Investigation of ERCP-Scope X-32

following detected contamination after cleaning and disinfection

--- REPORT OF THE FORENSIC ENGINEERING INVESTIGATION ---

Final version – May 15, 2017

This entire report, the case, the names of all involved parties and all details were put together as an education means for the Massive Open Online Course "Forensic Engineering" by taking aspects from several real cases, and modifying and combining these. Names of products, companies, hospitals and persons are purely fictional. This case should in no way be considered as reflecting any specific real case. Any resemblance of this case as a whole to existing cases or involved parties should be considered as purely coincidental.

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Author:

Dr. ir. Arjo Loeve

Staff lecturer BioMechanical Engineering & Clinical Technology
Project leader Engineering for Forensics
Coordinator CLHC – Center for Forensic Science and Medicine

TU Delft (Delft University of Technology)
Department of BioMechanical Engineering
Faculty of Mechanical, Maritime and Materials Engineering (3mE)
Delft, The Netherlands

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1. BACKGROUND – CONTAMINATION OF 'SCOPE X-32'

Recently the bacterium Pseudomonas Aeruginosa was found at the FeMC (Femostad Medical Center, Femostad, the Netherlands) in the tip of a Flexinc video duodenoscope type ERCP12 (further referred to as 'Scope X-32', where X-32 is the FeMC internal registration number of the contaminated scope). This bacterium persisted after manual cleansing and mechanical cleaning and disinfection in the Flexinc scope disinfecting machine type ETD12.

In order to find out why and where the bacteria could stay behind in the scope despite cleaning, it was decided to disassemble Scope X-32, while meticulously inspecting it and taking biological samples of it. Through these steps and the subsequent bacterial tests in a laboratory (hereinafter as a total referred to as *'the investigation),* it was attempted to discover if the persistence of the bacteria was caused by:

- Incorrect or insufficiently following of cleaning instructions
- Incorrect or insufficiently formulated cleaning instructions
- Insufficient functioning of any sealing in Scope X-32
- Other cause(s)

2. ABOUT THIS REPORT

Purpose of this report is to come to an objective determination of the ca use / causes of the persistence of the Pseudomonas Aeruginosa bacterium in Scope X-32. For this purpose, a factual record of the briefing, execution and results of the investigation is provided.

In this report, biological sample reference numbers are given as {0000}. Time stamps are given at the beginning of each new investigation action in green. Outcomes of the bacterial tests done in the laboratory on samples taken from Scope X-32 during the investigation are provided in the last chapter.

3. DISCLAIMER

Photos used in this report were taken by a professional photographer. The photos were corrected visually regarding color to compensate for deviations by changing light sources and using different cameras. (Overview and macro photos were made with a Nikon D300s and microscope photos with its connected camera). Colors may therefore still differ slightly from the actual colors as they would have been observed under daylight or under daylight lamps. Due to differences in color rendering by different monitors, printers or kinds of paper, possible deviations could be stronger.

Conclusions regarding observations should in no way be based on shades of color or specific characteristic, absolute color values based on the utilized photos.

4. BRIEFING

On May 7, 2014 an investigation team (hereinafter referred to as 'the investigation team'), consisting of representatives of the FeMC and the manufacturer Flexinc, as well as an independent expert of the Delft University of Technology ('TU Delft'), conducted the investigation at the manufacturing plant of Flexinc B.V., Hardinxveld, the Netherlands. At around 10:15h the investigation team gathered there.

A number of issues related to the people present are specifically addressed during the briefing:

- Arjo Loeve, as an independent expert from the TU Delft, takes care of reporting, photo/video shooting for recording, and will observe the process objectively and critically and will manage the investigation.
- Peter Pose takes care of the sampling and will wear latex gloves.
- Lin Lead takes care of the scope disassembly and will wear latex gloves.
- Claire Centaur takes care of the storage of the sample materials.
- Fredric McFarry takes care of the labeling and packaging of the samples.
- John Jones provides and operates auxiliary equipment, such as microscopes.

The investigation approach is discussed:

1. Sampling working channels and tip of Scope X-32 with a 3mm diameter, long flexible brush in order to find any residual patient material. Those samples will be taken in the clean room.

2. Step-by-step disassembly of Scope X-32. Before each disassembly step, the then visible parts of the scope will be visually inspected, photographed and sampled with flexible brushes and/or cotton tip swabs. After each disassembly step the removed parts will be packaged for later bacterial testing.

3. At a later stage, the packaged parts will be examined with an electron scanning microscope in order to check for damage or bacterial traces.

5. DISSASEMBLING AND SAMPLING

11:23h The work tables are disinfected and covered with sterile cloths. All team members are wearing protective coats, sterile gloves and surgical masks.

