PROCESS Study - Sampling protocol PENTAX ERCP duodenoscope

Unit Infection Prevention (UNIP)

Overview of critical changes	
Description	**date**

Draft process / Authorisation				
Role	**Name**	**Position**	**Signature**	**Date**
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1 PURPOSE

1.1 Goal

In the light of recent infectious outbreaks caused by contaminated duodenoscopes, including the outbreak in the Erasmus MC, we would like to ask your cooperation for the following:

In 2012, an outbreak of multidrug resistant microorganisms in our hospital was linked to the newest Olympus TJF-Q180V type duodenoscope. After the outbreak, the duodenoscope was investigated by Olympus and an independent expert. Upon visual inspection, this duodenoscope appeared to contain patient material under the forceps elevator despite reprocessing. The outbreak microorganism was cultured from the forceps elevator.

Further investigation showed that, compared to the old TJF-160VR duodenoscope, the specific design features of the TJF-Q180V duodenoscope hampered adequate cleaning and disinfection. In response to this the Olympus company has adjusted the operating instructions.

Several similar experiences were reported in other hospitals. Therefore, together with the Dutch Health Care Inspectorate (IGZ) our aim is to assess the prevalence of bacterial contamination of all Dutch duodenoscopes, with special attention for the distal tip and endoscope channels. Currently it is not clear whether our experience is a separate problem or whether this is a problem that is related to the specific design of the relevant duodenoscope. With this trial and your cooperation, we might be able to answer this question.

This study is in collaboration with the Dutch Association of Medical Microbiology (NVMM) and the Dutch Association of Gastroenterologists (NVMDL).

1.2 Duodenoscopes

- Please sample at least two duodenoscopes (no EUS echoendoscopes) that are reprocessed and ready for patient use, e.g.: after high level disinfection or after drying in the storage cabinet.
- If your centre uses Olympus TJF-Q180V duodenoscopes, please include this type of endoscope.
- If your centre owns other types of duodenoscopes, please sample two duodenoscopes of your own choosing.
- If you want to sample more duodenoscopes, please contact us for extra sampling materials at unitinfectiepreventie@erasmusmc.nl.

1.3 Definitions and abbreviations

See appendix.

2 SAMPLE SITES

- Forceps elevator
- Protection cap if removable
- Suction channel
- Air-/water channel
- Biopsy channel

3 MATERIALS

- Two personnel
- Non-sterile gloves
- Disposable cover sheet
- Three sterile syringes of at least 20ml in combination with a bottle with 100 ml of sterile physiological saline solution (NaCl 0.9%)
  or
  10 disposable pre-filled 10ml syringes with NaCl 0.9%.
  Use a separate and new syringe for each different channel.
- Three sterile suction needles
- Three sterile containers to collect at least 20ml of flush fluid
- One disposable plastic brush: Pentax tri-bristled cleaning brush CS6021T
- Disinfected cleaning adapter OF-B153 (“channel separator”)
- Disinfected rubber inlet seal OF-B190 (“instrument port closing cap”) and cleaning adapter OF-G17
- Disinfected metal wire cutter

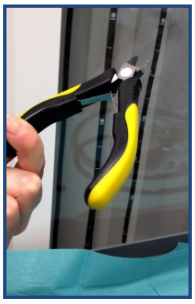


Figure 1: Wire cutter

Sample collection kit

The sample collection kit contains the following materials:

- Three sets of two vacutainers with a brown cap (9.5ml) and numbered pink label in triplicate.
- Three sets of ESwabs containing transport medium and numbered blue labels in duplicate.
- Application form
- Return envelope

4 SAMPLING PROCEDURE

4.1 Preparation of materials

- Prepare all materials needed for sampling of the duodenoscopes.
- Note on the application form the following data:
  - Sampling date
  - Manufacturer, type and unique endoscope code
  - Name of the hospital. This is not mandatory as anonymous participation is also possible. However, in that case the culture results cannot be returned.
- Disinfect the hands and put on non-sterile gloves.
- The duodenoscope can be sampled while lying in the automated endoscope disinfector or on a clean and disinfected surface using the disposable cover sheet.

4.2 Sampling

Forceps elevator

- Position the distal tip of the duodenoscope in a way that the forceps elevator and the surrounding area of the tip can be sampled with an Eswab.
- Unpack the Eswab and take the Eswab from its container.
- Brush multiple times with the Eswab above, under and around the forceps elevator, with the elevator in a lowered and raised position.
- The second person presents the opened container with transport medium. Insert the swab part of the Eswab in the container. Break the Eswab at the coloured breakpoint line. The second person closes the container and attaches a blue numbered label to the container. Put the second label with the same number on the form next to the “forceps elevator” box.

