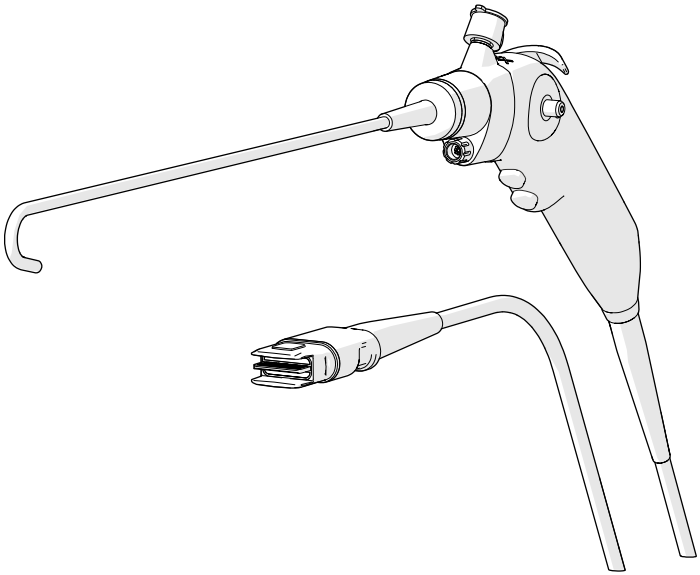
Spectar Video Nasopharyngoscopes

with and without working channel



Instruction for Use

XN S
XN P
XN HD
XN S20
XN P20

Ver.11 en • 30.09.2022

General

CE

XION GmbH
Pankstrasse 8
13127 Berlin
Germany

Fon: +49 (0)30 / 47 49 87 – 0
Fax: +49 (0)30 / 47 49 87 – 11
Email: info@xion-medical.com
www.xion-medical.com/en

1 Directions for Using the Manual

The instructions for use explain how to operate the medical device safely, properly and effectively.

Before using the product, please read the complete User Manual. Keep the User Manual within reach of the device. If you pass the device on to a third party, make sure to also pass on the User Manual.

XION GmbH assumes no liability whatsoever for damages caused by failure to observe the instructions in this User Manual.

Pictures and graphics are partly example representations that focus on the respective process (e.g. making a plug connection). In this User Manual, the devices shown in these sample illustrations may differ slightly from your device.

Table of Contents

2 Graphic Symbols Used

Symbol	Meaning
	Refer to instruction manual/booklet
	**Caution!** Failure to observe the instructions can lead to personal injury.
	**Note!** Failure to observe the instructions can lead to material damage.
	Tip
	Manufacturer
	Year of manufacture
	TYPE BF APPLIED PART
	Caution
IP 67	Degree of protection
	Article number
	Serial number
	Temperature limit
	Keep away from sunlight
	Keep dry
	Disposal of electrical equipment
CE	CE marking

3 Intended purpose

3.1 Intended use

XION Video Nasopharyngoscopes are flexible endoscopes for transient use in natural body orifices and body cavities. They are designed for endoscopic examinations of the nasopharynx, the nasal and mouth cavities, as well as the trachea and for stroboscopic observations of the larynx.

Devices equipped with a working channel can also be fitted with surgical instruments such as biopsy forceps or grasping forceps via the endoscope.

3.2 Intended user

The intended user is the physician who is trained/experienced in endoscopy and/or minimally invasive surgery, and who has read this User Manual.

This equipment is not intended for operation by medical assistants.

3.3 Indication

The use of the Video Nasopharyngoscopes is indicated when, from the point of view of the attending physician, a diagnosis of the nasopharynx, the nasal and mouth cavities, trachea and larynx with a flexible endoscope is indicated.

3.4 Contraindication

Contraindications that relate directly to the medical device, are currently unknown. The use of XION video nasopharyngoscopes is contraindicated if, in the opinion of a qualified physician, such an application would endanger the patient.

4 Safety Instructions

4.1 General

- This device may not be modified without the permission of the manufacturer.
- Mechanical stresses will shorten the service life of the device. Therefore, avoid pulling, knotting, twisting and kinking the insertion shaft and the connector cable.
- Connect and operate nasopharyngoscopes only under conditions that correspond to those specified in the Technical Data.
- Any serious incidents occurring in connection with the medical device must be reported to the manufacturer and the competent authority.

Side effects of flexible endoscopes

In general, complications can be caused by:

- the type of intervention,
- an unsuitable endoscope (e.g. size),
- the inexperience of operators.

Possible complications include:

- Pain and discomfort
- Oxygen desaturation
- Bleeding (epistaxis)
- Fever and infection
- Laryngospasms

4.2 Before using the product

- At the time of delivery, the device is in a non-sterile condition. Reprocess the product before the first and each subsequent application.
- Do not use the device immediately, if the transport temperature was below 0°C. The device can be used after it has acclimatized in the application environment for 24 hours.
- Visually inspect the device to ensure its functional safety and proper working condition. Do not use the device if it is damaged in any way that could jeopardize the patient, the user, or third persons.
- Check the bending function of the distal tip.
- Check the key functions of the video nasopharyngoscope.

