specific strains of micro-organisms, thus environmental contamination should be no problem. *The research team* knows about this marginal comment.

A discussion about the approach to *the investigation* has taken place.

7 Report Substudy II - 'Dismantling'

08:32 hrs *The research team* is located in the working space where *the investigation* will take place, dressed in the correct protective gear. The examination table and the tools to be used are disinfected with 70% ethanol. The table is covered with sterile cloths.

7.1 Dismantling Scope A

Entire Section 7.1 only concerns Scope A.

08:38 hrs The case containing **Scope A** is inspected and proves not to have been opened. The case containing Scope B is also unopened. The cases of Scope A and Scope B are opened and Scope A is laid on the examination table in the sealed bags.

08:44 hrs Scope A is taken out of the bags by P8 and the external inspection starts. The tip appears to have no anomalies in this first inspection.

Figure 27: The sealed cases containing Scope A (170485) en Scope B (179505).

Figure 28: (from left to right) Scope A on the examination table; Scope A unwrapped; The tip of Scope A.

08:47 hrs P1 takes various external dry samples:

- with a pernasal dry swab, the tip, including camera and accessible places around the forceps elevator and has P8 move the forceps elevator up and down to access as much as possible {7},
- with an Olympus MAJ-1888, the tip, including camera and accessible places around the forceps elevator and has P8 move the forceps elevator up and down to access as much as possible {8},
- the suction/biopsy channel using an Olympus Combibrush (BW412T), from the control section side all the way up to just inside the forceps elevator recess {9},
- with an Olympus combi-brush (BW412T), the suction/biopsy channel from the control section all the way up to the connector {10}.

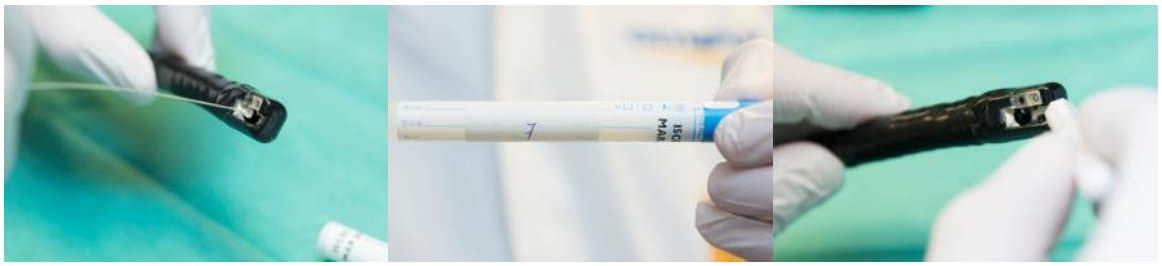


Figure 29: (from left to right) Sampling from tip {7}; Sample storage {7}; Sampling {8} using the MAJ-1888 brush.

Figure 30: (from left to right) Sample storage {8}; Sampling from suction/biopsy channel {9}; Sample storage {9}.

Figure 31: (from left to right) Sampling from suction/biopsy channel...; up to the input to the connector; Cutting the brush;Sample storage {10}

09:17 hrs Inspection of the channels with a borescope (Olympus iPlex-TX) brought by Olympus. The borescope is disinfected with 70% ethanol and then inserted into the tip and the suction/biopsy channel:

- Brown and white deposits in the forceps elevator region.
- Brown deposit behind the light cover glass
- Various scratches in the suction/biopsy channel, and one noticeable area of damage (~ 1 mm) in the distal section of the suction/biopsy channel.
- The Olympus representatives state that the channel does not appear to be from Olympus originally. The material is blue instead of white or clear (see appendix H) and appears to have a ribbed structure.
- When the borescope is inserted completely, the end of the suction/biopsy channel is not reached.

The borescope is inserted again from the control section to inspect the rest of the channel:

- Brown deposits at the input to the suction/biopsy channel.
- Several small scratches.

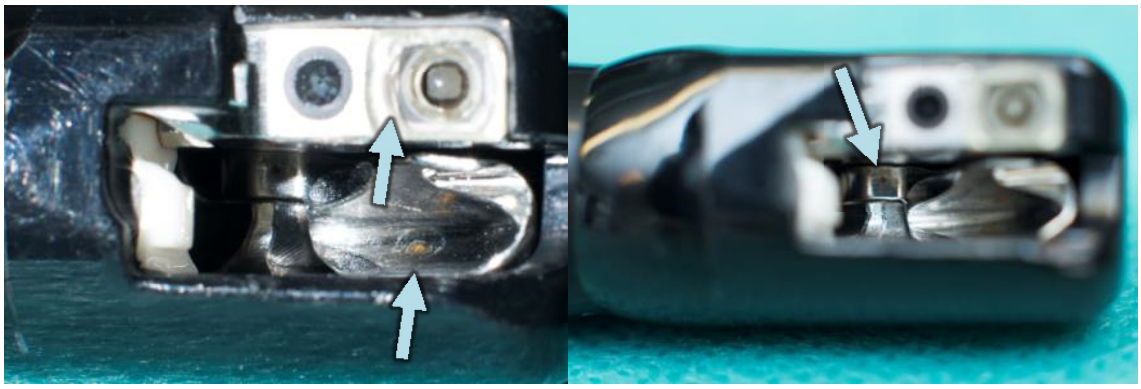


Figure 32: (from left to right) Close-up of the tip, with brown deposit in the forceps elevator and behind the light source cover glass; Brown deposit on several parts on and around the forceps elevator;

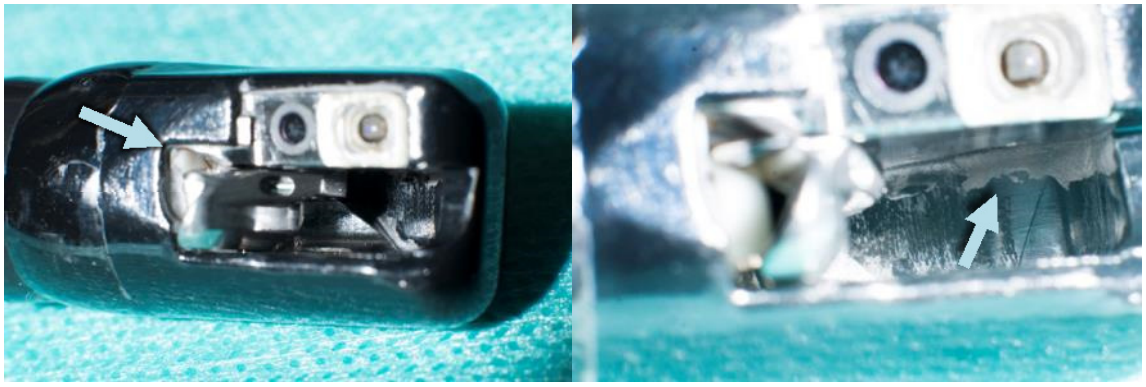


Figure 33: (from left to right) Red-brown deposits between the Z-block (the white part) and the tip housing; White, visually porous deposit in the forceps elevator area on the tip cover.

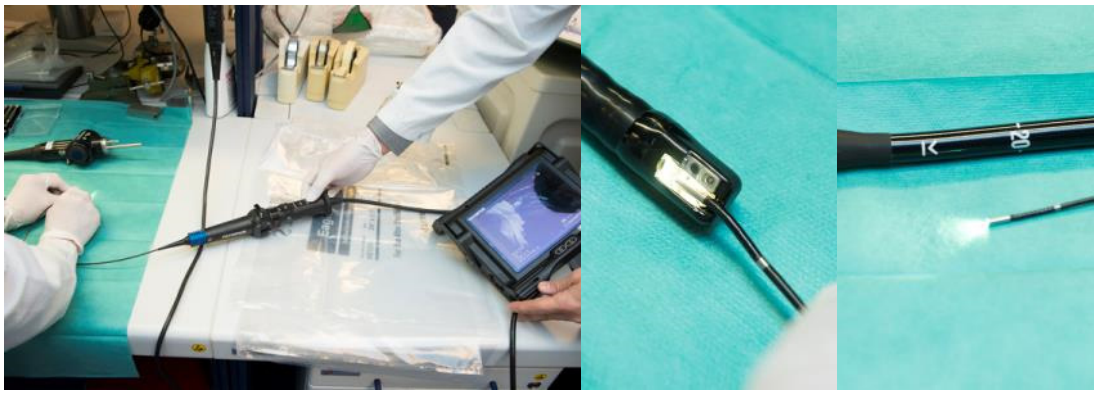


Figure 34: (from left to right) Suction/biopsy channel with borescope; Tip of the borescope in the forceps elevator area; Reference photo on which on can see the extent to which the borescope was inserted from the tip side of Scope A.

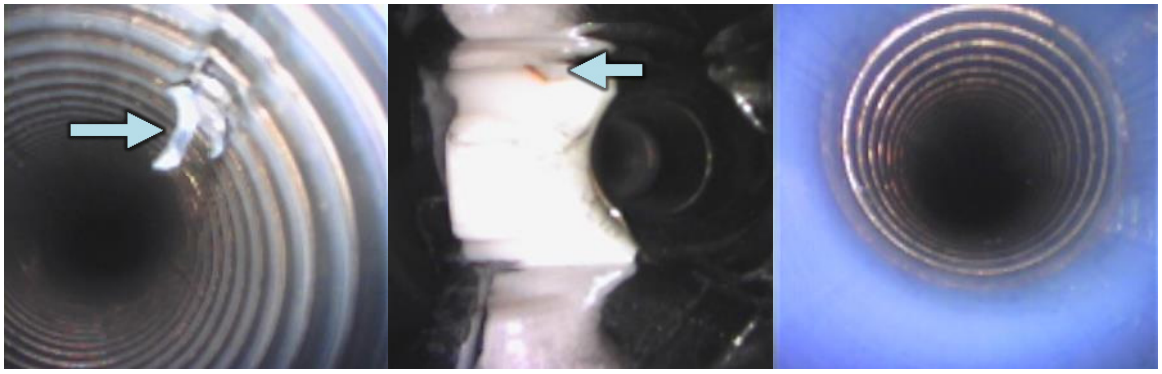


Figure 35: Borescope images. (from left to right) Damage in the suction/biopsy channel a few centimeters from the tip; Red-brown deposits on white Z-block; Part of the suction-biopsy channel viewed from the distal (tip) side toward the control section, where the smooth tube becomes the ribbed tube.

Figure 36: Borescope images. (from left to right) Brown deposit at input of suction/biopsy channel; Merging of entrance suction/biopsy channel to smooth tube of suction/biopsy channel; Merging of ribbed tube for suction/biopsy channel to smooth tube for suction/biopsy channel, shown from the control section towards the tip.

09:49 hrs P8 attaches Scope A to a scope tower to see how often the scope has been attached (571 times) and verifies that the serial number on the outside is consistent with the software.

09:50 hrs Scope A back on the examination table. P1 wipes down the entire exterior including all accessible areas around the forceps elevator with 70% ethanol and clean cloths and swabs.

09:53 hrs Further inspection. When P8 goes to remove the tip cover, a number of things are noticeable:

- Dent in the tip cover.
- The anterior bonding joint of the cardan rubber appears to have been tidily applied from the outside (see appendix H).

The anterior bonding joint of the cardan rubber was cut away by P8 and then a number of other things are noticeable:

- In the anterior bonding joint of the cardan rubber, a green thread was found, while Olympus uses black thread (see appendix H).
- The glue did not adhere well to the thread, and is lying on the thread and not between and below.
- The glue appears to be more brittle than the glue Olympus uses, according to P8.
- Under the glue, everything is fine.
- No Molykote powder is found under the cardan rubber, while there should be 0.3 g of Molykote powder present (see appendix H).

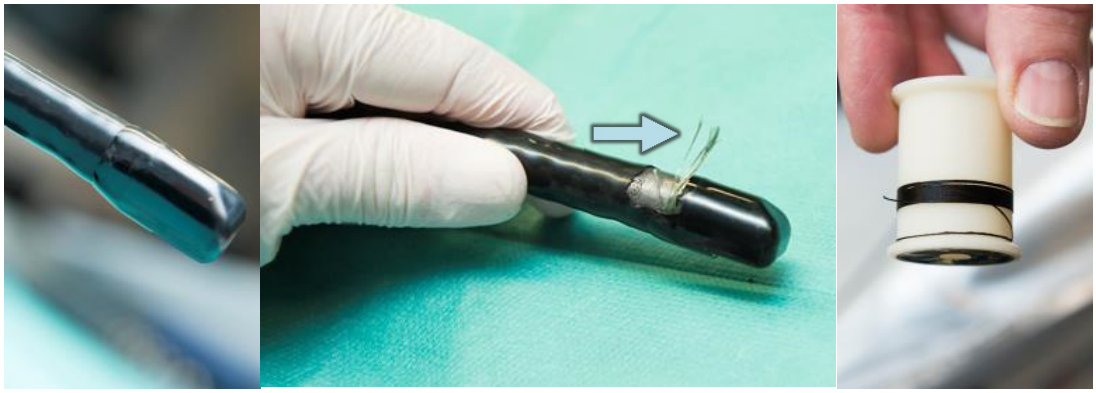


Figure 37: (from left to right) Dent in the tip cover; Green thread under the front bonding joint of the cardan rubber; Original black thread used by Olympus for bonding.

The pieces of front bonding joint on the cardan rubber are stored {11}. After removing the glue, the area exposed under the glue was sampled {12} and then disinfected with 70% ethanol.

The tip cover is removed by cutting through it, whereby a number of things become apparent:

- The tip cover feels harder than usual according to P8.
- The tip cover falls apart during removal. Olympus indicates that this should be tough and must be able to be removed nearly whole from the tip. This observation was recognized by AL from previous removals.

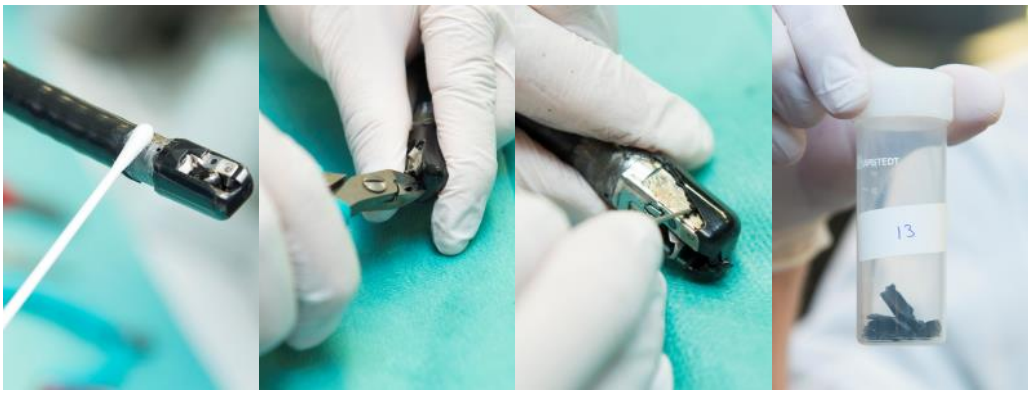


Figure 38: (from left to right) Sampling of front bonding joint of cardan rubber {11}; Cutting loose of tip cover; Loosening tip cover; Storage of tip cover pieces {13}.

The pieces of tip cover are stored for further analysis {13}, as well as pieces of black glue from underneath the tip cover {15}. P1 takes samples from the surfaces accessible under the tip cover and samples:

- the surfaces underneath the cover, including the lower side of the forceps elevator and the recess around the forceps elevator {14}, using a normal dry cotton swab,
- the surfaces underneath the cover, excluding the lower side of the forceps elevator and the recess around the forceps elevator, using a normal dry cotton swab, {17},
- only the lower side of the forceps elevator and the recess around the forceps elevator {18}, using a normal dry cotton swab,
- only the lower side of the forceps elevator and the recess around the forceps elevator {16}, using a pernasal dry swab.

The sections exposed under the tip cover are cleaned with 70% ethanol.

10:29 hrs **COFFEE BREAK.** *The research team* leaves the room. AL leaves last.

Figure 39: (from left to right) Sampling of tip parts underneath the cover {14}; Sampling underneath the cover {15}; Sampling of forceps elevator recess {16}.

10:51 hrs **END OF COFFEE BREAK.** *The research team* enters again. AL is the first to enter the room. All latex gloves, masks and hair nets are replaced by new, clean items.

10:59 AM P8 removes the arm cover. P1 samples using a pernasal dry swab to sample the exposed surfaces under the arm cover and the propulsion area of the forceps elevator {20}. Samples are also taken of the lever and the propulsion cable of the forceps elevator, while the latter is put into the raised and lowered positions. Arm cover is stored {19}. A number of issues are noticeable during and after removal of the arm cover:

- Insufficient (see appendix H) amount of black glue in the edge around the arm cover, through which there are openings in the seal.
- Brown deposit under the tip cover.
- P8 expresses doubts about the origins of the arm cover: a normal lip around the arm cover to make the arm cover easy to remove is missing according to P8.
- Arm cover is soldered to the tip, which is not consistent with Olympus standards (see appendix H).
- The glue is not everywhere on the arm cover, so the seal is not complete.
- Brown deposit under the arm cover.

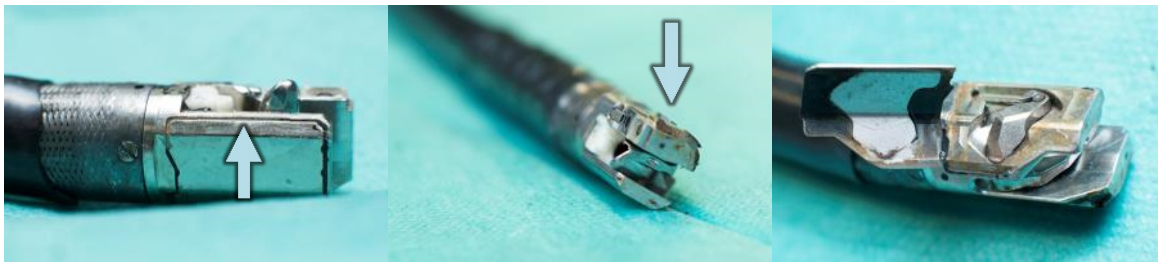


Figure 40: (from left to right) Side view of arm cover that shows part of the locking groove is without glue; Front view of tip with brown deposit; Opened arm cover, still attached to the tip due to soldering, with brown deposit underneath the arm cover.

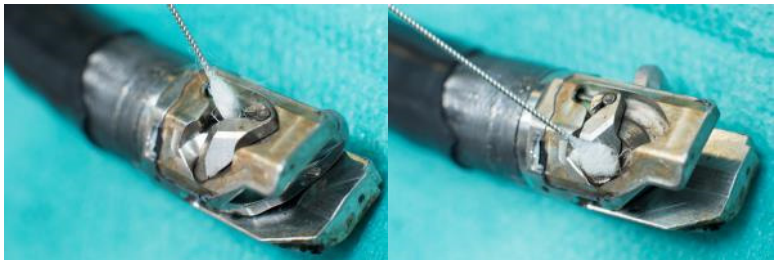


Figure 41: (from left to right) Sampling in the drive unit with partly raised forceps elevator {20}; Sampling in the drive unit with forceps elevator raised all the way {20};

The lever and lever shaft are removed as one unit. To achieve this, the propulsion cable is removed from the lever first. Then, the white glue is removed from the screw that attaches the forceps elevator to the lever shaft on the patient side. The lever and lever shaft and surrounding O-ring are removed. Screw {21}, lever and lever shaft {23}, O-ring {22} and forceps elevator {24} are each stored separately to be photographed and observed under a microscope (which is first disinfected with 70% ethanol).

Brown deposits are found:

- on the side of the drive unit on the lever,
- in the groove in the lever that housed the O-ring, both on the drive unit side and on the patient side,
- on the drive unit side and the patient side of the O-ring,

- on the patient side of the lever, especially where the forceps elevator was connected around the shaft,
- in the shaft opening of the forceps elevator, where the lever was attached,
- on the screw that attaches the forceps elevator to the lever shaft,
- on several areas of the forceps elevator.

P1 samples:

- firstly, the lever shaft opening and the forceps elevator recess in the area that could not be reached before removing the forceps elevator {26}, using a pernasal dry swab,
- only the lever shaft opening from the drive unit side {27}, using a pernasal dry swab.

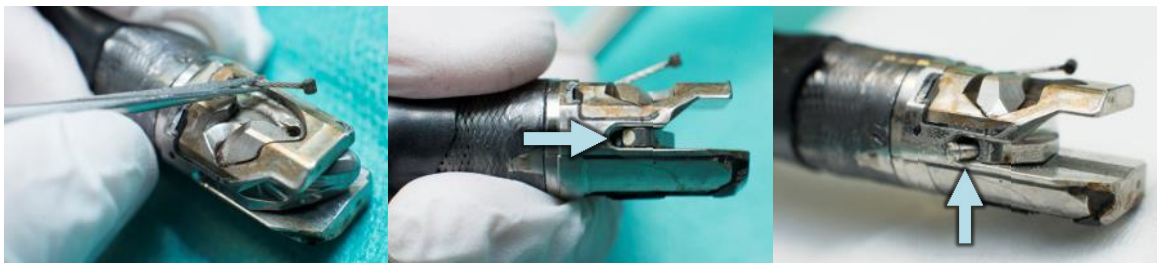


Figure 42: (from left to right) Removal of drive cable; White glue on screw with which the forceps elevator is fixed to the lever shaft; Screw removed with brown deposits on the screw thread.

Figure 43: (from left to right) Lever with lever shaft and O-ring; Brown deposit on the lever and both sides of the O-ring; Brown deposit on the lever and lever shaft on several surfaces.

Figure 44: (from left to right) O-ring next to screwdriver with 1mm diameter; Lever with lever shaft next to screwdriver with 1mm diameter; Lever with brown deposit on O-ring groove of lever shaft.

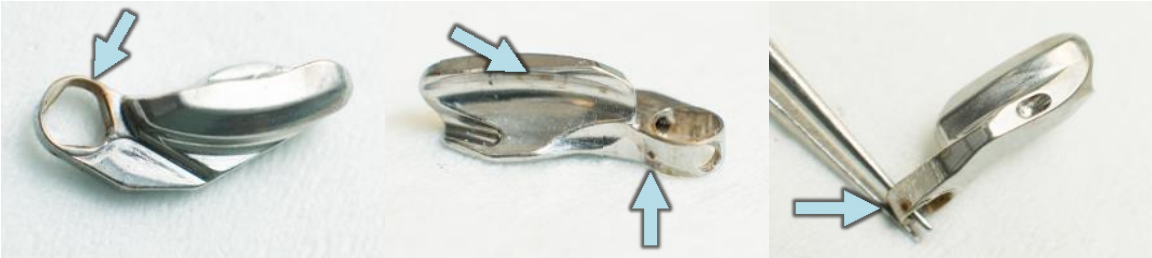


Figure 45: (from left to right) Forceps elevator with brown deposit in shaft opening; Forceps elevator with brown deposit in several places; Forceps elevator with brown deposit around the shaft opening.

Figure 46: (from left to right) Sampling underneath the forceps elevator {26}; Sampling of the lever shaft opening {26}; Sampling of the lever shaft opening {27}.

11:40 hrs The whole of Scope A's exterior is wiped using cloths and 70% ethanol. P8 starts to dismantle of the control section and the suction/biopsy channel. The dismantling of the suction/biopsy channel takes place in steps, whereby different parts are stored and observations are made:

- The rubber ring around the entry of the suction/biopsy channel appears not to be original, according to Olympus.
- When the distal cuff is removed, there appears to be no lubricant under it, which is not consistent with Olympus standards (see appendix H).
- There are several screws in the control section that do not have any green locking adhesive on. According to Olympus standards it should be there (see appendix H).
- Screws are easier than usual to remove (see appendix H).

Screws are stored {28}. Input to suction/biopsy channel including rubber and screws are stored {25}. Tip is removed from the cardan:

- Glue on the channel connections on the relevant connections of the tip appears to be black instead of white (see appendix H).
- The channels do not run parallel to the shaft (see appendix H), but cross at the distal end.

Suction/biopsy channel is disconnected at the control section. At the distal end, at the tip, the suction/biopsy channel is cut away a few centimeters from the tip so that the last distal centimeters of the suction/biopsy channel remain secured to the tip, considering that in that section there was a great deal of damage seen with the borescope. The removed section of suction/biopsy channel is stored {30}.

Figure 47: (from left to right) Rubber ring removed from input of suction/biopsy channel; Proximal sleeve of insertion tube with soapstone powder for removal; Underneath distal sleeve no Olympus brand name on insertion tube, insertion tube is not original; Inside control section, in which screws without bonding material are visible.

12:20 hrs **LUNCH BREAK.** *The research team* leaves the room. AL leaves last.

13:00 hrs **END OF LUNCH BREAK.** *The research team* enters again. AL is the first to enter the room. All latex gloves, masks and hair nets are replaced by new, clean items.

13:02 hrs P8 continues to remove the remaining section of suction/biopsy channel at the tip:

- Under the fixation glue, which is fully present, there does not appear to be a fixation wire, while according to Olympus, there the suction/biopsy channel must be attached to the connection at the tip with at least 9 wraps (see appendix H).

The remaining part of the suction/biopsy channel is first photographed and then carefully cut open lengthways, whereby the damage on the inside is avoided. After cutting open, the piece of the suction/biopsy channel is bent open and the damage can be clearly seen.

- There appears to be a deep groove with contamination.

The cut piece of suction/biopsy channel us stored {31}.

13:15 hrs The remaining parts are cut loose and stored:

- Air and water channels are cut loose from the tip and stored as one set {32}, as two channels merge through a Y-connector just before the tip and together form the flushing channel to the control section.
- Propulsion cable is cut loose at the control section and stored {33}.
- Propulsion cover is cut loose and stored {34}.
- Tip is cut loose (by cutting optic fibers and video cables) and stored {35}.
- Finally, the rest of the parts from the connector to the distal end of the shaft are stored as one piece {no number}.

13:24 hrs End of dismantling of **Scope A**.

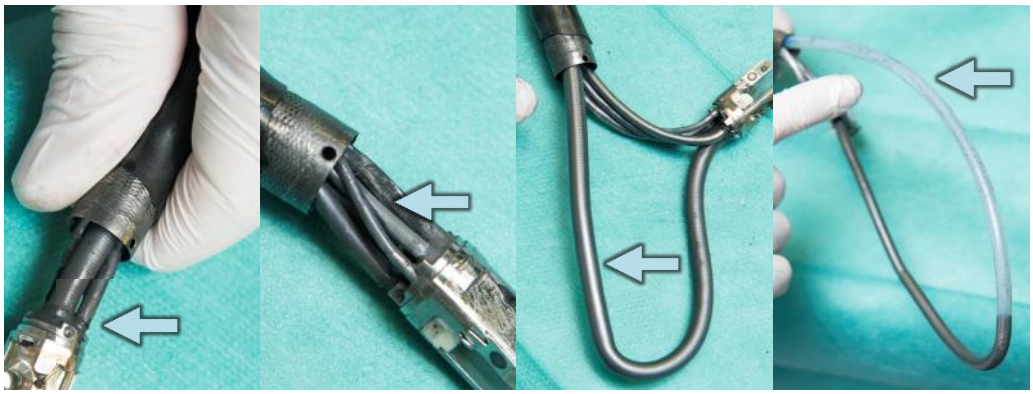


Figure 48: (from left to right) Black glued channels at the tip; Crossed channels at the tip; Non-original suction/biopsy channel (see appendix H); Smooth transparent part of the non-original suction/biopsy channel.

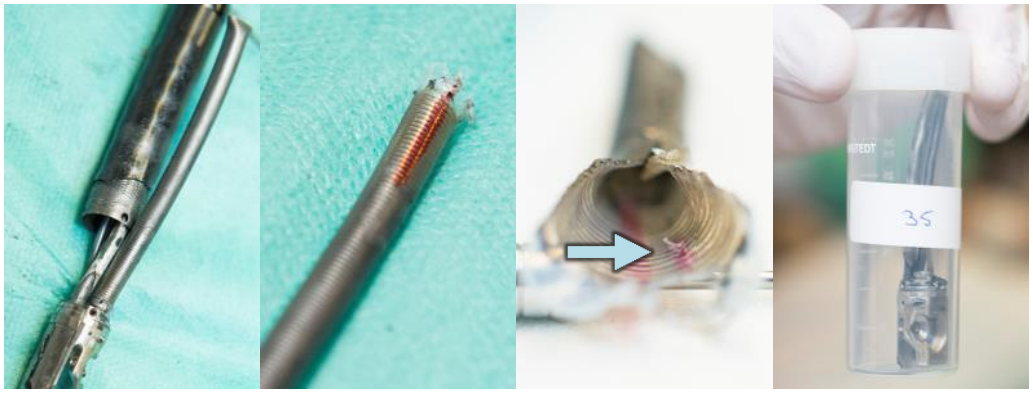


Figure 49: (from left to right) Removed suction/biopsy channel; Loose, distal piece of suction/biopsy channel with externally marked location of the internal damage; Detail of the internal damage in the suction/biopsy channel; removed tip.

7.2 Dismantling Scope B

Entire Section 7.2 only concerns Scope B. The examination table, microscope and tools are disinfected with 70% ethanol. As there are no more sterile cloths available, the examination table is covered with paper covers from a clean paper roll.

13:32 hrs The case containing **Scope B** is inspected and proves not to have been opened. The case is opened and Scope B is placed on the examination table in its closed bags. Scope B is taken out of the bags by P8 and the external inspection starts.

- The distal and proximal bonding joints of the cardan rubber are irregular, thicker than usual (see appendix H) and show a great deal of loosening.

P1 takes various external dry samples:

- with a pernasal dry swab, the tip, including camera and accessible places around the forceps elevator and has P8 move the forceps elevator up and down to access as much as possible {36},
- with an Olympus MAJ-1888, the tip, including camera and accessible places around the forceps elevator and has P8 move the forceps elevator up and down to access as much as possible {37},
- the suction/biopsy channel using an Olympus Combibrush (BW-412T), from the control section side all the way up to just inside the forceps elevator recess {38},
- with an Olympus combi-brush (BW-412T), the suction/biopsy channel from the control section all the way up to the connector {39}.

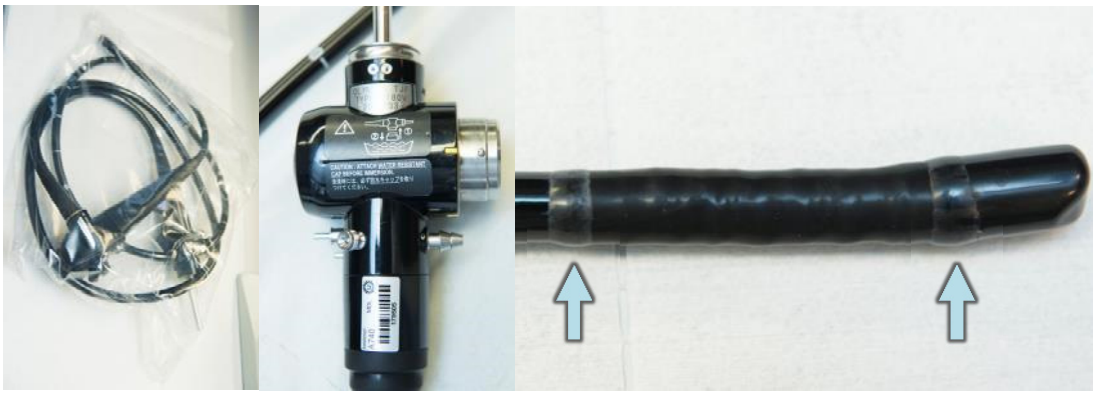


Figure 50: (from left to right) Scope B in undamaged sterile bag; Connector of Scope B; Distal part of Scope B with irregular bonding joints of the cardan rubber showing traces of releasing.

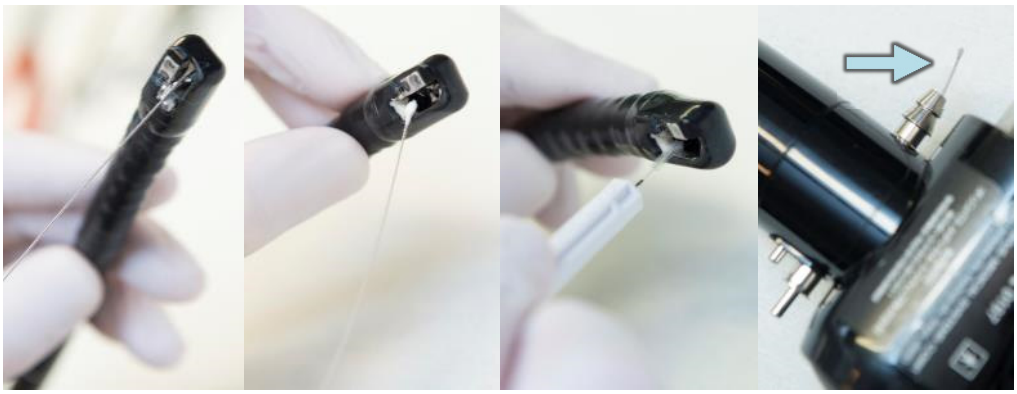


Figure 51: (from left to right) Sampling of forceps elevator recess with forceps elevator raised...; and lowered {36}; Sampling of forceps elevator recess using MAJ-1888 brush {37}; Brush from the input of the suction/biopsy channel at connector {39}.

13:58 hrs Upon photographing the tip, a cleft not filled with glue is visible between the tip cover and the tip. Inspection of the channels with a borescope brought by Olympus. The borescope is disinfected with 70% ethanol and then inserted into the tip and the suction/biopsy channel:

- White deposits in the forceps elevator recess.
- Space between the frame of the tip and the tip cover visible around the forceps elevator recess. Tip cover does not line up properly.
- Several scratches and something that looks like small fibers in the suction/biopsy channel.
- The Olympus representatives state that this channel does not appear to be from Olympus originally either. The material is blue instead of white or clear (see appendix H) and appears to have a ribbed structure.

When the borescope is inserted completely, to inspect the rest of the suction/biopsy channel is still not reached. The borescope is inserted again from the control section to inspect the rest of the channel:

- Several small scratches.

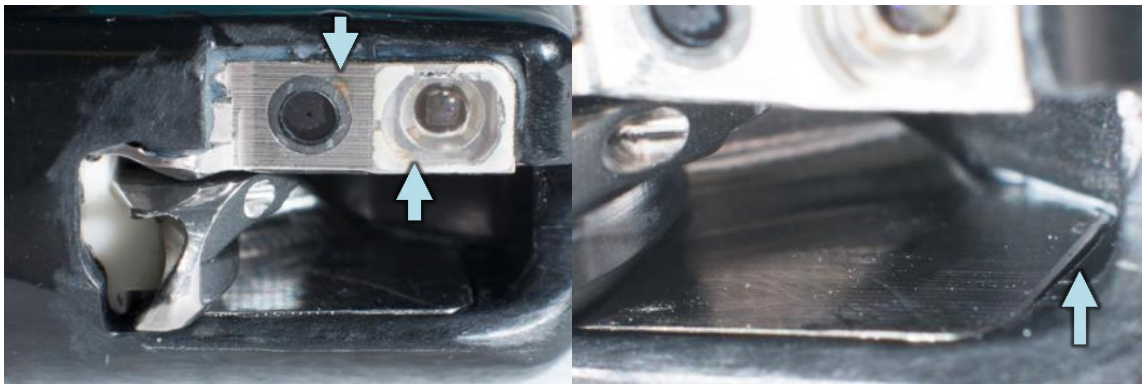


Figure 52: (from left to right) Close-up of the tip with brown deposit behind the cover glass; Space between the frame of the tip and the tip cover, the tip cover does not line up properly.