11:31h Sampling the Scope X-32 parts described and shown below with sterile, 3 mm diameter, flexible brushes. After sampling, each brush is collected in a new and sterile sample jar. Samples taken of:

- Working channels {5379 and 5396} (Figure 1).
- The cavity behind the forceps elevator {5388} (Figure 2).

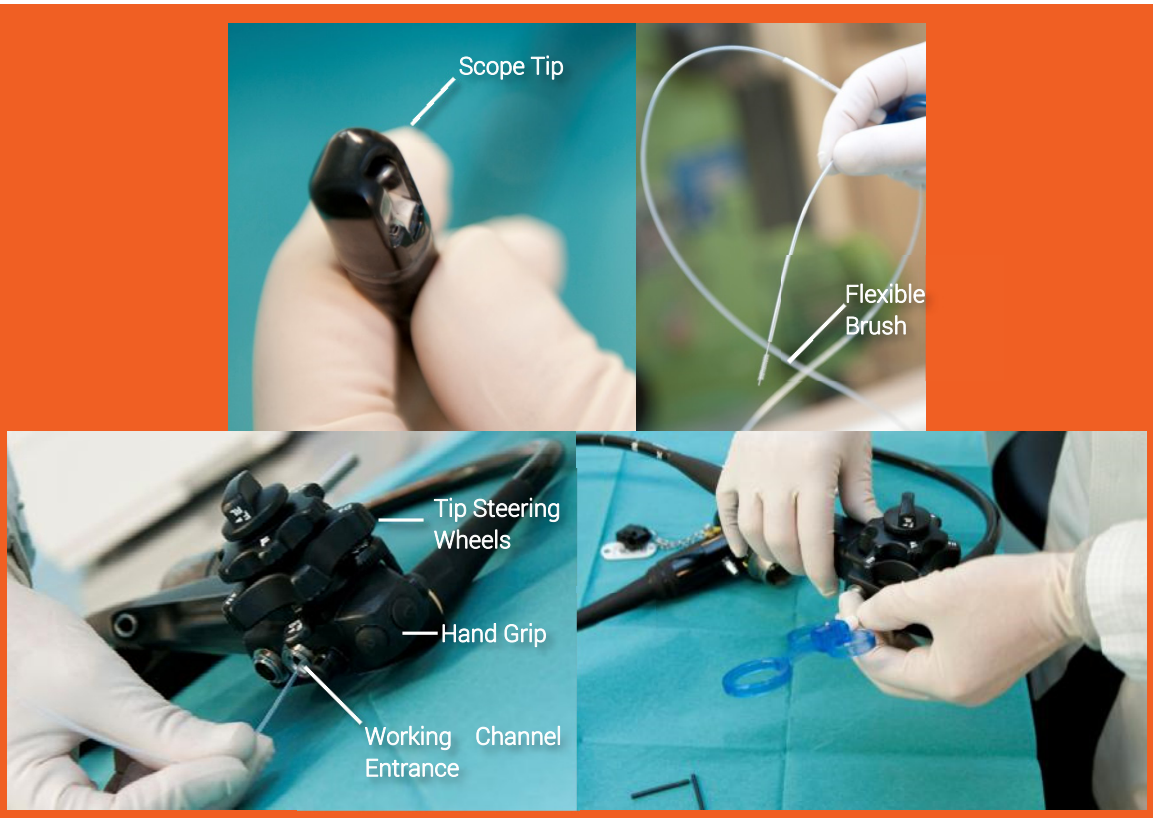

Figure 1: (Top) Tip of Scope X-32 and the flexible brush used for (Bottom) sampling the working channels.

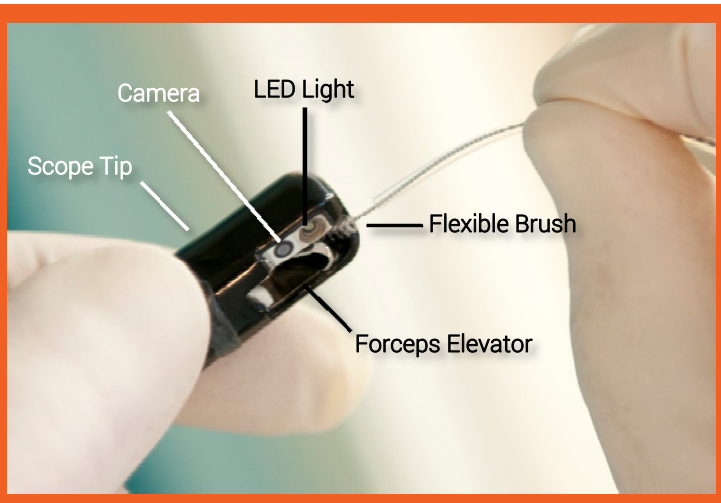

Figure 2: Sampling of the cavity behind the forceps elevator with a flexible brush.