- Check the surface of the flexible shaft for damage (rough surfaces, sharp edges or protruding parts).
- Before using the application and after changing any settings, check the image orientation and the live image playback.

4.3 Product application

- The device shall be used only by physicians who, through their specialist qualifications, can ensure that it is handled in the proper intended manner.
- Veezar video nasopharyngoscopes can only be operated in conjunction with the EndoCOMPACT Veezar.
- The medical device is **NOT** suitable for operating in potentially explosive areas and/or in oxygen enriched environments. For example, when using combustible and volatile skin cleaning and skin disinfecting substances, make sure that the device is not used in a hazard zone as defined by the manufacturer.
- The device is **NOT** suitable for using in MRI rooms.
- Avoid contact between the nasopharyngoscope and sharp objects (scalpels/ needles).
- When removing the nasopharyngoscope from the body orifice/body cavity, it is essential to first ensure that the distal end is in a relaxed state (the distal tip must not be angled/bent on removal).
- Before removing the nasopharyngoscope from a body orifice/body cavity, it is essential to first remove all instruments from the working channel.
- It is essential to ensure that the nasopharyngoscope is properly connected before it can be used as an application part!

High- energy light at distal tip

High-energy endoscopic light may exit from the distal end of the nasopharyngoscope. Deposits in the fibre-optic output area, insufficient work distances or direct tissue contact can result in high temperatures above 41°C and possible tissue damage due to thermal radiation. Heat-sensitive or flammable surfaces may be damaged or they may ignite.

- Direct light exposure can lead eye injuries. You should therefore prevent any person from looking directly into the light exit.
- Always avoid direct contact with tissue in the light exit area!
- Keep the light-exit at the distal tip of the insertion shaft clean.
- Store the nasopharyngoscope on suitable padding.

4.4 Transport and storage

- Do **NOT** transport the video-nasopharyngoscope hanging by its cable.
- Avoid direct incidence of sunlight, X-rays, sudden severe temperature variations or heating above 60 °C.
- Protect the device against moisture.
- We recommend hanging storage in a suitable cupboard.

4.5 Reprocessing

- Before cleaning the device at any time, first disconnect it from the camera processor.
- Do **NOT** reprocess the nasopharyngoscope by means of steam sterilization (autoclaving).
- Do **NOT** clean the nasopharyngoscope in an ultrasonic bath.
- Before reprocessing, remove the microphone. Do **NOT** immerse the microphone and do **NOT** reprocess it by machine.
- Before **Insertion** in liquids: ETO cap **Slimm off**.
- before **sterilisation** (packaging): ETO cap **apply**.

4.6 Devices with working channel

- After deployment and before reprocessing: Use a brush to ensure that the channel is not being clogged by contaminants.
- The working channel (diameter 2.0 mm) is designed exclusively for surgical instruments that have a smaller diameter.
- Insert surgical instruments carefully into the working channel. Strong mechanical resistance during insertion can damage the working channel and your surgical instruments.
- Always push the instrument to be used completely through the working channel.
- The distal tip **MUST NOT** be angled off when there is an instrument within the angular range of the insertion shaft.
- Always use the union nut to mount/dismount the channel attachment. When you turn the channel attachment, the leverage is too great: The threaded insert in the device may come loose. Your device will then leak.

4.7 Electromagnetic Compatibility (EMC)

Mobile RF communications equipment (radios including their accessories such as antenna cables and external antennae) should only be used at a distance greater than 30 cm from the components identified by XION and from the conductor lines of the system. Failure to observe this requirement can significantly reduce the performance of the device.

Using XION accessories, converters or lines in combination with equipment other than the specified XION devices and systems can lead to increased emissions or a reduction in the immunity of the system.

Using any accessories, transformers and conductor lines other than those specified, with the exception of transformers and conductor lines that are offered by XION in the scope of supply or as spare parts for XION components, can lead to increased electromagnetic noise emissions or cause a decrease in electromagnetic immunity of the system and thus result in faulty operation.

5 Product description

Video nasopharyngoscopes comprise an insertion shaft with a distally bendable tip and the handle.
Located on the handle are the control lever for bending the distal tip, two function keys, an integrated microphone, the connection port for the leak tester and/or the ETO ventilation cap, as well as the combined connector cable with the Spectar Connector.

The XN S20 and the XN P20 also have a working channel with an internal diameter of 2.0 mm.

5.1 Performance features

- Ideal for use in stroboscopy and swallowing diagnostics
- Freely programmable function keys
- Integrated microphone – fixed microphone position and therefore comparable measurement values
- Maximum flexibility and torsional stiffness of the insertion shaft
- Ergonomic and symmetrically shaped handle
- CDD-E compatible (cleaning and disinfecting device for endoscopes).