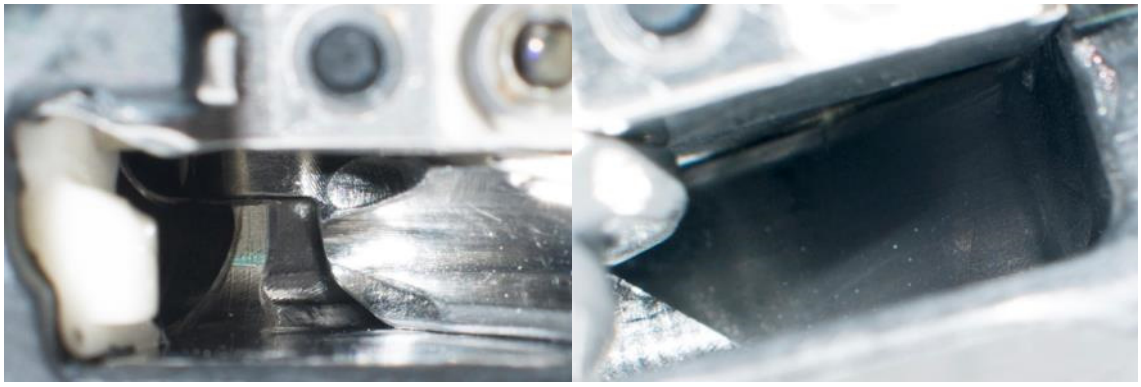


Figure 53: (from left to right) Clean-looking space behind the forceps elevator, at the output of the suction/biopsy channel; Clean-looking forceps elevator recess and tip cover.

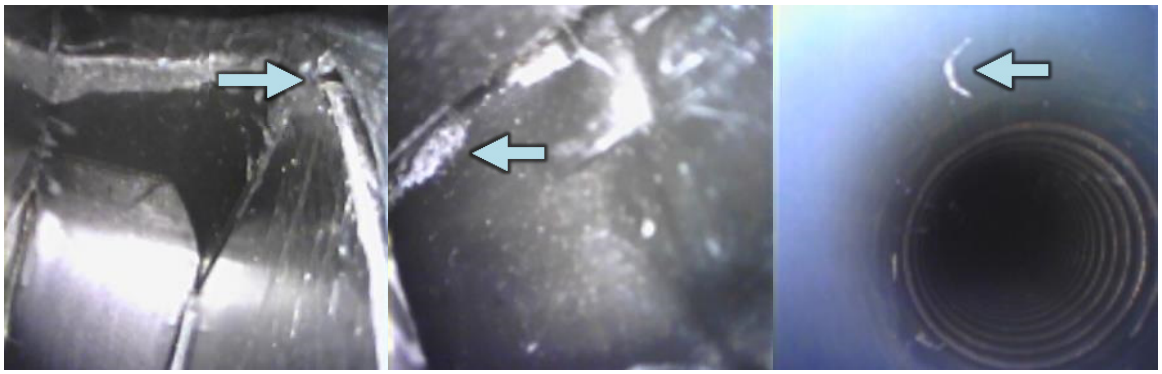


Figure 54: Borescope images (from left to right) Clearly visible space between the frame of the tip and the tip cover; Some white deposits in the rim of the forceps elevator recess; Fiber in the suction/biopsy channel, just before the merge from smooth tube (distal) to ribbed tube (proximal).

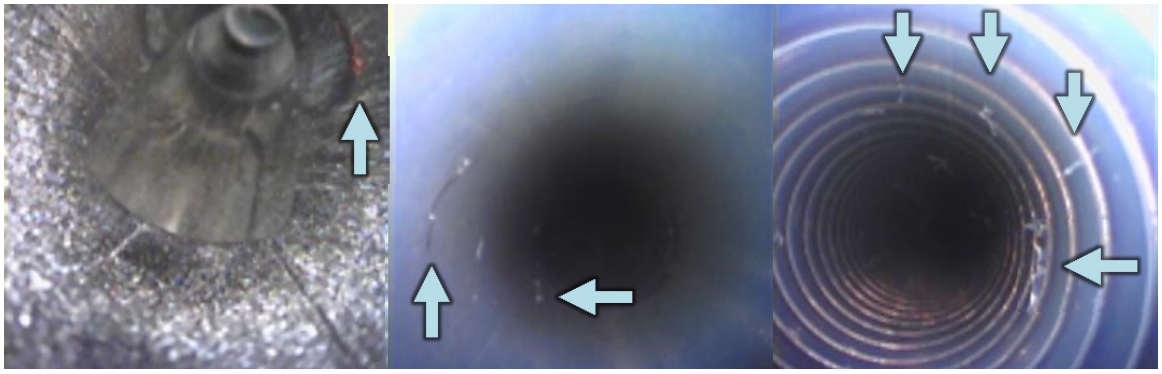


Figure 55: Borescope images (from left to right) Red-brown deposit in the input of the suction/biopsy channel in the control section; Fibers in the smooth tube of the suction/biopsy channel; Fibers in the ribbed tube of the suction/biopsy channel.

14:33 hrs **COFFEE BREAK.** *The research team* leaves the room. AL and P1 remain, P1 cleans all of Scope B with 70% ethanol, clean cloths and swabs.

14:36 hrs AL and P1 leave for a coffee break.

14:55 hrs **END OF COFFEE BREAK.** *The research team* enters again. AL is the first to enter the room. All latex gloves, masks and hair nets are replaced by new, clean items.

14:56 hrs P8 attaches Scope B to a scope tower to see how often the scope has been attached (287 times) and verifies that the serial number on the outside is consistent with the software.

14:58 hrs The anterior bonding joint of the cardan rubber is cut away by P8, which reveals a number of things, very consistent with the other scope:

- In the anterior bonding joint of the cardan rubber, a green thread was found, while Olympus uses black thread (see appendix H).
- The glue did not adhere well to the thread, and is lying on the thread and not between and below.
- The glue appears to be more brittle than the glue Olympus uses, according to P8 (see appendix H).
- Under the glue, everything is fine.
- There is hardly any Molykote powder found under the cardan rubber, while there should be 0.3 g of Molykote powder present (see appendix H).

The pieces of front bonding joint on the cardan rubber are stored {40}. After removing the glue, the area exposed under the glue was sampled {41} and then disinfected with 70% ethanol.

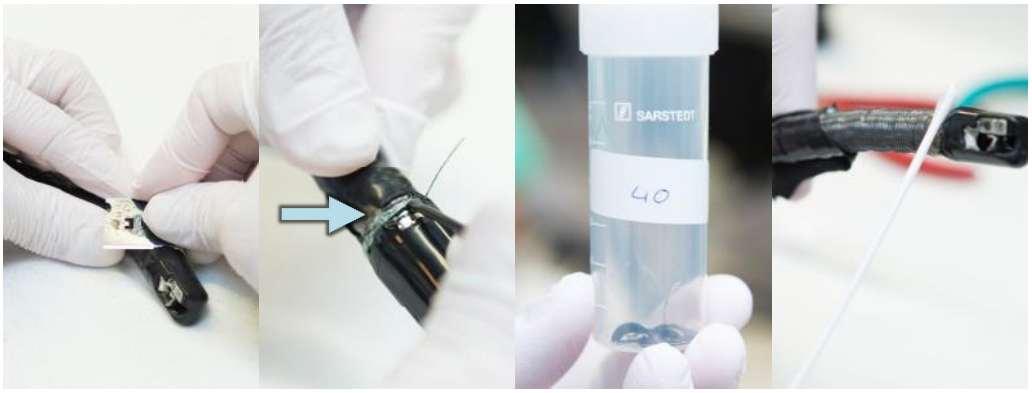


Figure 56: (from left to right) Cutting loose the front bonding joint on the cardan rubber. Green thread underneath the first bonding joint of the cardan rubber; Stored pieces of bonding {40}; Sampling under the front bonding joint of the cardan rubber and underneath the cardan rubber.

15:11 hrs The tip cover is removed by cutting through it, whereby a number of things become apparent:

- According to P8, the tip cover feels harder than normal and according to P8 is not original either.
- The tip cover falls apart during removal instead of being tough and being able to be removed nearly whole.
- The black glue under the tip cover is softer than what Olympus uses, according to P8.
- Brown deposit can be seen under the tip cover.
- The glue under the tip cover is softer than what Olympus uses, according to P8.

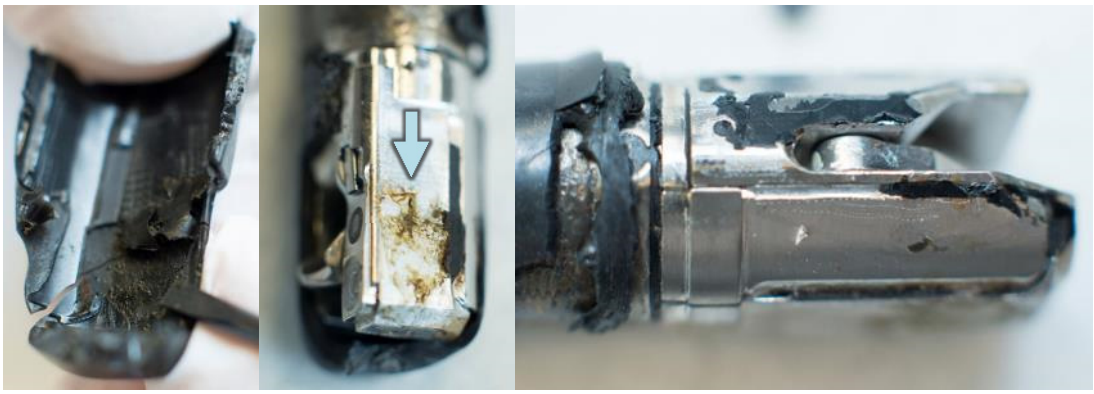


Figure 57: (from left to right) Brittle structure of the tip cover; Brown deposit under the tip cover; Black glue underneath the tip cover.

15:31 hrs The pieces of tip cover are stored for further analysis {42}. P1 takes samples from the surfaces accessible under the tip cover and samples:

- the surfaces underneath the cover, including the lower side of the forceps elevator and the recess around the forceps elevator {45}, using a normal dry cotton swab,

- the surfaces underneath the cover, excluding the lower side of the forceps elevator and the recess around the forceps elevator, using a normal dry cotton swab, {46},
- only the lower side of the forceps elevator and the recess around the forceps elevator {47}, using a normal dry cotton swab,
- only the lower side of the forceps elevator and the recess around the forceps elevator {48}, using a pernasal dry swab.
- the observed brown deposit underneath the cover {44} using a clean scalpel. A clean scalpel from the same packaging is stored for reference {43}.

The sections exposed under the tip cover are wiped with 70% ethanol.

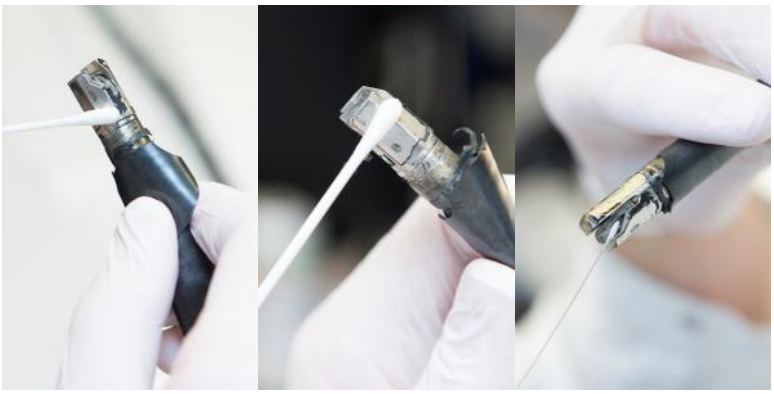


Figure 58: (from left to right) Sampling underneath the tip cover {47}; Sampling underneath the tip cover {47}; Sampling in the forceps elevator recess {48}.

15:41 hrs P8 removes the arm cover. P1 samples uses a normal dry swab to sample the exposed surfaces under the arm cover and the propulsion area of the forceps elevator {50}. Samples are also taken of the lever and the propulsion cable of the forceps elevator, while the latter is put into the raised and lowered positions. Arm cover is stored {51}. A number of issues are noticeable during and after removal of the arm cover:

- Insufficient amount of black glue in the edge around the arm cover, through which there are openings in the bonding joint.
- P8 expresses doubts about the origins of the arm cover: a normal lip around the arm cover to make the arm cover easy to remove is missing according to P8.
- Arm cover is soldered to the tip, which is not consistent with Olympus standards (see appendix H).
- The glue is not everywhere on the arm cover (see appendix H), so the bonding joint is not complete.
- The "extra" cavity in the tip (see figure 60) appears to P8 not to be original. When reviewing the photos of the other scope, this cavity also appears to be present there.
- A piece of black glue that fits into the "extra" cavity is found to be stuck to the arm cover and is stored separately {49}.

Figure 59: (from left to right) Brown deposit under the tip cover; Opening in the bonding joint on the arm cover;

Soldered arm cover.

Figure 60: (from left to right) Removed arm cover with the imprint of black glue in the shape of the "extra cavity"; "Extra cavity" in the tip housing; Brown deposit under the arm cover.

16:00 hrs The lever and lever shaft are removed as one unit. To achieve this, the propulsion cable is removed from the lever first. Then, the white glue is removed from the screw that attaches the forceps elevator to the lever shaft on the patient side. The lever and lever shaft and surrounding O-ring are removed. Screw {55}, lever and lever shaft {53}, O-ring {52} and forceps elevator {54} are each stored separately to be photographed and observed under a microscope (which is first disinfected with 70% ethanol).

Brown deposits are found:

- on the side of the drive unit on the lever,
- in the groove in the lever that housed the O-ring, both on the drive unit side and on the patient side,
- on the drive unit side and the patient side of the O-ring,
- on the patient side of the lever, especially where the forceps elevator was connected around the shaft,
- in the shaft opening of the forceps elevator, where the lever was attached,
- on the screw that attaches the forceps elevator to the lever shaft,

P1 samples:

- firstly, and after removing the lever with lever shaft, the lever shaft opening and the forceps elevator recess in the area that could not be reached before removing the forceps elevator {56}, using a pernasal dry swab,
- only the lever shaft opening from the drive unit side {57}, using a normal dry swab.

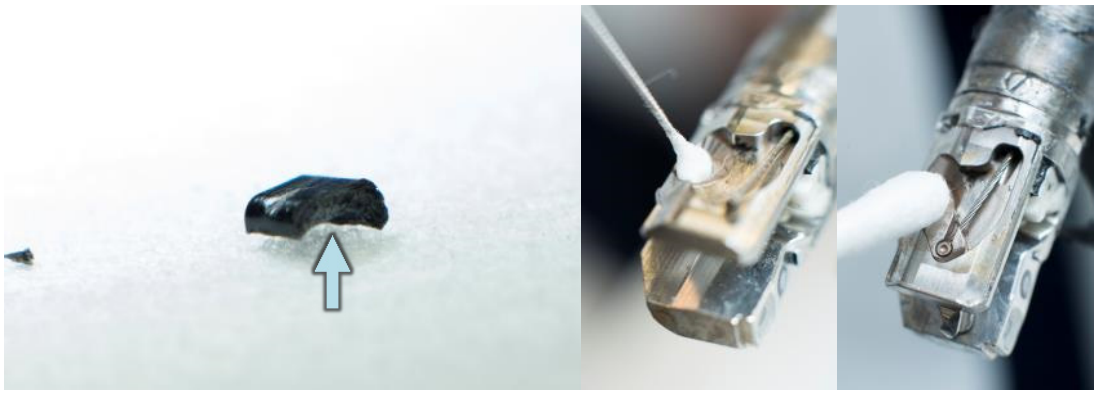


Figure 61: (from left to right) Brittle broken piece of tip cover; Sampling underneath the arm cover {56}; Sampling the lever shaft opening {57}.

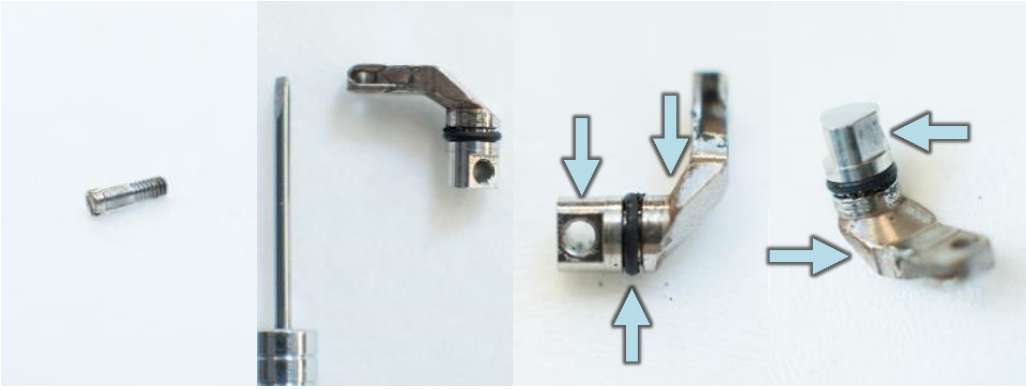


Figure 62: (from left to right) The screw that affixed the forceps elevator to the lever shaft; Lever with lever shaft and O-ring next to a 1mm diameter screw driver; Brown deposit on the lever, lever shaft and O-ring; Brown deposits on both drive section side (lower arrow) and patient side (upper arrow).

Figure 63: (from left to right) Forceps elevator with brown deposit in the shaft opening; Forceps elevator; O-ring met brown deposit next to a 1 mm diameter screwdriver; Lever with lever shaft next to a 1 mm diameter screwdriver, brown deposit in O-ring groove both on drive unit side and patient side.

16:18 hrs The entire exterior of Scope B is wiped using cloths and 70% ethanol. P8 starts to dismantle of the control section and the suction/biopsy channel. The dismantling of the suction/biopsy channel takes place in steps, whereby different parts are stored and observations are made:

- Upon removal of the ring around the input of the suction/biopsy channel, moisture is discovered there. A sample is taken of the moisture with a normal dry swab {59} and stored {58}.
- No lubricant is found under the distal cuff of the control section, which should be there (see appendix H).
- There are several screws in the control section that do not have any green locking adhesive on them. According to Olympus standards it should be there (see appendix H).
- Screws in Scope B are more tight than in Scope A, but also do not contain any green locking adhesive. On screws where there is red locking adhesive, one can see that the screws have been removed and the locking adhesive was not replaced (see appendix H).
- Screws and other dismantled parts are stored {61}.
- The rubber at the entrance to the suction/biopsy channel is covered with a white material which looks like silicone gel. According to Olympus standards, a thin layer of silicone oil should be used (see appendix H).
- Input to suction/biopsy channel, rubber and screw are stored {60}.

- The shrink sleeve in the control section at the end of the suction/biopsy channel is in a non-standard location (see appendix H).
- Clear signs of moisture in the form of deposits are visible on the exterior of the channels in the control section.

Figure 64: (from left to right) Soapstone powder is applied to be able to slide the distal cuff of the control section over the insertion tube; Under the distal cuff there is no Olympus brand name, insertion tube is not original; Water droplets under the rubber ring of the entrance to the suction/biopsy channel in the control section; Input valve with O-ring has material which looks like silicone gel.

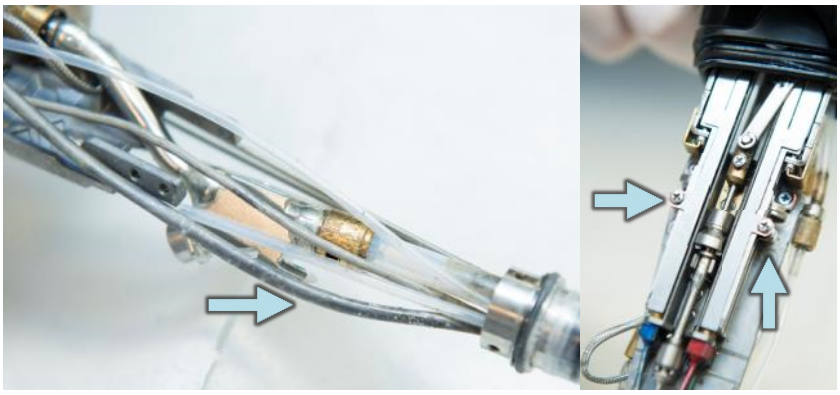


Figure 65: (from left to right) Channels in the control section, moisture damage traces on the exterior of various channels; Control section interior and screws with missing green locking adhesive.

16:34 hrs The tip is removed from the cardan, whereby different parts are stored and observations are made:

- There is black glue on the fixation screws on the tip, which according to Olympus standards should be white (see appendix H) and should not be applied in the screws. This makes removal of the tip very difficult.
- Glue on the channel connections on the relevant connections of the tip is black instead of white (see appendix H).
- Under the fixation glue of the channel connections it appears this time that there is a fixation wire, but it is not black, but green (see appendix H).
- The channels of this scope run parallel to the shaft.
- The outer layer of the suction/biopsy channel is eaten away in some places up to the reinforcement coil
- Molykote lubricant is nearly completely missing (see appendix H).

Suction/biopsy channel is disconnected at the control section. At the distal end, by the tip, the suction/biopsy channel is cut loose and then stored {62}. Air and water channels

are cut loose from the tip and stored as one set {64}, as two channels merge through a Y-connector just before the tip and together form the flushing channel to the control section.

- There is some doubt about the authenticity of the water and air channels, but after measuring the channel diameters (water channel 1.55mm and air channel 1.9mm, both in Scope A and Scope B), and after analyzing the Y-connector of Scope B, this part appears to be original.
- Propulsion cable is cut loose at the control section and stored {63}.
- Propulsion cover is cut loose and stored {65}.
- Tip is cut loose (by cutting optic fibers and video cables) and stored {66}.

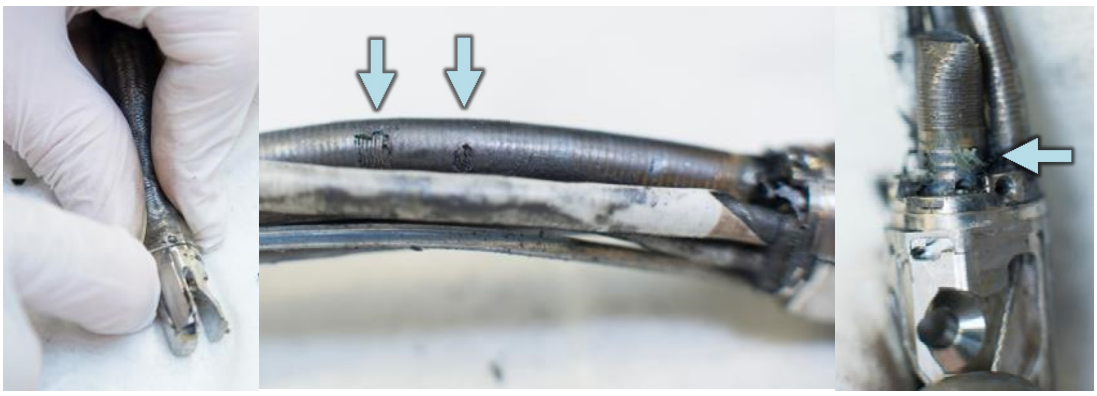


Figure 66: (from left to right) Screws from the tip attachment are hard to remove because they are covered with glue; Seriously damaged exterior sleeve of suction/biopsy channel; Green wire visible in black fixation glue of the suction/biopsy channel.

Before storing, the interior of the control section is inspected and severe moisture damage is discovered:

- A lot of green deposits on the parts behind the control buttons. Most likely strong copper oxidization.
- Steel oxidization on structural components.

The rest of the parts from the connector to the distal end of the shaft are stored as one piece {no number}.

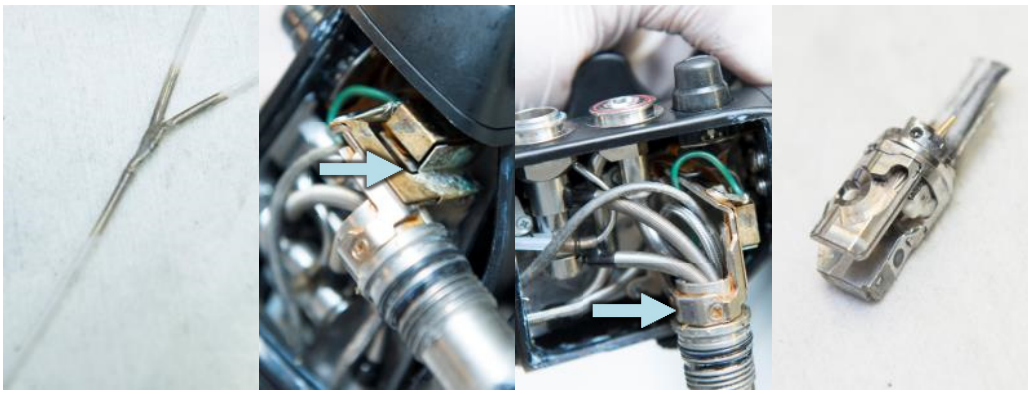


Figure 67: (from left to right) Y-connector water air channel; Strong oxidization around electrical circuit in control section; Strong oxidization on coupling parts of the signal tube; removed tip of Scope B.

17:20 hrs End of dismantling of **Scope B**.

8 Follow-up discussion

After completion of dismantling Scope A and Scope B, there is a short follow-up discussion where several matters are mentioned and agreed:

- During the dismantling of the scopes P4 called up the maintenance reports for Scope A and Scope B and from this it appears that both scopes have **undergone maintenance and repairs to the channels**, but that additional details are not clear. This will be requested from the party who performed the maintenance on the scopes. Maintenance and repairs to Scope A and Scope B are carried out by a third party, known to the author and all parties involved, who performed the repairs contracted by UMC Utrecht and for discretion will be called **"the repair company"** here.
- P6 asks if it is possible to have the fibrous material found in the biopsy channels examined to find out what kind of material it is. There is also curiosity about the material of the biopsy channels themselves. AL indicates that he will look for options for this, but that the question is only relevant if the repair company indicates that it never replaced the parts suspected of not being authentic.
- The Olympus technicians indicate that they are of the unanimous opinion that **many parts are not original**.
- **Part of the stored bonding material** of the cardan rubber on the tip cover will be transferred from UMC Utrecht to Olympus, so that they can identify what type of glue this is.
- **Stored parts** will undergo microbiological testing as soon as possible and then be cleaned so that they are available for AL to undergo further examination if desired.
- All **inspection, repair and maintenance records** regarding Scope A and Scope B will be collected by **UMC Utrecht and Olympus B.V.** and sent to AL.
- **UMC Utrecht** will send the **cleaning and disinfection protocols** applicable in the time Scope A and Scope B were being used and were contaminated to AL.
- **Scanning electron microscope** photos will be taken by **UMC Utrecht and TU Delft** of relevant parts in an attempt to identify the brown deposits. The results of this are found in "Appendix G - Scanning electron microscope photos and explanations".

9 Independent expert opinion

Cleaning and disinfection protocols

Observations and interpretations: The endoscopy department of the UMC Utrecht follows their own written protocol "Internal cleaning of endoscopes" when cleaning the scopes. This protocol dates from June 7, 2013 and in it the notifications from the field safety notice from Olympus dated January 15, 2013 are not included. Even the later field safety notices published by Olympus and the revised instruction manual issued on June 1 2015 (see appendix D for a chronological overview), were not included in the written protocol by UMC Utrecht. Employees of the endoscopy department were in fact informed of the different field safety notices and were considered to have known:

- That the fixed distal tip cover can no longer be removed and for that reason the channel of the forceps elevator cable no longer had to be rinsed.
- the forceps elevator requires extra attention. it should be brushed using combination brush BW-412T/MAJ-1339.
- That the forceps elevator must be rinsed with a water gun, while the endoscope is submerged in detergent (and not with the Olympus prescribed injection syringes with detergent).
- the forceps elevator must be at 45 degrees for cleaning in the ETD3.

From the actions not included in the written protocol but which were known it is assumed that the staff were sufficiently trained to understand and follow these instructions. However, even including these actions, there were various deviations between the instructions for manual (pre-)cleaning from Olympus and implementation at UMC Utrecht (see Appendix E "Audit of cleaning and disinfection protocols of UMC Utrecht"). Because the scopes became contaminated at different times (Scope A on January 13, 2015 and Scope B on June 6, 2015), the situation is considered from the Olympus instruction status on these two dates. "Protocol" here means the all of the written UMC Utrecht protocol plus the known actions which were not included in it:

Viewed from the Olympus instruction status of January 13, 2015:

Deviations of the UMC Utrecht protocol from the Olympus instructions

- Only air was used to rinse in the treatment room, not water.
- The detergent used was "Dr. Weigert Neodisher Mediclean Forte 0.5 – 3%". This agent is alkaline, but Olympus prescribed pH neutrality.
- Leakage test is not always carried out under water as standard on the CSD, but only in case of suspected leakage.
- Brushing of the forceps elevator is not prescribed in detail.
- Brushing of the ventilation openings is not prescribed in detail.
- No detergent is aspirated via the suction/biopsy channel, but this channel is flushed with a water gun while the scope is submerged in the detergent.
- Recesses of the forceps elevator are not flushed with 30 ml syringes with detergent, but with a water gun while the scope is submerged in detergent.
- Channels are not flushed with air after manual cleaning, but left to drip dry above the sink.

Deviations of the UMC Utrecht protocol from the Olympus recommendations

- Forceps elevator is only brushed with the BW-412T and not again with MAJ-1888 or a similar product.

Viewed from the Olympus instruction status of Monday, June 15, 2015:

Deviations of the UMC Utrecht protocol from the Olympus instructions

- In the treatment room, during manual pre-cleaning, detergent is still aspirated, as was prescribed in the previous Olympus instructions, but is replaced by the instruction that only clean water must be used. Duration of suction is not dictated, Olympus recommends 30s.
- In the treatment room only air is used to flush (time not specified, Olympus recommends 10s) and not with water (Olympus recommends 30s).
- The forceps elevator is not raised and lowered three times under water in the treatment room.
- The detergent used was "Dr. Weigert Neodisher Mediclean Forte 0.5 – 3%". This agent is alkaline, but Olympus prescribed pH neutrality.
- Leakage test is not always carried out under water as standard on the CSD, but only in case of suspected leakage. Forceps elevator is not moved in this case either.
- Brushing of the forceps elevator is not prescribed in detail.
- Brushing of the ventilation openings is not prescribed in detail.
- No detergent is aspirated via the suction/biopsy channel, but this channel is flushed with a water gun while the scope is submerged in the detergent.
- Forceps elevator is only brushed with the BW-412T and not again with MAJ-1888 or a similar product.
- Recesses of the forceps elevator are not flushed with 30 ml syringes with detergent, but with a water gun while the scope is submerged in detergent.
- Channels are not flushed with air after manual cleaning, but left to drip dry above the sink.

In the treatment room, even after June 1, 2015 according to Olympus instructions, room before June 1, 2015, detergent was *aspirated*instead of clean water. Even though this was strictly seen as a deviation from the manufacturer instructions after June 1, 2015, it is improbable that this would have negative effects on cleaning. *Not flushing* with water would more probably have a negative effect on cleaning, but validation reports from Olympus should clarify this.

The detergent used in manual cleaning, Dr. Weigert Neodisher Mediclean Forte 0.5 – 3%, is alkaline (pH 10.1) and thus does not meet the manufacturer specification that a pH neutral detergent must be used at all times. Whether this alternative detergent resulted in worse or better cleaning or if the scopes could have been affected by the detergent used cannot be determined without further research.

The leak test with the leak test pump (Olympus MU-1) was not done under water as a rule, but only if there was a suspicion of a leak. Small leaks are very hard to see under water. Direct visual observation of air leaks outside of the water is even harder and in the event of a leak of packages or channels in the scope itself even impossible. In those cases "hearing it leak" could offer the solution, but that only works if the leak is sufficiently loud and exceeds the environmental noise. This deviation in the leak test can thus very probably led to leaks not being noticed or noticed too late, through which moisture and micro-organisms may have entered the scopes and persisted through multiple use cycles.

thee detailed instructions regarding brushing were not in the UMC Utrecht protocol. Whether this detail should have been included depends on how well the personnel is trained and intrinsically followed the detailed instructions provided by Olympus.

The failure to suction detergent, but instead flushing the suction/biopsy channels with water using a water gun may have had favorable as well as unfavorable effects. The higher pressure of the flushing could have had a better cleaning effect. Because water was used and not detergent, this may have destroyed any mechanical advantage through the more unfavorable surface tension and chemical composition of water compared to detergent. Namely because the channels are long and narrow, the flow resistance is relatively high, which reduces the potential advantage of higher pressure. In addition, the channels come into lest contact with detergent when using the water gun.

From the observations, doubt arose about whether the flushing with 30 ml syringes resulted in sufficient force and flow for the areas more difficult to reach around the forceps elevator to remove all contamination there and whether the deviation in the UMC Utrecht protocol whereby a water gun was used was a better cleaning procedure than the instructions from Olympus. The use of water instead of detergent to reach the difficult areas around the forceps elevator could, just as with the flushing of

channels, have resulted in less thorough cleaning, but by blasting these places directly, the beneficial effect of the water gun appears to be more probable.

However, even if a water gun cleans better, one must take into consideration the instruction in the Olympus reprocessing manuals; "Do not use air or water pressure higher than 0.5 MPa (5 kgf/cm^2, 71 psi) when flushing endoscope channels with air or liquids". A higher pressure can damage the endoscope." Whether the pressure used conformed to this has not been investigated.

With the current information we cannot determine the extent to which the deviations in the cleaning protocols of UMC Utrecht from the recommendations and instructions from Olympus may have had an influence on the persistence of the MR Klebsiella in Scope A and Scope B. Flushing with a water gun with water instead of an injection syringe and the use of a different detergent may for example, have had positive as well as negative effects. However, not moving the forceps elevator up and down during cleaning, the improper performance of the leak test and not using the MAJ-1888 brush resulted in higher risks of the persistence of micro-organisms than the procedure prescribed or advised by the manufacturer.

Suggestions: Ensure that the cleaning protocols are kept up-to-date and strictly follow the manufacturer's regulations. The recommendation is to follow the advised but not obligatory measures. If it is decided to deviate from the manufacturer's recommendations, make sure that there is substantiated an documented validation of the in-house cleaning protocols. Ensure that the employees are always aware of the protocols, that a hard copy of these protocols is available in the space where the execution takes place and that employees know where to find these documents. If despite these measures there is still persistence of micro-organisms, the cause must be found. The manufacturer could formulate recommendations as instructions and should work on easier to clean constructions to make following the instructions easier in practice and thus stimulate those instructions being followed.

Cultures

Observations and interpretations: The positive cultures traceable to the index isolate from flushing the suction/biopsy channels of both scopes indicated that in both scopes, at least until August 19, 2015, the MDR Klebsiella persisted in the suction/biopsy channel of the tip. The quantity found had already reduced significantly since the previous samples had been taken on August 14, 2015. The MDR Klebsiella was no longer found in the same cultures from December 15, 2015. The disappearance of the MDR Klebsiella could be connected to the repeated flushing (eventually flushed clean) or the long time period between the first and last culture (does not thrive in dry environment).

