

PROCESS Study - Sampling protocol Olympus ERCP duodenoscope

Unit Infection Prevention (UNIP)

Overview of critical changes	
Description	date

Draft process / Authorisation				
Role	Name	Position	Signature	Date
Author	W. de Groot	Infection Prevention Specialist		15-04-2015
Verification	I. Sleutel	Quality officer		15-04-2015
Verification	M.M.A. Timmermans	Quality officer		15-04-2015
Conformation	M. Vos	Medical microbiologist		15-04-2015
Conformation (Quality System)	I. Sleutel	Quality officer		15-04-2015

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
- Forceps elevator wire channel
- Suction 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 disinfected auxiliary water tube MH-974 (elevator wire channel)
- Sterile disposable adapters (Combifix) in combination with the biopsy valve MB-358
- One disposable plastic brush: Olympus single-use combination cleaning brush BW-412T
- Disinfected channel plug MH-944 ("channel separator")
- Disinfected metal wire cutter

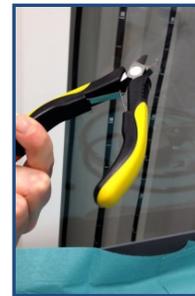


Figure 1: Wire cutter

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 ES swabs 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 disinfectant 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 such 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.

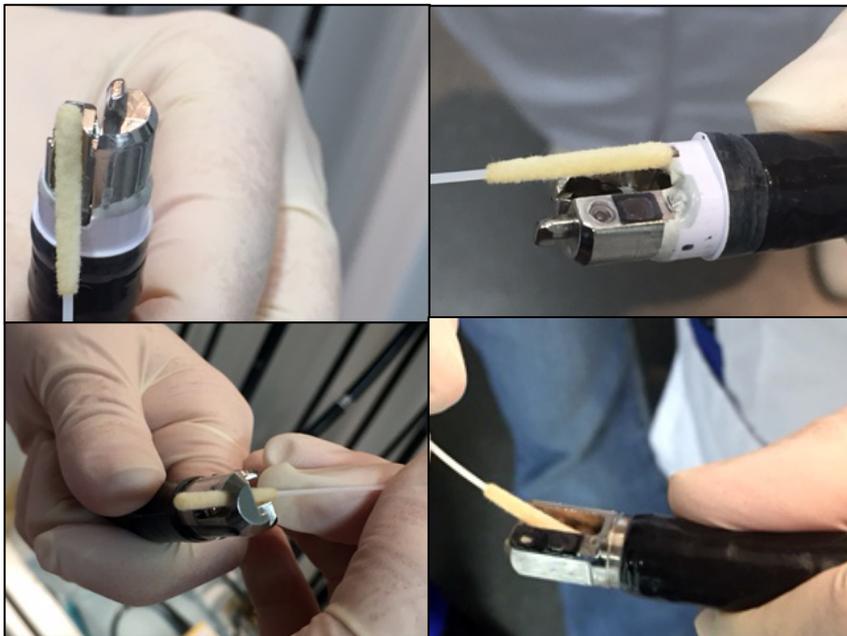


Figure 2: Sampling of the forceps elevator

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.

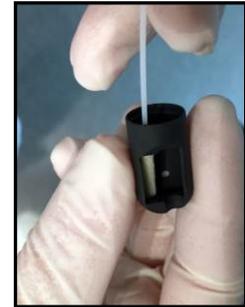


Figure 3: Protection cap

Flush forceps elevator wire channel

- Use a disinfected auxiliary water tube MH-974 to connect a syringe to the elevator channel plug of the elevator wire channel.
- 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 auxiliary water tube connected to the elevator channel plug.
- Flush the saline in the 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 “Elevator wire channel” box.



Figure 4: Syringe connected to the elevator wire channel with an auxiliary water tube

Flush suction channel

- Put a disinfected channel plug MH-944 (“channel separator”) on the endoscope. Close the instrument channel port with the biopsy valve cap attached to the channel plug.
- 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 5: Channel plug with biopsy valve cap



Figure 6: Syringe connected to suction nipple

Flush biopsy (instrument) channel

- Put a disinfected channel plug MH-944 (“channel separator”) on the endoscope.
- If necessary, use a sterile tube or an adapter in combination with biopsy valve MB-358 to connect the syringe to the channel
- 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.