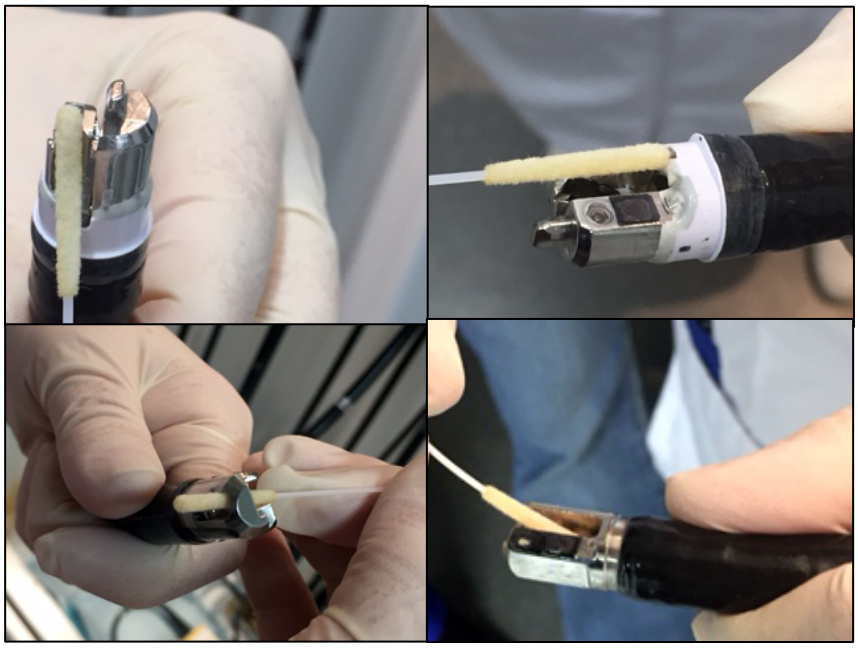


Figure 2: Sampling of the forceps elevator

Removable protection cap

- Unpack the Eswab and take the Eswab from its container.
- Brush the inside of the protection cap several times with the Eswab.
- The second person presents the opened container with transport medium. Insert the swab part of the Eswab in the container. Break the Eswab at the coloured breakpoint line.
- The second person closes the container and attaches a blue numbered label to the container. Put the second label with the same number on the form next to the “protection cap” box.

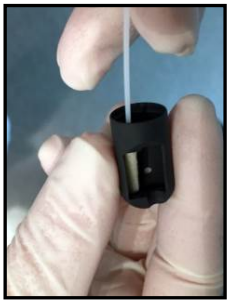


Figure 3: Sampling of the protection cap

Flush suction channel

- Put a disinfected cleaning adapter OF-B153 (“channel separator”) on the endoscope. Close the instrument channel inlet with a disinfected rubber inlet seal OF-B190 (“instrument port closing cap”).
- Draw up at least 20ml of NaCl 0.9% in a sterile syringe or use disposable pre-filled 10ml syringes with NaCl 0.9%. *Explanation: use enough saline solution to collect at least 20ml in a sterile container.*
- Connect the syringe to the suction nipple.
- Flush the saline into the suction channel and collect it in a sterile container at the tip of the endoscope. Pull the plunger of the syringe up and down three times during flushing: flush air with the syringe through the channel to make sure all saline is collected in the container.
- Connect a sterile suction needle to the syringe.
- Draw up the collected flush fluid in the syringe.
- Inject the syringe into a vacutainer. The vacuum pulls 9.5ml of flush fluid into the vacutainer. Inject the syringe in a second vacutainer for the remaining 9.5ml.
- Attach a numbered pink label to the vacutainer and a label with the same number to the second vacutainer. Put the third label with the same number on the form next to the “Suction channel” box.