Cultures during *the investigation* resulted in some positive results with small amounts of micro-organisms, but there was no more MR Klebsiella in evidence (appendix C). Except for one, all positive cultures resulted in small amount of mainly bacteria often present on the skin. *The investigation* was performed under conditions which could no guarantee that skin bacteria contamination would not take place, because a specifically identifiable MR Klebsiella was being sought. Therefore no value can be assigned to these positive cultures. In the moisture around the rubber ring at the entrance to the biopsy channel of Scope B, a small amount or rare and possibly clinically relevant micro-organism was found. This falls outside of the current case, however.

Suggestions: If possible, have an earlier detailed investigation in unexpected subsequent cases, shorter after positive cultures. This could lead to the determination of the precise locations where the procreator is located in the scopes and thus to a better determination of the cause of the persistence.

Integrity of seals and connections

Observations and interpretations: The tip of scope B was visually considerably cleaner than that of Scope a, but Scope B had also been in use for a considerably shorter time. A certain number of issues caused doubts about the integrity of seals in the tip:

- Brown deposit behind the light cover glass of Scope A and the light and camera glass of Scope B
- Brown deposit under the tip covers of both scopes.

- Brown deposit under the arm covers of both scopes.
- Incomplete bonding joints of the arm covers of both scopes.
- Brown deposit around and on the O-ring of both scopes
- Irregular and poor bonding joints on cardan rubber of Scope B
- Non-original types of glue and thread in the bonding joints of both scopes

The brown deposits behind the light cover glass of Scope A and that behind the light cover glass and camera glass of Scope B led us to think that these areas may not have been well sealed, at least at some time, through which growth of micro-organisms, deposits of fluid residue or affectation of any coating may have occurred. Leak routes may have run directly via the shortest path to the outside or indirectly via another leak into the interior of the scope.

The brown deposit under the tip covers of both scopes and the incomplete sealing under the tip covers showed that moisture and/or micro-organisms may have been introduced under the tip covers. The glue seal of the arm cover found under the tip cover appears in both scopes to be incomplete. Some grooves around the arm cover were not completely filled with glue and thus formed an assumed leak route into the interior of the scopes.

On the lever, the lever shaft and O-ring, as well as in the groove in the lever shaft containing the O-ring, there was brown deposits found in both scopes both on the drive section side as well as the patient side. This suggests that the moisture could enter from all of these places. Considering that brown deposits were also found in the drive spaces, it is not impossible that both scopes had moisture incursion to the drive space via the O-ring and/or via the arm cover and/or via the operating cable after a leak in the insertion tube or the suction/biopsy channel. The route via the O-ring is discussed in detail in the report "Investigation of Olympus TJF-Q180V Scoop regarding contamination found after cleaning and disinfection" from 2012. Thus it cannot be ruled out that moisture or micro-organisms migrated from around and over the O-ring from the drive to the patient side or vice versa, but in the current case a migration via the incomplete seals of the arm cover or via the operation cable to another leak is at least as probable. Because after a leak there is a risk that moisture or micro-organisms can remain in the interior of the scope (in principle closed off from the patient), it is important that all seals function well in all directions.

The scanning electron microscope photos (see appendix G) show where brown deposits were found on the O-ring and under the arm covers, structures which are similar to the structures which were observed on the same scale with a known presence of products of oxidation in combination with bacteria or biofilms. In addition to these indicative structures, the images did not offer any further reason for a direct determination of the presence of bacteria or biofilms.

The revised seals of the cardan rubbers performed by the repair company appear in Scope A and Scope B not to be consistent with how they were delivered by Olympus (see appendix H). The green thread should have been surrounded by properly adhering glue, through which the glue and the thread would have formed a single entity. In the fixation of the suction/biopsy channel of Scope A, the fixation thread under the glue was missing entirely. In addition it was determined that the repair company used a different glue than Olympus, except for the sealing of the screw holes in the tip and the gluing of the light cover glass.

The extent to which all deviations from the original gluing methods had an influence on the seal quality cannot be directly determined, but it is assumed that by the improper adherence of glue and thread there was a poorer seal around the cardan connection. In addition, the bonding joint of the cardan rubber of Scope B was loose, which can indicate a leak or the onset of a leak. Furthermore, moisture or micro-organisms could remain under loose sections, even after repeated cleaning.

Suggestions: The original design of the O-ring seal may have played a role in the persistence of micro-organisms. It is possible that the revisions to the existing Olympus TJF-Q180V scopes announced on January 15, 2016 in the USA and Europe and which will be phased in during the spring and other changes to cleaning and disinfection instructions will offer a solution to this. Check the existing seals of all scopes and ensure objective, critical, quantitative measurement of the seal integrity.

The CE label (and thus quality assurance) of these scopes is based on constructions, material choices, tests and validation studies set up by the manufacturer. Therefore, check the extent to which the procedures of the repair company deviate from those of Olympus. If there is a change to the original construction by the use of non-original parts, other materials and other glues in repairs, there is a strong recommendation (whether it happened or not) that this change be linked to a substantiated and

documented test of the suitability of the new parts and construction and to investigate or guarantee that the CE label remains valid after the change to the structure.

By performing the checks and tests listed, if an unexpected occurrence of this type of case arises, it will be more clear which possible leak routes can be ruled out earlier and more easily.

Moisture damage and material damage

Observations and interpretations: The dent in the tip cover of Scope A may, if this happened after it was secured to the tip, the paired deformation of the material may have been the cause of the local release of seals, but no further indications of this were found.

The fact that Molykote was missing under the cardan rubbers of both scopes forms a risk of damage to the cardan rubber through friction with the cardan sleeve. The Molykote must also provide lubrication between channels and cardan. We assume that the damage to the outside of the suction/biopsy channel in Scope B is a result of the lack of MolyKote.

The damage in the suction/biopsy channel of Scope A could, considering the type of the damage, be a survival location for micro-organisms formed by shelters in the flush stream.

In Scope B, on the outside of the channels in the control section, deposits were found which were unanimously characterized by the research team as traces or moisture. This confirmation corresponded completely with the observation of considerable oxidation around the electrical connection in the control section and on the connection parts of the signal tube in the control section. The maintenance history of Scope B (registrations from the repair company and in the internal system of UMC Utrecht) also showed that there was a question of a leak in Scope B. Fluids and micro-organisms could have remained in the control section through this.

Suggestions: Prevent damage of working channels from sharp objects, both during use and during manual cleaning. Examine if and the extent to which the ribbed tubes used by the repair company for the suction/biopsy channel are more easily damaged than the original tubes and avoid the use of these non-original tubes if they are indeed more fragile.

Regular inspection of the channels with a borescope, should be a relatively inexpensive and useful manner to be able to detect damage in the channels in a timely manner. If the damage which could lead to leaks is detected in a timely manner, the risk of micro-organisms intruding into the interior of the scope and thus entering a patient after a repair, is minimized.

The instructions for cleaning and disinfection from the manufacturer apply in principle to an undamaged instrument which has the CE labeled form and construction. As soon as an instrument is damaged or modified, there is a chance that even the most perfect conformity to the cleaning instructions will not result in a clean instrument.

During preventative and corrective maintenance add Molykote or a proven equivalent lubricant under the cardan rubber in a sufficient amount. Preferably follow the manufacturer's instructions.

For repairs after a leak, make sure that there has been adequate cleaning, disinfection and drying of the interior of the scope to prevent micro-organisms moving from the scope to the outside if there is a leak or seal failure, and to prevent any moisture present causing damage through oxidation. If the interior is clean and all seals reliable, detecting later sources of contamination, directions and causes will be easier to find and less expensive.

Design and cleaning

Observations and interpretations: Brown deposits were found in places on the patient side of both scopes, which were totally not accessible to brushes and which were probably difficult to reach for flushing or drying, namely at:

- the part of the lever shaft that is enclosed by the forceps elevator,
- the fixing screw in the forceps elevator,

- the O-ring
- and the groove for the O-ring in the lever shaft
- and in the recess for the lever shaft in the forceps elevator.

It is clear that between the lever shaft and the forceps elevator, moisture or micro-organisms could penetrate, while there is no space or accessibility for brushes or a strong flow. On the scanning electron microscope images (see appendix G) one can see that this brown deposit consist of combinations of powdery material similar to products of erosion or oxidation, materials that very much look like combinations of the products of oxidation with bacteria and materials which appear to have an organic character. Based on the measurements taken, however, it is not possible to provide a conclusion on the actual and exact composition of these materials.

On various areas in the forceps elevator spaces, white and brown deposits were found. These areas are mostly well or reasonably accessible to brushes or flushing, so that it appears that these deposits remained or oxidation occurred through insufficient efficacy of flushing or drying somewhere in the manual or automatic cleaning, disinfection or drying process.

At the input to the suction/biopsy channel on the control section of Scope B, a liquid was found under the rubber ring around the input. This liquid should not have been present after the entire cleaning, disinfection and drying process, and have formed a hotbed for micro-organisms. The high viscosity of the white substance which looks like silicone gel could have contributed to the fluid remaining, if this liquid was included in the application of the gel or if the gel prevented air flow for drying.

Suggestions: Regardless of whether the brown deposits at the listed unaccessible places contained oxidation or biofilms, these places should be well sealed off, then cleaned well to prevent the risks of persistence of micro-organisms. If moisture can permeate to these types of poorly accessible places, micro-organism can probably do that too.

During cleaning, pay extra attention to the correct brushing, flushing and drying of the tip, brown deposits were found there as well on, for example, the chromed, easily accessible part of the forceps elevator. This finding shows that persistence of MR Klebsiella cannot be ruled out by using sub-standard cleaning, disinfection and drying techniques.

Spaces behind and under the forceps elevator should be made more accessible. In the current design, the MAJ-1888 should now ensure for better cleaning. Now that brushing with MAJ-1888 is obligatory, include the MAJ-1888 in the cleaning protocol. The validation reports from Olympus should show whether the new instruction from Olympus should have been sufficiently effective to prevent a persistence of MR Klebsiella.

Identify the composition and origin of the white deposits in the forceps elevator of Scope A. If this proves to be a residue of cleaning chemicals from manual pre-cleaning, it would be good to finish off the manual cleaning with flushing the forceps elevator recess, using clean water, after the scoop is removed from the detergent. If the white deposit proves to be a residue of cleaning chemicals from the ETD3, there should be a validation of whether the tip is always flushed properly at the end of the machine cleaning process.

Check that the drying cabinets function properly and are not opened too often and that all scopes always get the set drying time, but also if this drying time is actually sufficient. It may be that the scopes, possibly despite following the instructions, remain wet for too long and thus oxidation occurred even in easily accessible locations on the tip of Scope A and Scope B, and moisture remained at the entry of the suction/biopsy channel of Scope B.

Authenticity and quality of parts

A reminder: Maintenance and repairs to Scope A and Scope B are carried out by a third party, known to the author and all parties involved, who performed the repairs contracted by UMC Utrecht and for discretion will be called "the repair company" here.

Observations and interpretations for Scope A: From repair reports and requests for information from the UMC Utrecht and the repair company, it appears that in this scope, leaks occurreda number of times, after which in each case the following parts were or had to be replaced:

- Insertion tube
- Suction/biopsy channel

- Suction/biopsy channel bonding joints
- Drive sleeve
- Cardan rubber
- Cardan rubber bonding joints
- Cardan sleeve
- Tip cover
- Tip cover bonding joint
- Brush cables
- Brake knob L/R including O-rings

Parts replaced by the repair company were replaced with "new reproduction parts", not with original Olympus parts (see appendix F). In addition, the concerns about the glue used appear to be justified, considering that the repair company used glue different from that used by Olympus (see appendix F).

In addition, it appeared that the bonding joints of cardan rubber, arm cover, channels and tip cap deviated at many points from how these scopes should normally be constructed (see appendix H) or are even defective: The sealing was not complete everywhere and the adhesion to the connection threads was poor. There was hardly any Molykote powder under the cardan rubber, which is necessary for good protection of the cardan rubber, among other things. The arm cover was, contrary to Olympus standards, soldered to the tip. Glue seals on the arm cover were incomplete, so openings occurred. The attachment of the suction/biopsy channel contained sufficient glue, but no fixation thread which would have guaranteed a safe and reliable attachment.

The rubber ring around the entrance to the suction/biopsy channel on the control section of Scope A and Scope B appeared after comparison (see appendix H) to be 0.15 mm thicker (axial) than the original, new item from Olympus with comparable interior and exterior diameters. There were no reasons to assume that this difference contributed to the persistence of MR Klebsiella.

According to P8, the arm covers in Scope A and Scope B did not appear to be original. AL could not confirm any differences between the arm covers of Scope A and Scope B and an original, new arm cover from Olympus (see appendix H). Therefore, this observation by P8 was not supported by AL.

Observations and interpretations for Scope B: From repair reports and requests for information from the UMC Utrecht and the repair company, it appears that in this scope, leaks occurreda number of times, after which in each case the following parts were or had to be replaced:

- Insertion tube
- Suction/biopsy channel
- Suction/biopsy channel bonding joints
- Cardan rubber
- Cardan rubber bonding joints
- Cardan sleeve
- Cardan section
- Tip cover
- Tip cover bonding joint
- Drive sleeve
- Propulsion cable
- Brush cables, including sleeves and attachment parts

Parts replaced by the repair company were replaced with "new reproduction parts", and thus not with original Olympus parts (see appendix F). In addition, it was confirmed that the repair company used glue different from that used by Olympus (see appendix F).

In addition, it appeared that the bonding joints of cardan rubber, arm cover, channels and tip cap deviated at many points from how these scopes should normally be constructed (see appendix H) or even defective: The sealing was not complete everywhere and the adhesion to the connection threads was poor. There was hardly any Molykote powder found under the cardan rubber. Molykote is necessary for good protection of the cardan rubber, among other things. It is therefore probable that the lack of Molykote did contribute to the damage to the suction/biopsy channel through friction.

The arm cover was, contrary to Olympus standards (appendix H), soldered to the tip. The arm cover was open on Scope B during the repairs and was not well sealed with glue. In addition, Olympus prescribes that after each opening of the arm cover, a new arm cover is installed. Considering that the arm cover had to be opened by the repair company, it must have been replaced by a non-original alternative (no

indications of this found) or reused: both not consistent with Olympus standards. No lubrication under the distal cuff. The rubber at the entrance to the suction/biopsy channel is covered with a white material which looks like silicone gel. Normally this is transparent, thin silicone oil. The shrink sleeve with which the suction/biopsy channel was connected to the control section, was not in the usual location.

Taking everything into account, it is very possible that one or more of the observed irregularities in the repairs done by the repair company on Scope A and Scope B, as well as the incomplete bonding and sealing of arm cover and tip cover, the lack of sufficient Molykote and the deviating attachments of the suction/biopsy channels did contribute to the persistence of the MR Klebsiella.

Suggestions: Investigate whether this case involves two incidents which coincidentally came together in the current case, or whether the observed irregularities in repairs by the repair company are structural in nature. Critical control and validation of the quality of the repair work in all repaired scopes appears to be advisable. Even more so because this has possible consequences for the repaired instruments regarding the validity of the CE label. If the quality of the repair work is guaranteed, ruling out potential causes of persisting micro-organisms in unexpected future cases will make finding the cause easier and less expensive.

Summary

Observations and interpretations: The aim of the investigation is an attempt to identify whether the persistence of the multi-drug resistant bacteria is caused by:

- incorrect or incomplete execution of the cleaning and disinfection regulations,
- incorrect or incomplete formulation of the cleaning and disinfection guidelines,
- damage or construction defects affecting the endoscopes, or
- other causes.

Incorrect or incomplete execution of the cleaning and disinfection regulations, The UMC Utrecht deviated in a number of points from the recommendations and instructions from Olympus. However, even if the Olympus recommendations and instructions guarantee complete cleaning, it is not clear for every deviation found whether this could have contributed to the persistence of the MR Klebsiella.

Whether the use of detergent which did not meet the Olympus regulations and the use of a water gun may have had a positive or negative effect on the cleaning will have to be investigated further. It is evident, however, that it is of great importance to thoroughly clean the areas around the forceps elevator and to brush with the correct materials thoroughly and preferably rinse with detergent and to move the forceps elevator sufficiently.

The leak test was not normally performed by UMC Utrecht under water. This can conceivably lead to the late detection of leaks and the persistence of leaks and the incursion of moisture and/or micro-organisms during an unknown number of use cycles.

Incorrect or incomplete formulation of the cleaning and disinfection guidelines, It is clear that according to early cases involving the Olympus QJF 180-V, the instructions from Olympus have been updated. These updates may very plausibly lead to improved cleaning. Whether these improved instructions from Olympus (version dated 2015) are sufficient can only be tested using validation measurements, which should be provided by Olympus.

The UMC Utrecht protocol "Internal cleaning of endoscopes" has been incomplete since 2013 and partially incorrect. From 2013, Olympus gave repeated instructions and recommendations for cleaning in the reprocessing instructions, Field Safety Notices and information letters, which were not all implemented by UMC Utrecht. Even though users should have done their best to follow the *recommendations* it is understandable and not inconceivable that the degree of compliance with recommendations was lower in users than is ideal, because they were formulated too freely. Simplification of the cleaning instructions (without making them less effective and thus probably necessarily coinciding with design improvements) should be able to improve compliance with the instructions.

Damage or construction defects affecting the endoscopes: The suction/biopsy channel of Scope A had *damage near the tip*. This damage is clearly visible on both the Nikon D800 photos and the scanning electron microscope, as well as the fact that it continues onto the spring winding of the wall of the tube.

It is not implausible that MR Klebsiella could have persisted in the space under this damage. However, this can no longer be observed in the latest tests and the scanning electron microscope images. The *traces of oxidation and interior deposits* found on Scope B indicate remaining moisture, which may have contained microorganisms. In the case of a leak somewhere of poorly functioning seal or bonding, this moisture could have found its way into the suction/biopsy channel, into the recess around the forceps elevator, or into patients.

The observed construction defects/deviations occurring during repairs by the repair company could nearly all have contributed to the persistence of MR Klebsiella. Unless there was a *direct location or route for the retention or incursion* or micro-organisms in the scope, or whether there was *a route in the direction of the patient for microorganisms to remain after a(repaired leak)* in the scope. In any case, the following potential locations or routes for the persistence of MDR Klebsiella can be indicated in Scope A:

- the incomplete bonding of the arm cover
- and the incorrectly executed connection of the suction/biopsy channel.

In Scope B, these are:

- the incomplete bonding of the arm cover,
- the incorrectly executed connection of the suction/biopsy channel,
- the detached cardan bonding joints,
- the poor connection of the tip frame to the tip cover,
- and the damaged sleeve of the suction/biopsy channel, probably caused by the lack of Molykote.

Other causes: The opportunities for design improvement of the Olympus QJF 180-V have already been discussed at length in a previous report (A.J. Loeve, 2012 "Investigation of Olympus TJF-Q180V Scopes regarding contamination found after cleaning and disinfection"). These included, among other things, better cleaning of the construction around the forceps elevator. It may be necessary to add that brown deposits were also found between the lift shaft and the forceps elevator and around the screw in the forceps elevator. However, formation of these deposits are part of the design or are caused by the maintenance performed by the repair company cannot be determined in this case.

A final conclusion regarding the location of and reasons for the persistence of the MR Klebsiella cannot be given, due to the coincidence of two complicating situations:

1. The dismantling investigation was started too late after the contaminations, so that MDR Klebsiella was no longer found and the location of the persistence could not be determined.
2. There is a combination of potential cleaning deficits at the UMC Utrecht, not conforming to the original CE labeled version of the repairs to the scopes performed by the repair company and design related hindrances in the thorough cleaning of the scopes.

During *the investigation* there were deviations on a number of aspects, irregularities and concerns found which all separately or together could have contributed to the persistence of the MR Klebsiella. To be able to make concluding statements in the future on these types of findings, it is advisable to reduce the number of potential causes as far as possible. Suggestions have been made to this effect.

Appendix A - Investigation plan

Working plan: TJF-Q180V endoscopes research UMC Utrecht

Date Sunday, December 13, 2015
Subject Research working plan on persistent contamination of TJF-Q180V endoscopes.
Authors P1, infection prevention expert at UMC Utrecht; AL, researcher in biomechanical engineering TU Delft; P2, physician-microbiologist UMC Utrecht

Introduction
A multi-drug resistant *Klebsiella pneumoniae* (henceforth MDR *Klebsiella*) was discovered in two TJF-Q180V endoscopes of the UMC Utrecht after repeated cleaning and disinfection. In order to identify the persistence of the bacteria, further research will be carried out on the endoscopes.
This document will describe the content and the method of the investigation to be carried out. This document was approved by the UMC Utrecht, Olympus Nederland and the Technical University of Delft (TU Delft) prior to the start of the investigation.

Participating parties, location, division of tasks and investigation results
This research is a joint effort from UMC Utrecht, Olympus and the TU Delft. Table 1 lists the role and division of tasks for each participating party.
The cleaning and disinfection of the TJF-Q180V endoscopes prior to the investigation will take place in the UMC Utrecht. The dismantling of the endoscopes will take place at Olympus Nederland in Zoeterwoude.

Code the names below if the document is made public!

Name	A	B	Function	Institution	Role
Dr. A.J. Loeve, MSc	x	x	Researcher Biomechanical Engineering	TU Delft	Independent expert
P8		x		Olympus	Scope dismantling
P7				Olympus	
P6				Olympus	
P1	x	x	Infection Prevention Expert	UMC Utrecht	Microbiological sampling
P2			Physician-Microbiologist	UMC Utrecht	Microbiological control supervisor, sampling assistant
P4			Instrument technician	UMC Utrecht	Observer
P3	x		Disinfection employee	UMC Utrecht	Cleaning and disinfection of endoscopes
P10	x		Senior CSD consultant	Olympus BV	Supervision of cleaning and disinfection of endoscopes

P9				Olympus BV	
P12			Physician-investigator	Erasmus MC	Recording of visual material (video)
P13			Investigator	TU Delft	Support by AL and P12
P5			Infection prevention expert	UMC Utrecht	Sampling assistant
P15			Physician-microbiologist in training	UMC Utrecht	Sampling assistant

Table 1. Investigation participants A=critical participant part I; B=critical participant part II.

- As the independent expert from the TU Delft, AL will take photos of each process step of the endoscope parts, keep notes and write a technical report on the results of the investigation.
- AL has the final authority to make decisions regarding the investigation steps to be taken.
- P1 will take the samples.
- P2 is responsible for the storage, logistics and elaboration of the samples.
- P8 will look after the dismantling the endoscopes.
- The microbiological research will be carried out by the Microbiological Laboratory of the UMC Utrecht.

The report of the research will state which participants from table 1 are present during which part of the investigation. During breaks or other reasons why one of the critical participants (column A and B) are not able to be present, the investigation must be interrupted. The investigation will only be resumed once all critical participants are present again.

Objective

The aim of the investigation is to identify the cause of the persistent contamination of the two TJF-Q180V endoscopes of the UMC Utrecht. An attempt will be made to identify whether the persistence of the MDR *Klebsiella* is caused by:

- incorrect or incomplete execution of the cleaning and disinfection regulations,
- incorrect or incomplete formulation of the cleaning and disinfection guidelines,
- damage or construction defects affecting the endoscopes, or
- other unforeseen circumstance(s).

Material

In this investigation, the two endoscopes (table 2) of the type TJF-Q180V (henceforth: endoscopes) will be studied. These endoscopes were manufactured by Olympus and are the property of the UMC Utrecht.

Table 2: ERCP endoscopes UMC Utrecht information

Serial Number	**Inventory number**	**Type**	**Manufacturer**	**Purchase date**
2101841	170485	TJF-Q180V	Olympus	9/16/2011
2304233	179505	TJF-Q180V	Olympus	9/16/2013

Microbiological monitoring has repeatedly isolated MDR *Klebsiella* from both endoscopes. The isolated MDR *Klebsiella* from the two endoscopes were indistinguishable after molecular typing and are therefore considered identical.

UMC Utrecht took the endoscopes out of service as of August 13, 2015.

Method

The research consists of two substudies. In the first part of the investigation (day 1), the endoscopes will be cleaned and disinfected in accordance with the guidelines from Olympus Nederland. After cleaning and disinfection, the endoscopes are dried. In the second part of the investigation the endoscopes will be dismantled. With this, a functional inspection and microbial tests will be carried out. Further explanation on the two substudies below.

Substudy I (December 15, 2015)

Prior to dismantling, the endoscopes will be sampled for cultivation, subjected to several tests, and cleaned and disinfected according to the Olympus manual. The cleaning and disinfection will be carried out using equipment and resources from the UMC Utrecht as much as possible, and supplemented with material from Olympus where necessary. The cleaning and disinfection is carried out by UMC Utrecht employee(s).

1. Sampling of cultures
   1.1. The tip of the scope and the channels are sampled for cultivation by Olympus.
2. Execution of tests
   2.1. Air supply, water supply, and suction volume of both endoscopes are measured by Olympus.
3. Execution of cleaning and disinfection of the endoscopes
   3.1. The Olympus manual for cleaning and disinfection of the scope is strictly adhered to during cleaning and disinfection. Cleaning and disinfection is carried out in the UMC Utrecht and using the materials and resources available at the UMC Utrecht; where necessary supplemented by Olympus Nederland.
   3.2. The pre-cleaning is carried out by employees of the GE&L department.
   3.3. Cleaning and disinfection is carried out by CSD employees (Central Scope Disinfection) of the UMC Utrecht.
   3.4. Functional tests that must be carried out during the cleaning and disinfection process in accordance with the manual by Olympus, such as the leakage test, are also carried out.
   3.5. CSD employees will carry out the cleaning in accordance with normal procedure; Olympus Nederland provides guidance (based on Manual Olympus TJF-Q180V Version 5.0 - 05/2015).
   3.6. The entire process of cleaning and disinfection will be recorded as photo and/or video material.
   3.7. After disinfection, the scopes are sampled for cultivation again by Olympus.
   3.8. The endoscopes will be dried in a drying cabinet from the UMCU.
   3.9. The endoscopes are sealed and the seal is photographed.
   3.10. On December 16, the endoscopes were taken by AL to Olympus Nederland in Zoeterwoude.

Substudy II (December 16, 2015, possible overrun to December 17)

One endoscope is inspected first and microbiological samples are taken (points 1 and 2). Then it is completely dismantled before the second endoscope receives the same treatment.

The following working method is adopted during dismantling:

- All tools used for dismantling are sterilized and stored in sterile conditions before dismantling starts.
- The working area is covered with a sterile cloth, and the endoscope is placed on the cloth. Dismantling takes place on the cloth.
- Several sterile culture plates are placed on and around the working area used for dismantling, in order to check the surrounding conditions.
- Container for recovery is sterilized and stored in sterile conditions before dismantling starts.
- The persons carrying out the dismantling and sampling for cultures are wearing clean overcoats, mouth masks, caps and sterile gloves. Gloves are changed when necessary.

- Sampling for cultures must be done without cross-contamination occurring. In order to prevent cross-contamination, a new stick must be used every time a sample for cultures is taken in a new place.

The investigation consists of the following parts as a minimum:

1. Visual inspection, photography and microbiological check
   1.1. A visual inspection will take place prior to dismantling
   1.2. Attention will be especially focused on:
      1.2.1. the distal end of the endoscope, the tip and the part underneath the forceps elevator
      1.2.2. feed through the closure of the forceps elevator channel on the side of the tip and the control section
      1.2.3. A small diameter fiberscope will be used wherever possible, to record images of the recesses.
   1.3. All findings are recorded, whereby photography and video recordings are used.

2. Microbiological check
   2.1. Samples will be taken from the distal end of the endoscopes, using the same type of brush that the scope was cleaned with during the cleaning process. The brush was moved along the accessible part of the tip and the part underneath the forceps elevator.
   2.2. After taking samples using the cleaning brush, samples are taken from the tip of the endoscopes using a thin cytology brush and a nasopharyngeal culture swab. Possibly also places that cannot be reached by manual pre-cleaning.

3. Taking samples of interior channels
   3.1. Samples are taken of the interior channels using a (cytology) brush or spiral brush. The brushes are not brought into contact with the distal end/forceps elevator. The limit is directly at the output of the channel.

4. Step-by-step dismantling of the endoscopes
   4.1. The relevant part of each dismantling step is visually inspected and externally sampled. After external inspection and sampling, the part was first cleaned as thoroughly as possible externally (to prevent discussion in the previous report regarding the bacteria on/under the cap) with ethanol. After each dismantling step, the dismantled and therefore cleared parts are visually inspected, sampled and if necessary, cleaned externally before the next part is started.
   4.2. As a minimum, the following parts are subjected to research as described in 5.1: the distal end and the forceps elevator, the interior of the endoscope shaft, the forceps elevator channel and the forceps elevator cable, the suction/biopsy channel, the water-air channel, the interior of the handle and the interior of the cover on the tip.
   4.3. Each dismantled part is individually stored in a sterile container and/or sterile safety bag.
   4.4. Visual inspection is recorded on photographs.
   4.5. Sampling for microbiological tests is carried out by using swabs or cytology brushes. It can be decided that dismantled parts are microbiologically tested in an enrichment medium.
   4.6. If deemed relevant, parts of the endoscopes will be examined using an electron microscope at a later stage, for additional visual inspection and to study the presence of biofilms.

After completion of the investigation, all research material, including culture material and all non-dismantled parts of the TJF-Q180V endoscopes is transported back to the proprietor, UMC Utrecht.
If deemed necessary by the independent expert, there can be deviation from the abovementioned plan, and/or additional research can be carried out.

Microbiological research will consist of bacterial cultures at a minimum. Extra material will also be taken for molecular study. If deemed necessary, additional diagnostics will be carried out on the samples taken.

Reporting of research findings

The research findings will be processed into a written report by the independent expert. This report will be provided to all participating parties. After the report has a status of final, the report will be made public for interested parties. Up to the time of publication of the final report, all parties involved have a duty of confidentiality.

Appendix B – OLYMPUS training checklist cleaning and disinfection of Olympus TJF-Q180V

Table B.1: Checklist used or manual pre-cleaning and disinfection of the studied Olympus TJF-Q180V scopes, Scope A and Scope B, as also used by Olympus B.V. In order to be able to indicate which steps have been carried out for both scopes, a column has been added so that there can be an indication of 'Point concluded' for two scopes. Gray-colored parts have not been completed, as these are not applicable. Checklist has been included as Appendix with the consent of Olympus B.V.

Hospital		
Department		
Point concluded	**Scope A**	**Scope B**
1. First cleaning cycle in the treatment room		
1.1. Wipe the input part using wet, clean, lint-free cloth or sponge	V	V
1.2. Place the forceps elevator in the lowest position	V	V
1.3. Aspirate water (30 sec water, 10 sec air)	V	V
1.4 Raise and lower the forceps elevator three times during suction	X Omitted	V
1.5. Flush air-water channel using water and air through cleaning valve (30 sec water, 10 sec air)	V	V
1.6. Remove valves and supply tubes	V	V
1.7. Organizational aspects: transport/waiting time/services	N/A	N/A
2. Leakage testing		
2.1. Attach leakage test cap / connect leakage test adaptor	V	V
2.2. Carry out the leakage test	V (16:01 wet)	V (4:36 PM wet)
3. Manual cleaning		
3.1. Immerse endoscope in water with detergent	V	V
3.2. Clean endoscope exterior using a soft brush or lint-free cloth	V	V
3.3. Brush around the forceps elevator and instrument channel (A)	V	V
3.4. Raise and lower the forceps elevator three times in the detergent	V	V
3.5. Brush the channels (C)	V	V
3.6. Aspirate detergent through suction/biopsy channel and instrument channel using flushing adaptors and suction pump (30 sec) **[ed.: 8*50ml syringe due to absence of suction pump]**	V	V
3.7. Raise and lower the forceps elevator three times during aspiration	V	V
3.8. Brush forceps elevator recesses three times using the MAJ-1888 brush (B)	V	V
3.9. Raise and lower the forceps elevator three times in the detergent	V	V
3.10. Flush the interior of the forceps elevator (using 30ml syringe twice in upper position and twice in lower position of the forceps elevator until no more dirt is visible)	V	V
3.11. Flush water-/ air channel using detergent through cleaning adaptor (3*30ml)	V	V
3.12. Flush the channels using water (3*30ml) through cleaning adaptor (immersed). **[ed.: Subsequently also using air (3*30ml) and for flushing using water, the detergent is forgone.]**	(16:18 out of water) V	(16:44 out of water) V

4. Miscellaneous		
4.1. Cleaning, disinfection, and sterilization of accessories (valves)	N/A	N/A
4.2. Content of manuals discussed	N/A	N/A
4.3. Operational manual available	N/A	N/A
4.4. Reprocessing manual available	N/A	N/A

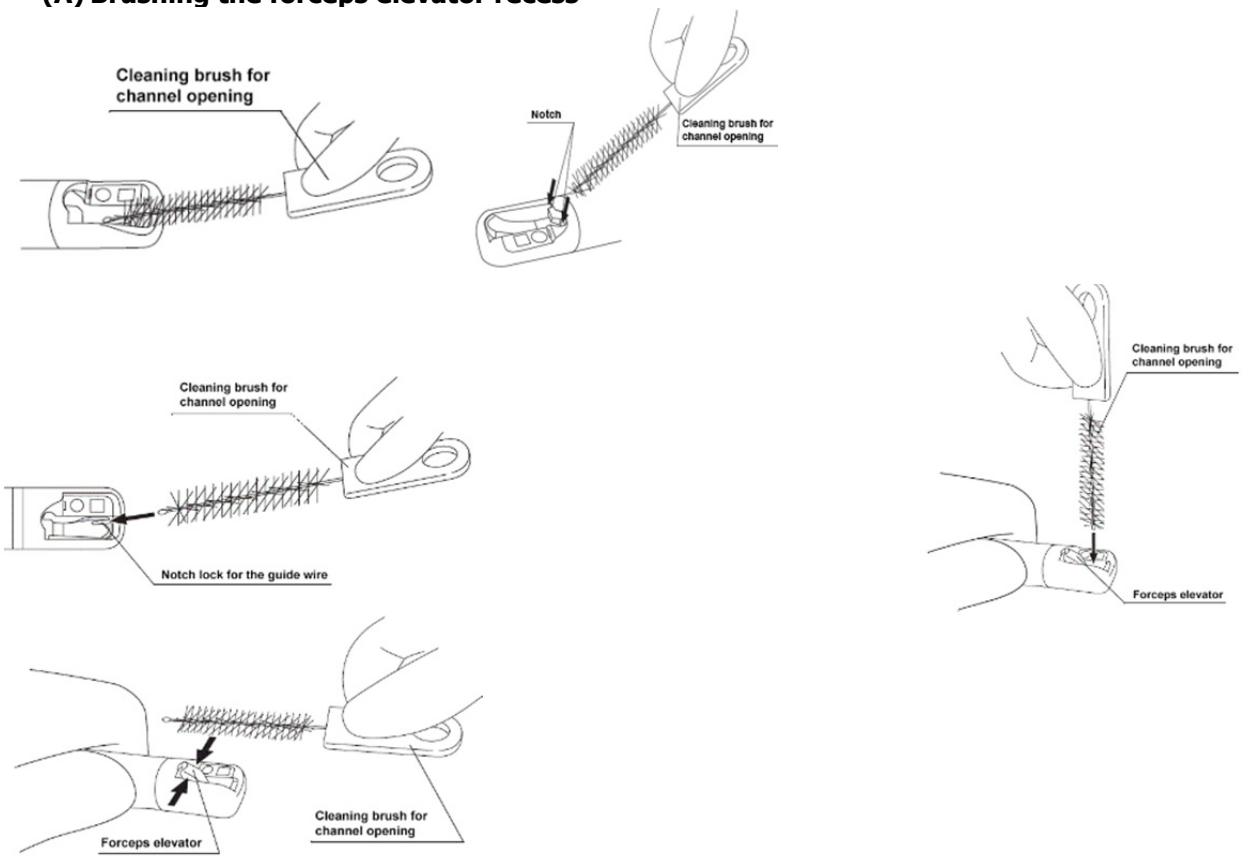
4.5. Disclaimer: The instruction manual contains important information for safe and effective use of the Olympus instruments. Read the manual and the instructions for use carefully and use the instruments as described.