11:40h *The investigation team* continues in the manufacturing hall. The rest of the investigation will take place here.

11:43h Lin makes the first cut in the sealing of the cardan rubber, directly behind the tip of the scope and then observes air bubbles in the sealing. Arjo requests to pause in order to first take photos of the sealing (Figure 3).

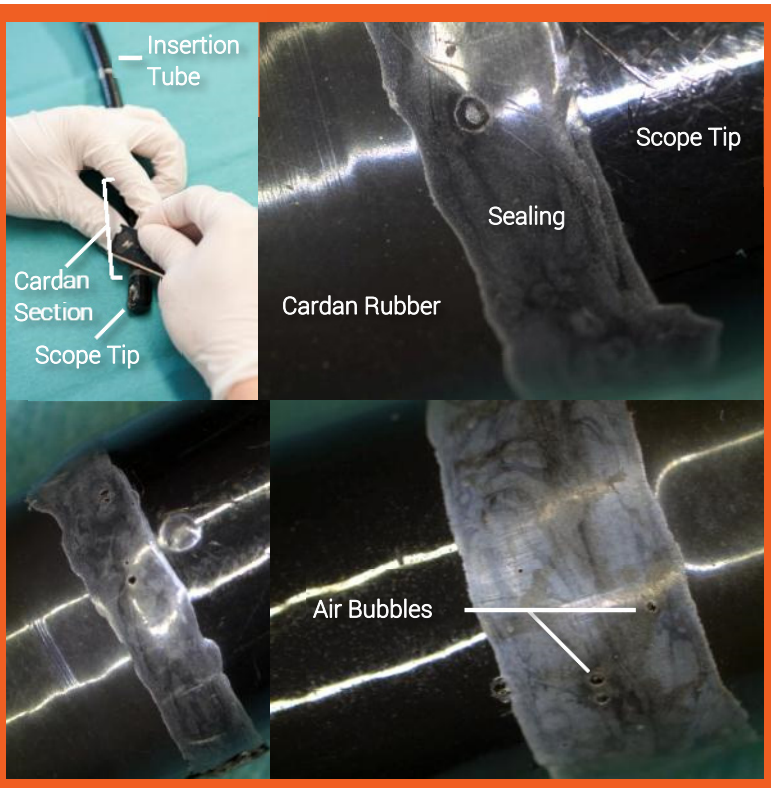

Figure 3: Cutting the seal between the cardan rubber and the tip open. Microscope photos of the air bubbles (some of them are open) in the yet untouched parts of the sealing.

Investigation of the scope camera and LED (Light Emitting Diode) light in the tip shows:

- brownish scale **behind** the cover glass of the LED light (Figure 4)
- cracks in the sealing of the tip housing around the camera and LED light (Figure 4)

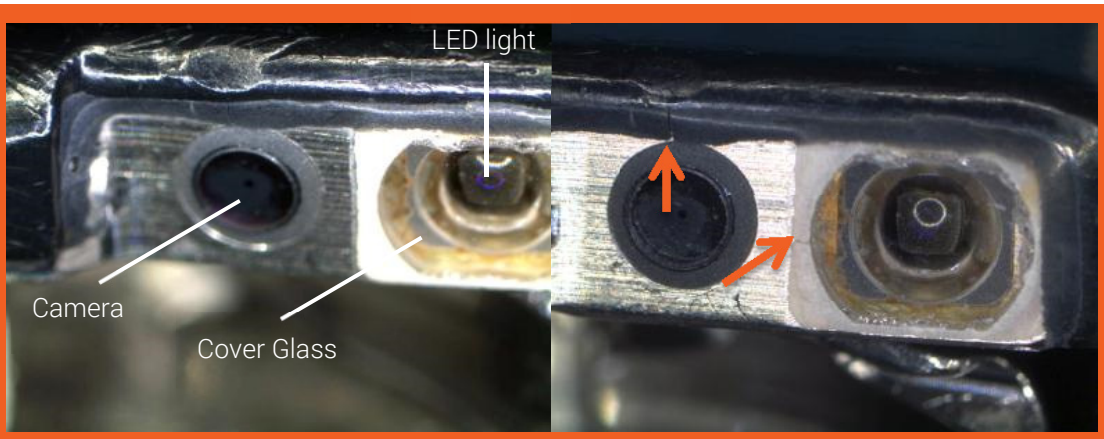

Figure 4: Visual inspection of Scope X-32 camera housing. (Left) It is clearly visible that brownish scale is located behind the cover glass. (Right) The vertical arrow points to the tear in de sealing of the tip housing. Another tear in de sealing next to the camera is indicated with the diagonal arrow.