Spectar Video Nasopharyngoscope XN P20 and XN S20

- Working channel, Ø 2.0 mm

5.2 Product variants

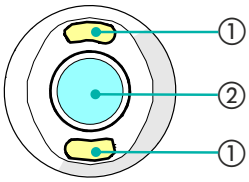
XN HD Standard design with Ø 3.6 mm shaft diameter

XN S Standard design with Ø 3.4 mm Shaft diameter

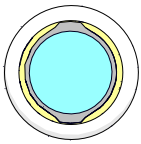
XN P Version with Ø 2.7 mm Tube diameter

XN P20 Model with Ø 4,7 mm shaft diameter and with Ø 2.0 mm working channel

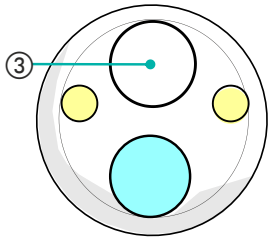
XN S20 Model with Ø 5.0 mm shaft diameter and with Ø 2.0 mm working channel



XN S / XN HD



XN P



XN S20 / XN P20

1	Fibre-optic cable	2	Lens	3	Working channel

5.3 Device components

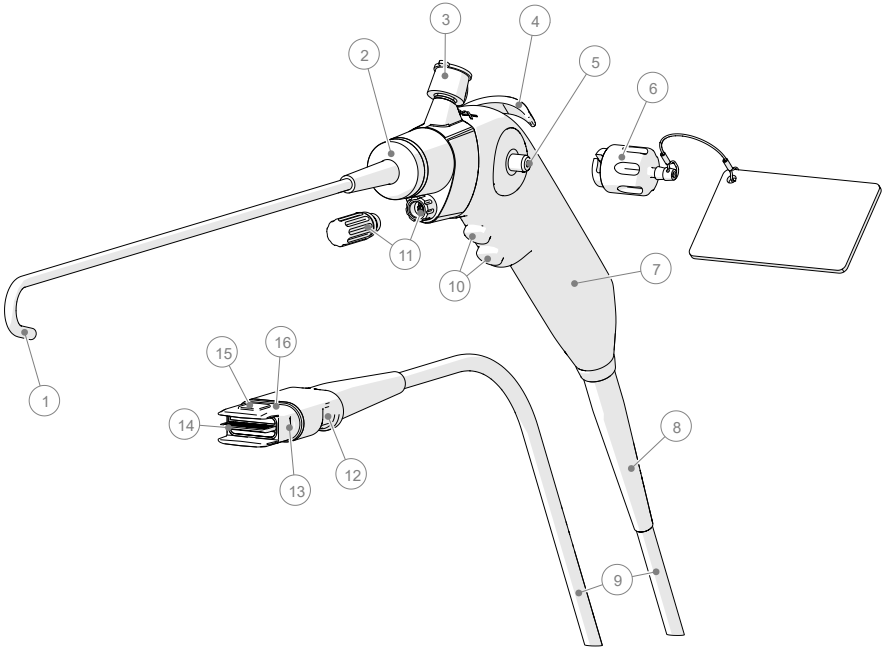


Illustration 1: Device components XION Video Nasopharyngoscopes, XN series

1	Introducer shaft with distal tip	9	Connector cable
2	Anti-kink device for the insertion shaft	10	Function keys **1** and **2**
3	Inlet working channel with mounted sealing cap (XN S20 / XN P20)	11	Integrated microphone / Reprocessing plug
4	Control lever for bending the distal tip	12	Recessed handle
5	Connection for leak tester/ RDG-E (tester connection) XION or Olympus	13	Latching groove
6	ETO ventilation cap with instruction label	14	Plug contacts
7	Handle	15	Code notch
8	Kink protector for the connecting cable	16	Spectar Connector housing

5.4 Scope of Delivery

After unpacking, first please check the goods for shipment damage. In the event of any damage, use key words to describe the apparent extent of damage and report it to your dealer or manufacturer.

Article	Article number
Spectar video nasopharyngoscope XN P20	329 309 561
Spectar video nasopharyngoscope XN P20 with OLY valve*	329 309 561OLY
Spectar video nasopharyngoscope XN P	329 309 301
Spectar video nasopharyngoscope XN P with OLY valve*	329 309 301OLY
Spectar video nasopharyngoscope XN HD	329 309 401
Spectar Video Nasopharyngoscope XN HD with OLY valve*	329 309 401OLY
Spectar video nasopharyngoscope XN S	329 309 402
Spectar video nasopharyngoscope XN S with OLY valve*	329 309 402 OLY
Spectar video nasopharyngoscope XN S20	329 309 661
Microphone for video nasopharyngoscopes	327 009 020
reprocessing stopper for microphone connector	327 009 006
Leak tester	130 009 012
Leak tester for OLY valve*	327 009 212
connector kit for XION endoscopes to CDD-E	130 009 014
ETO ventilation cap	130 009 010
ETO cap for OLY valve*	130 009 011
XION set protective bag for return of repair goods	CA903057
Transport case for flexible endoscopes EV-Nx, XN x	327 009 012
For flexible endoscopes with working channel	
Cleaning brush, Ø 5.0 mm, length 600 mm, with ball	207 060 350
Rinsing hose for working channel	200 009 006
Sealing cap for working channel	200 009 005