This checklist is intended as an aid for the instruction and is not a replacement for the manual. The application of other instructions than those included in the manual are for the account and the risk of the hospital.

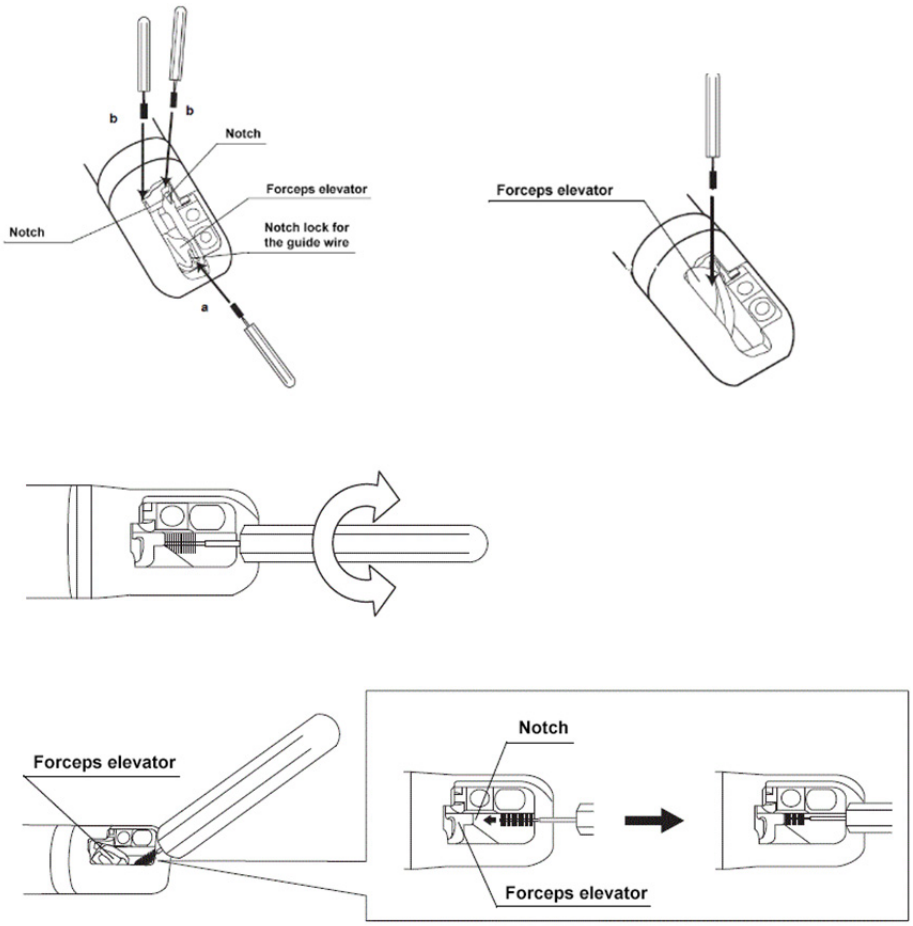
Signing of this document confirms the receipt of the instruction by Olympus Nederland.

Name DSMH/DSRD/	Signature	Date
Name of Olympus employee		

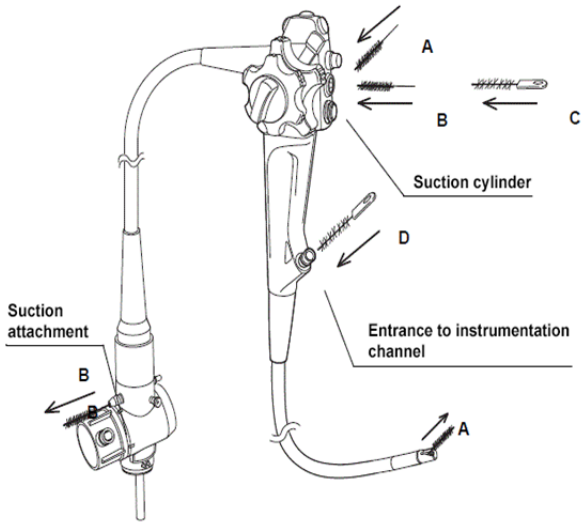
(A) Brushing the forceps elevator recess



(B) Brushing the forceps elevator recess



(C) Brushing the channel



Appendix C - Registration information of parts and cultures UMC Utrecht

*Table C.1: Registration numbers and descriptions of stored parts and locations of culture samples and results of cultures, taken during the investigation. Where the column 'Sample material' contains the value **'PART'**, the entire object as mentioned in the column 'Stored part or sample location of culture' is stored in clean, sealed packaging. Samples for culture taken by Olympus were sent to an external laboratory by Olympus for further analysis and are therefore not listed here. This list was made by UMC Utrecht and adapted for legibility in this document (regarding layout and terminology, but not content) by AL. In the cultures taken, one grown colony corresponded with 10 CFU (colony forming units) per 100 ml of a liquid sample. If no colony grew, the number of CFU/100 ml was then <10 CFU/100 ml.*

No.	Scope	Stored part of sample location of culture	Sample material	Date of sample	Date of lab action	Lab no. UMCU:	Culture result
1	B	tip for R&D	Pernasal dry swab	12/15/2015	12/15/2015	15-621913	No microorganisms
2	B	suction/biopsy channel for R&D	Physiological saline	12/15/2015	12/15/2015	15-621917	**<10 CFU/100 ml**
3	B	water/air channel for R&D	Physiological saline	12/15/2015	12/15/2015	15-621921	**<10 CFU/100 ml**
4	A	tip for R&D	Pernasal dry swab	12/15/2015	12/15/2015	15-621925	No microorganisms
5	**A**	**suction/biopsy channel for R&D**	**Physiological saline**	**12/15/2015**	**12/15/2015**	**15-621926**	**<10 CFU/100 ml**
6	**A**	**water/air channel for R&D**	**Physiological saline**	**12/15/2015**	**12/15/2015**	**15-621927**	**<10 CFU/100 ml**
7	A	tip for dismantling	Pernasal dry swab	12/16/2015	12/17/2015	15-622707	No microorganisms
8	A	tip for dismantling	for MAJ-1888	12/16/2015	12/17/2015	15-622709	No microorganisms
9	A	suction/biopsy channel for dismantling	for BW-412T	12/16/2015	12/17/2015	15-622710	No microorganisms
10	**A**	**connector side suction/biopsy channel control section**	**for BW-412T**	**12/16/2015**	**12/17/2015**	**15-622712**	**Gram positive strain, not to be determined further, because not medically relevant and not included in the Malditof library (sporadic)**
11	A	front bonding joint of cardan rubber	**PART**	12/16/2015	-	-	*Not cultured.*
12	A	Metal underneath cardan rubber bonding joint	Dry swab	12/16/2015	12/17/2015	15-622714	No microorganisms
13	A	cover	**PART**	12/16/2015	-	-	*Not cultured.*
14	A	tip without cover entire area	Dry swab	12/16/2015	12/17/2015	15-622716	No microorganisms
15	A	glue without cover	**PART**	12/16/2015	-	-	*Not cultured.*
16	A	tip without cover	Pernasal dry swab	12/16/2015	12/17/2015	15-622717	No microorganisms
17	A	tip without cover exterior	Dry swab	12/16/2015	12/17/2015	15-622719	No microorganisms
18	A	tip without cover interior	Dry swab	12/16/2015	12/17/2015	15-622722	No microorganisms
19	A	arm cover	**PART**	12/16/2015	-	-	*Not cultured.*

No.	Scope	Stored part of sample location of culture	Sample material	Date of sample	Date of lab action	Lab no. UMCU:	Culture result
20	A	underneath arm cover	Pernasal dry swab	12/16/2015	12/17/2015	15-622724	No microorganisms
21	A	screw	**PART**	12/16/2015	-	-	*Not cultured.*
22	A	O-ring	**PART**	12/16/2015	-	-	*Not cultured.*
23	A	arm	**PART**	12/16/2015	-	-	*Not cultured.*
24	A	elevator	**PART**	12/16/2015	-	-	*Not cultured.*
25	A	Input suction/biopsy channel control section	**PART**	12/16/2015	-	-	*Not cultured.*
26	**A**	**forceps elevator recess + sleeve shaft recess**	**Pernasal dry swab**	**12/16/2015**	**12/17/2015**	**15-622725**	**Micrococcus luteus (sporadic) [red.: skin bacteria]**
27	**A**	**sleeve shaft recess from arm side**	**Pernasal dry swab**	**12/16/2015**	**12/17/2015**	**15-622726**	**Brevibacterium casei (sporadic) [red.: skin bacteria]**
28	A	control section parts	**PART**	12/16/2015	-	-	*Not cultured.*
29	A	suction/biopsy channel middle section	**PART**	12/16/2015	-	-	*Not cultured.*
30	A	suction/biopsy channel distal part (ribbed)	**PART**	12/16/2015	-	-	*Not cultured.*
31	A	suction/biopsy channel distal end cut open damage	**PART**	12/16/2015	-	-	*Not cultured.*
32	A	water/air channel	**PART**	12/16/2015	-	-	*Not cultured.*
33	A	propulsion cable forceps elevator	**PART**	12/16/2015	-	-	*Not cultured.*
34	A	channel propulsion cable forceps elevator	**PART**	12/16/2015	-	-	*Not cultured.*
35	A	scope tip	**PART**	12/16/2015	-	-	*Not cultured.*
36	B	(1709505) tip for dismantling	Pernasal dry swab	12/16/2015	12/17/2015	15-622727	No microorganisms
37	B	tip for dismantling	for MAJ-1888	12/16/2015	12/17/2015	15-622728	No microorganisms
38	B	suction/biopsy channel for dismantling	for BW-412T	12/16/2015	12/17/2015	15-622729	No microorganisms
39	B	suction/biopsy channel for dismantling	for BW-412T	12/16/2015	12/17/2015	15-622730	No microorganisms
40	B	cardan rubber front bonding joint	**PART**	12/16/2015	-	-	*Not cultured.*
41	B	metal underneath cardan rubber front bonding joint	Dry swab	12/16/2015	12/17/2015	15-622731	No microorganisms
42	B	cover	**PART**	12/16/2015	-	-	*Not cultured.*
43	N/A	Clean scalpel	**PART**	12/16/2015	-	Do not culture!	*Not cultured.*
44	B	scraping of oxidation? + scalpel	**PART**	12/16/2015	-	Do not culture!	*Not cultured.*

No.	Scope	Stored part of sample location of culture	Sample material	Date of sample	Date of lab action	Lab no. UMCU:	Culture result
45	B	tip without cover entire area	Dry swab	12/16/2015	12/17/2015	15-622732	No microorganisms
46	B	tip without cover exterior	Dry swab	12/16/2015	12/17/2015	15-622733	No microorganisms
47	B	forceps elevator recess (not underneath cover)	Dry swab	12/16/2015	12/17/2015	15-622735	No microorganisms
48	B	forceps elevator recess	Pernasal dry swab	12/16/2015	12/17/2015	15-622736	No microorganisms
49	B	particle from recess in distal tip	**PART**	12/16/2015	-	-	*Not cultured.*
50	B	swab underneath arm cover	Dry swab	12/16/2015	12/17/2015	15-622737	No microorganisms
51	B	arm cover	**PART**	12/16/2015	-	-	*Not cultured.*
52	B	O-ring	**PART**	12/16/2015	-	-	*Not cultured.*
53	B	arm	**PART**	12/16/2015	-	-	*Not cultured.*
54	B	forceps elevator	**PART**	12/16/2015	-	-	*Not cultured.*
55	B	screw on elevator	**PART**	12/16/2015	-	-	*Not cultured.*
56	B	recess under arm cover	Pernasal dry swab	12/16/2015	12/17/2015	15-622738	No microorganisms
57	B	forceps elevator recess interior	Dry swab	12/16/2015	12/17/2015	15-622739	No microorganisms
58	B	rubber ring biopsy input	**PART**	12/16/2015	-	-	*Not cultured.*
59	**B**	**biopsy input (moisture)**	**Dry swab**	**12/16/2015**	**12/17/2015**	**15-622740**	**Stenotrophomonas maltophilia 1-10 colonies (1+) Enterobacter cloacae 1-10 colonies (1+) [red.: clinically relevant bacteria]**
60	B	input biopsy	**PART**	12/16/2015	-	-	*Not cultured.*
61	B	control section parts	**PART**	12/16/2015	-	-	*Not cultured.*
62	B	suction/biopsy channel	**PART**	12/16/2015	-	-	*Not cultured.*
63	B	cable guide wire forceps elevator cable	**PART**	12/16/2015	-	-	*Not cultured.*
64	B	water/air channel	**PART**	12/16/2015	-	-	*Not cultured.*
65	B	forceps elevator cable channel	**PART**	12/16/2015	-	-	*Not cultured.*
66	B	scope head	**PART**	12/16/2015	-	-	*Not cultured.*

Table C.2: Registration numbers and descriptions of culture samples and results of cultures, taken prior to the investigation. The 'index isolate' refers to the bacterial strain that was taken from the infected patients. This list was made by UMC Utrecht and adapted for legibility in this document (regarding layout and terminology, but not content) by AL.

Scope	Date of sample	Location of sample	Microorganism	Quantitative	Comment
A	8/14/2015	Suction/biopsy channel	*Klebsiella pneumoniae*	>200 cfu/20ml	Not distinguishable from index isolate
			Stenotrophomonas maltophilia	>200 cfu/20ml	
			Pseudomonas aeruginosa	>200 cfu/20ml	
			Enterobacter cloacae complex	>200 cfu/20ml	
		Suction/biopsy channel	*Klebsiella pneumoniae*	>200 cfu/20ml	Not distinguishable from index isolate
			Klebsiella oxytoca	>200 cfu/20ml	
			Stenotrophomonas maltophilia	>200 cfu/20ml	
			Pseudomonas aeruginosa	>200 cfu/20ml	
		Cotton swab tip	No microorganisms cultured		Thick cotton wool used only
	8/19/2015	Suction/biopsy channel	*Citrobacter freundii*	1 cfu/20ml	
			Staphylococcus epidermidis	12 cfu/20ml	
			Stenotrophomonas maltophilia	22 cfu/20ml	
			Enterobacter cloacae complex	1 cfu/20ml	
			Coagulase-negative staphylococci	1 cfu/20ml	
		Suction/biopsy channel	*Klebsiella pneumoniae*	75 cfu/20ml	Not distinguishable from index isolate
			Citrobacter freundii	13 cfu/20ml	
			Stenotrophomonas maltophilia	>200 cfu/20 ml	
		Cotton swab tip	No microorganisms cultured		Thin culture stick used as well
B	8/14/2015	Suction/biopsy channel	*Klebsiella pneumoniae*	28 cfu/20ml	Not distinguishable from index isolate
			E. coli	3 cfu/20ml	
		Suction/biopsy channel	*Enterococcus faecium*	1 cfu/20ml	
		Cotton swab tip	No microorganisms cultured		Thick cotton wool used only
	8/19/2015	Suction/biopsy channel	*Klebsiella pneumoniae*	6 cfu/20ml	Not distinguishable from index isolate
			E. coli	4 cfu/20ml	
		Suction/biopsy channel	*Enterococcus faecium*	1 cfu/20ml	
		Cotton swab tip	No microorganisms cultured		Thin culture stick used as well

Appendix D – Summary of cleaning instructions history TJF-Q180V

History of field safety notices, manuals and additional instructions issued by Olympus for TJF-Q180V, as well as the commissioning and disposal dates of the examined scopes, Scope A and Scope B. This appendix merely contains summaries. The full texts of these documents can be requested from Olympus B.V.

September 16, 2011 **Purchase of Scope A**

January 14, 2013 *Olympus letter: "Field Safety Information: Safe reprocessing of the TJF-Q180V." Ref.: SI2013-1/«Number».*

Reminder of the importance of following the instructions for reprocessing, as a result of "a recent incident with a contaminated OLYMPUS duodenovideoscope TJF-Q180V". Incl. brochure one A4-size sheet with memory aids. Incl. **recommendation** for exceptional cases: "The MAJ-1888 brush is suitable for serious soiling or when the reprocessing is to take place at a later time. This brush is able to reach deeper into the forceps elevator."

September 16, 2013 **Purchase of Scope B**

August 4, 2014 *Instructions reprocessing; article number: NL-8600388, Edition 4.0 – 07/2014*

Page 41 lists the following instruction: "The use of the single-use soft brush (MAJ-1888, sold separately) **facilitates** the procedure around the forceps elevator."

Page 47 recommends the following: "In order to clean the forceps elevator more thoroughly, cleaning with the single-use soft brush (MAJ-1888) in accordance with the procedures described below is **recommended**."

August 4, 2014 *Olympus letter: "Important:: Field Safety Corrective Action." Ref.: SI2014-3-4/147/-002/D11010837*

Update cleaning instructions of TJF-Q180V, once again emphasizing the **recommendation** for using the MAJ-1888 brush. A mention that the reprocessing manual has been amended. This probably refers to Issue 4.0 - 07/2014, but this is **not** explicitly mentioned in the letter.

April 10, 2015 *Olympus letter: "Important:: Field Safety Notice." Ref.: SI2015-1/148/-001/D11010837*

Reprocessing Instructions for the Olympus TJF-Q180V duodenoscope, containing a **reminder** of the importance of strict adherence to the instructions issued by Olympus, and specifically to the Field Safety Notice of August 4, 2014.

June 1, 2015 *Olympus letter: Important: "Updated instructions for OLYMPUS TJF - Q180V duodenoscope." Ref.: 148-003/ D11010818.*

With regards to amended reprocessing manual and cleaning brush MAJ-1888 - or MyBrush Brushes (art. no. E0427985). Is issued including amended reprocessing manual, article number: NL-8600388, Version 5.0 – 05/2015, containing **obligation** for the mentioned use of the MAJ-1888 brush. **So from this moment on, hospitals are obliged to use the MAJ-1888.**

August 13, 2015 **Decommissioning of Scope A and Scope B.**

Appendix E - Audit of cleaning and disinfection protocols at UMC Utrecht

Auditverslag: Reiniging en desinfectie TJF-Q180V duodenoscoop

Datum	30 november 2015
Auteur	Camiel Wissink
Onderwerp	Audit reiniging en desinfectie TJF-Q180V endoscoop

Aanleiding

Twee Olympus TJF-Q180V endoscopen van het UMC Utrecht zijn geïdentificeerd als transmissie bron van een multi-resistentie Klebsiella pneumoniae (vanaf hier MR Klebsiella) naar patiënten. De endoscopen bleken persisterend gecontamineerd met de MR *Klebsiella,* vastgesteld middels herhaalde kweken uit de afzuig- en biopsiekanalen. Dit document geeft de audit weer die is verricht op de reiniging en desinfectie procedure van de endoscoop TJF-Q180V.

Divisie Laboratoria en Apotheek

Ziekenhuishygiëne en Infectiepreventie

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Deskundige infectiepreventie

Tel 088 755 35 05
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Toetsingskader

Als toetsingskader is gehanteerd:

- Gebruiksaanwijzing Olympus TJF-Q180V. Versie 5.0 – 05/2015. Verstuurd aan het UMC Utrecht op 1 juni 2015.

Tevens wordt er in het verslag verwezen naar; (tabel 1)

1. Field Safety Notice (FSN) TJF-Q180V. 7 Januari 2013.
2. Brief Olympus Nederland. FSN voor de Olympus TJF-Q180V. 10 april 2014.
3. Brief NVMM (Nederlandse Vereniging voor Medisch Microbiologie). Veiligheidswaarschuwingen bij ERCP endoscoop TJF-Q180V. 17 juli 2014.
4. Brief Olympus Nederland. Bijgewerkte instructies TJF-Q180V duodenoscoop. 1 juni 2015.

Methode

De reiniging en desinfectie procedure is geaudit door het protocol te toetsen aan de Gebruiksaanwijzing Olympus TJF-Q180V (Versie 5.0 – 05/2015). Daarnaast zijn interviews afgenomen met uitvoerende medewerkers van de CSD (Centrale Scopen Desinfectie).

Gepoogd is antwoord te geven op onderstaande vragen:

1. Zijn de FSN opgevolgd/ geprotocolleerd?
2. Zijn er items uit de Olympus Gebruiksaanwijzing (Versie 5.0) die niet zijn uitgevoerd en/of geprotocolleerd?

Resultaten

Tijdens de gebruiksperiode van de TJF-Q180V in het UMC Utrecht is er meerdere keren berichtgeving geweest over de reiniging en desinfectie van de TJF-Q180V. Deze meldingen zijn uiteengezet in tabel 1 waarbij de resultaten van de toetsing (protocol en interview) ook zijn opgenomen.

Bezoekadres:
Heidelberglaan 100
3584 CX Utrecht

Postadres:
Huispostnummer Q05.2.314
Kamernummer Q05.2.311
Postbus 85500
3508 GA Utrecht

Tabel 1: Meldingen omtrent reiniging en desinfectie TJF-Q180V op volgorde van datum melding

Verzenddatum en afzender	**Inhoud**	**Handeling in CSD protocol UMCU?**	**Bekend onder CSD medewerkers?**
15 januari 2013, Olympus	• Vaste distale beschermkap, hierdoor tangenlift kanaal niet spoelen • Borstel de voor en achterkant van de tangenlift • Tangenlift in hoek 45 graden tijdens machinale desinfectie	Nee, protocol is niet herzien n.a.v. de FSN	• Medewerkers zijn op de hoogte van de vaste distale beschermkap • De tangenlift wordt geborsteld met MAJ-1339 (combinatieborstel BW-412T) • Tangenlift wordt gespoeld met waterpistool terwijl endoscoop ondergedompeld in reinigingsmiddel • Medewerkers zijn op de hoogte van tangenlift stand (45 graden) bij automatische reiniging en desinfectie stap
17 juli 2014, NVMM	Verwijzing naar FSN 15-1-2013	Nee, protocol is niet herzien n.a.v. de FSN.	
10 april 2015, Olympus	Verwijzing naar eerdere FSN van 4 augustus 2014.	Nee, protocol is niet herzien n.a.v. de FSN	
1 Juni 2015, Olympus	Bijgewerkte gebruiksaanwijzing • Spoelen rondom tangenlift • Gebruik het MAJ-1888-borsteltje	Nog niet geïmplementeerd	Nee, nog niet geïmplementeerd. Handelingen hier boven beschreven worden uitgevoerd.

Omdat het protocol niet is herzien n.a.v. de FSN is besloten om het protocol te herschrijven met de toevoegingen die de CSD medewerkers wel zeggen uit te voeren. Dit protocol is vervolgens getoetst aan de Gebruiksaanwijzing (versie 5.0) van Olympus. Alle (mogelijke) afwijkingen ten opzichte van de gebruiksaanwijzing zijn hieronder genoemd.

Handeling Gebruiksaanwijzing Olympus	**Discrepantie met UMCU protocol/uitvoering**
<u>Op de behandel kamer:</u>	
Zuig water aan (30 seconden)	Er wordt reinigingsmiddel aangezogen, de duur is niet beschreven
Beweeg tijdens het onderdompelen en afzuigen de tangenlift 3 keer op en neer	Wordt niet uitgevoerd op de behandelkamer, wel op de CSD. Endoscoop is binnen zeer korte tijd na gebruik op CSD aanwezig (<15 min., tenzij in de nacht uitgevoerd. Tijd kan dan oplopen tot 1 uur)
Spoel het lucht-/water kanaal met water en lucht (30 seconden water, 10 seconden lucht)	Het lucht-/water kanaal wordt alleen doorgeblazen met lucht, niet beschreven hoe lang.
<u>Lektest op CSD:</u>	

Voer de lektest onder water uit en beweeg het distale eind en beweeg de tangenlift	Lektest wordt niet standaard onder water uitgevoerd. De test wordt wel onder water uitgevoerd als er verdenking is op lekkage. Distale eind wordt wel bewogen maar tangenlift niet.
Voorreiniging op de CSD:	
Maak gebruik van BW-412T en MAJ-1888.	Er wordt gebruik gemaakt van de combinatie borstel BW-412T zonder de MAJ-1888
Tangenlift borstelen en in detail genoemd hoe uit te voeren (Tot hoever inbrengen, op welke wijze inbrengen en hoe vaak borstelen en welke oppervlakken tangenlift).	Wel beschreven dat het tangenlift moet worden geborsteld, niet in detail beschreven hoe en wat
Borstelen ventiel openingen en in detail genoemd hoe uit te voeren	Wel beschreven dat de ventiel openingen moeten worden geborsteld, alleen niet tot hoe ver inbrengen en hoe uit te voeren (bv. rond draaien)
Reinigingsmiddel aanzuigen via instrumentatiekanaal en afzuigkanaal m.b.v. afzuigpomp	Er wordt niet gebruik gemaakt van een afzuigpomp. De inwendige kanalen worden m.b.v. een waterpistool doorgespoten met water. De endoscoop ligt dan ondergedompeld in reinigingsmiddel. De inwendige kanalen worden voor en na het raggen door gespoten met het waterpistool. Er wordt visueel gecontroleerd of er water/lucht uit het door te spuiten kanaal stroomt.
Uitsparing bij de tangenlift borstelen met de MAJ-1888	Het tangenlift wordt met de BW-412T geborsteld.
Uitsparing bij de tangenlift spoelen met 30 ml spuit met reinigingsvloeistof	Er wordt geen gebruik gemaakt van een losse spuit. De tangenlift wordt met een waterpistool gespoeld. De endoscoop ligt dan ondergedompeld in reinigingsmiddel.
Spoel inwendige kanalen met lucht door met reinigingsadapter	Endoscoop wordt niet met lucht doorgeblazen. Voor machinale desinfectie worden de inwendige kanalen van de endoscoop boven de reinigingsbak leeg laten lopen.

Conclusie

Geconcludeerd kan worden dat de FSN (15 januari 2013, Olympus) waar herhaaldelijk naar wordt verwezen bekend is onder de CSD medewerkers, maar niet is geprotocolleerd in het reiniging en desinfectie protocol.

De belangrijkste verschillen tussen de werkwijze in het UMC Utrecht en de gebruiksaanwijzing van Olympus (versie 5.0) betreffen het gebruik van het borsteltje MAJ-1888 en het gebruik van een afzuigpomp bij reiniging.

Het borsteltje MAJ-1888 is genoemd in de FSN van Olympus van 15 januari 2013, maar niet verplicht gesteld door Olympus. Op 1 juni 2015 heeft Olympus een bijgewerkte Gebruiksaanwijzing gestuurd, met o.a. de verplichting van gebruik van het MAJ-1888 borsteltje. Deze gebruiksaanwijzing is niet volledig geïmplementeerd in het UMC Utrecht. Op 13 augustus zijn de TJF-Q180V endoscopen buiten gebruik gesteld. Het borstelen van de tip met het MAJ-1888-borsteltje was op dat moment nog niet geïmplementeerd.

Daarnaast wordt er een aantal stappen met een waterpistool uitgevoerd, waar Olympus adviseert om gebruik te maken van een slangen set waarbij m.b.v. een afzuigpomp de kanalen met reinigingsmiddel worden doorgespoeld. De endoscoop ligt tijdens het doorspuiten met het waterpistool wel in een bak met reinigingsmiddel, waardoor de kanalen waarschijnlijk grotendeels gevuld zijn met reinigingsmiddel voor het doorspuiten met het waterpistool.
Uit deze audit kan niet worden opgemaakt wat de invloed is van deze afwijkende handelingen ten opzichte van de gebruiksaanwijzing van Olympus op het resultaat van het reinigings- en desinfectieproces van de endoscopen.

Appendix F - Repair and glue details of Scope A and Scope B.

The maintenance management system of the UMC Utrecht showed that Scope A and Scope B underwent considerable repairs to the insertion tube, whereby many parts were replaced (as was suspected during the investigation). Cause for these repairs was damage to the insertion tube. After the first repair, both scopes underwent a second repair under warranty conditions as a result of leakage. At the request of AL, on December 17, 2015, P9 asked the repair company to provide the following for the examined scopes:

1. *Complete repair history.*
2. *Which parts were replaced with reproduction parts. If at all possible, an itemized composition of parts if it is partly original.*
3. *Specification of glue used for cardan rubber.*
4. *Specification of glue used for channels*
5. *In addition, a white glue is discovered on a screw in the forceps elevator section at the distal end that is also used by Olympus. What was incomprehensible that this line seemed original, but really couldn't have been original because the forceps elevator section proved to be a reproduction. Could you please answer this question?*

The requested information was delivered by e-mail on December 21, 2015 by the repair company, as cited below. Considering that Olympus does not sell parts to third parties, all of the parts used by the repair company were new reproduction parts.

Scope A: Serial number 2101841 (TJF-Q180V)

A repair was carried out on this scope by the repair company in May/June 2014, whereby at least the following were replaced: ***Image conductor sleeve, cable sheath, cardan sleeve, brush cables including soldering stoppers, suction/biopsy channel, cardan rubber, distal end cap, brush button, U/D and brake button L/R including o-rings, side cover videoscope.*** A number of parts were replaced again by the following repair on 08-May-2015 (quote date).

1. *First repair at the repair company on 08-May-2015. Second on 05/21/2015 (warranty from first).*
2. *Used [red.: replaced] parts from the repair on 08-May-2015:* ***Image conductor sleeve, cable sheath, cardan sleeve, brush cables including soldering stoppers, biopsy channel, cardan rubber, distal end cap, brake button L/R including o-rings.*** *Used parts for repair on 5/21/2015:* ***Cardan rubber, videoscope side cover.***
3. *Cemedine CA-149, this glue is also used by the Pentax company. We use the same mixing ratio as Pentax Nederland.*
4. *same as 3.*

Scope B: Serial number 2304233 (TJF-Q180V)

1. *First repair at the repair company on 22-Jan-2015, second on 12-Mar-2015 (warranty on first).*
2. *Used parts in the repair on 22-Jan-2015 (considering that Olympus does not sell parts to third parties, all of the parts used by the repair company are new reproduction parts):* ***Image conductor sleeve, cable sheath, cardan sleeve, brush cables, suction/biopsy channel, cardan rubber, distal end cover, brake lever L/R incl. O-rings, elevator channel, elevator cable, elevator cable sheath, elevator connector tube, elevator channel pipe.*** *Used parts for repair on 3/12/2015:* ***Cardan rubber.***
3. *Cemedine CA-149, this glue is also used by the Pentax company. We use the same mixing ratio as Pentax Nederland.*
4. *same as 3.*

Regarding question 5, the repair company responded:

Every now and then, we are given original Olympus glue by a hospital that bonds cardan rubbers in-house. The sealing of the light lens as well as the screw holes in the distal end are bonded using the Olympus glue.

Reason [ed.: for use of other glue] is that the Cemedine CA-149 with white coloring discolors over time and does not look OEM and we do not want that.

Because the names of parts in this report do not always match those given by the repair company, there is a list of parts below which were replaced per scope with the names used in this report.

Table F.1: Parts in the insertion section (insertion tube including tip) of Scope A and Scope B which were replaced by the repair company in every case.

Scope A		Scope B	
Name of part as in this report	Name as used by the repair company	Name of part as used in this report	Name as used by the repair company
Insertion tube	Image conductor sleeve	Insertion tube	Image conductor sleeve
Drive sleeve	Cable sheath	Drive sleeve	Cable sheath
Cardan sleeve	Cardan sleeve	Cardan sleeve	Cardan sleeve
Brush cables	Brush cables	Brush cables	Brush cables
Suction/biopsy channel	Suction/biopsy channel	Suction/biopsy channel	Suction/biopsy channel
Cardan rubber	Bending section cover	Cardan rubber	Bending section cover
Tip cover	Distal end cover	Tip cover	Distal end cover
		Drive sleeve	Elevator channel
			Elevator channel pipe
			Elevator cable sheath
		Propulsion cable	Elevator cable
			Elevator connector tube

Appendix G - Scanning electron microscope images and explanatory notes

The stored and sampled components of scope A and scope B were scanned in UMC Utrecht by P1 with a scanning electron microscope. In order to assess the quality of the O-rings, the TU Delft (Dr. Iulian Apachitei) did the same with a new, unused O-ring supplied by Olympus. This appendix contains a selection of scanning electron microscope images of the most important parts that were found to have brown deposits, with explanatory notes. Larger versions of all photos can be found at the end of this report.

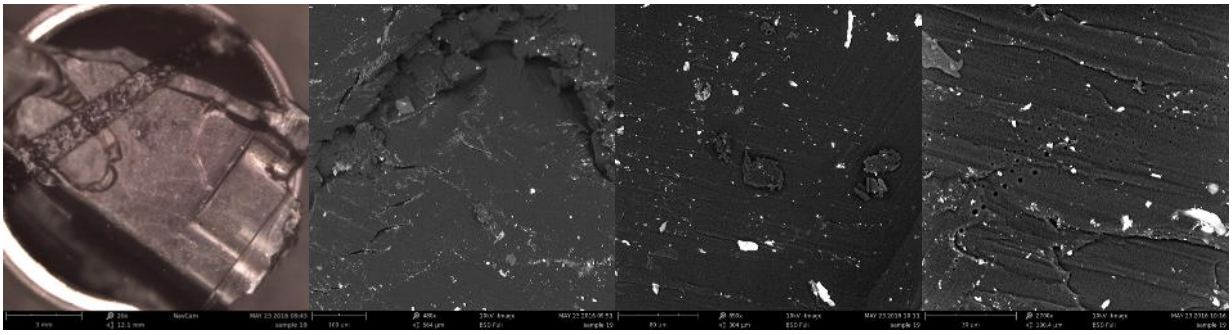

Figure G01: (from left to right) Interior piece tip cover Scope A; Detail scan (480x). Structure of the plastic; Detail scan (890x). Surface structure with particles; Detail scan (2700x). Visible air bubbles.

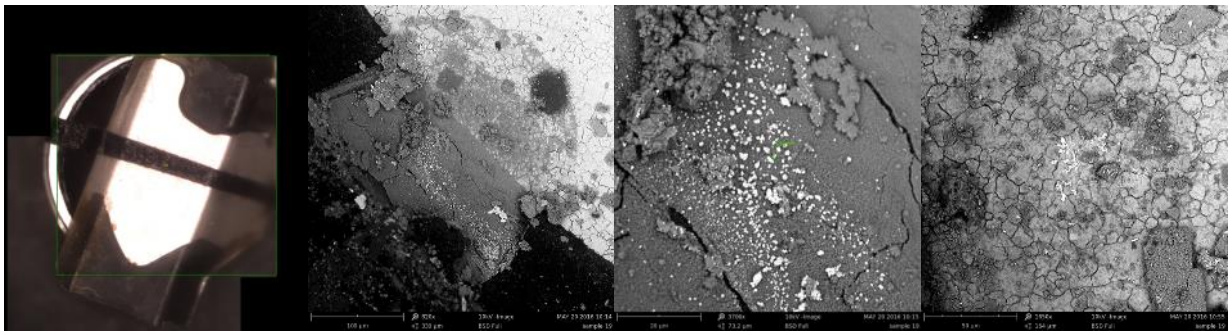

Figure G02: (from left to right) Interior arm cover Scope A; Detail scan (820x). Dried up material; Detail scan (7700x). Dried up, organic-looking material; Detail scan (1650x). Dried up, organic-looking material.