Figure 7: Adapter

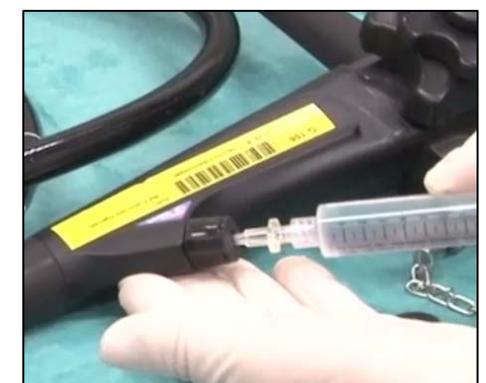


Figure 8: Flush biopsy channel

Brush of the biopsy (instrument) channel and suction channel

- Sampling the biopsy/suction channel with the BW-412T plastic disposable brush.
- Firstly, insert the brush through the suction nipple into the suction channel and push the brush trough. Secondly, insert the brush straight into the suction cylinder and push the brush trough to the suction nipple. Thirdly, insert the brush downwards into the suction cylinder and push the brush trough the biopsy channel. Lastly insert the brush into the instrument channel port and push the brush trough the biopsy channel.
- The second person helps to guide the brush to prevent environmental contamination of the brush during insertion and removing of the brush.
- 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 11: Suction nipple



Figure 10: First insertion suction cylinder



Figure 9: Second insertion suction cylinder

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

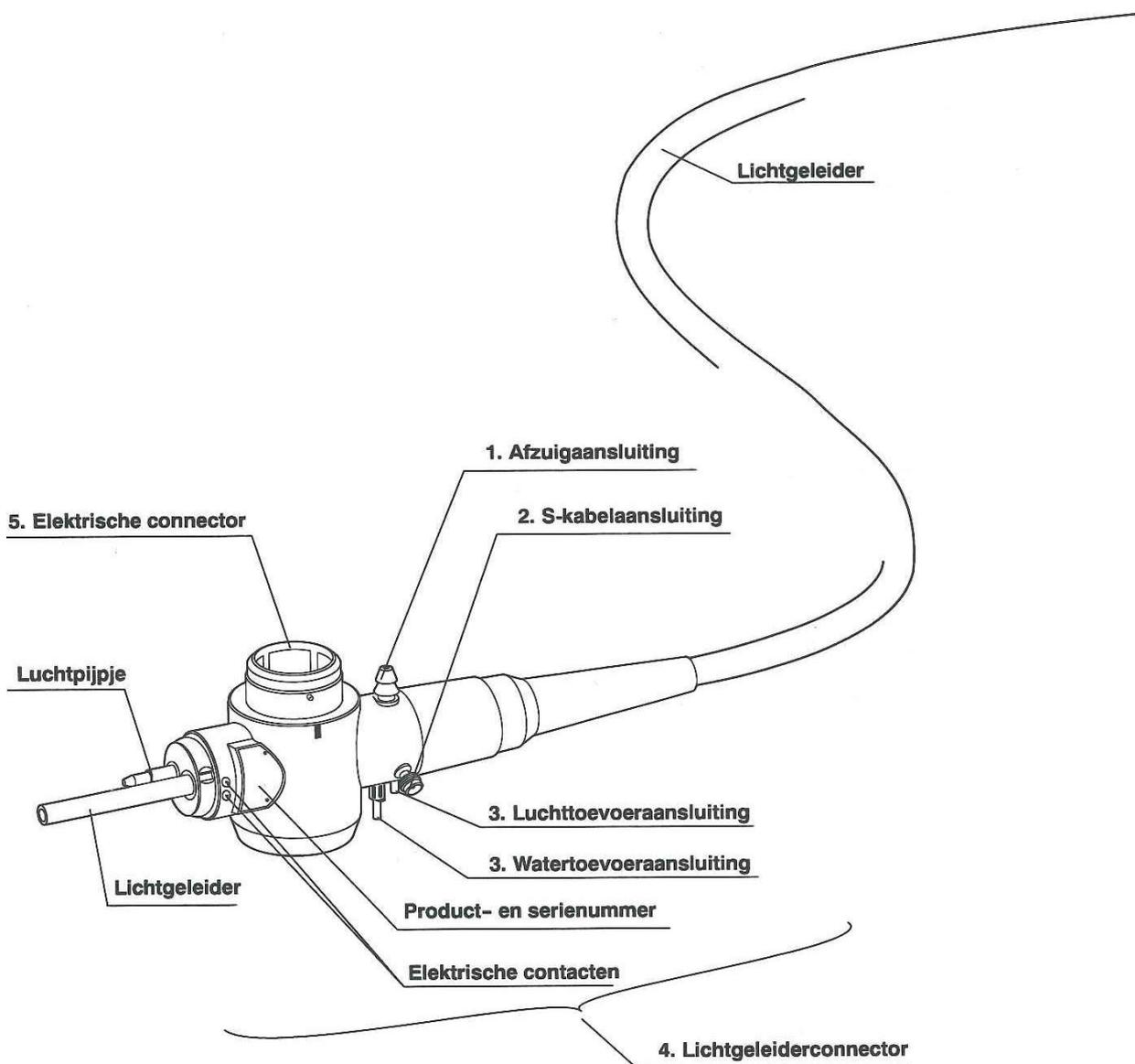
7 ATTACHMENTS

Attachment 1 - Legend
 Attachment 2 - Nomenclature Olympus TJF-160VR
 Attachment 3 - Nomenclature Olympus TJF-Q180V