Photos of the elevator cavity in which the forceps elevator moves show (Figures 5 and 6):

- scratches and grooves on the tip housing surfaces under the forceps elevator,
- whitish scale on the tip housing and brownish scale on the metal surrounding the forceps elevator. Scale is sampled by scraping with a scalpel {5412, 5423, 5434}.

Figure 5: Visual inspection of the elevator area, which is the space around the forceps elevator.
(Top row) Overview of the elevator area with the forceps elevator moved all the way up.
(Middle row) Scratches and grooves below and behind the forceps elevator; the arrows point to the scratches.
(Bottom row) Whitish and brownish scale (arrows) on the surface along which the forceps elevator moves.

Figure 6: From left to right: scraping a sample of the whitish and brownish scale using a scalpel; overview of the work setting; cutting off scalpel point for packaging.

12:22h

Lin removes the sealing that connects the hard plastic cap of the tip with the cardan rubber. This sealing is packaged for testing {5445}. Next, after removing the sealing and a part of the cardan rubber, the section of the steerable part of the tip that became exposed is sampled with a swab {5456, 5467} (Figure 7).

Figure 7: (Leftmost two) Removing and packaging of the sealing between the hard plastic cap of the tip and the cardan rubber that covers the cardan section (steerable section of the scope). (Far right) Sampling under the cardan rubber.

Lin removes the hard plastic cap from the tip by cutting it open, which is then packaged {5478} (Figure 8). Next, the area exposed under the cap is sampled {5489, 5490} (Figure 8).

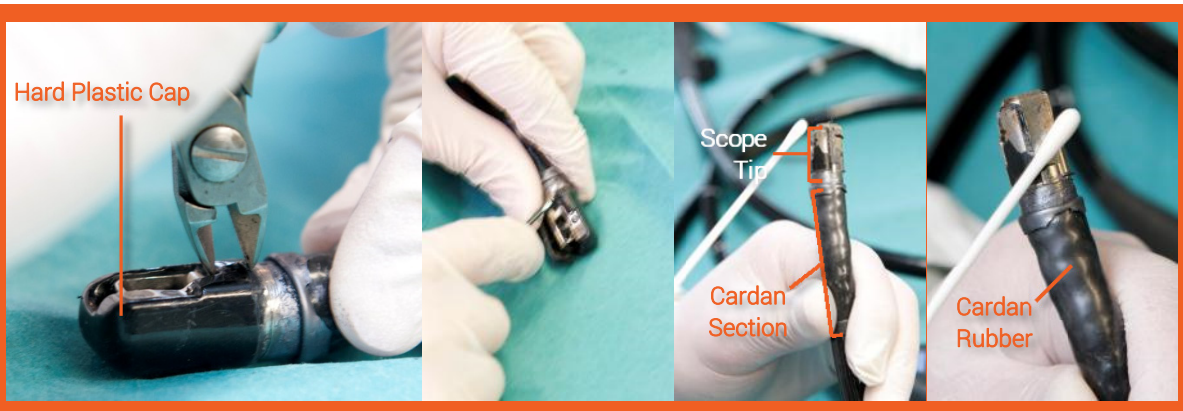

Figure 8: (Leftmost two) Cutting open and prying loose the hard plastic cap off the tip. (Rightmost two) Sampling the exposed parts under the removed hard plastic cap.

An attempt was made to sample behind the forceps elevator using a flexible brush because swabs were too thick. This worked partially, but the space was too limited for the brush to sample the entire area behind the forceps elevator {5521} (Figure 9).

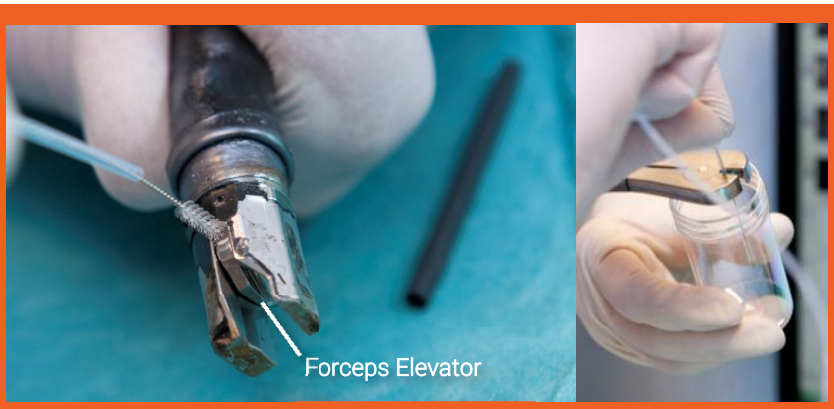

Figure 9: Sampling behind the forceps elevator with a flexible brush.