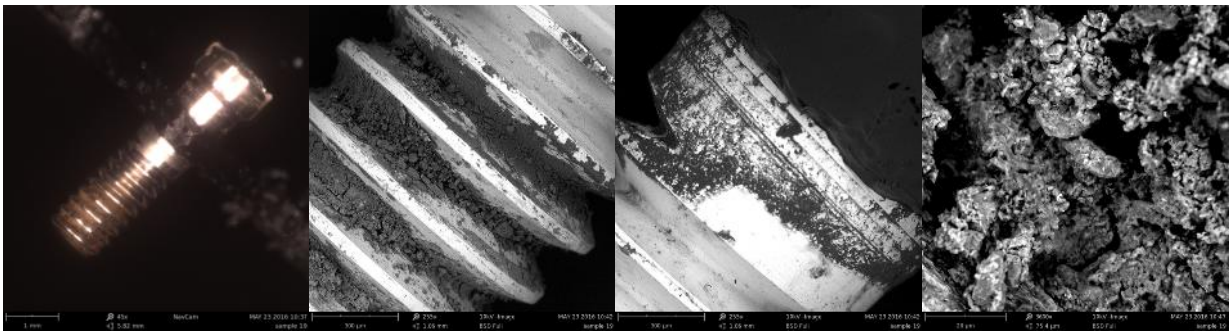

Figure G03: (from left to right) Forceps elevator screw Scope A; Detail scan (255x). Powdery, brown material in screw thread; Detail scan (255x). Powdery brown deposit on screw neck; Detail scan (3600x). Powdery brown deposit with organic characteristics.

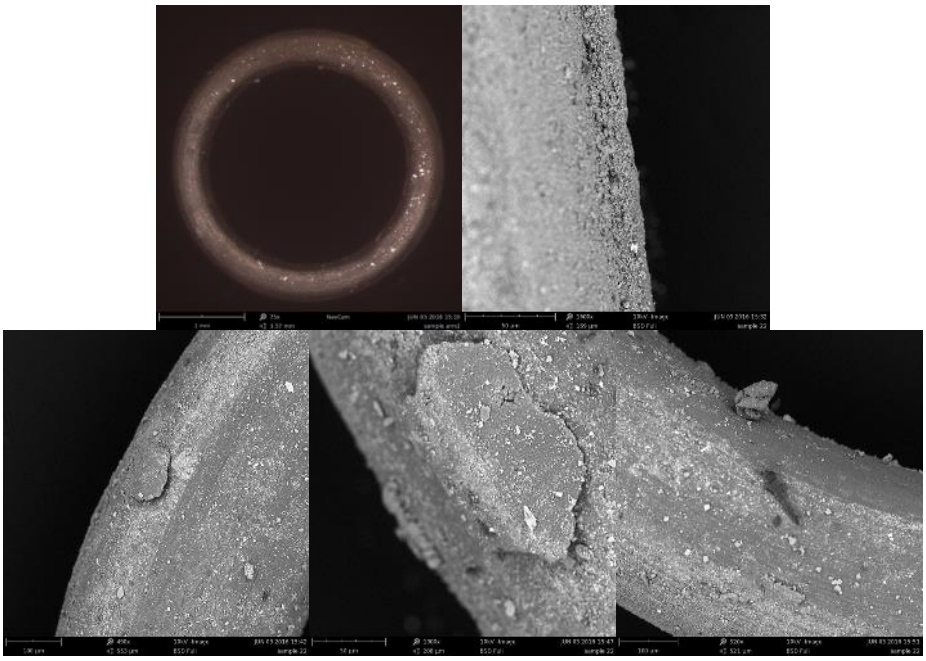

Figure G04: (from left to right) O-ring Scope A; Detail scan (1600x). Porous, rough surface; Detail scan (490x). Damaged surface; Detail scan (1300x). Damaged surface; Detail scan (520x). Loose particles.

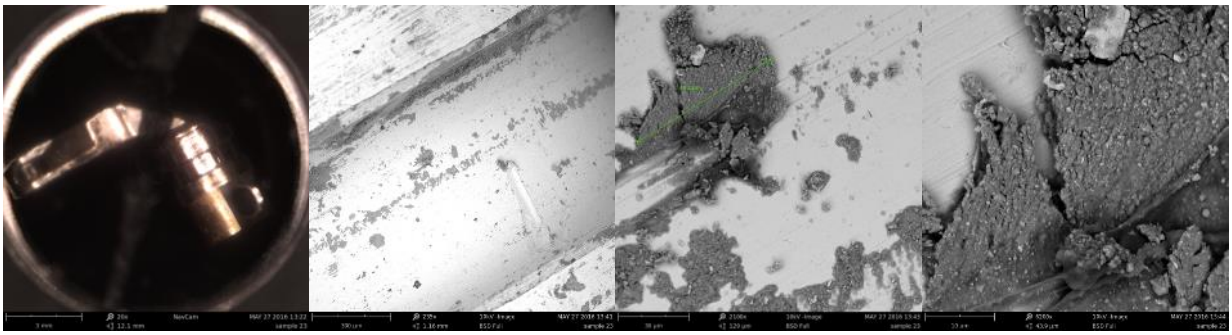

Figure G05: (from left to right) Lever with lever shaft Scope A; Detail scan (235x). Brown deposit in groove for the O-ring; Detail scan (2100x). Part of brown deposit; Detail scan (6200x). Brown deposit is visually similar to oxidation products that develop in the presence of bacteria.

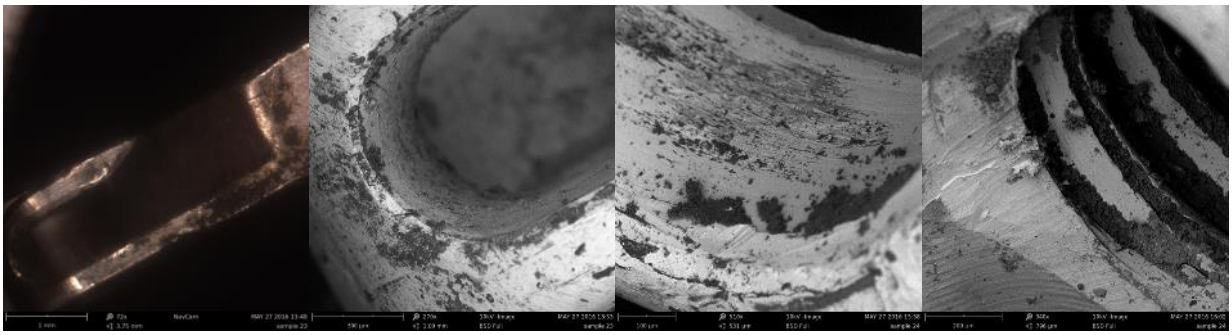

Figure G06: (from left to right) Lever Scope A; Detail scan (270x). Brown deposit in lever; Detail scan (510x). Brown deposit in lever; Detail scan (340x). Brown deposit in screw thread in lever shaft.

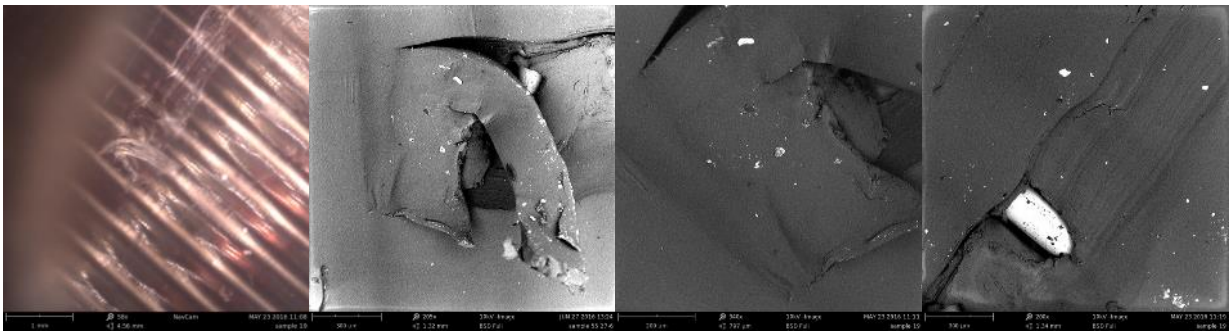

Figure G07: (from left to right) Damage in suction/biopsy channel Scope A; Detail scan (205x). Damage looks clean, save for some small particles; Detail scan (340x). Very little particles on damage; Detail scan (200x). Damage has penetrated to underneath the spring winding in the wall.

Figure G08: (from left to right) Lever with lever shaft Scope A; Detail scan (740x). Brown deposit in lever shaft screw recess; Detail scan (250x). Packed material in lever. Visually similar to oxidation products that develop in the presence of bacteria; Detail scan (340x). Dried up, powdery material on the lever.

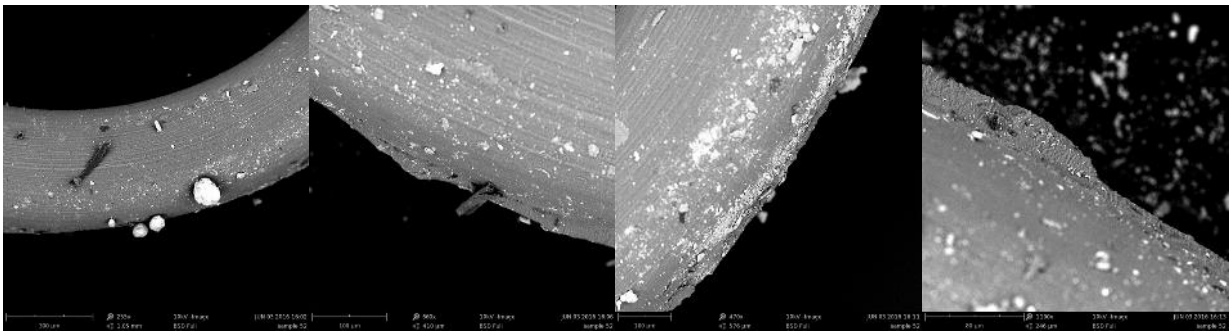

Figure G09: (from left to right) Detail scan O-ring Scope B (255x). Reasonably smooth surface and some particles; Detail scan (660x). Surface roughness on the exterior rim; Detail scan (470x). Surface roughness on the exterior rim and particles on the surface; Detail scan (1100x). Surface roughness on the exterior rim.

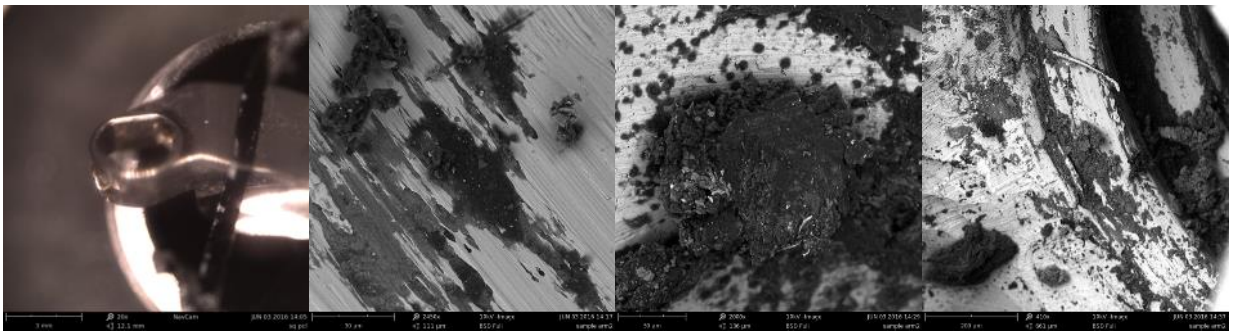

Figure G10: (from left to right) Forceps elevator Scope B; Detail scan (2450x). Brown deposit in lever shaft recess looks organic; Detail scan (2000x). Material is visually similar to oxidation products that develop in the presence of bacteria; Detail scan (410x). Brown, powdery deposit and organic-looking particles in lever shaft recess screw thread.

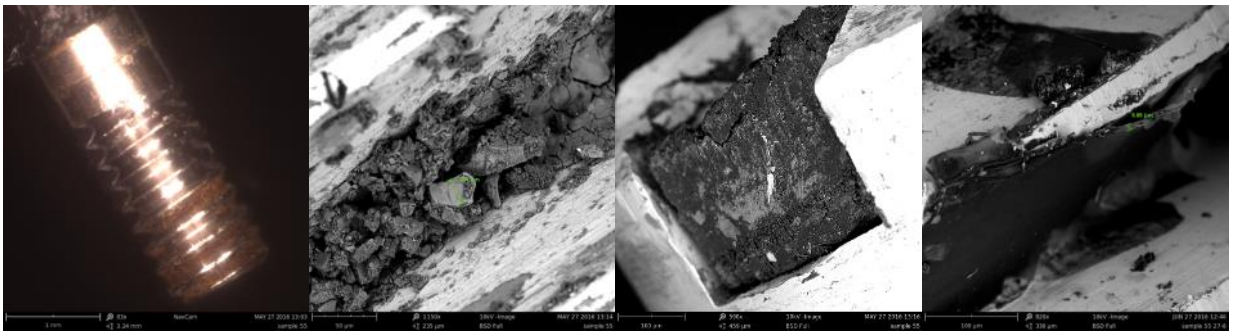

Figure G11: (from left to right) Forceps elevator screw Scope B; Detail scan (1150x). Powdery, brown material in screw thread. Above right, visible that material is dried up and seems crumbled loose; Detail scan (590x). Material in screw head; Detail scan (820x). Glue residue (black in the photo) on the screw thread.

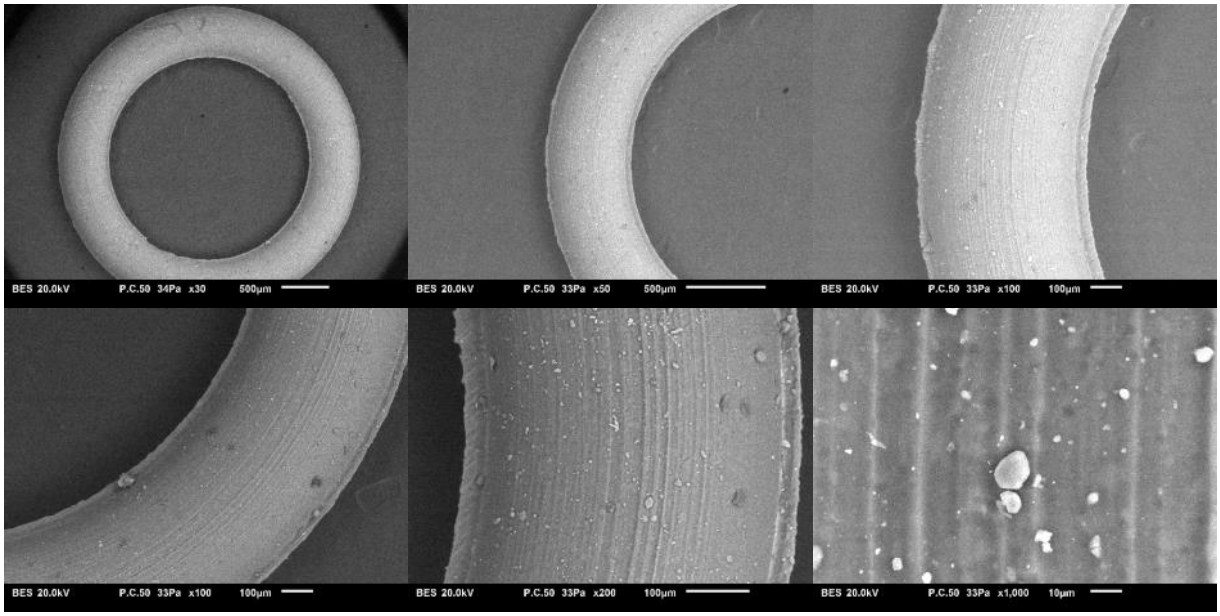

Figure G12: (from left to right, bottom to top) New, clean, unused O-ring as used in Olympus QJF 180-V; Detail scan (50x); Detail scan (100x). Surface is regular and smooth. Tangential production traces. Frayed collar from production process; Detail scan (100x). Little particles on damage; Detail scan (200x). Presence of some particles seems unavoidable even with clean work; Detail scan (1000x).

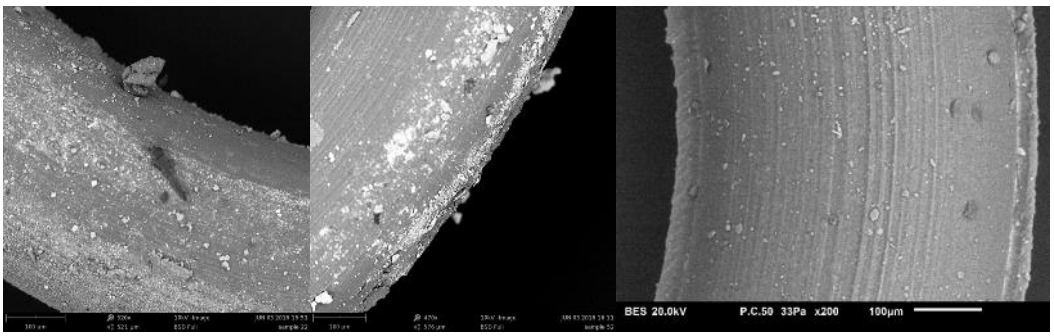

Figure G13: Comparison of used and unused O-rings.
(from left to right) O-ring Scope A (longest in operation); O-ring Scope B (shortest in operation:); New O-ring (unused).

Appendix H - Determination of Olympus standards for assembly and maintenance

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For reasons of IP-sensitivity the contents of this page have been removed.

Appendix I - Contact sheets of all photos for the investigation


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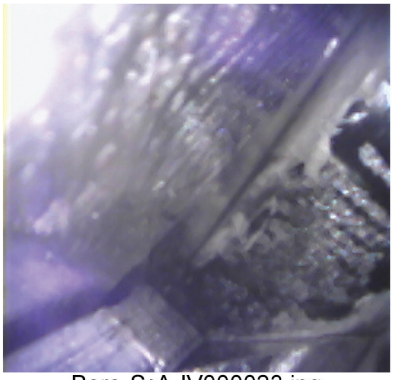
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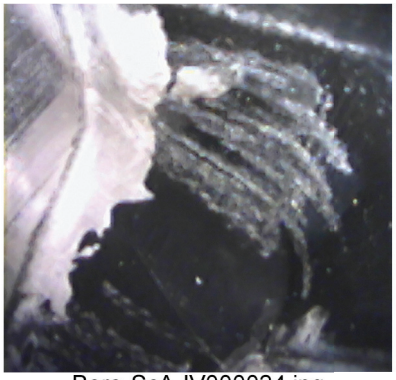
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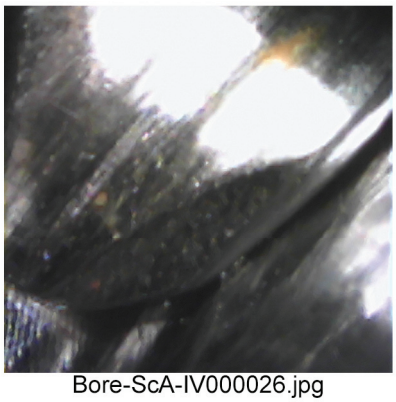
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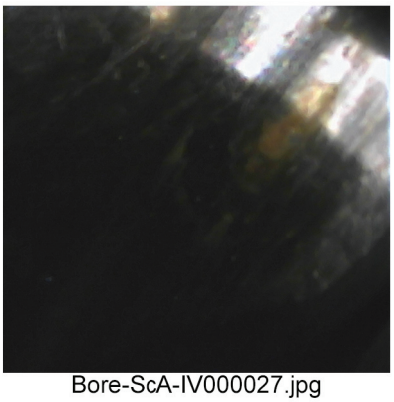
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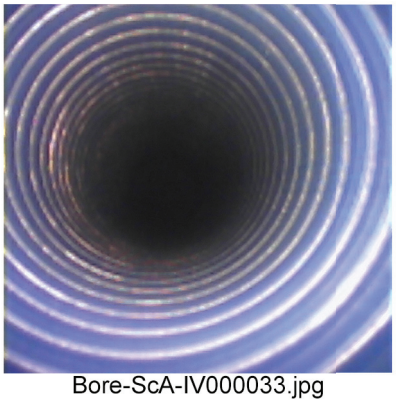
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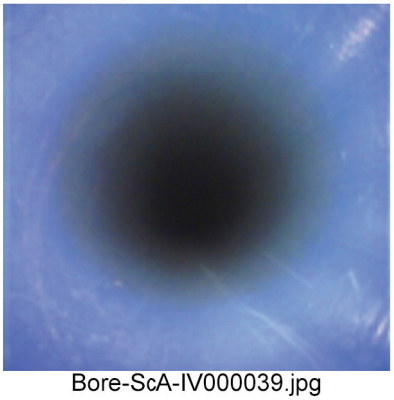
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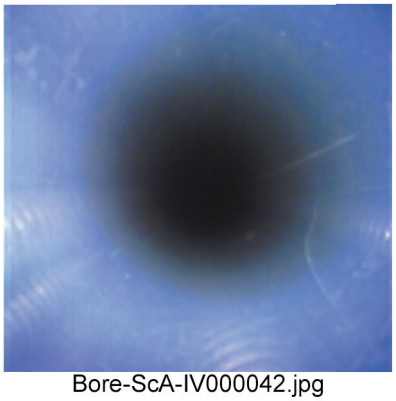
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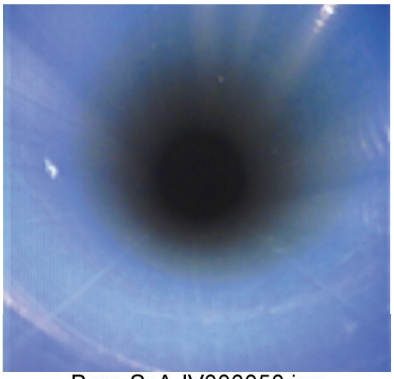
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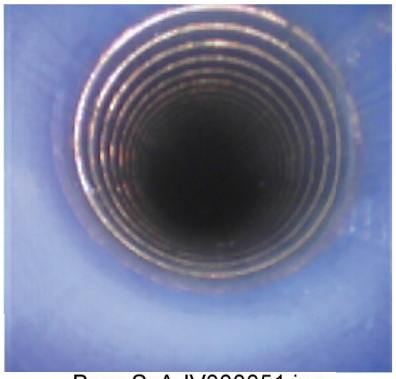
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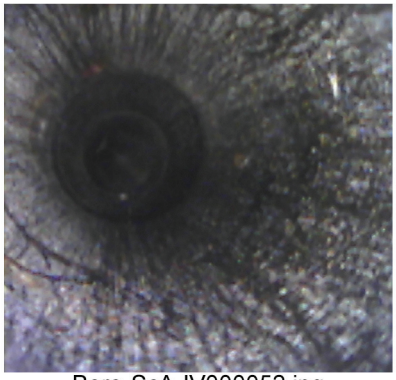
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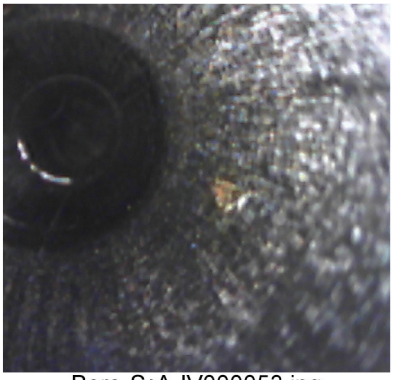
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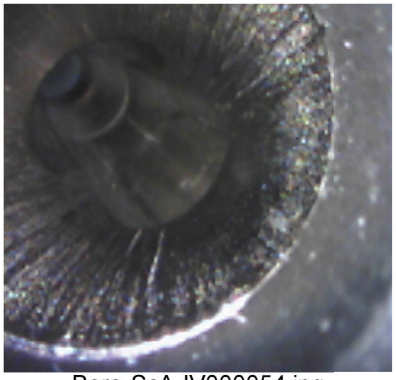
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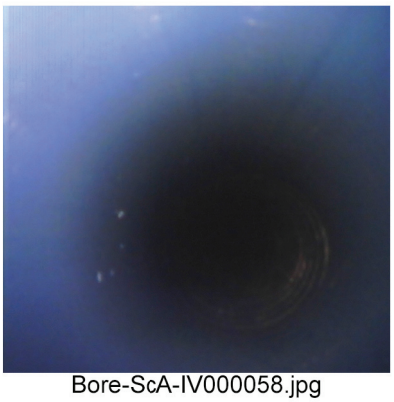
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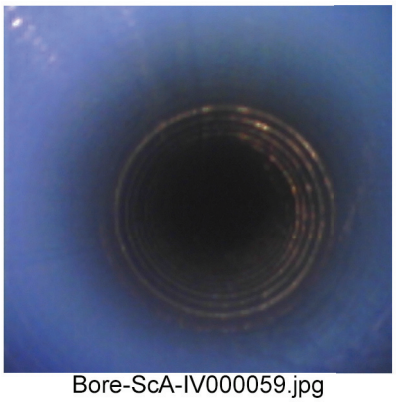
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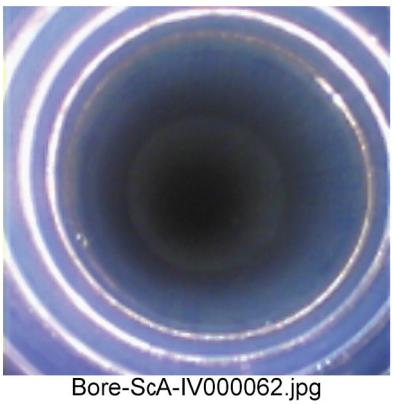
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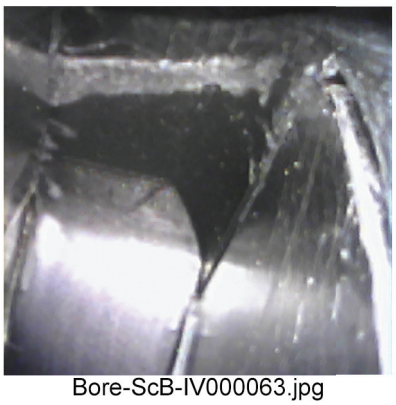
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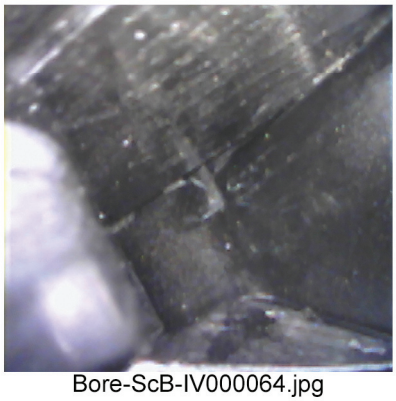
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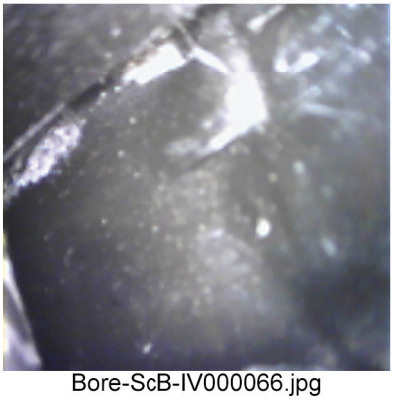
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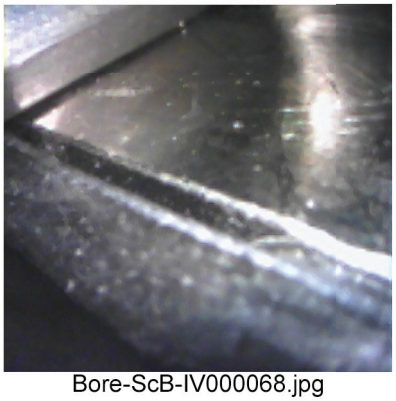
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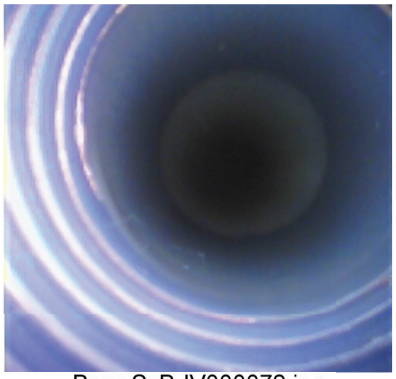
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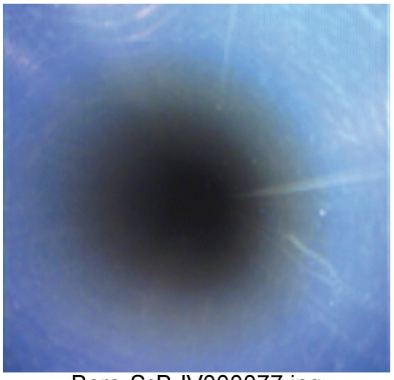
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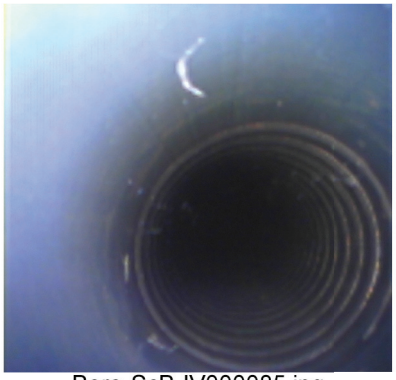
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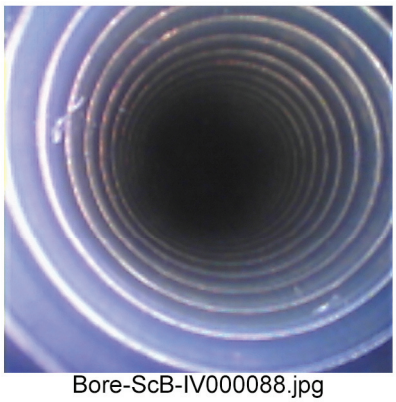
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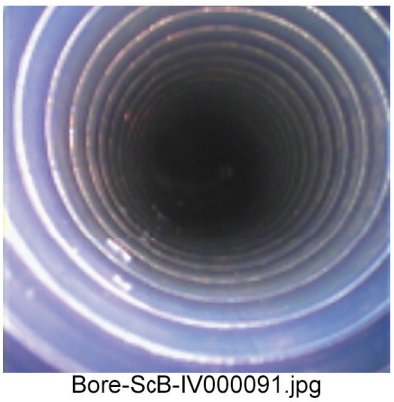
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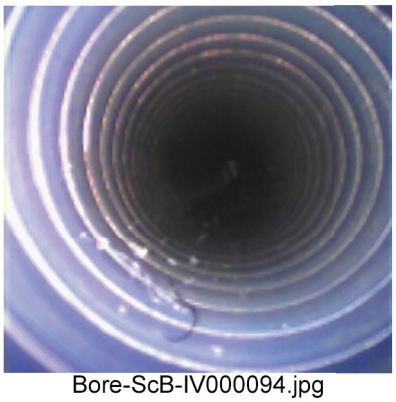
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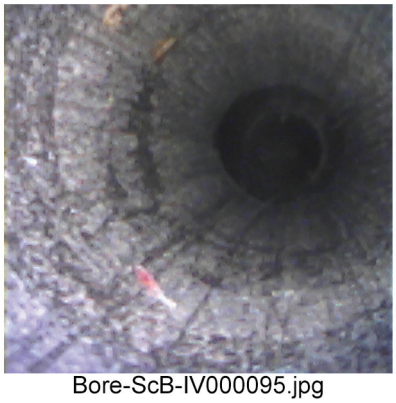
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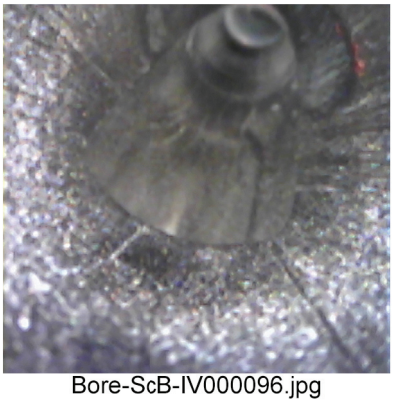
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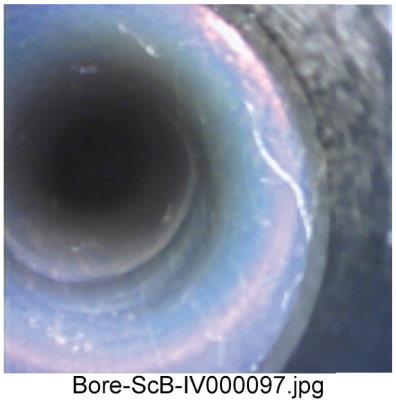
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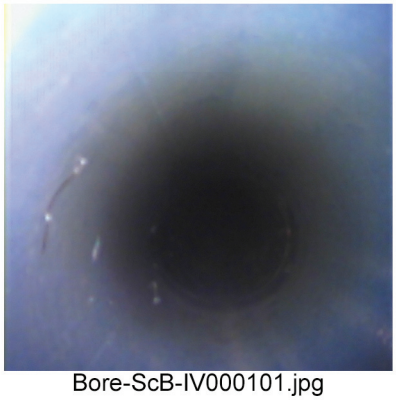
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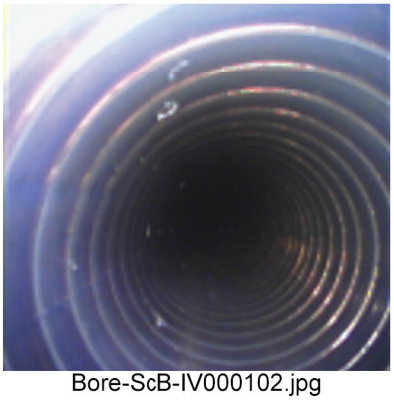
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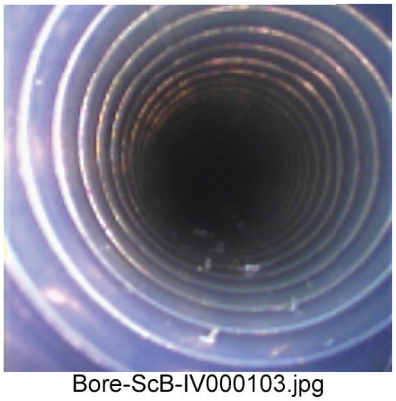
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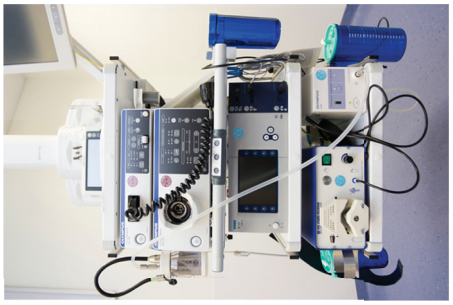
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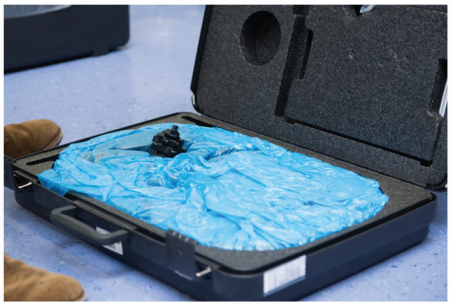