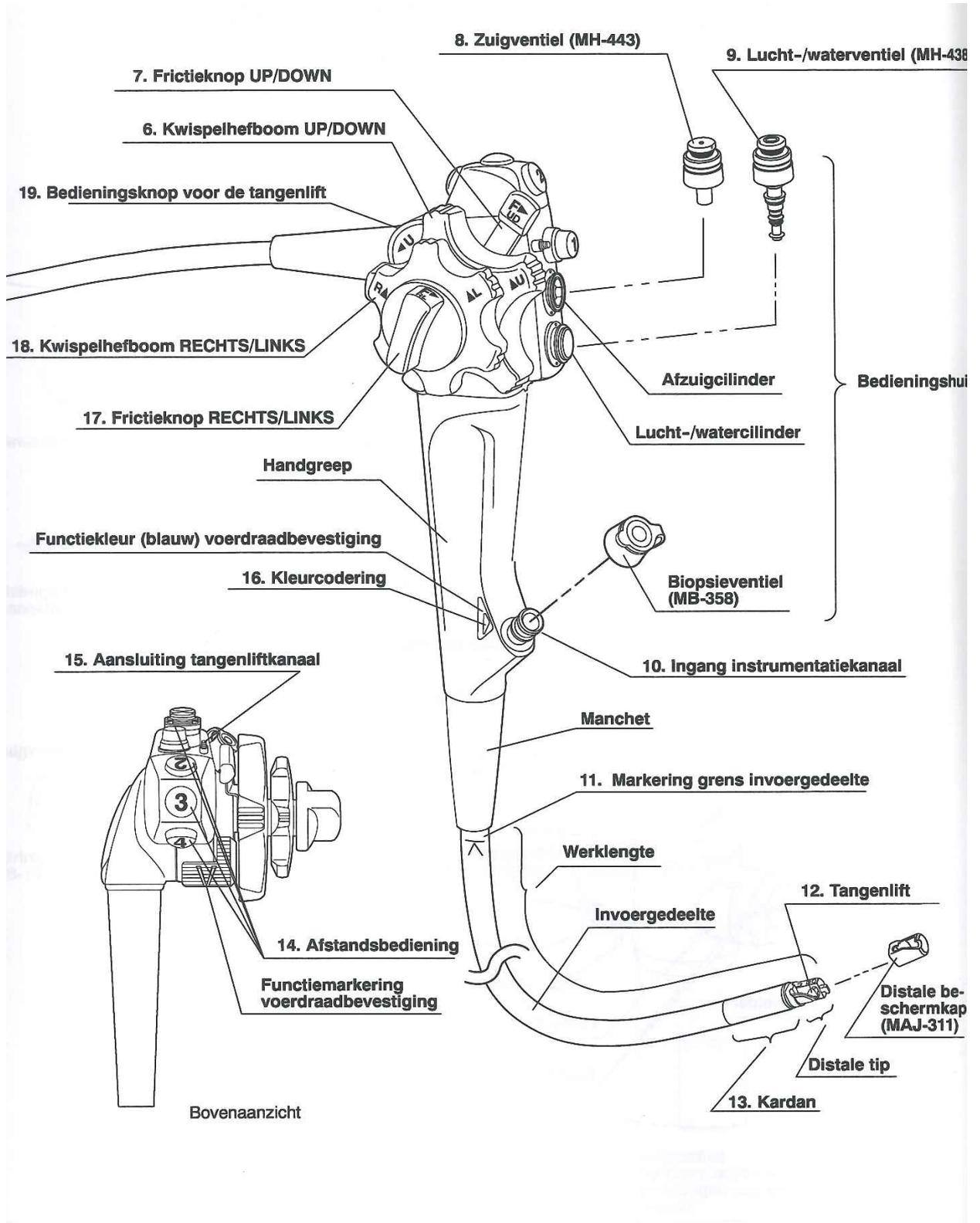
Attachment 1 - Legend

- | | | | |
|---------------------------|---|-----|-------------------------------------|
| • Forceps elevator | - | 12. | <i>Tangenlift</i> |
| • Distal tip | - | | <i>Distale tip</i> |
| • Protection cap | - | | <i>Distale beschermkap</i> |
| • Elevator channel plug | - | 15. | <i>Aansluiting tangenliftkanaal</i> |
| • Suction nipple | - | 1. | <i>Afzuigaansluiting</i> |
| • Suction cylinder | - | | <i>Afzuigcilinder</i> |
| • Air/water cylinder | - | | <i>Lucht-/watercilinder</i> |
| • Instrument channel port | - | 10. | <i>Ingang Instrumentatiekanaal</i> |
| • Biopsy valve | - | | <i>Biopsieventiel</i> |