Table 1: Scope of delivery

* OLYMPUS compatible connector

5.5 Technical Data

Spectar Video Nasopharyngoscope	XN HD	XN S	XN S20	XN P	XN P20
Article number	329 309 401	329 309 402	329 309 661	329 309 301	329 309 561
Optical data					
Field of view	90°	90°	30°	120°	120°
Depth of field	10 to 50 mm	30 to 100 mm	30 to 100 mm	5 to 50 mm	5 to 50 mm
Mechanical Data					
Angulation up/down			130 / 130°		
Working channel			Ø 2.0 mm		Ø 2.0 mm
Working length	320 mm	320 mm	380 mm	320 mm	320 mm
Weight			500 g		
Cable length			3 m		
Tube diameter	3.7 mm	3.4 mm	5.5 mm	2.7 mm	4,7 mm
Tube diameter distal	4.4 mm	3.7 mm	5.5 mm	3.0 mm	4,8 mm
Interfaces					
Plug connector	Spectar Connector				
Ambient conditions operation					
Temperature	+10°C to +35°C				
Ambient conditions storage and transport					
Temperature	-10°C to +60°C				
Classification					
Application class	BF				
Type of protection	IP67				
Type of protection (microphone)	IP30				
Conformity	CE				
Norm conformity	IEC 60601-1; IEC 60601-1-2				

Table 2: Technical Data XION video nasopharyngoscopes

5.6 Combination with other medical devices

XION video nasopharyngoscopes have no own power supply and cannot be connected to a mains supply.

They can only be used in conjunction with XION Spectar camera processors.

When used in conjunction with the intended Camera Processor, XION Video Nasopharyngoscopes meet the requirements for Class BF.

5.7 Compatibilities

XION Video Nasopharyngoscopes with a Spectar Connector are compatible with XION Camera Processors equipped with a Spectar Connector connection.

Working channel

The working channel of the XN P20 and XN S20 is designed for non-active medical instruments, which are specifically designed to be guided through an endoscopic working channel.

Sizes of medical instruments that may be introduced:

- Diameter: ≤ 1.8mm
- Length: ≥ 500 mm

Caution!
With regard to usage and reprocessing, please also refer to the instruction manuals of the
medical instruments being used!

5.8 Integrated microfone and Clip microfone

The XN-series video nasopharyngoscopes are equipped with an integrated microphone for voice recording or for synchronization in stroboscopic applications.

If a video nasopharyngoscope and a clip microphone are attached to a MATRIX Spectar Camera Processor, the camera processor switches off the integrated microphone of the video nasopharyngoscope. Only the clip microphone will then be available to you for voice recording.

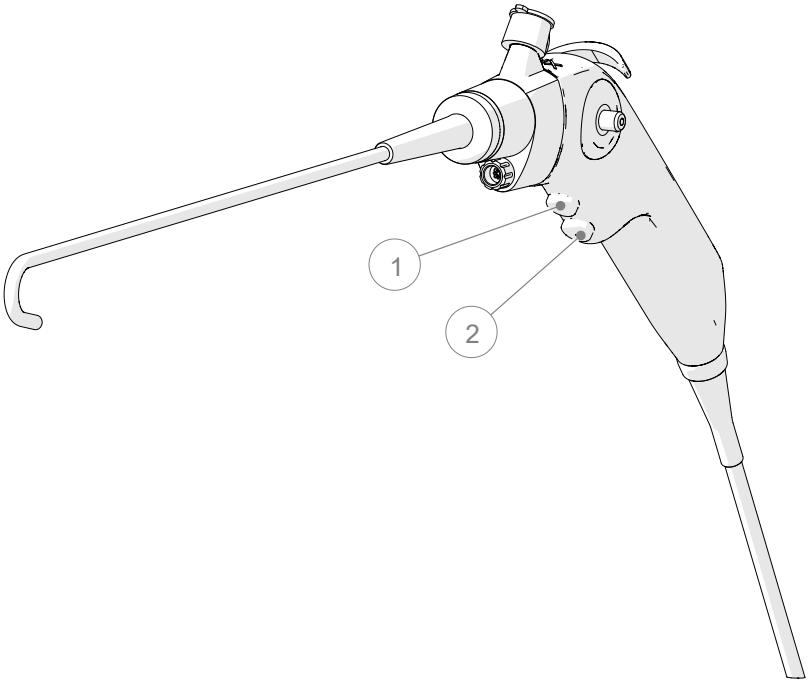
To specify whether either the integrated microphone of the camera head or the clip microphone is to be available for voice recording, you can set your choice in the menu of your MATRIX Series Spectar Camera Processor (Menu -> Miscellaneous -> Microphone).

6 Product Application

Caution!
At the time of delivery, the device is in a non-sterile condition. Reprocess the product before the first and each subsequent application.

6.1 Function keys

Your XION Video Nasopharyngoscope has two function keys.



1	Function key 1	2	Function key 2

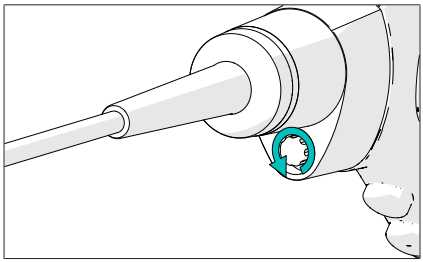
The function that is triggered by pressing a button will depend on the respective system configuration.