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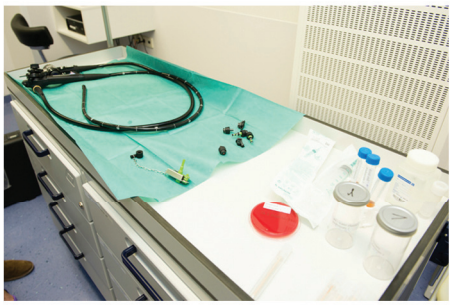

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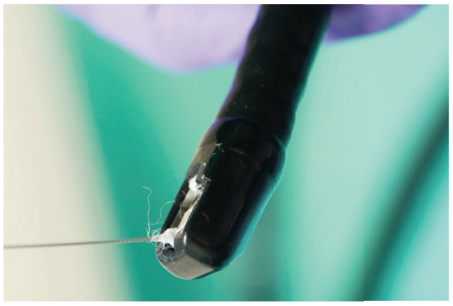

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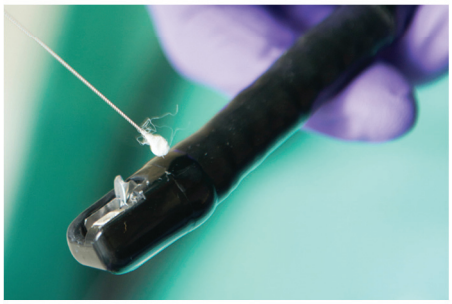

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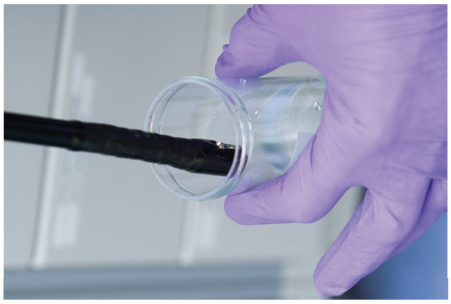

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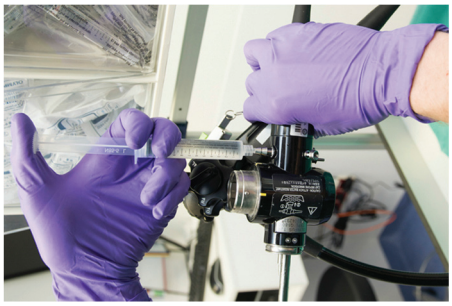

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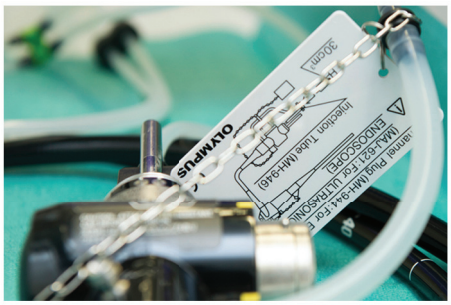

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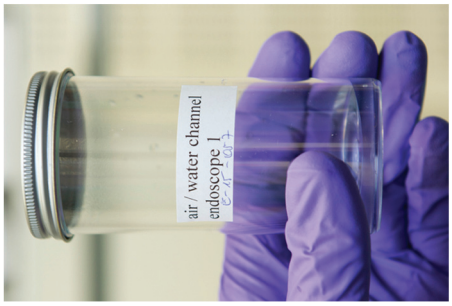

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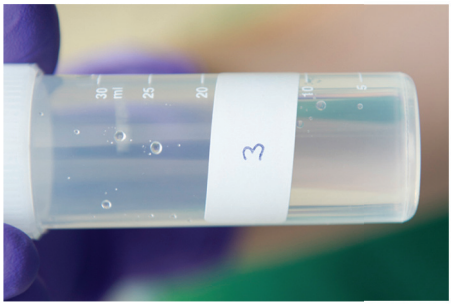

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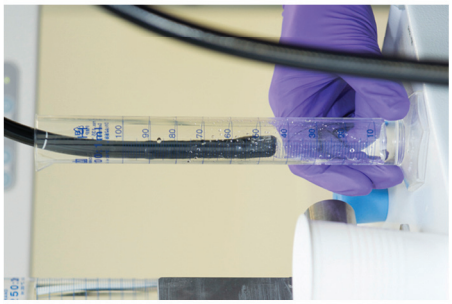

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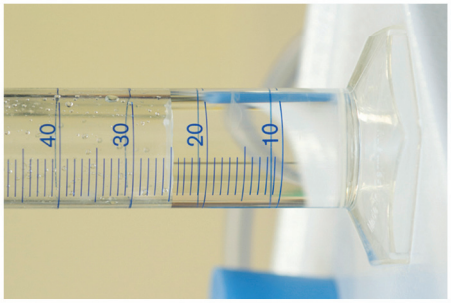

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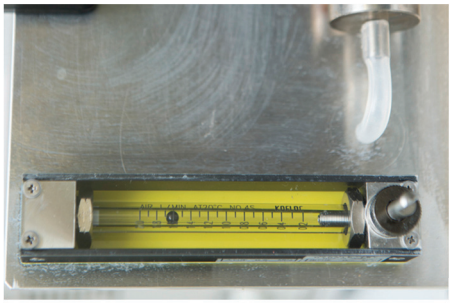

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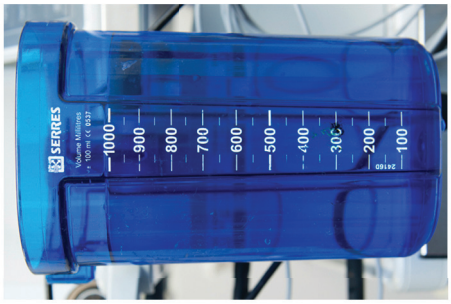

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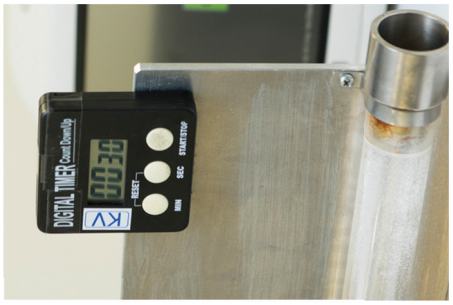

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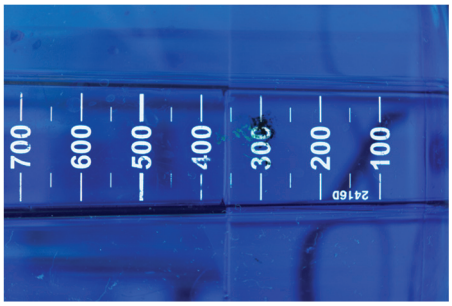

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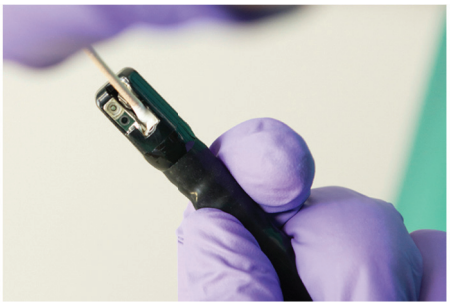

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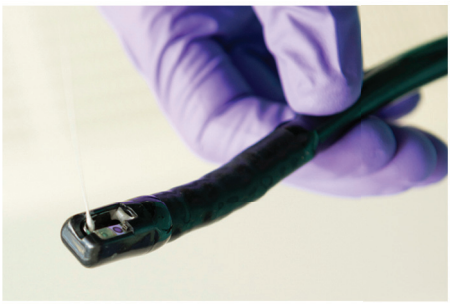

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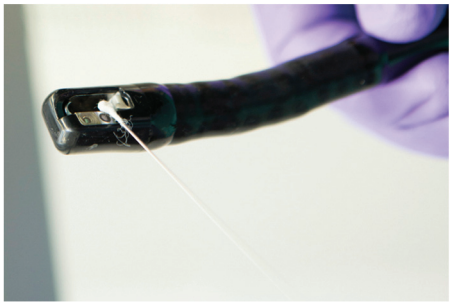

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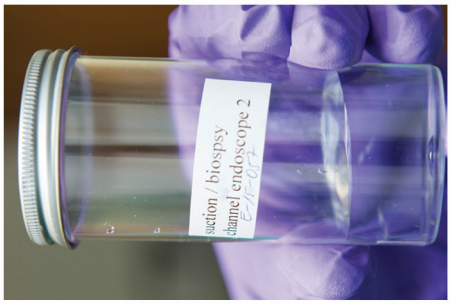

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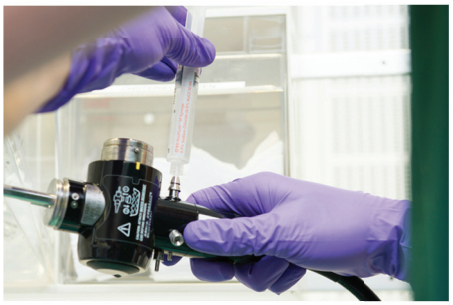

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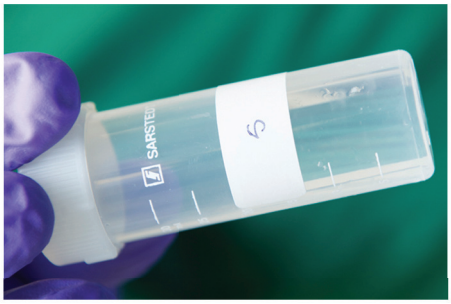

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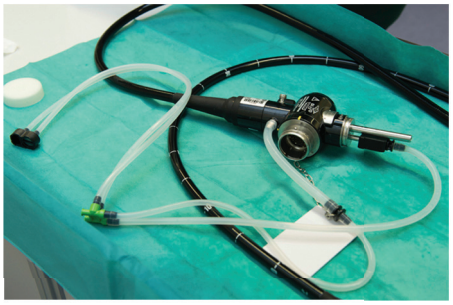

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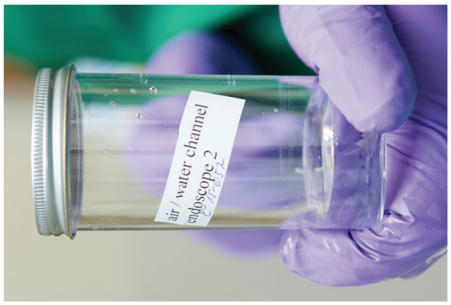

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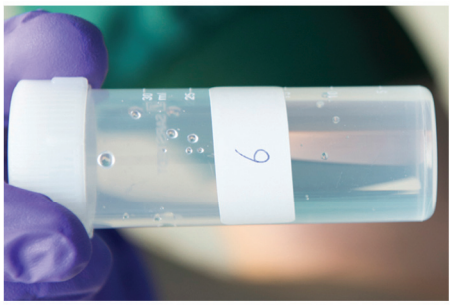

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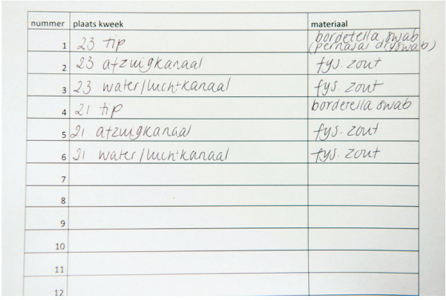

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2	23 afzuigkanaal	fys. zout
3	23 water/lucht kanaal	fys. zout
4	21 HP	bordetella swab
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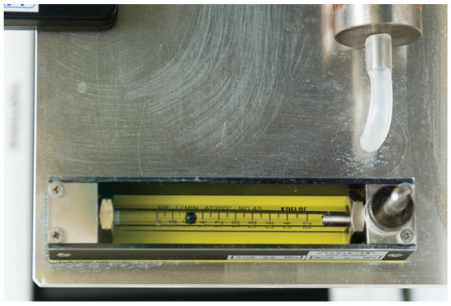

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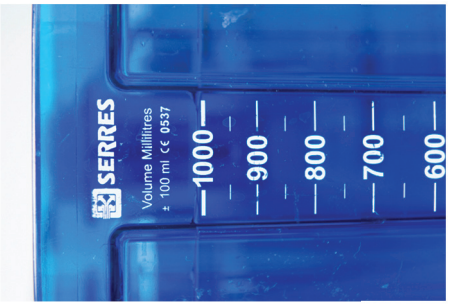

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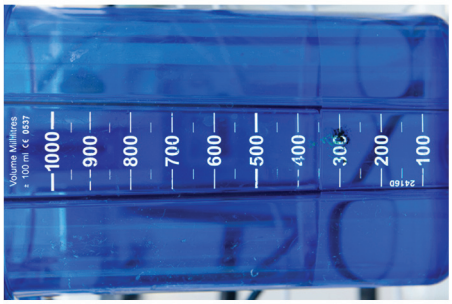

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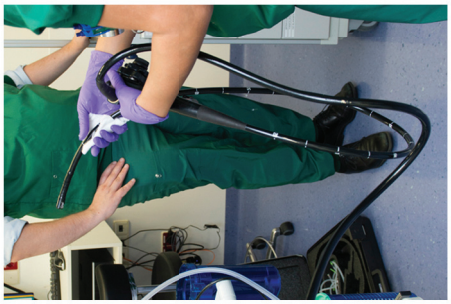

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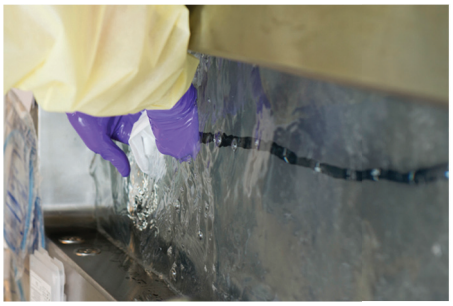

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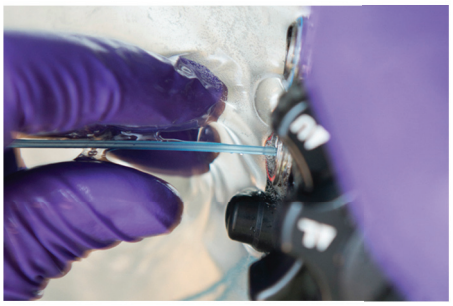

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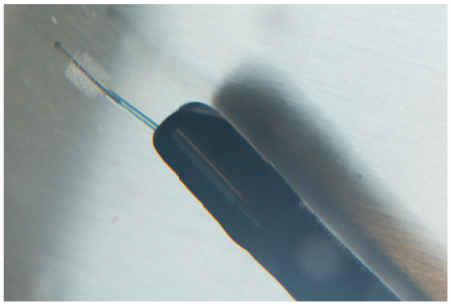

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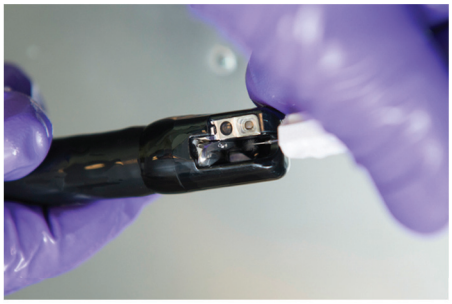

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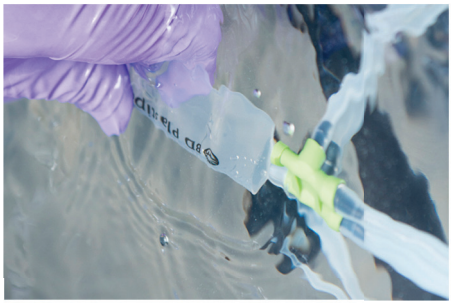

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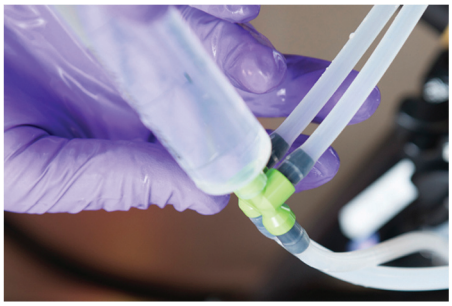

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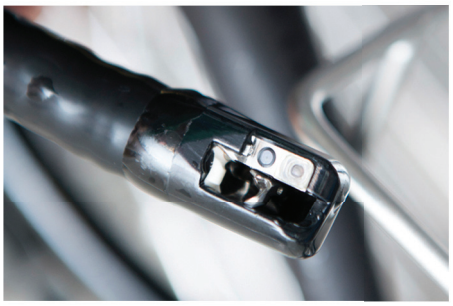

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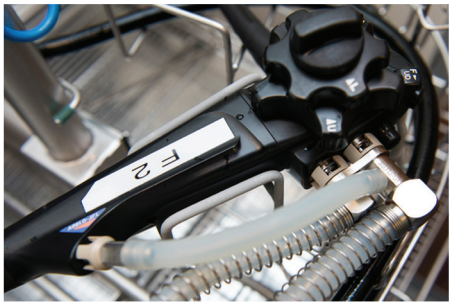

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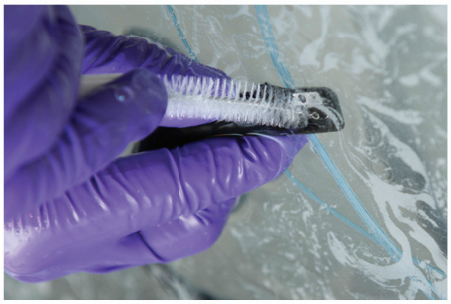

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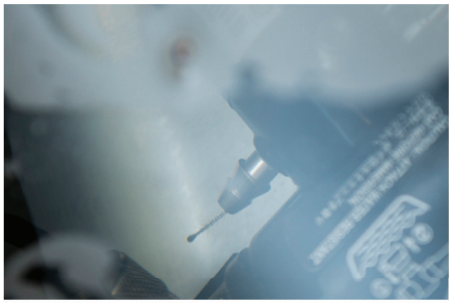

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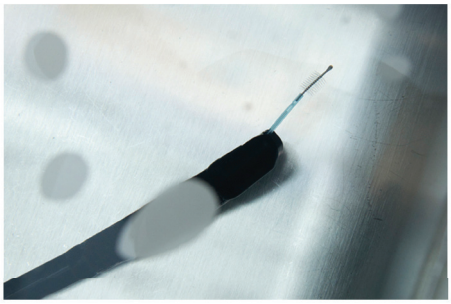

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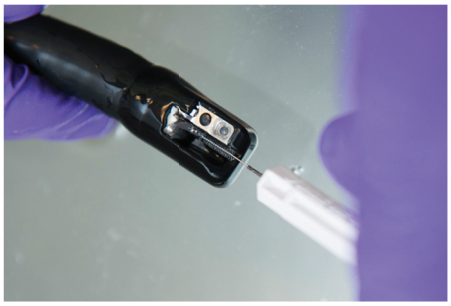

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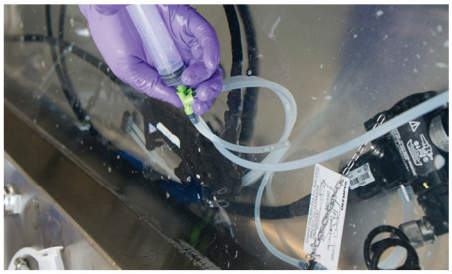

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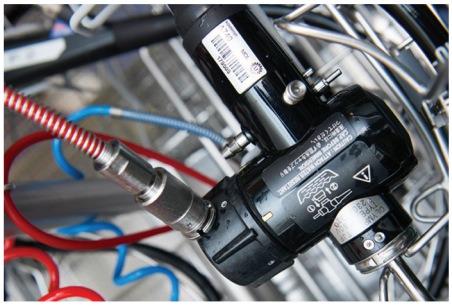

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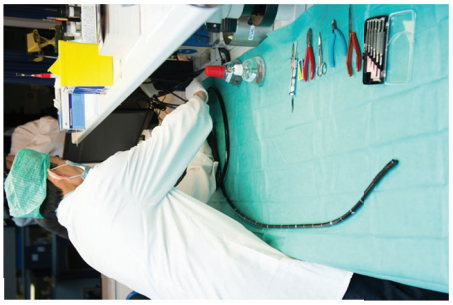

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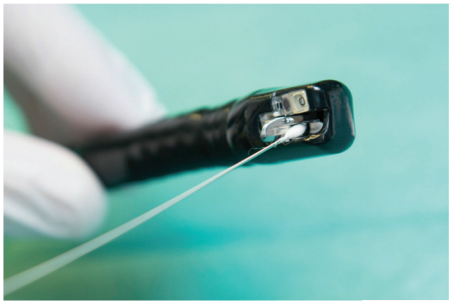

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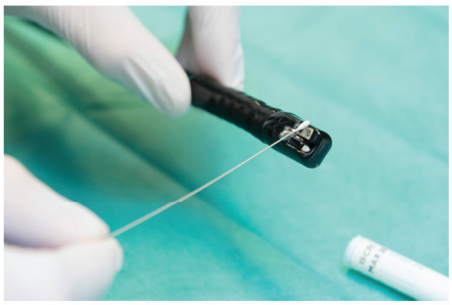

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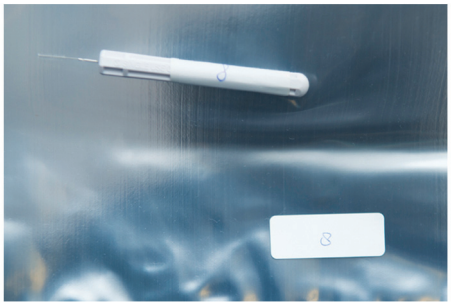

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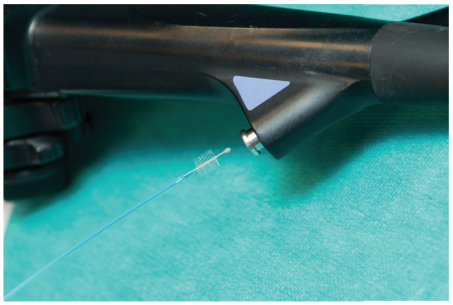

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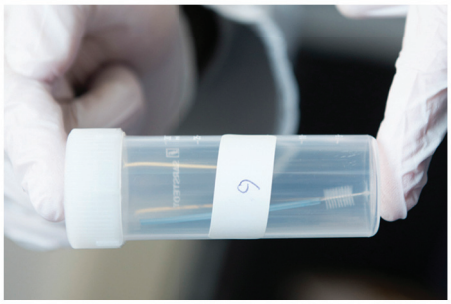

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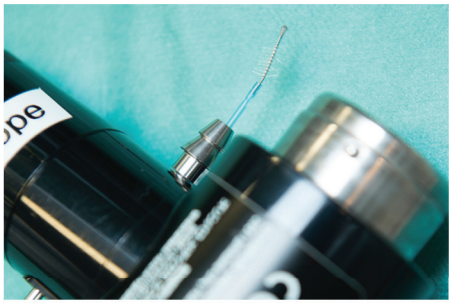

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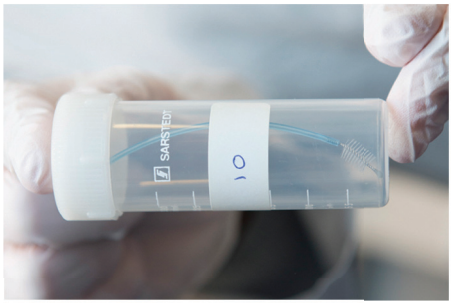

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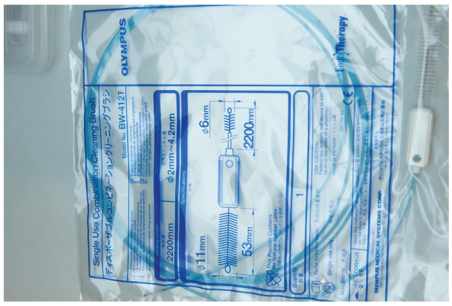

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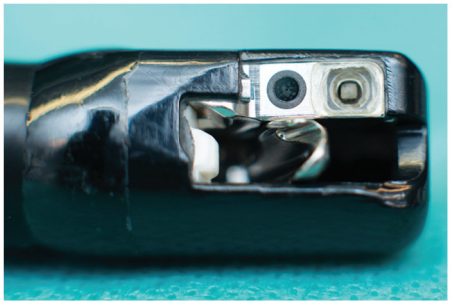

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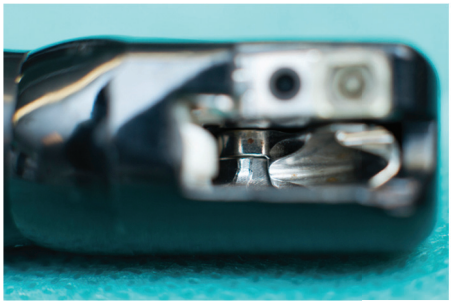

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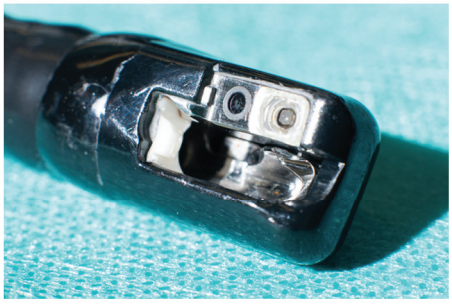

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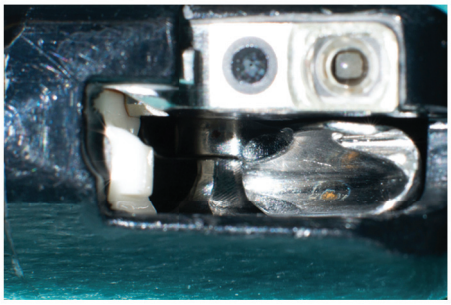

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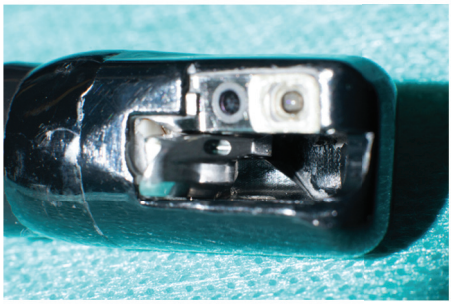

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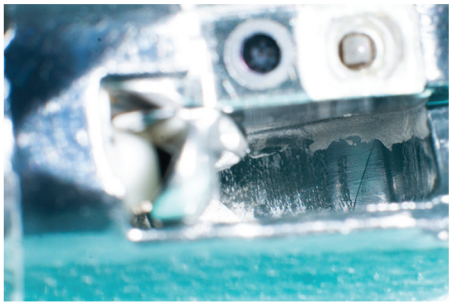

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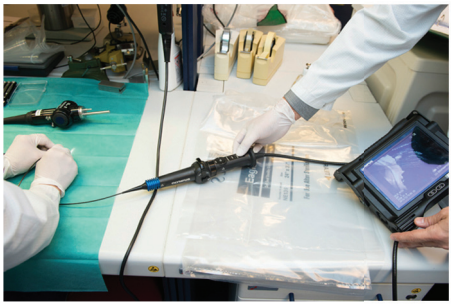

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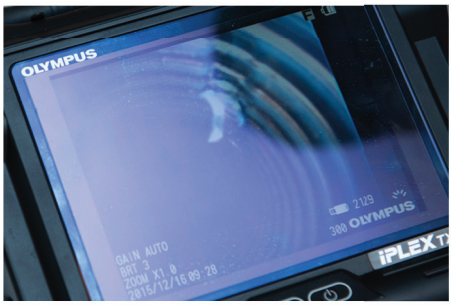

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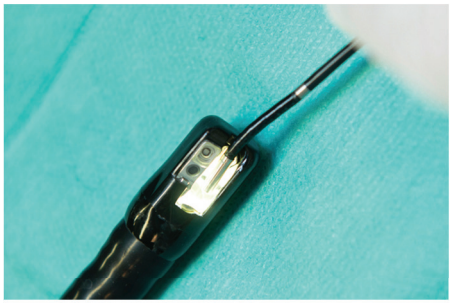

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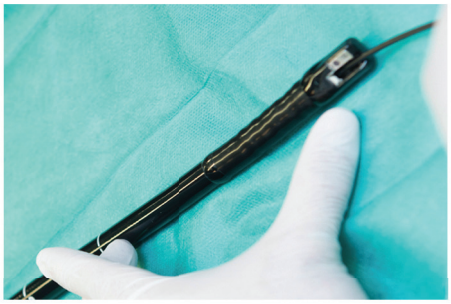

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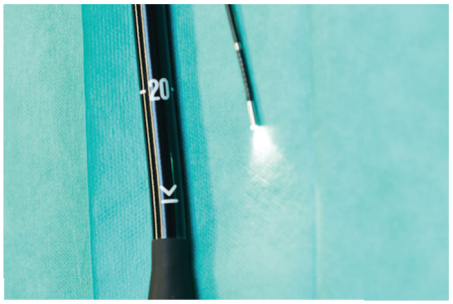

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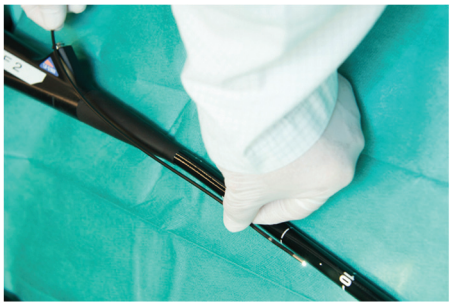

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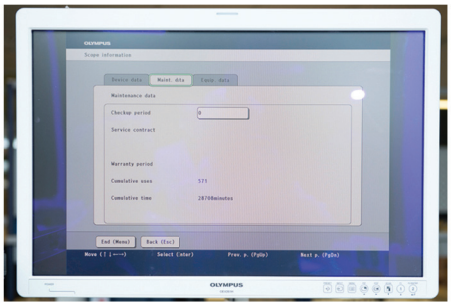

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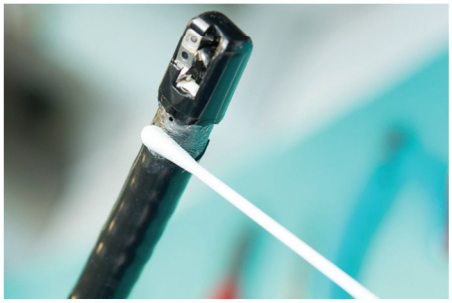

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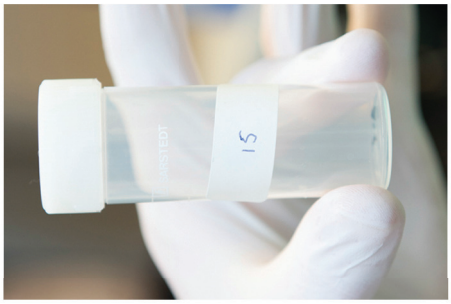

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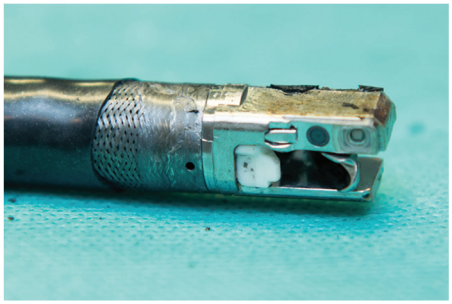

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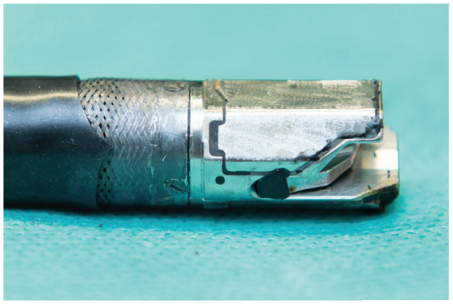

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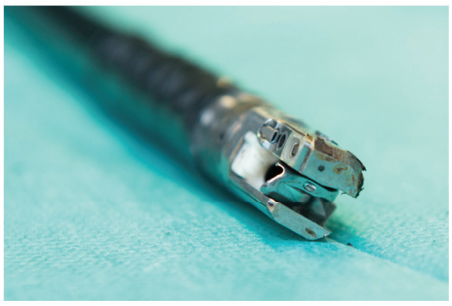

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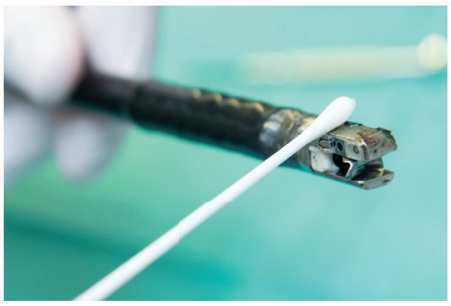

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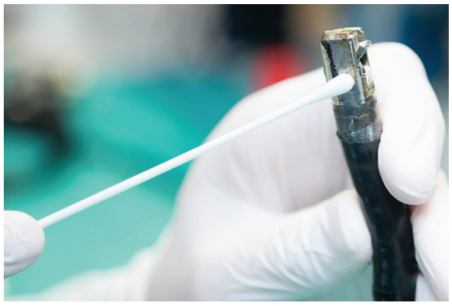

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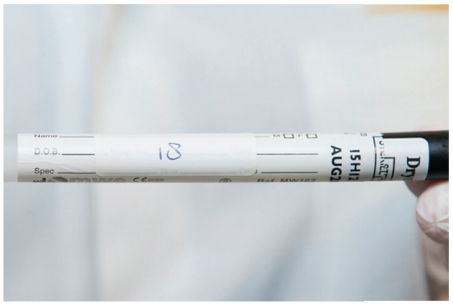

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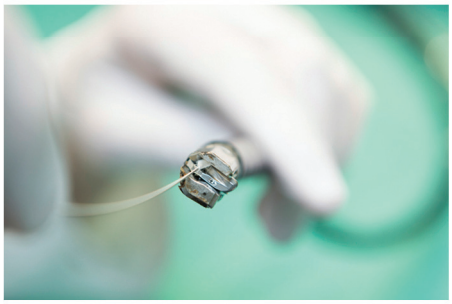

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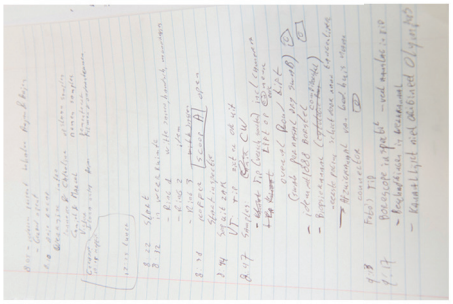

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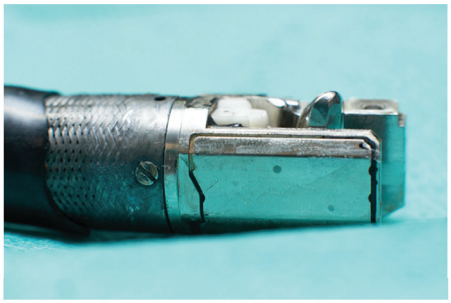

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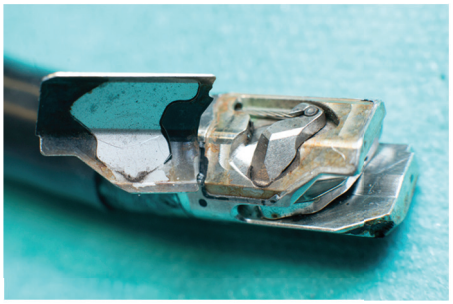