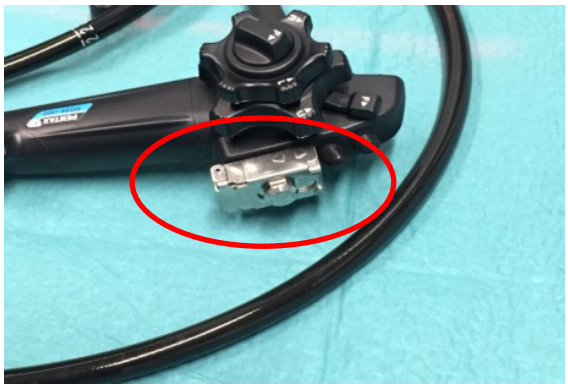


Figure 4: Cleaning adapter

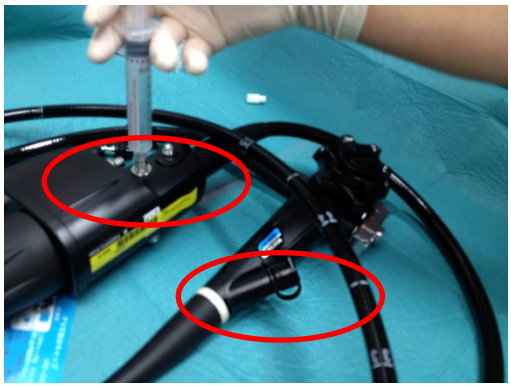


Figure 5: Flush suction channel and inlet seal

Flush biopsy (instrument) channel

- Put a disinfected cleaning adapter OF-B153 (“channel separator”) on the endoscope.
- Draw up at least 20ml of NaCl 0.9% in a sterile syringe or use disposable pre-filled 10ml syringes with NaCl 0.9%. *Explanation: use enough saline solution to collect at least 20ml in a sterile container.*
- Connect the syringe to the instrumentation port of the biopsy channel.
- Flush the saline into the biopsy channel and collect it in a sterile container at the tip of the endoscope. Pull the plunger of the syringe up and down three times during flushing: flush air with the syringe through the channel to make sure all saline is collected in the container.
- Connect a sterile suction needle to the syringe.
- Draw up the collected flush fluid in the syringe.
- Inject the syringe into a vacutainer. The vacuum pulls 9.5ml of flush fluid into the vacutainer. Inject the syringe in a second vacutainer for the remaining 9.5ml.
- Attach a numbered pink label to the vacutainer and a label with the same number to the second vacutainer. Put the third label with the same number on the form next to the “Biopsy channel” box.

Flush air/water channel

- Put a disinfected cleaning adapter OF-B153 (“channel separator”) on the endoscope. Close the instrument channel inlet with a disinfected rubber inlet seal OF-B190 (“instrument port closing cap”).
- Draw up at least 20ml of NaCl 0.9% in a sterile syringe or use disposable pre-filled 10ml syringes with NaCl 0.9%. *Explanation: use enough saline solution to collect at least 20ml in a sterile container.*
- Put the cleaning adapter OF-G17 on the air/water port and connect the syringe to the adapter.
- Flush the saline into the suction channel and collect it in a sterile container at the tip of the endoscope. Pull the plunger of the syringe up and down three times during flushing: flush air with the syringe through the channel to make sure all saline is collected in the container.
- Connect a sterile suction needle to the syringe.
- Draw up the collected flush fluid in the syringe.
- Inject the syringe into a vacutainer. The vacuum pulls 9.5ml of flush fluid into the vacutainer. Inject the syringe in a second vacutainer for the remaining 9.5ml.
- Attach a numbered pink label to the vacutainer and a label with the same number to the second vacutainer. Put the third label with the same number on the form next to the “Air/water channel” box.

Figure 6: Flush air/water channel with the OF-G17 adapter

Brush of the biopsy (instrument) channel and suction channel

- Sampling the biopsy/suction channel with the Pentax tri-bristled cleaning brush CS6021T.
- Firstly, insert the blue tip of the brush through the suction nipple into the suction channel. Push the brush trough and pull the brush out of suction cylinder. Secondly, insert the brush into the suction cylinder. Push the brush trough and pull the brush out of the distal tip. Lastly insert the brush into the instrument inlet. Push the brush trough the biopsy channel (instrument channel) and pull the brush out of the distal tip.
- The second person helps to guide the brush to prevent environmental contamination of the brush during insertion and removing of the brush.
- Cut off the tip of the brush part with a disinfected metal wire cutter. After sampling the second person presents the opened container with transport medium. Insert the brush in the container. Cut the brush part with a disinfected metal wire cutter.
- The second person closes the container and attaches a blue numbered label to the container. Put the second label with the same number on the form next to the “brush” box.

Figure 8: First insertion in suction nipple

Figure 7: Third insertion in instrument port

4.3 Preparation for transport

- Place the used vacutainers and transport containers with the Eswabs/brush in the plastic blister pack and the absorbent material. Put the closed blister pack in the safety bag and close the safety bag.
- Place the entire package in the plastic return envelope and close the envelope.
- The package is now ready for shipment, postage is not necessary.

5 COMMENTS

Not applicable.