For detailed descriptions of the functions available, please refer to the Instructions for Use of the camera processor to which your video nasopharyngoscope is connected.

6.2 Installation of the integrated microphone

If your video nasopharyngoscope has a reprocessing plug plugged into it (for example, due to preceding cleaning/disinfecting), this reprocessing plug can be removed to fit the microphone in its place.

- First, unscrew the reprocessing plug (if installed) by turning it counter-clockwise, and then pull it out.



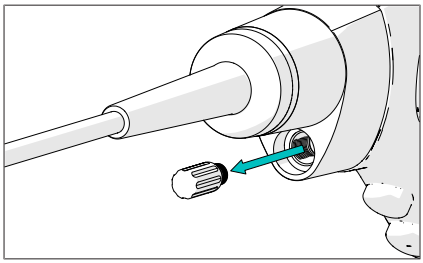
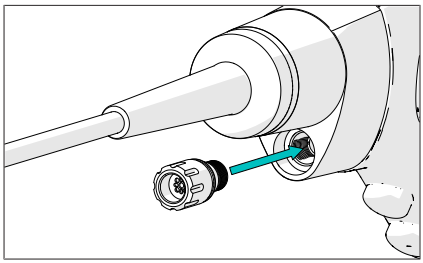


Illustration 2: Remove the reprocessing plug

- Screw the microphone in by turning it clockwise, tighten it hand-tight.



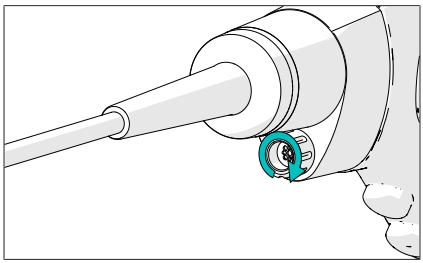


Illustration 3: Installing the microphone

6.3 Using the working channel

The XN P20 and the XN S20 video nasopharyngoscopes are equipped with a working channel (Ø 2 mm) for using surgical instruments such as a biopsy forceps or grasping forceps.

In the basic condition of the device, the working channel is closed with a sealing cap.

1. Open the working channel by folding open the cover of the sealing cap (2).
2. Insert the instrument into the working channel (1).

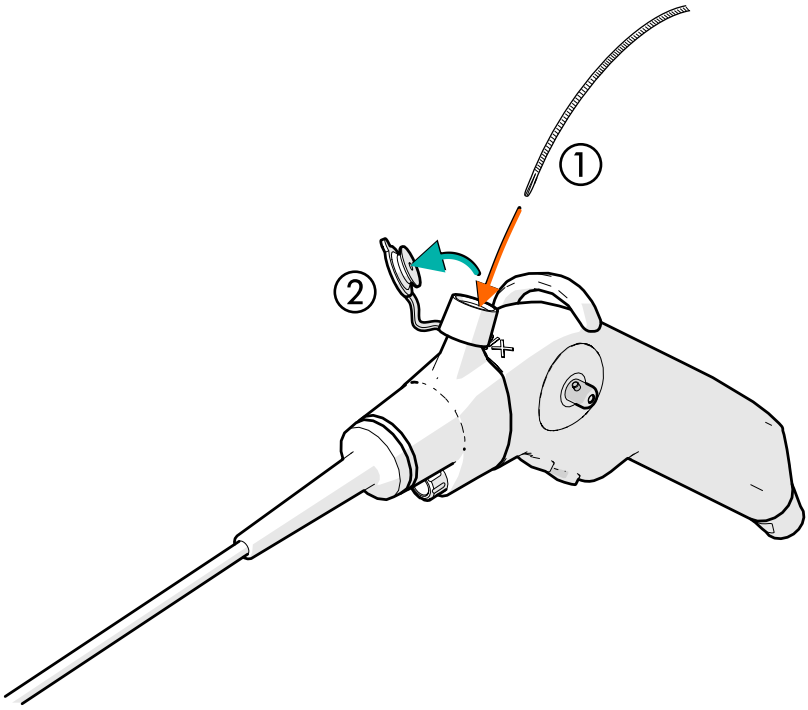


Illustration 4: Open the working channel and insert the instrument

Note!
Always slide the instrument to be used through the entire working channel. Never bend the distal tip when the tip of the instrument is within the bending range of the introducer shaft (see picture). The mechanics of your instrument could be damaged.