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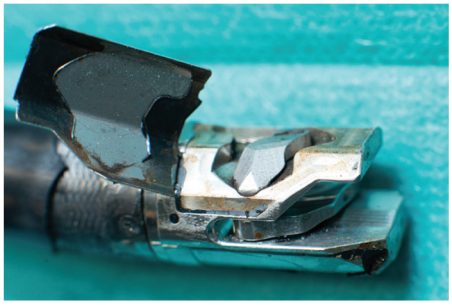

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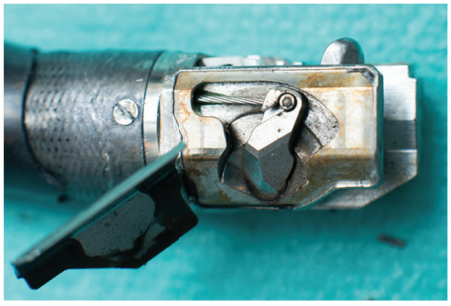

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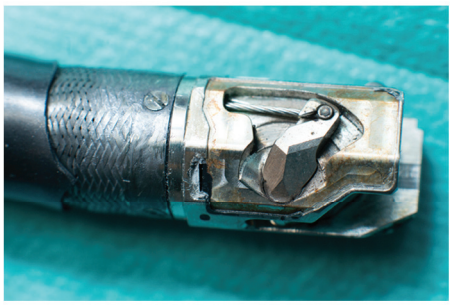

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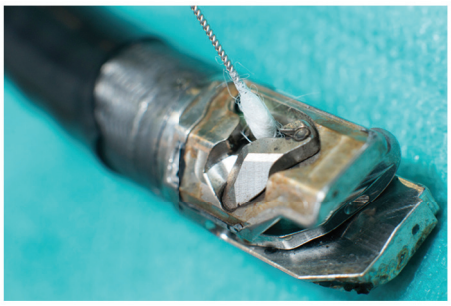

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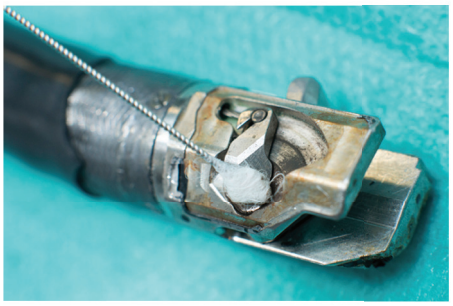

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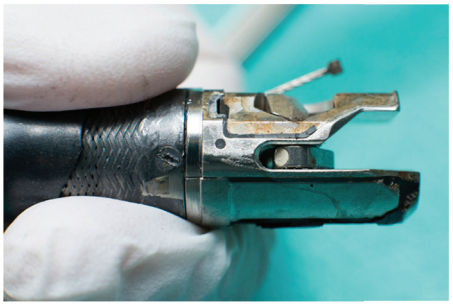

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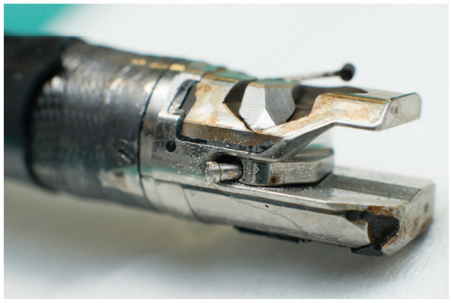

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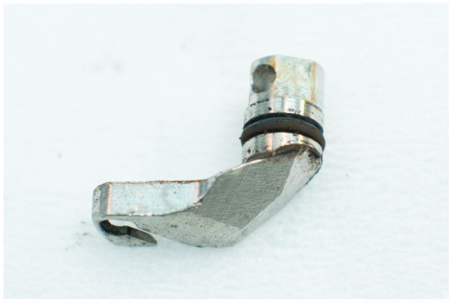

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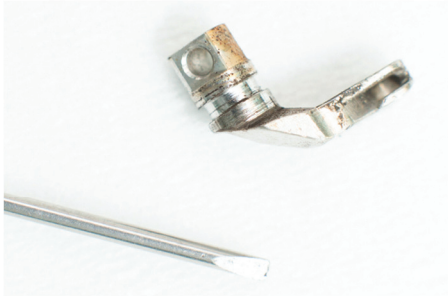

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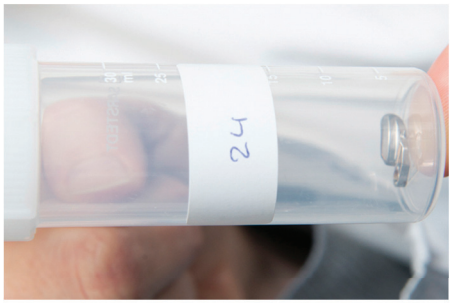

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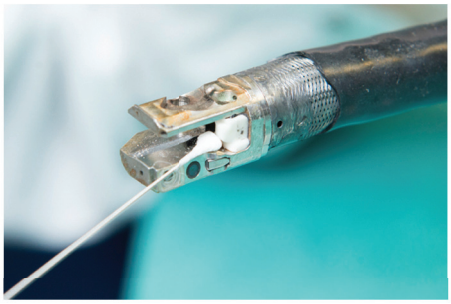

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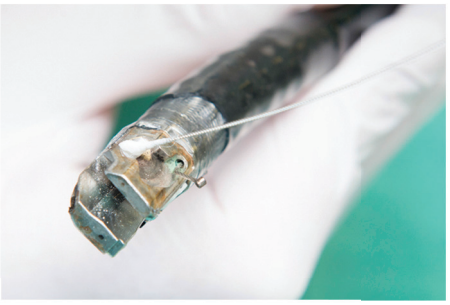

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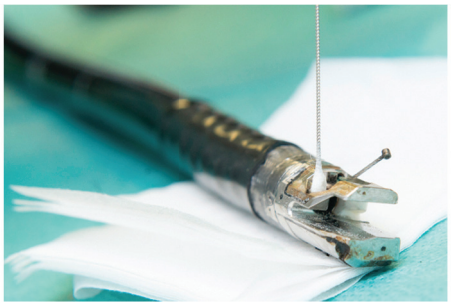

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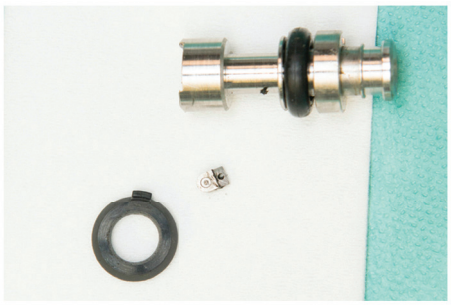

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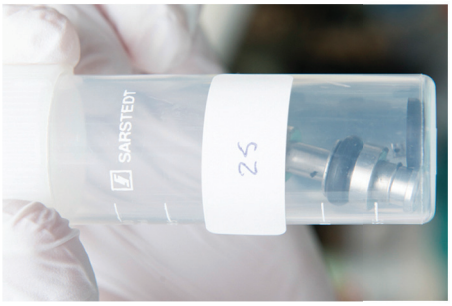

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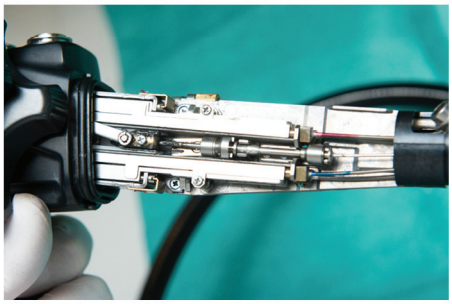

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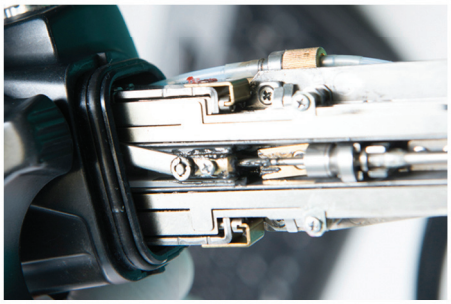

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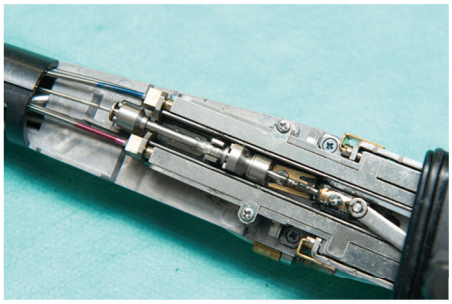

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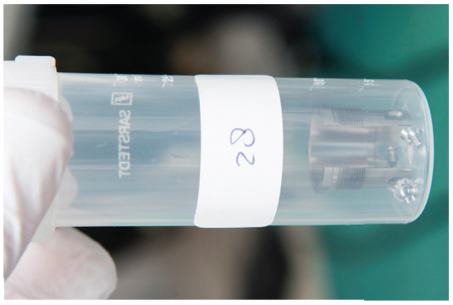

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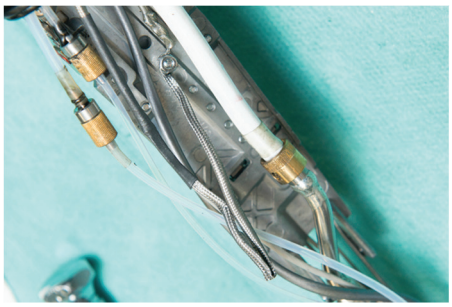

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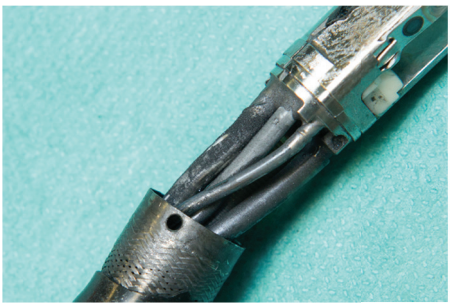

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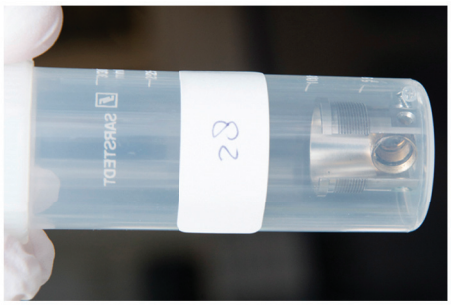

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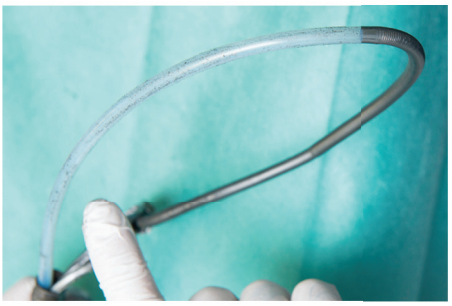

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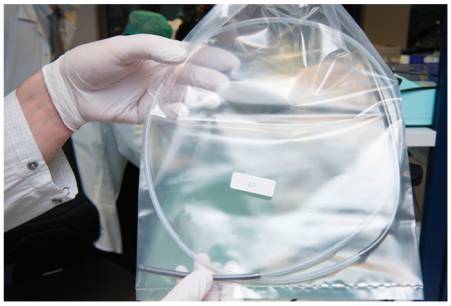

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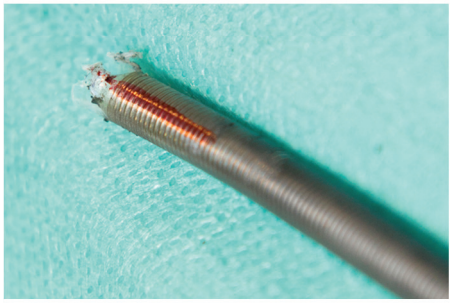

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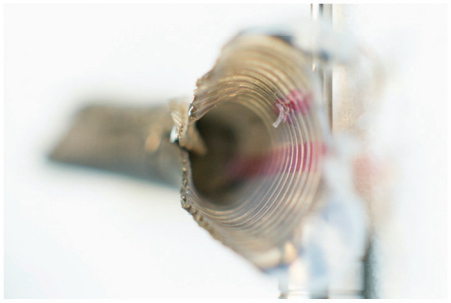

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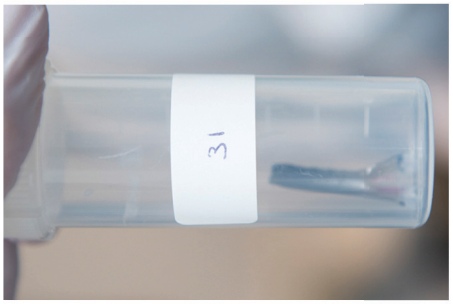

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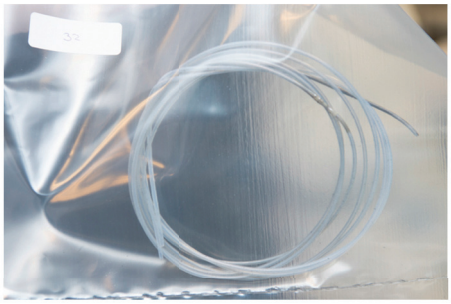

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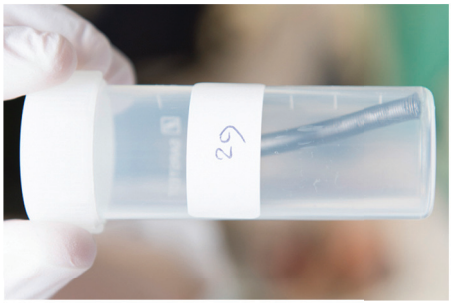

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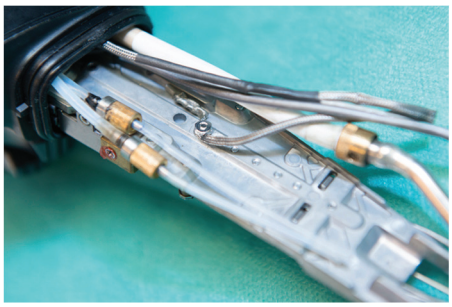

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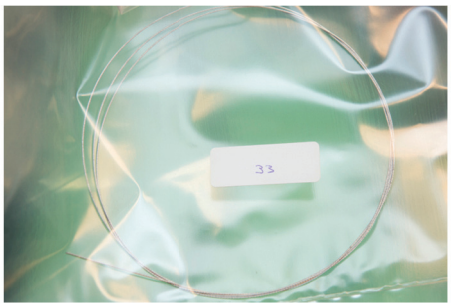

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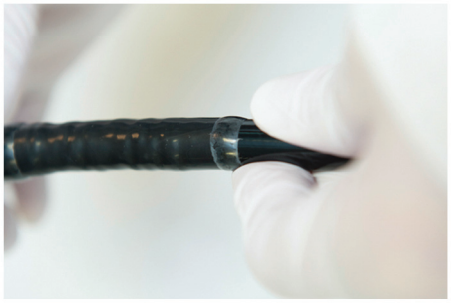

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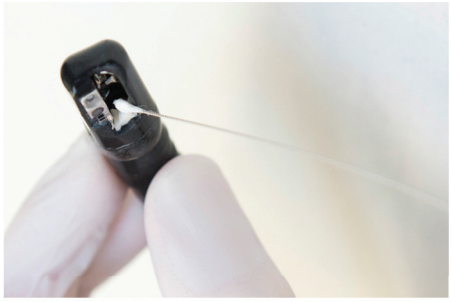

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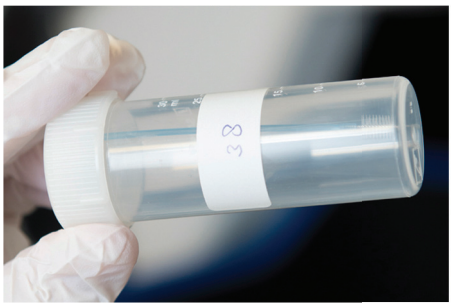

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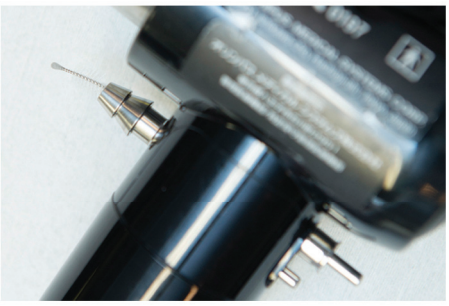

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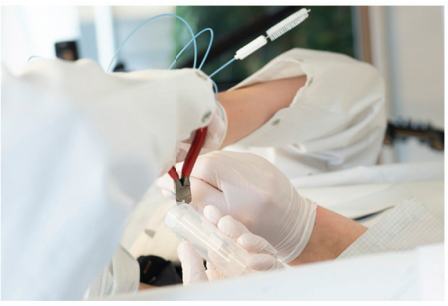

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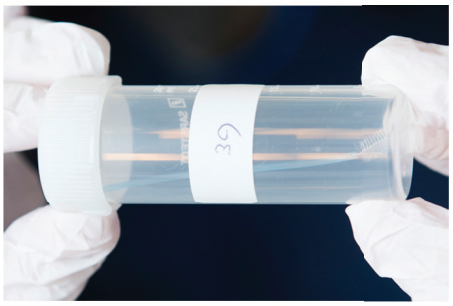

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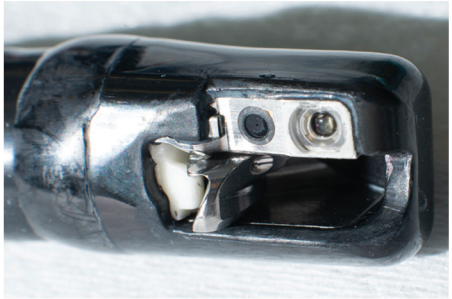

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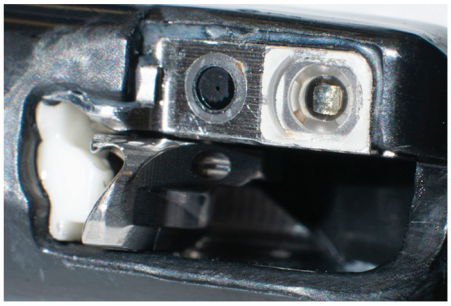

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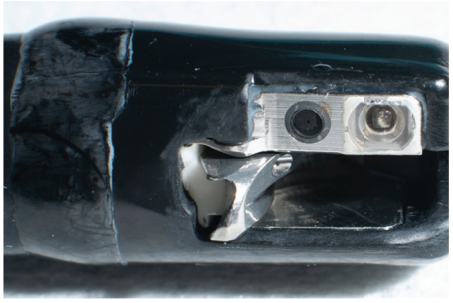

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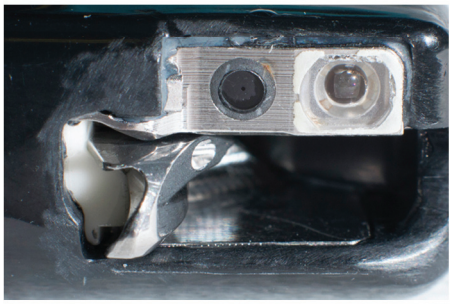

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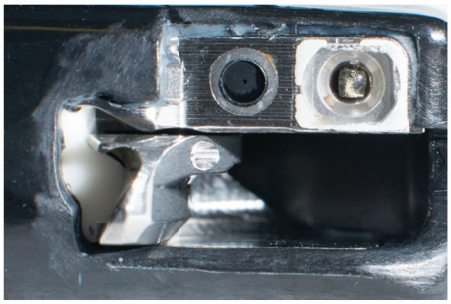

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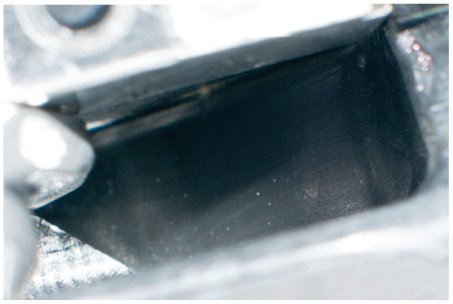

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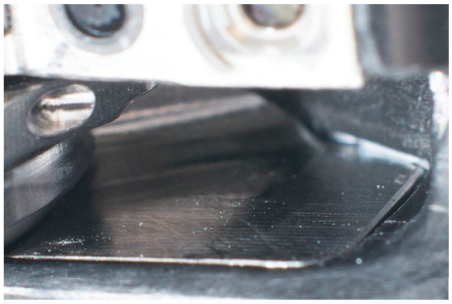

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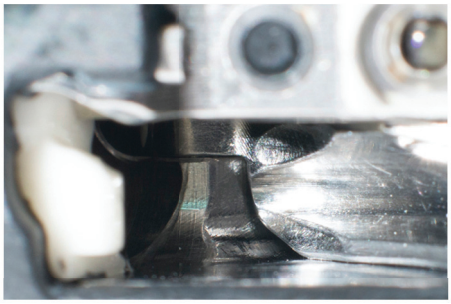

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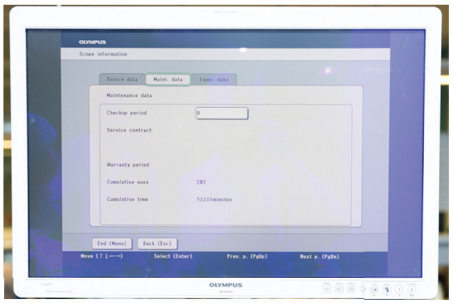

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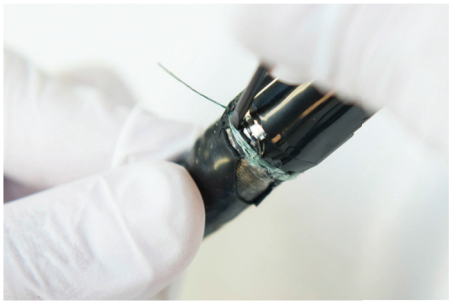

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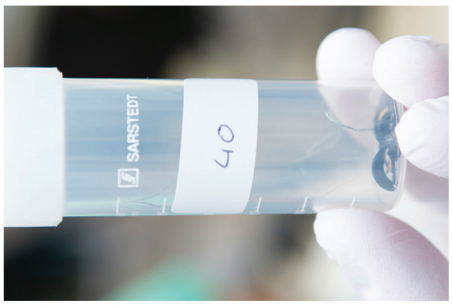

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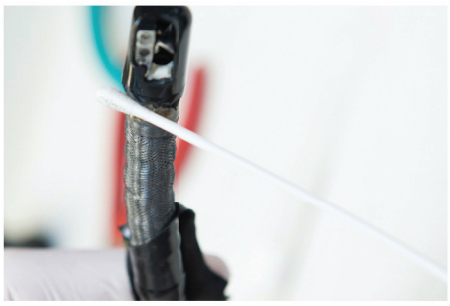

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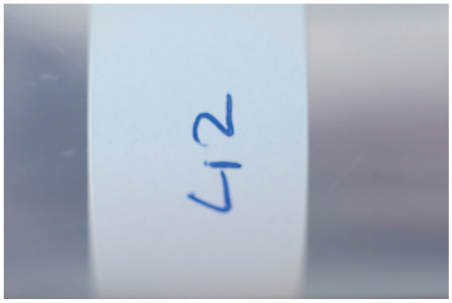

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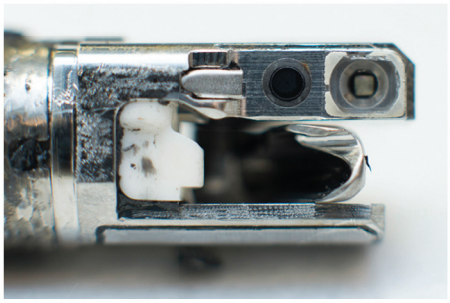

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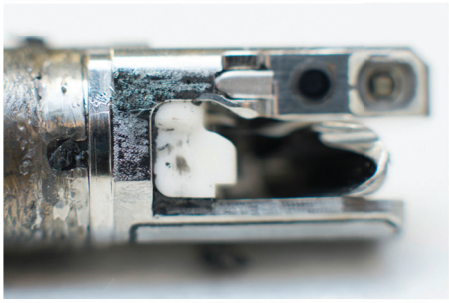

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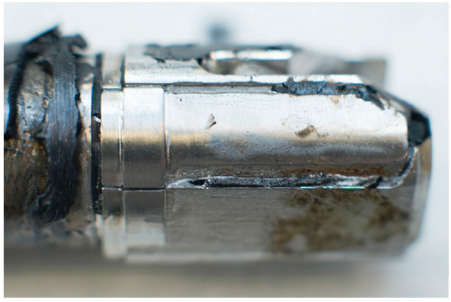

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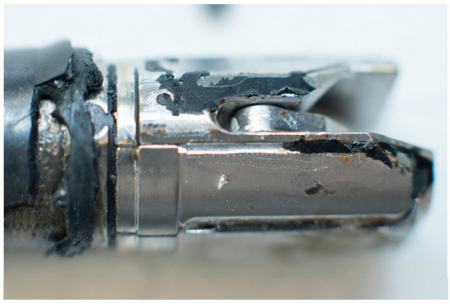

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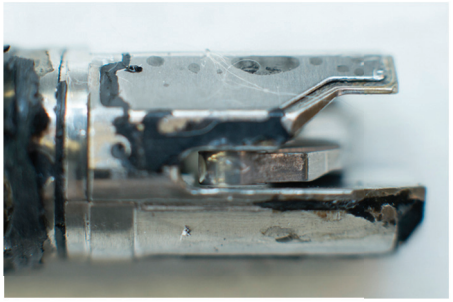

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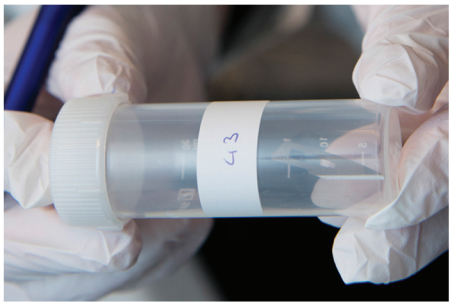

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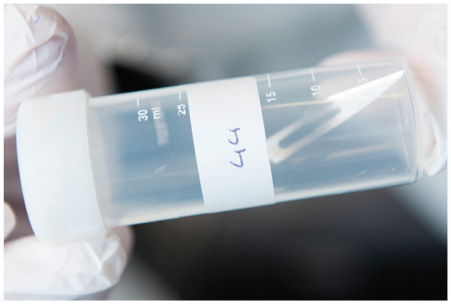

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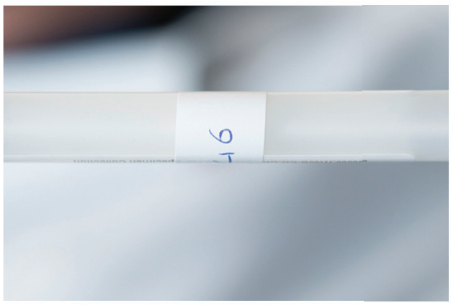

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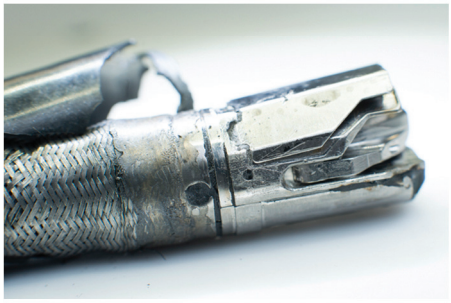

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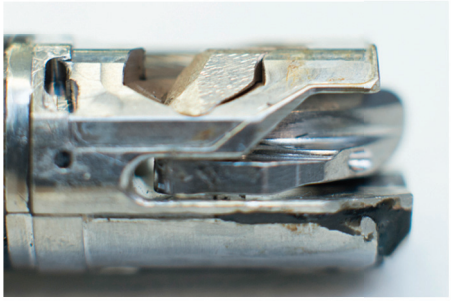

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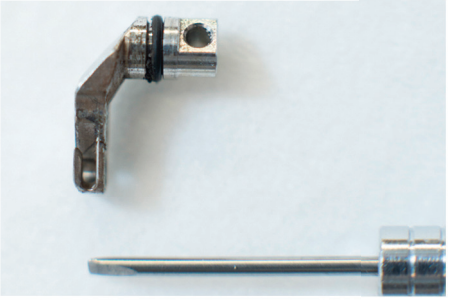

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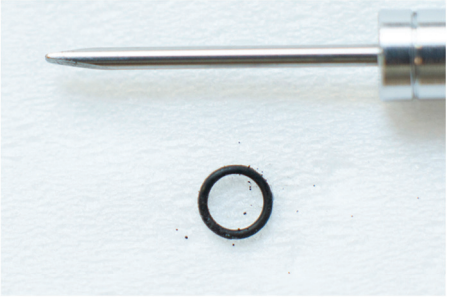

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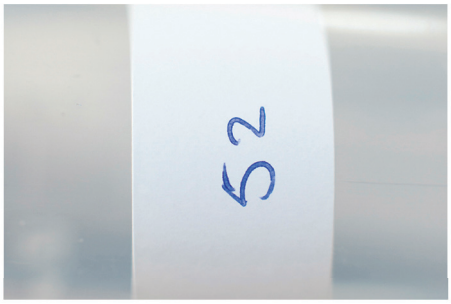

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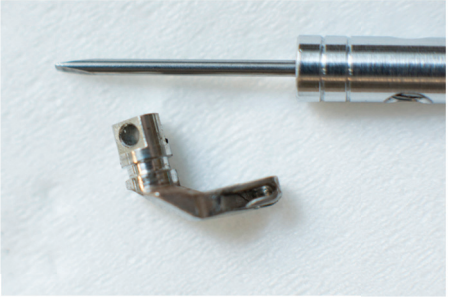

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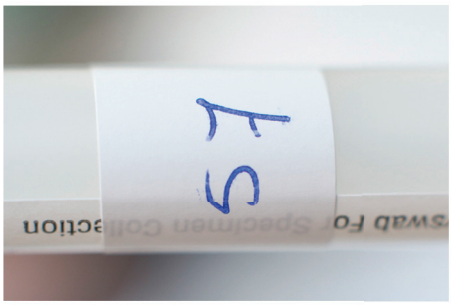

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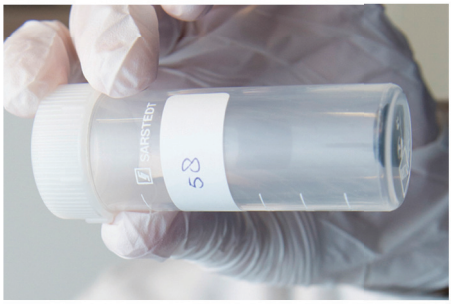

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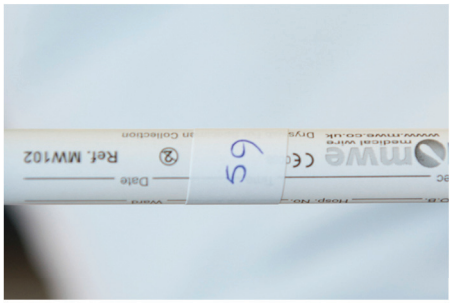

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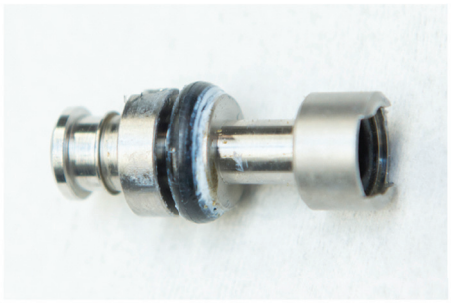

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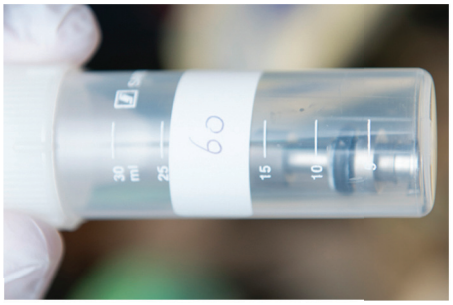

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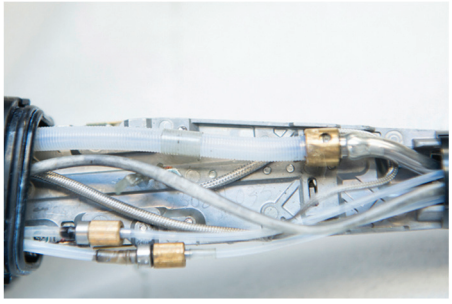

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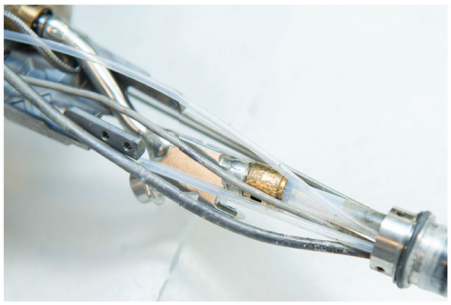

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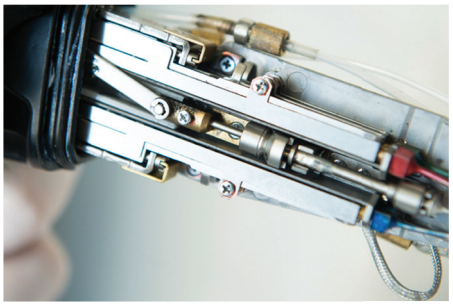

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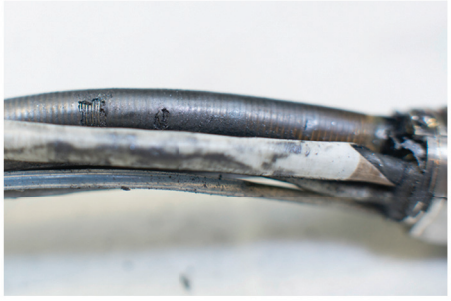

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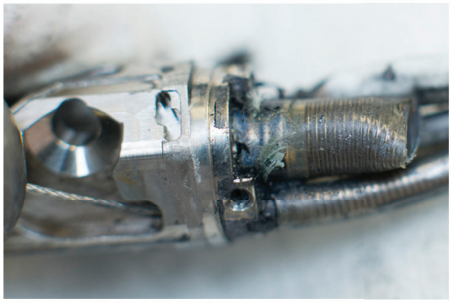

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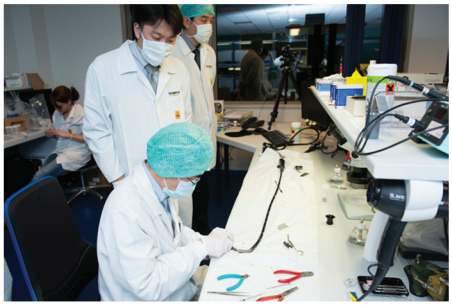

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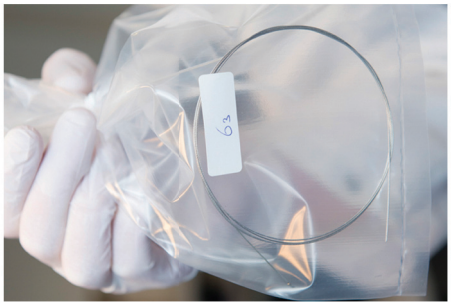

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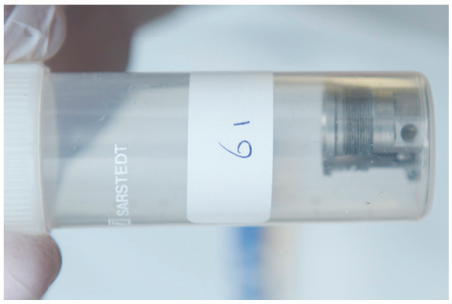