Microscopic inspection of the actuation axle that runs through the forceps elevator to rotate it (Figure 10) revealed that there was a lot of axial play on the axle: It could clearly move back and forth between the two walls that enclose the elevator.

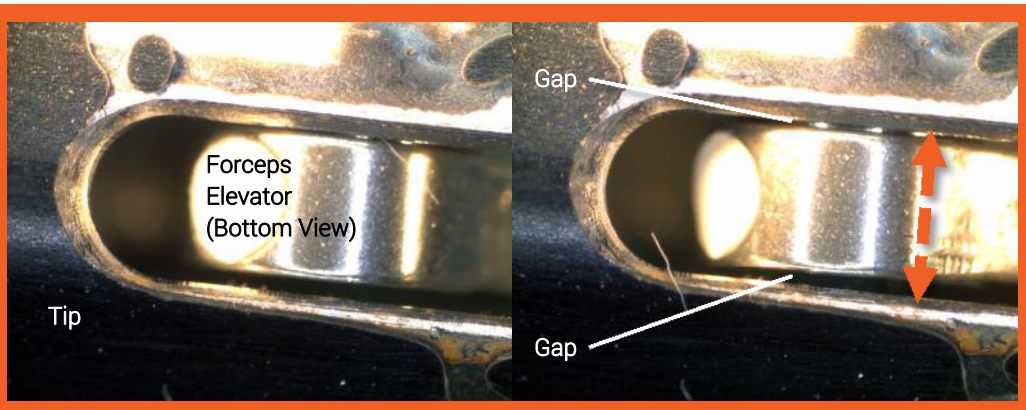

Figure 10: Microscope images of the forceps elevator hinge. The axial shifting of the forceps elevator and the resulting gaps due axial play are clearly visible in the two photos. The dashed arrow indicates the direction of axial motion that the forceps elevator makes when being rotated.
Gap sizes depended on position of forceps elevator and varied between 0 and 0.2 millimeters.

12:56h LUNCH BREAK. All participants leave the manufacturing hall and continue with *the investigation* only after Arjo is present again.

13:27h

CONTINUATION. *The investigation team* is present again in the manufacturing hall. Lin removes the cover plate that covers de actuator area of the forceps elevator (Figure 11). The cover plate is packaged for further testing {5609}. The actuation cable is sampled twice with swabs {5542, 5558} (Figure 12).

The investigation team clearly notices that all metal surfaces inside the opened actuator area are covered in brown scale. Bacterial testing of the samples will have to show whether this is oxidation, blood or something else.

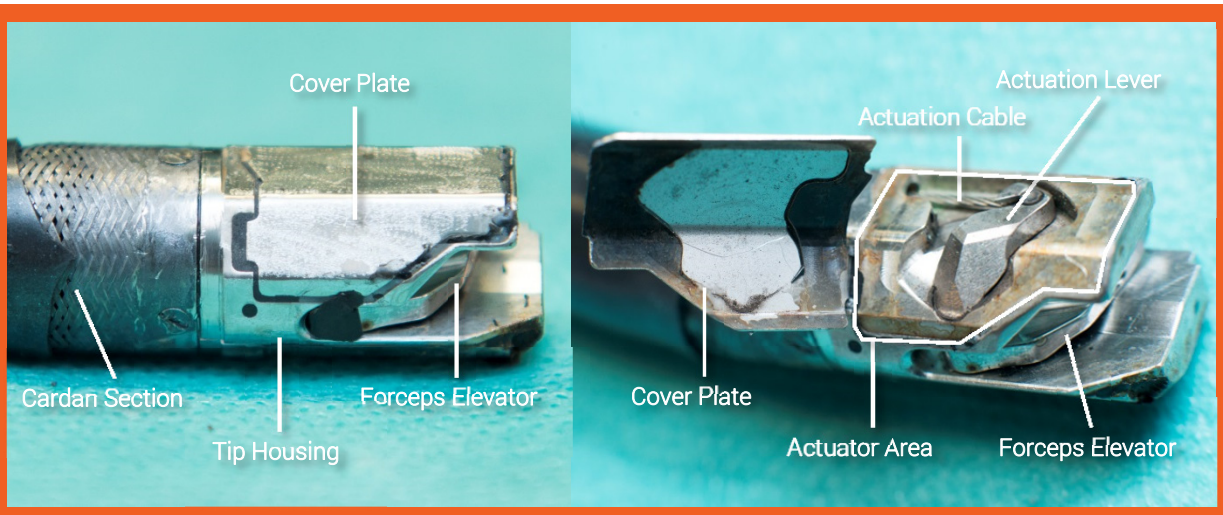

Figure 11: (Left) Tip with the cover plate still closed. (Right) Tip with the cover plate opened, revealing the actuator area.