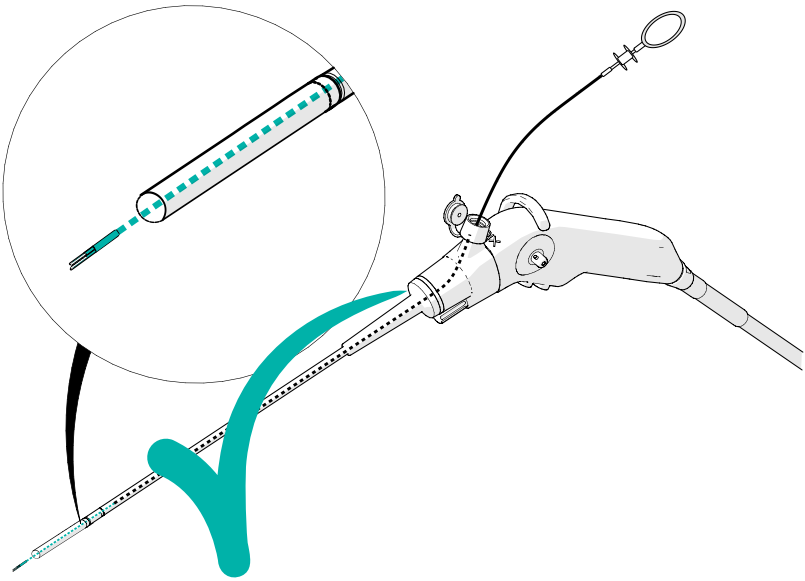


Illustration 5: Instrument completely introduced

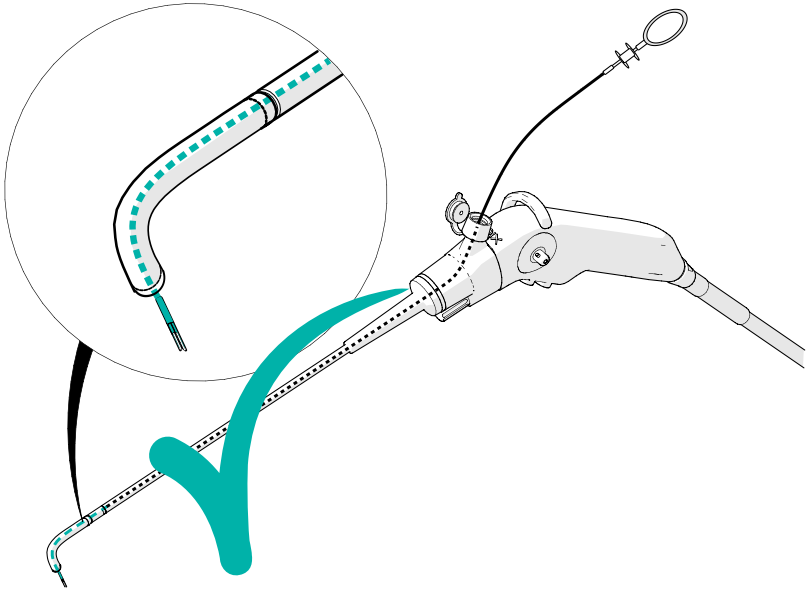


Illustration 6: Instrument passed through the entire working channel before bending

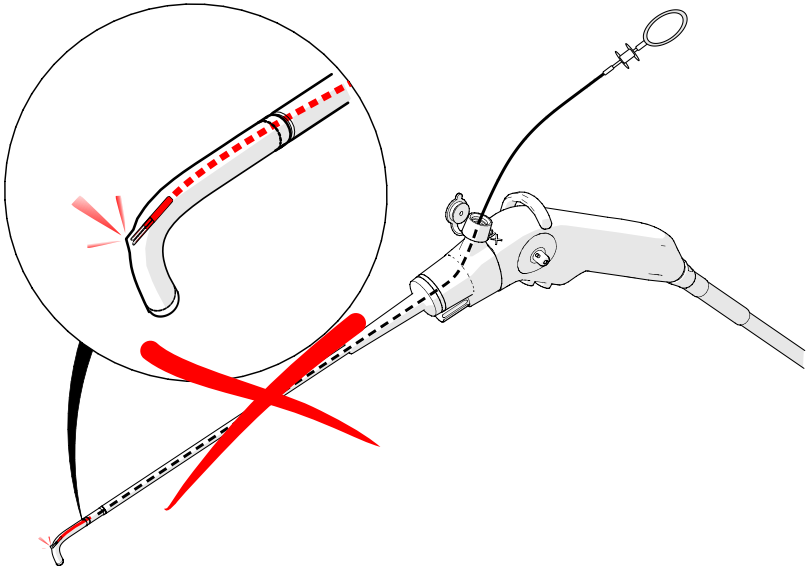
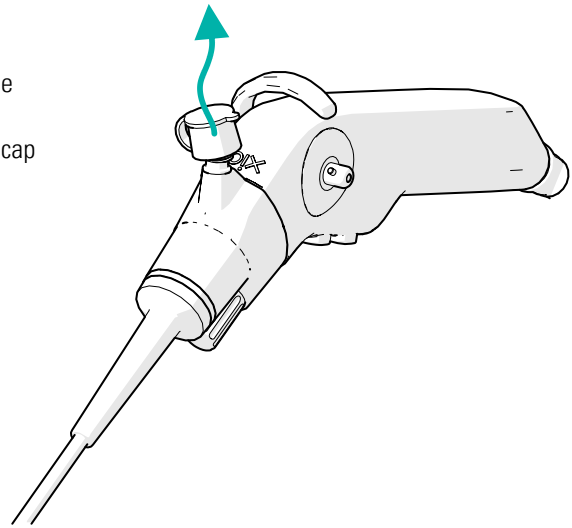