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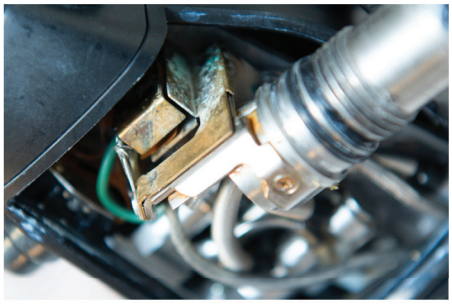

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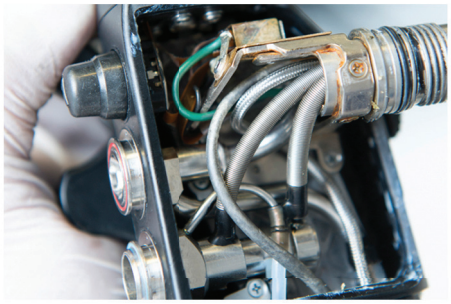

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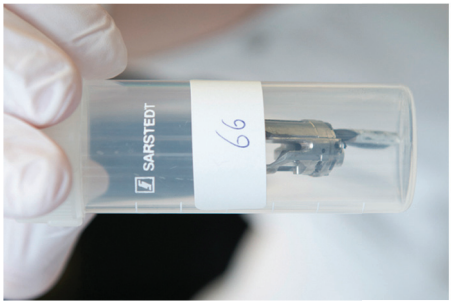

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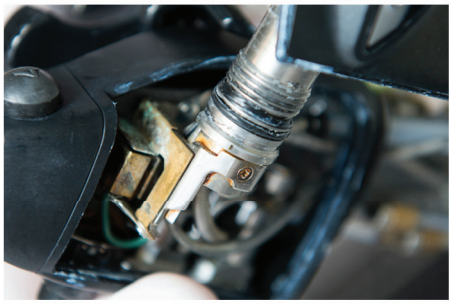

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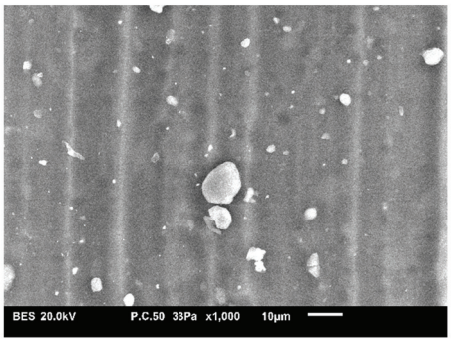

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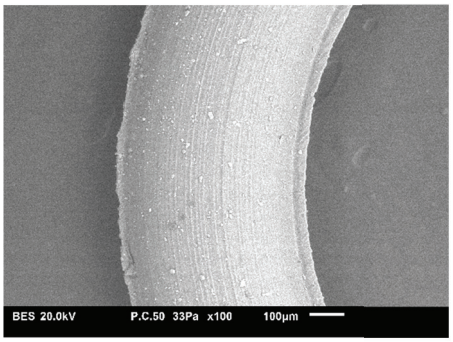

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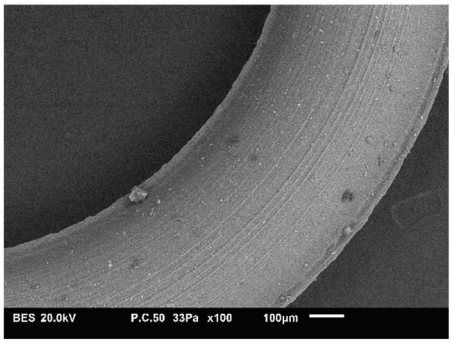

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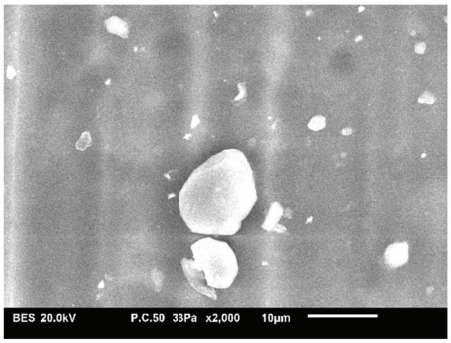

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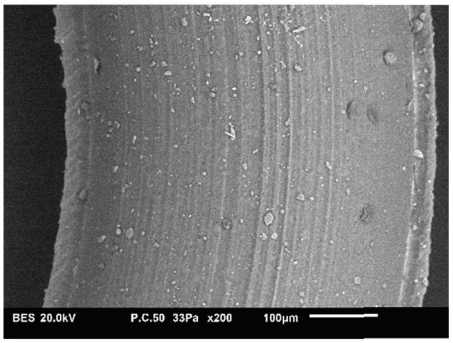

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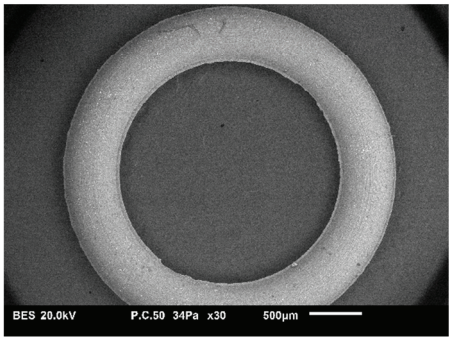

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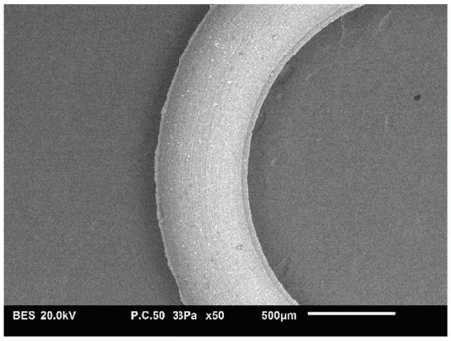

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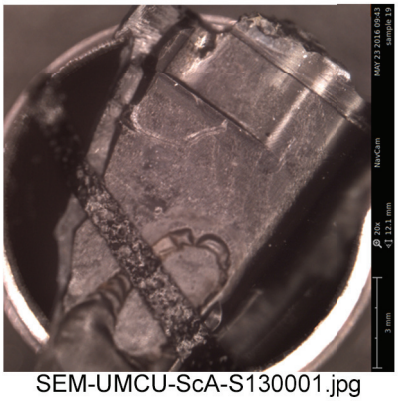

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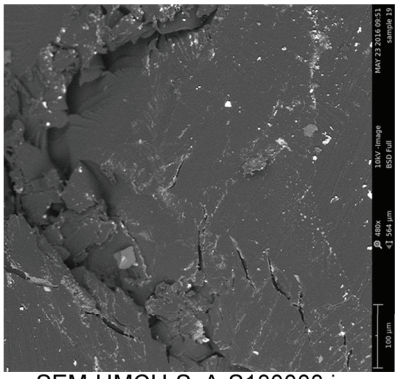

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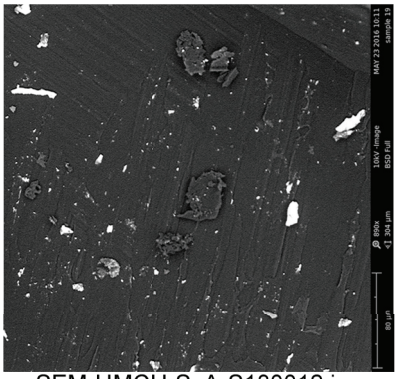

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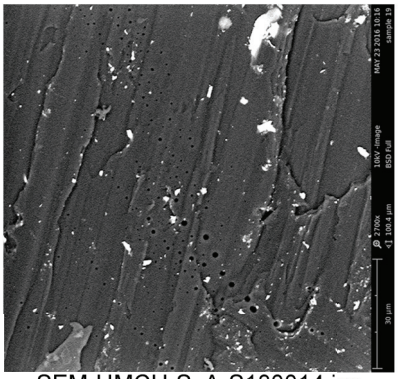

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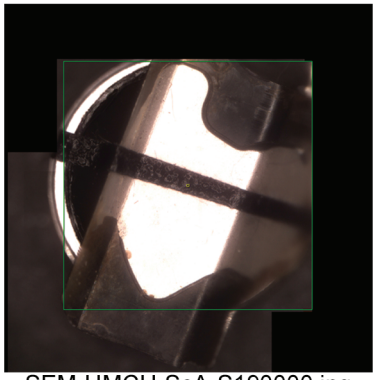
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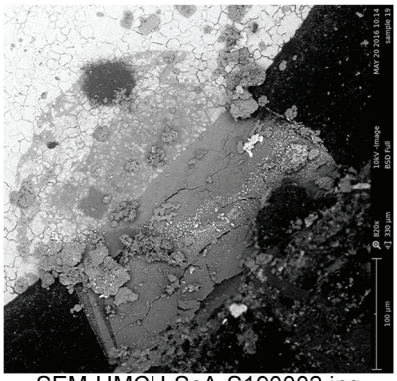
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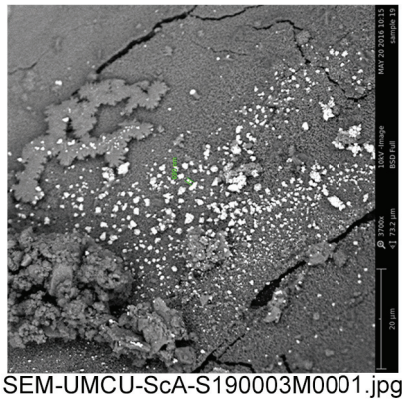
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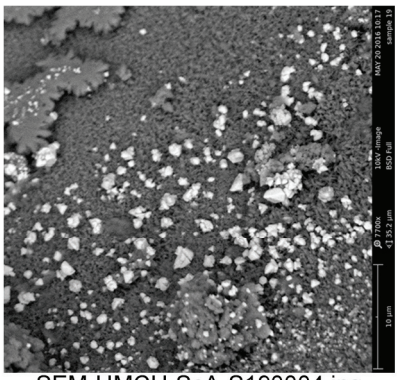
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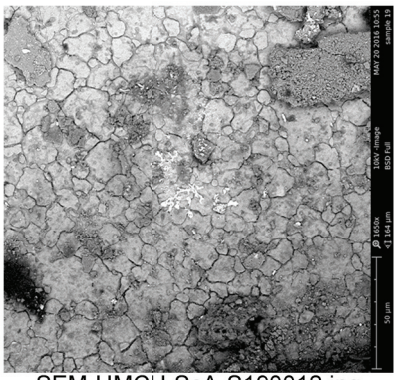
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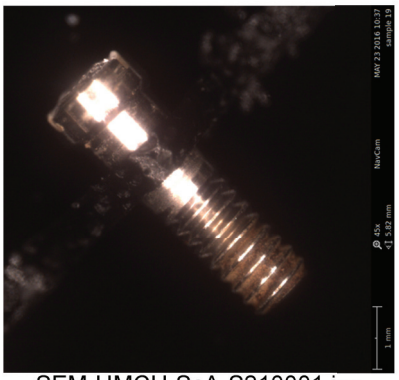
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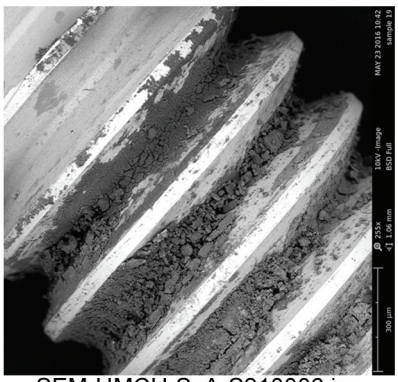
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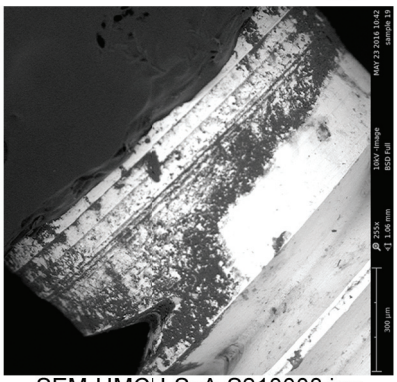
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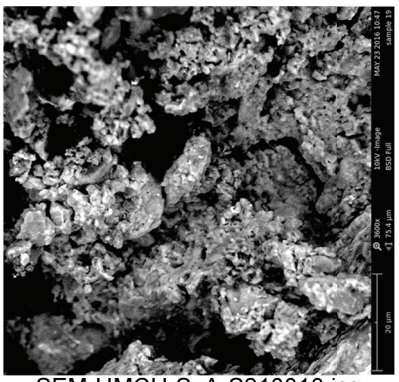
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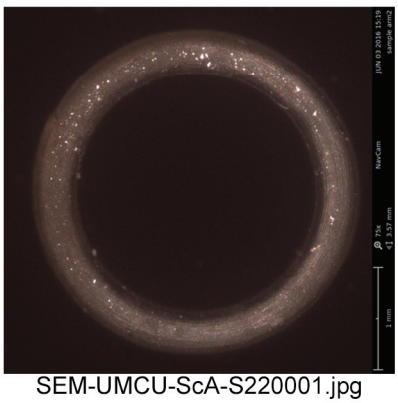
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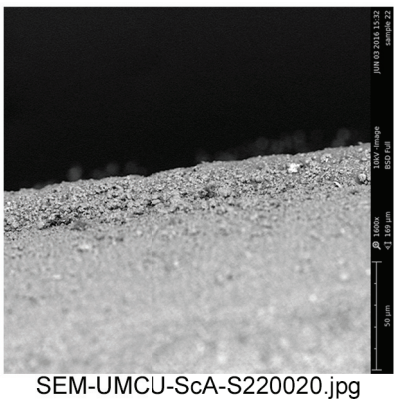
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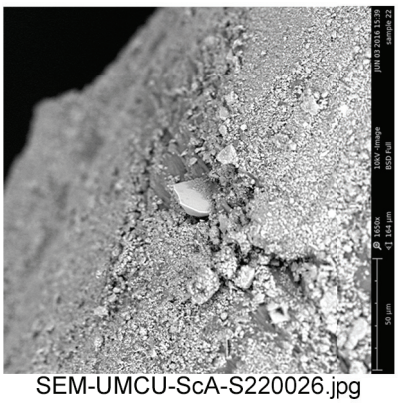
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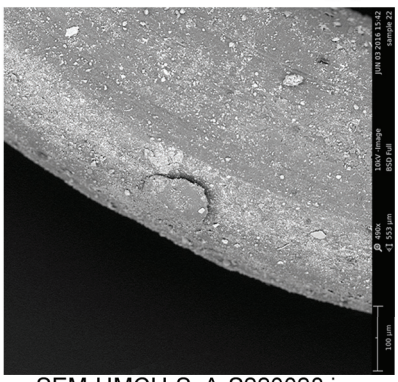
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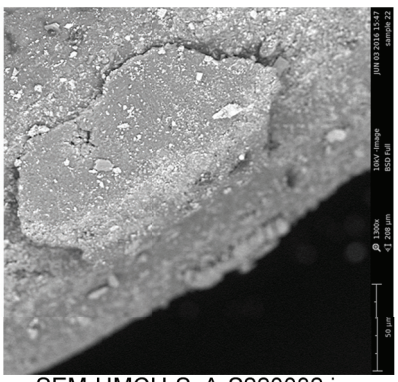
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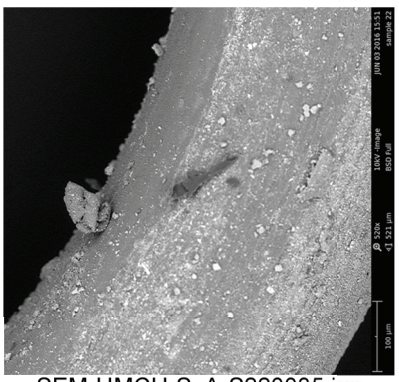
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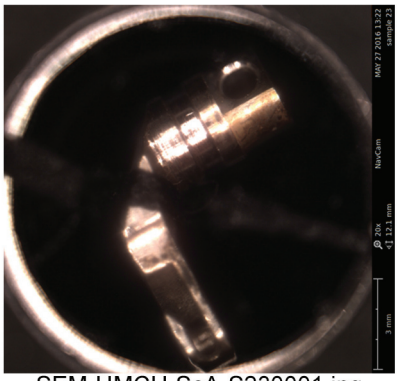
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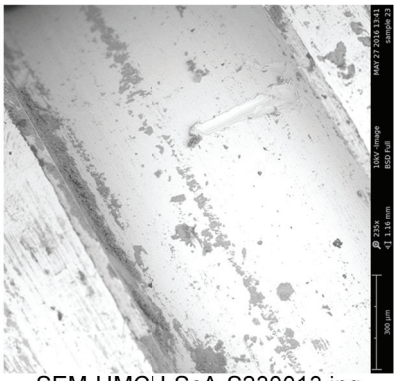
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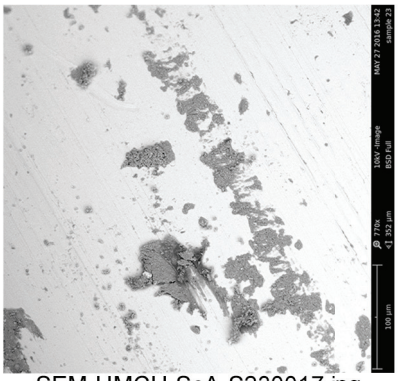
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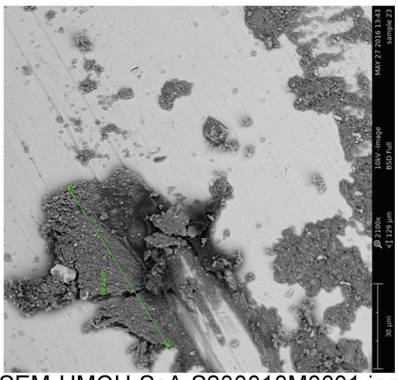
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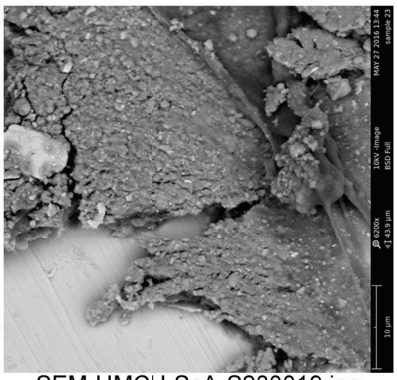
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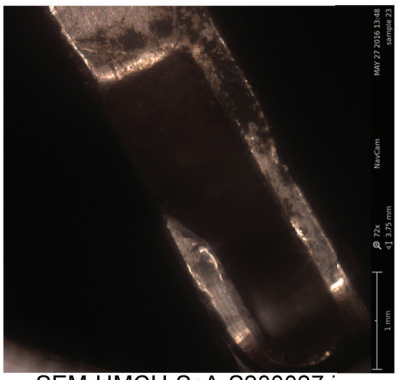
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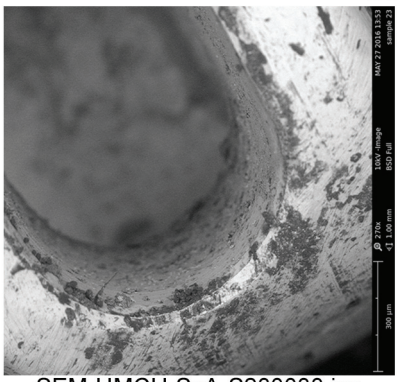
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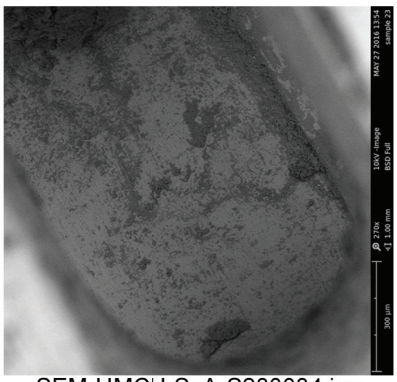
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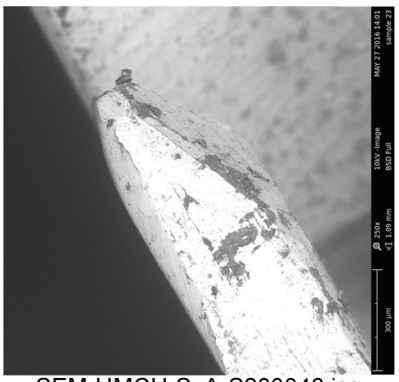
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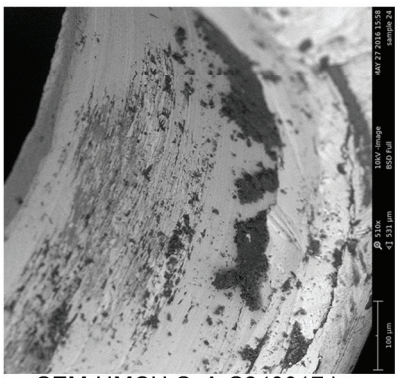
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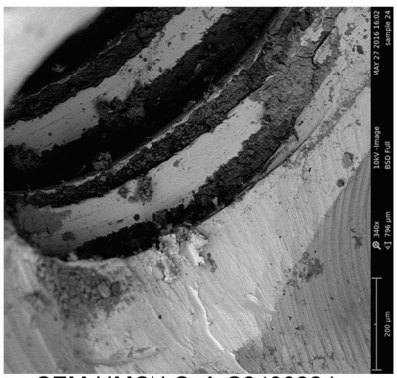
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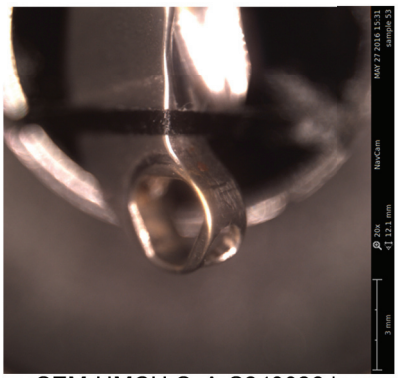
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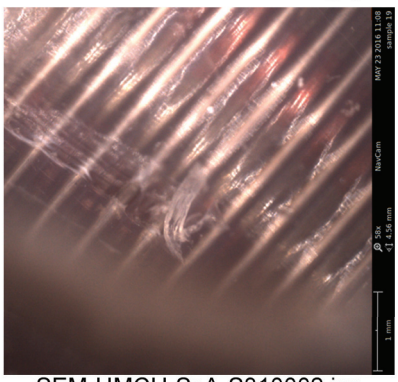
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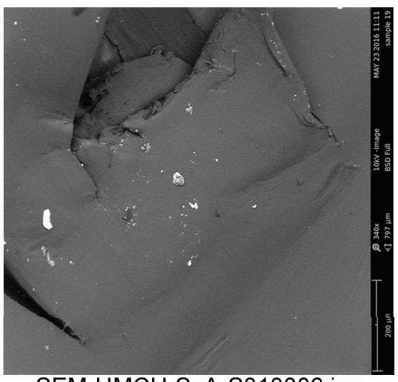
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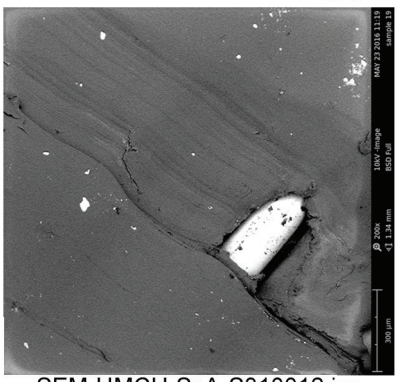
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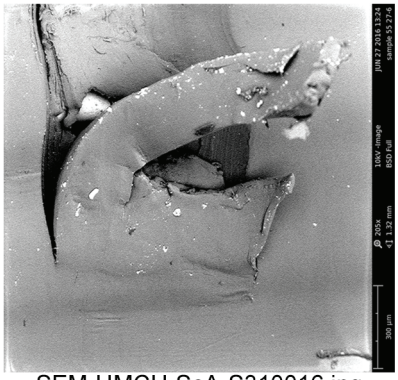
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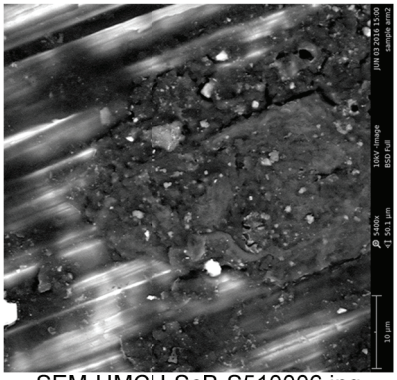
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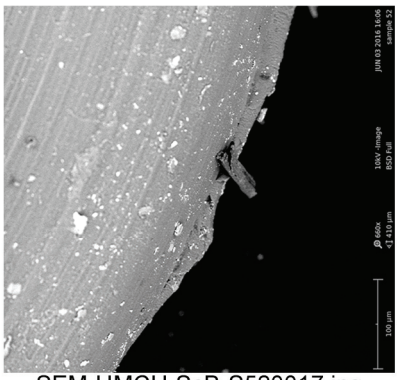
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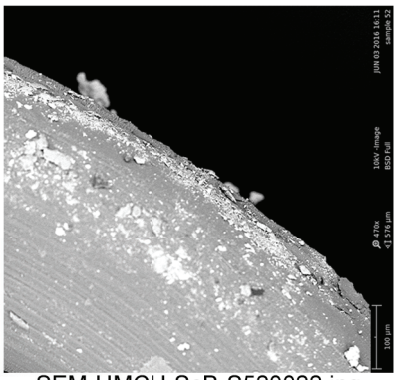
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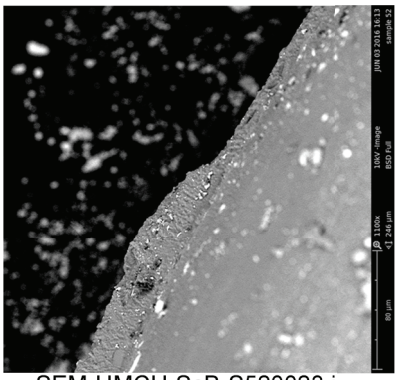
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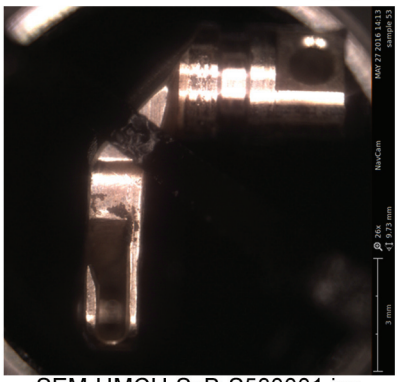
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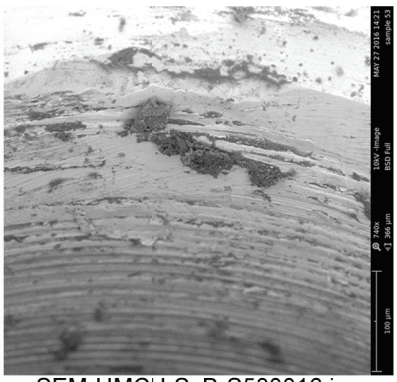
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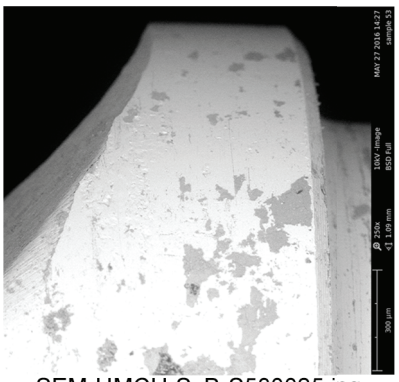
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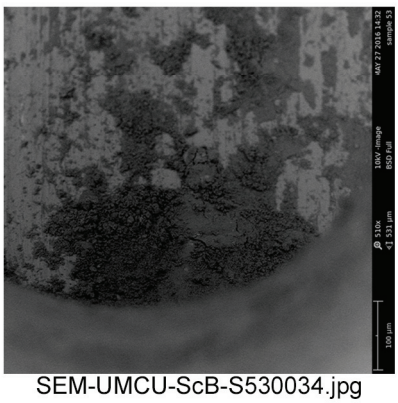
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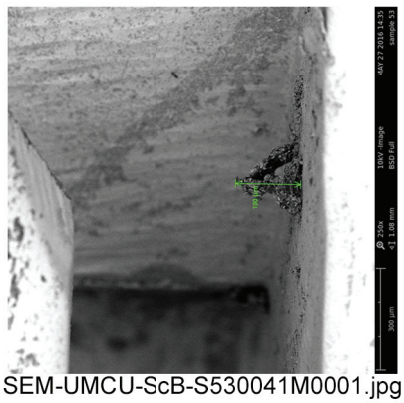
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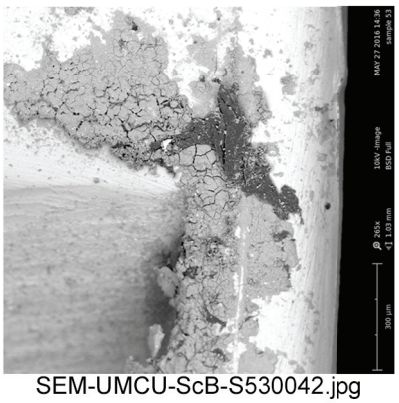
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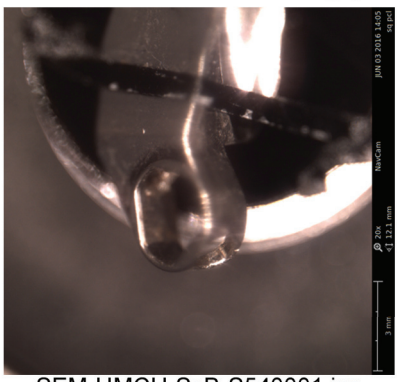
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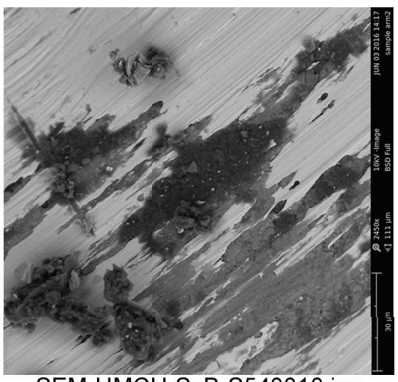
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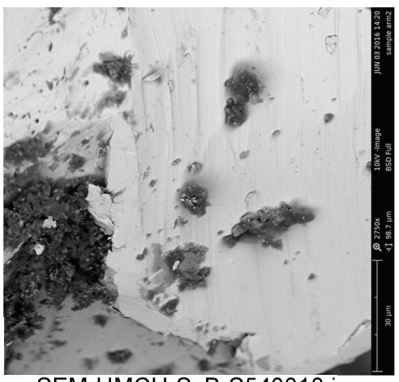
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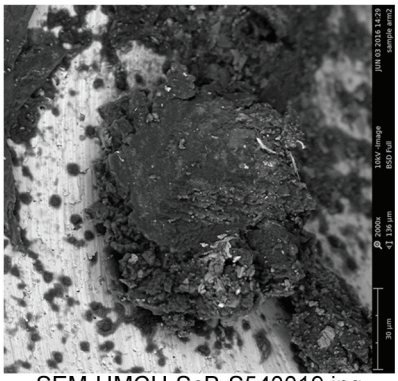
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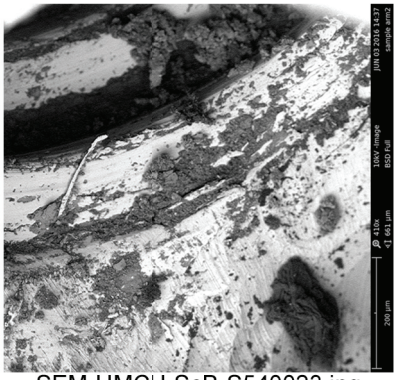
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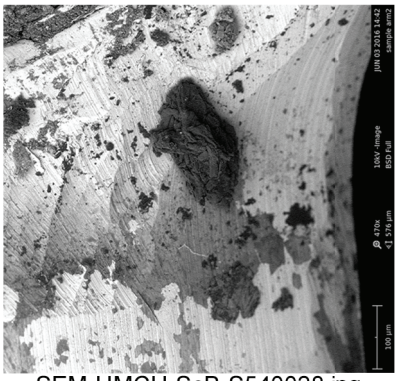
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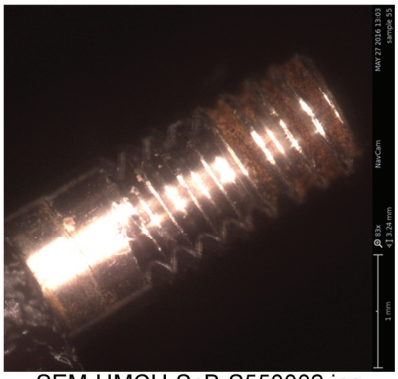
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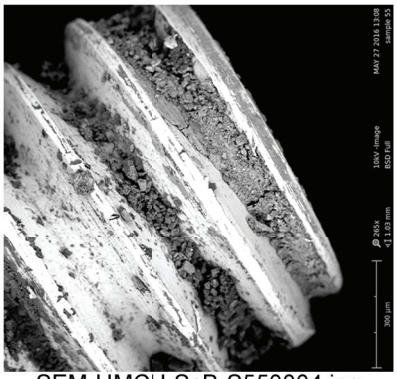
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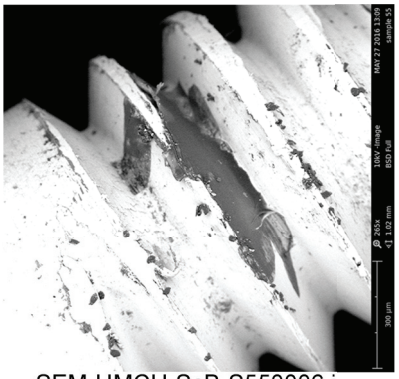
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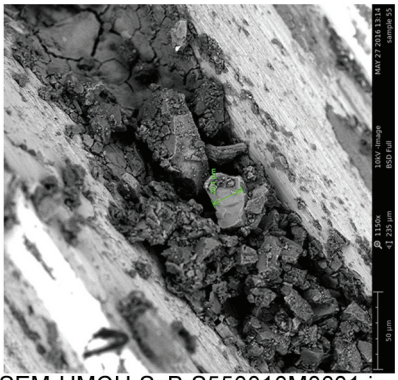
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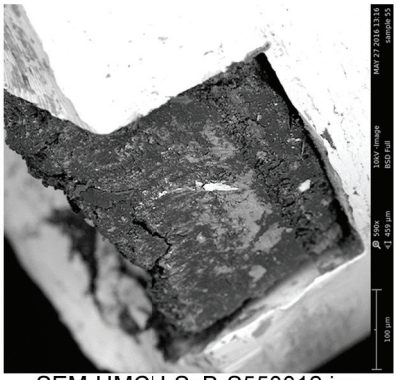
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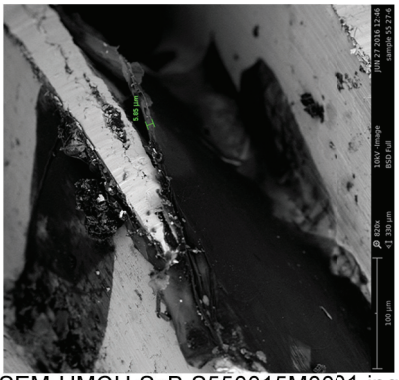
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