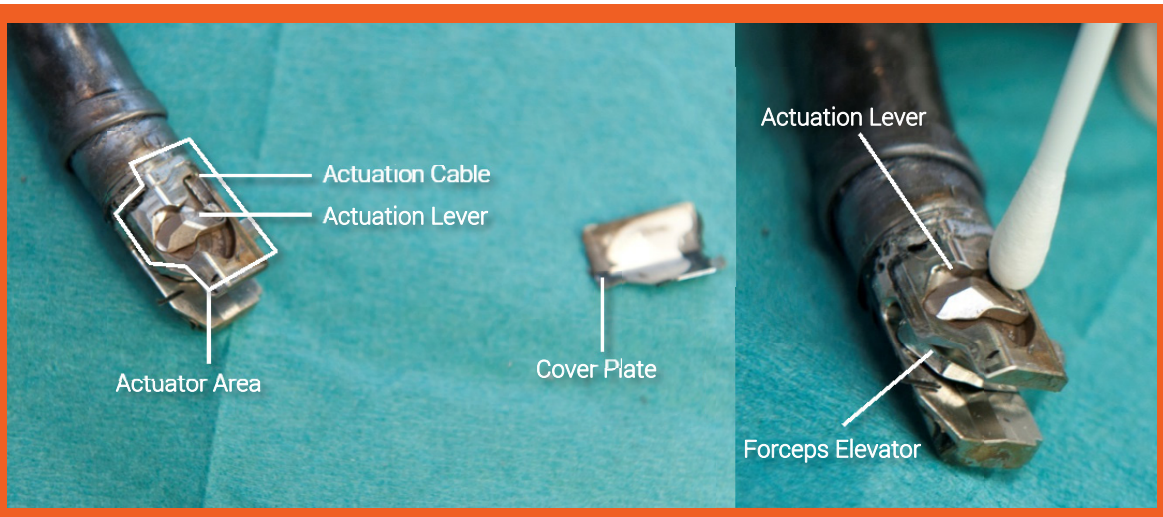

Figure 12: (Left) Removal of the cover plate from the actuator area (arrow) of the forceps elevator. (Right) Sampling the actuation cable of the forceps elevator.

Four swab samples were taken from the actuator area, the area containing the actuation lever with which the forceps elevator is rotated {5560, 5573, 5584, 5599} (Figure 13).

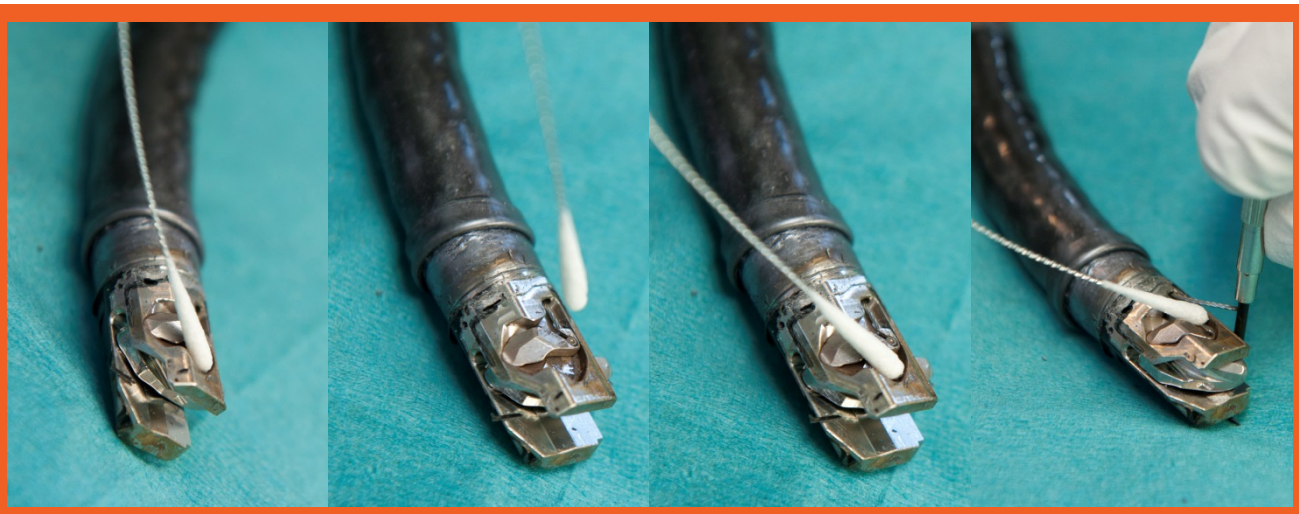

Figure 13: Sampling of the actuator area in which the actuation lever of the forceps elevator is housed.