6 REFERENCES

FO-0249	Erasmus MC Application form endoscope cultures PROCESS Study
AN-0055	Erasmus MC Microbiological surveillance testing of endoscopes

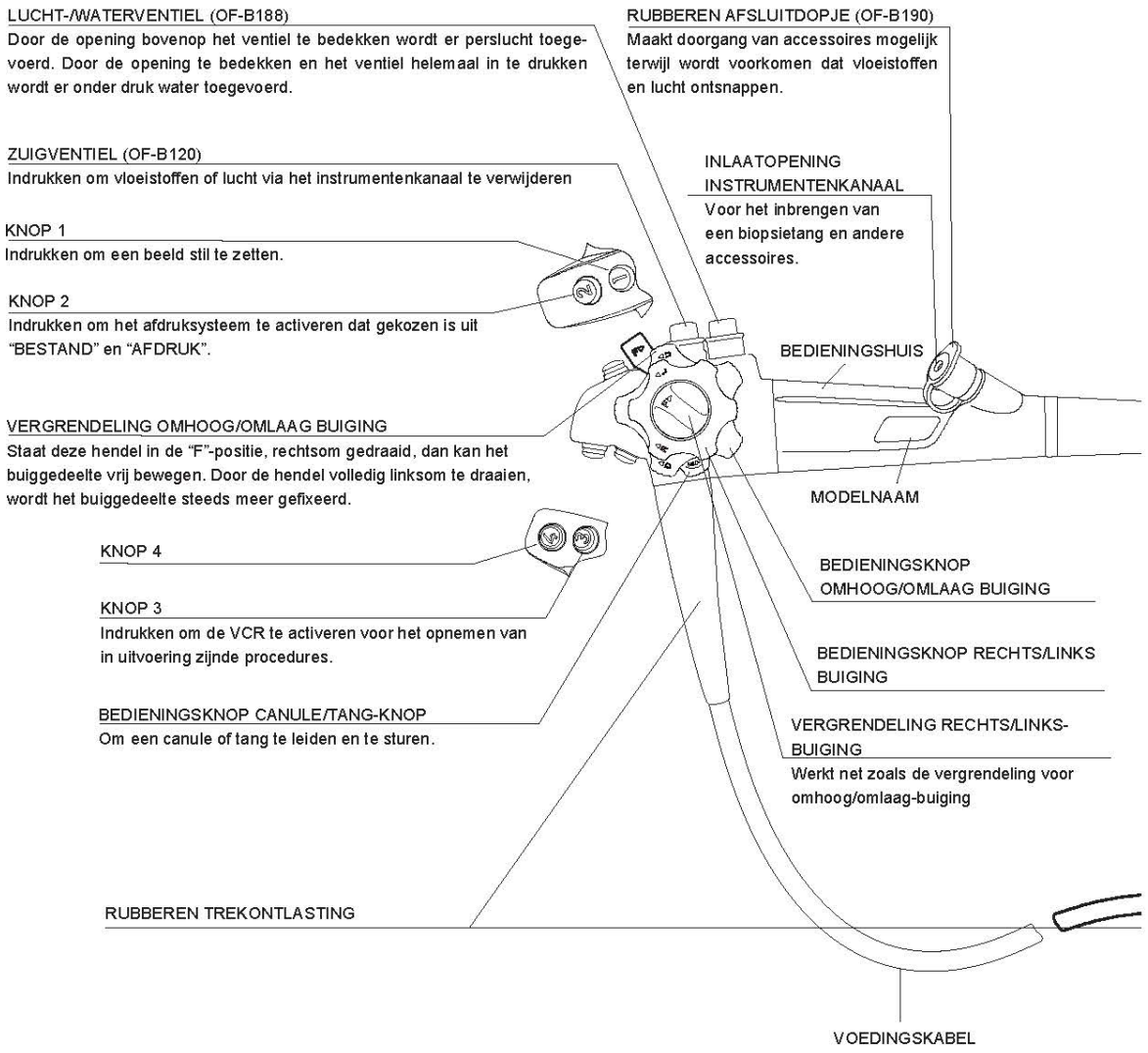
7 ATTACHMENTS

Attachment 1 - Legend
Attachment 2 - Nomenclature Pentax ED34-i10T

Attachment 1 - Legend

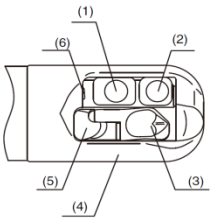
- Forceps elevator - *Canule/Tanglift*
- Distal tip - *Distaal uiteinde*
- Protection cap - *Distaal kapje*
- Elevator channel plug - *Aansluiting tangenliftkanaal*
- Suction nipple - *Zuignippel*
- Suction cylinder - *Zuigcilinder*
- Air/water cylinder - *Lucht-/watercilinder*
- Instrument channel port - *Inlaatopening instrumentenkanaal*

Attachment 2: Nomenclature PENTAX ED34-i10T



Distaal uiteinde

ED34-i10T



(1) Beeldlens
(2) Lichtpen
(3) Canule/tanglift
(4) Distaal kapje (OE-A55)
(5) Instrumentenkanaal
(6) Lucht-/watermondstuk