Illustration 7: Instrument within the angular range of the insertion shaft

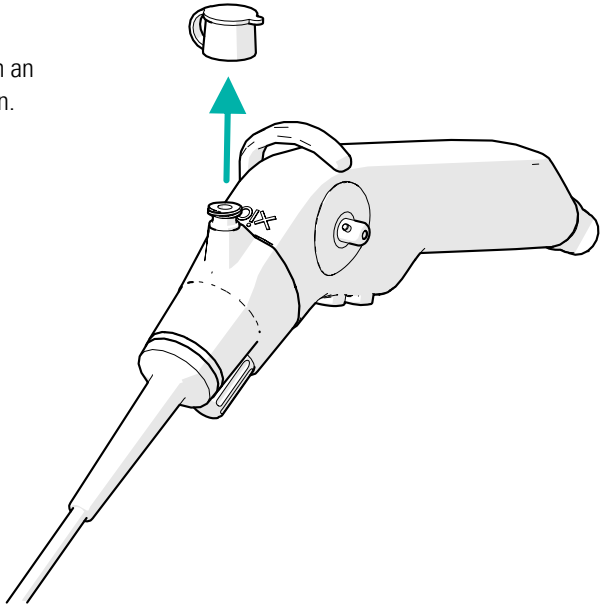
6.4 Installing a channel attachment

To install a channel attachment, proceed as follows:

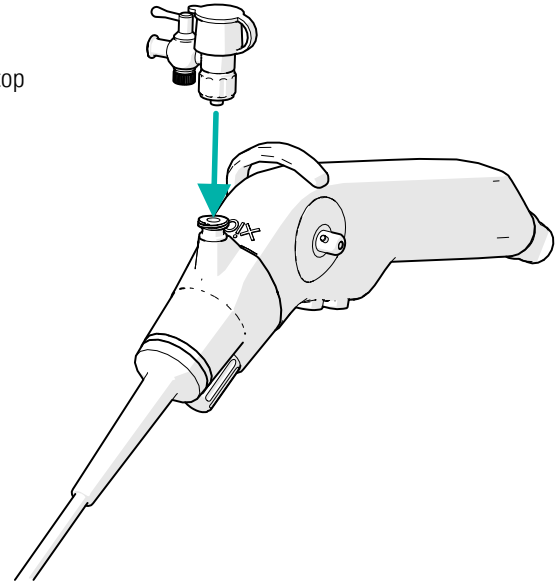
1. The sealing cap is located on the introducer stud of the working channel. Remove the sealing cap from the introducer stud.



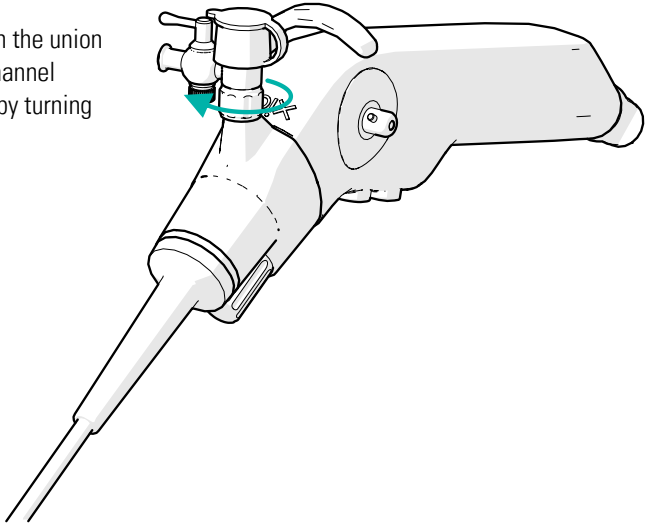
2. Pull the cap off in an upwards direction.



3. Place the channel attachment from the top on to the introducer stud of the working channel.



4. Hand-tighten the union nut of the channel attachment by turning clockwise.



Note!
Always use the union nut to mount/dismount the channel attachment. When you turn the channel attachment, the leverage is too great: The threaded insert in the device may come loose. Your device then leaks.

6.5 Functional test

Caution!
Each time before using the video nasopharyngoscope on a patient, it is essential to first perform a visual inspection and a functional test!

6.5.1 Visual inspection

- Check the video nasopharyngoscope for integrity, wear and tear (rough surfaces, sharp edges or protruding parts) and hygiene condition.

- External damage on the insertion shaft can be made visible with a cotton swab. Wipe the cotton swab over the entire surface of the insertion shaft. Then check it for cotton wool residues.
- Hold the device as shown opposite. Bend the flexible insertion shaft and make hand movements in the direction of the arrow. Make sure that the insertion shaft has a continuous elasticity and can be bent smoothly into a semicircle.