13:54h

The actuation lever and actuation axle form a single part. It is taken from the actuator area and put under the microscope (Figure 14). There is a rubber O-ring around the actuation axle that should create a water and bacteria tight seal between the actuator area and the patient.

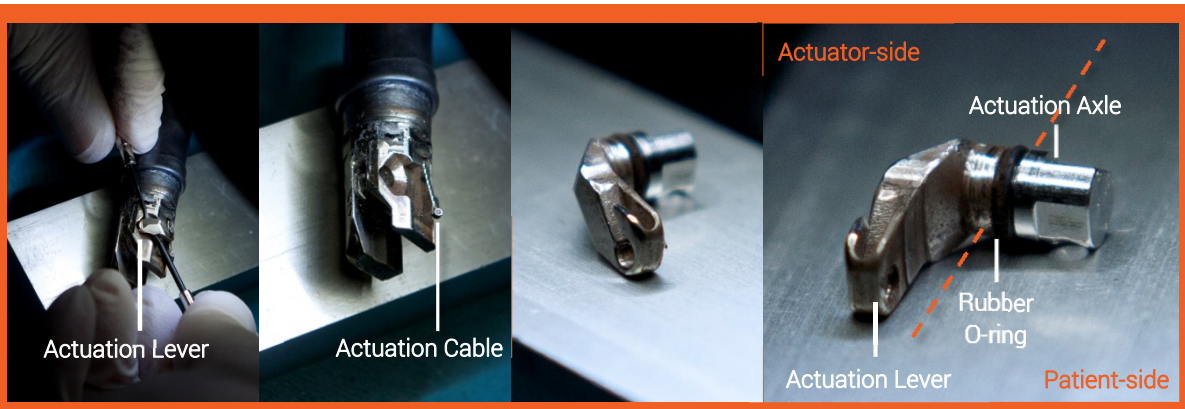

Figure 14: From left to right: removing the actuation lever with actuation axle; actuator area from where the lever was removed; actuation lever with actuation axle and O-ring photographed from the side that was in the actuator area; actuation lever with actuation axle and O-ring photographed from the patient-side.

All surfaces of the lever and actuation axle that were located in the actuator area (the actuator-side) were covered with brown scale (Figure 15). The actuation axle looks clean at the side where the forceps elevator (and thus the patient) was located, the patient-side.

The actuation lever is sampled twice with swabs at the actuator-side {5613, 5620} and the actuation axle is sampled twice on the patient-side, where it was located in the forceps elevator {5636, 5648}.

The difference between the brown-scaled actuator-side and the clean looking patient-side of the actuation lever with actuation axle is clearly visible (Figure 15). The O-ring shows

signs of wear and is covered with brown scale on the actuator-side. On the patient-side of the O-ring the brown scale is present too, but to a lesser extent.

Lin removes de O-ring from the actuation axle. The O-ring is packaged for further testing {5651}. The same goes for the forceps elevator and the actuation lever with actuation axle {5682, 5695}.

14:23h **The investigation** is terminated at this point because several members of **the investigation team** have to catch a plane home. The tip of Scope X-32 is packed in a sterile bag and the rest of the scope is stored in a case.