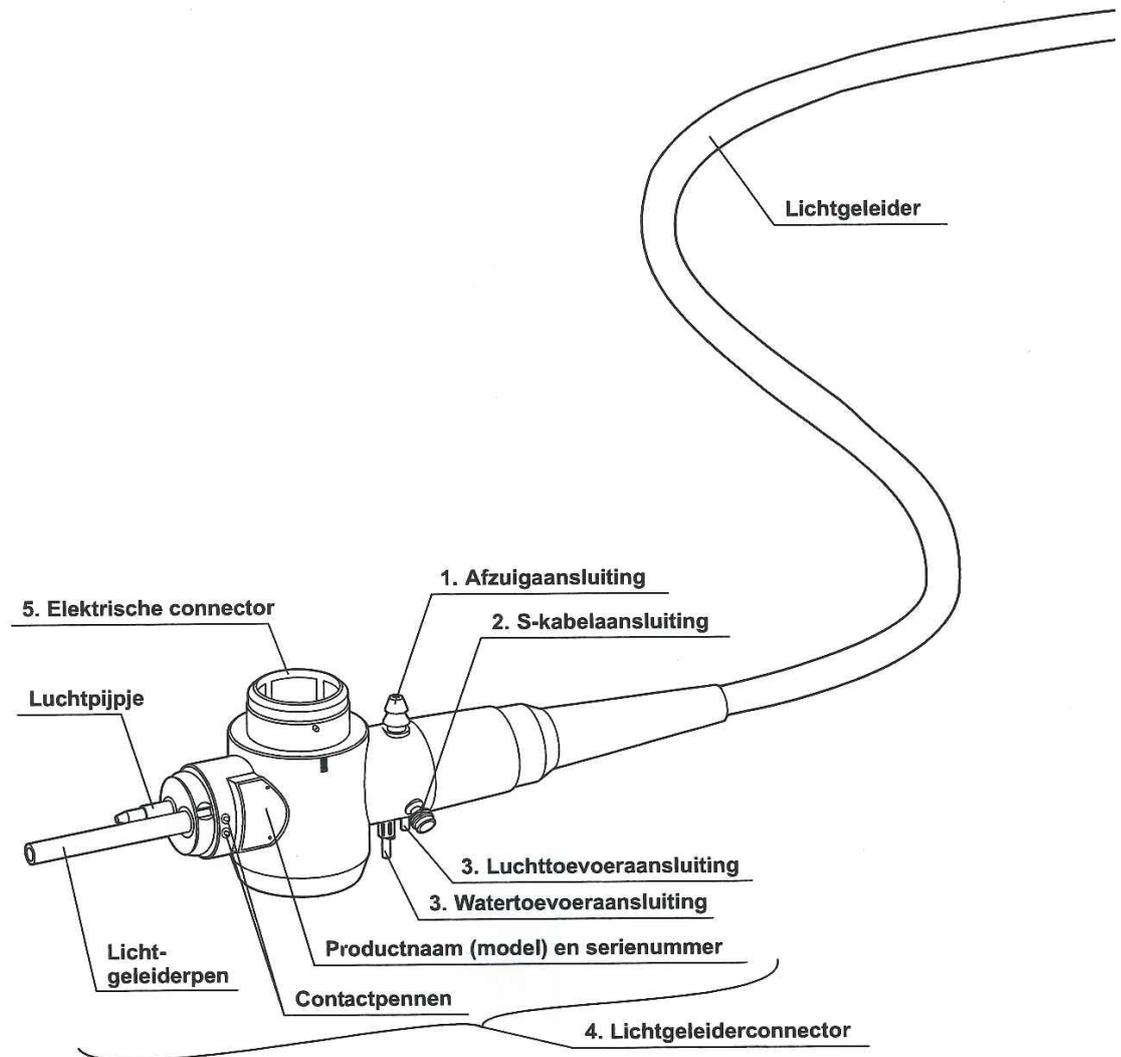
Attachment 2: Terminology OLYMPUS TJF-160VR



SOPnr.	ME-0084
Date 1 st version	15-04-2015
Version nr.	001
Date version	15-04-2015
Pages	10 / 12



Attachment 3: Terminology OLYMPUS TJF-Q180V



SOPnr.	ME-0084
Date 1 st version	15-04-2015
Version nr.	001
Date version	15-04-2015
Pages	12 / 12