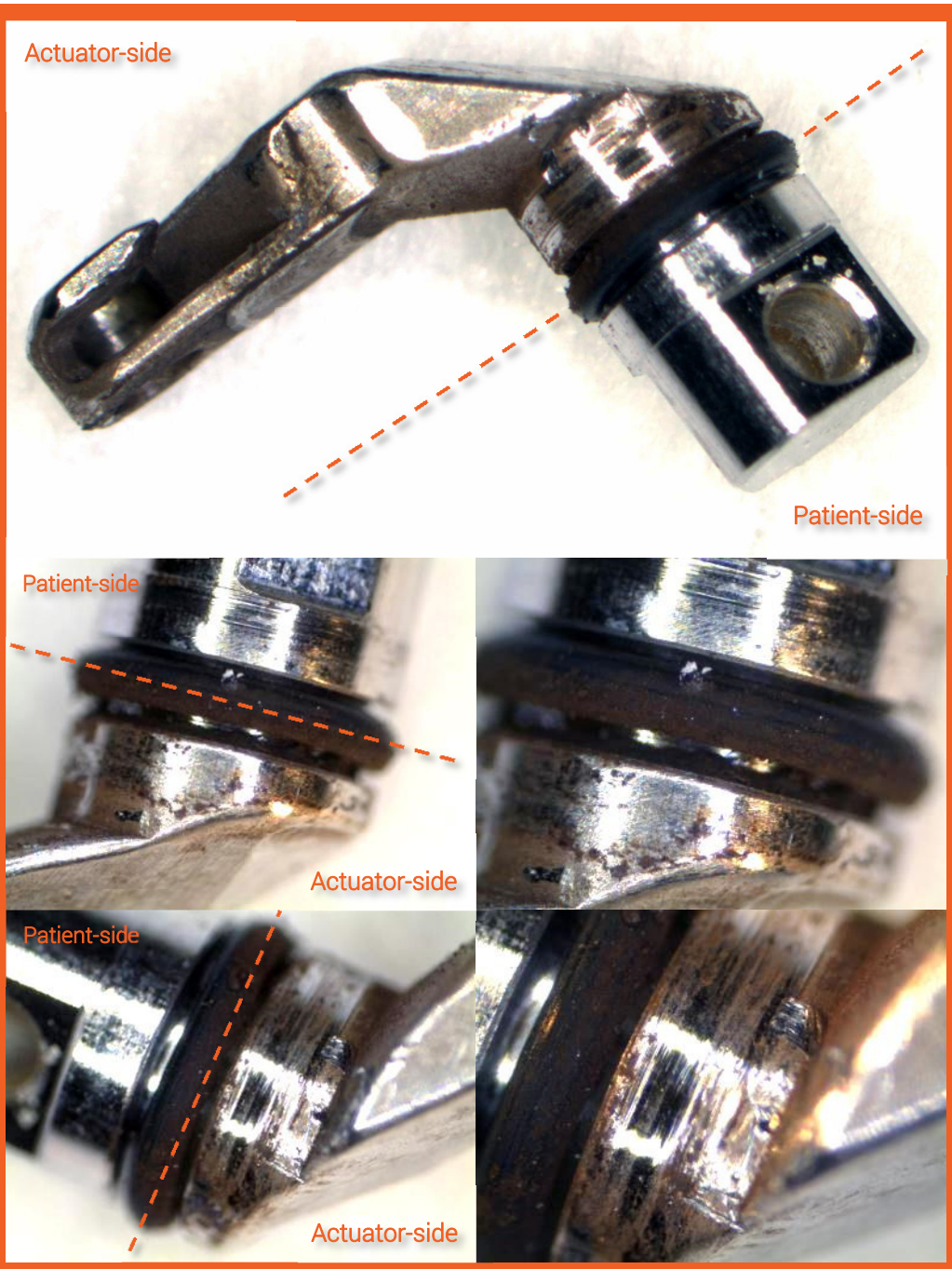

Figure 15: Microscope images of the actuation lever with actuation axle and O-ring. In the bottom set of four photos the right hand photos are enlargements of the middle sections of the left hand photos.

6. LAB TEST RESULTS OF SCOPE X-32 SAMPLES

Table A.1: Laboratory test results for Pseudomonas Aeruginosa bacterium on samples taken from Scope X-32.

Material / Location	Sample #	Pseudomonas Aeruginosa bacteria found
Working Channel	5379	NO
Area behind forceps elevator	5388	NO
Working Channel	5396	NO
Scrapings of white & brown scale in elevator area 1	5412	NO
Scrapings of white & brown scale in elevator area 2	5423	NO
Scrapings of white & brown scale in elevator area 3	5434	NO
Tip cap sealing	5445	NO
Bending section under tip cap sealing 1	5456	NO
Bending section under tip cap sealing 2	5467	NO
Hard plastic cap	5478	NO
Tip under hard plastic cap 1	5489	NO
Tip under hard plastic cap 2	5490	NO
Area around and behind forceps elevator	5521	NO
Actuation cable 1	5542	YES
Actuation cable 2	5558	NO
Actuator area 1	5560	YES
Actuator area 2	5573	YES
Actuator area 3	5584	NO
Actuator area 4	5599	YES
Cover plate of actuator area	5609	YES
Actuation lever on patient-side 1	5613	NO
Actuation lever on patient-side 2	5620	NO
Actuation lever on actuator-side 1	5636	YES
Actuation lever on actuator-side 2	5648	YES
O-ring	5651	YES
Forceps elevator	5682	NO
Actuation lever	5695	YES