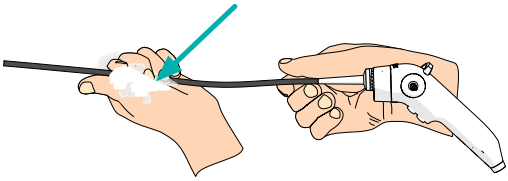


Illustration 8: Wipe insertion shaft with cotton wool

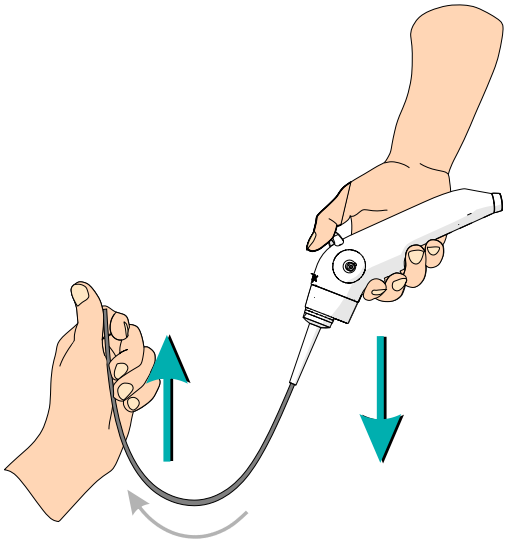


Illustration 9: Examining the insertion shaft

- Make sure that the flexible material of the insertion shaft is not deformed or buckled at any point. See Pre-cleaning at the point of use - Insertion shaft [▶ 40].
  In the event that deficiencies are detected, please proceed as described in the corresponding section in chapter Pre-cleaning at the point of use - Insertion shaft [▶ 40].

Caution!
In the event of damage and/or defects to/in the device, do not continue using the device. Replace the device.

- Check that the light-emitting area as well as the lens at the distal tip of the insertion shaft are not contaminated, scratched or damaged.
  Also check the integrity of the bending zone of the distal tip, as well as the bonding points between the bending zone and the shaft sleeve/shaft tip.

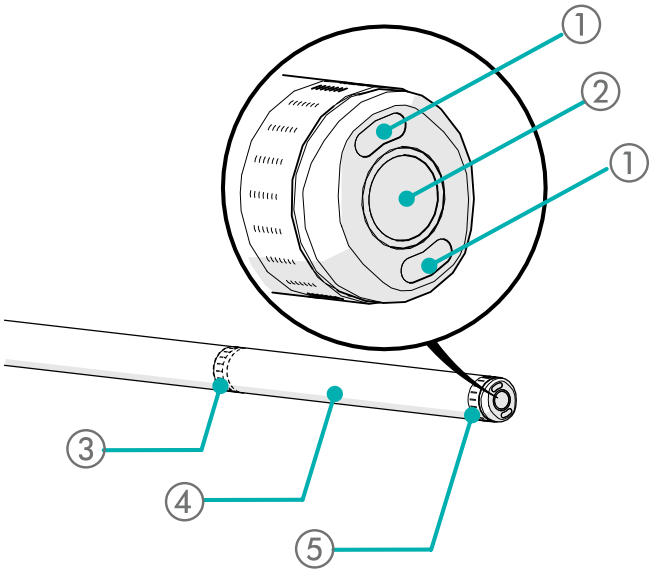


Illustration 10: Distal tip and bending zone of the XION video nasopharyngoscope

1	Light exit	4	Bending zone
2	Lens	5	Bond to the shaft tip
3	Bond to shaft sheathing		

6.5.2 Function test

- Connect the video nasopharyngoscope to the XION Camera Processor and check image reproduction as well as the key functions.

For a detailed description of the functions, please consult the user manuals of the respective Camera Processor being used.

- Check the bending function of the distal tip. For this purpose, move the control lever alternately in both directions up to the stop.

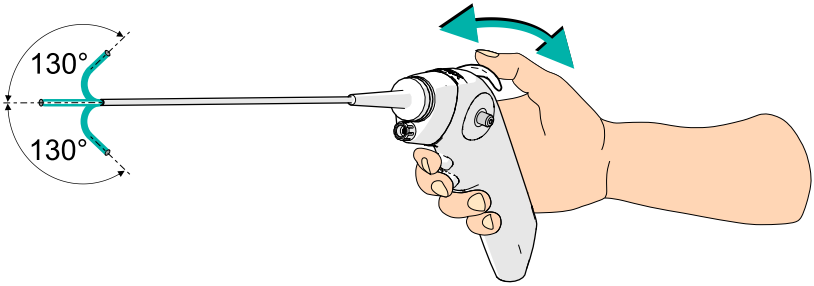


Illustration 11: Function test for the distal tip

While doing so, check that the distal tip moves evenly in both directions up to the maximum bending deflection.

Ensure that the control lever can be used to move the distal tip smoothly and evenly without obstruction.

Caution!
In the event of damage and/or defects to/in the device, do not continue using the device. Replace the device.

6.6 Plug connection

The connection between the application part and a XION Spectar Camera Processor is established by means of a Spectar Connector. Plug this connector into the CAM connector socket located on the front side of the camera processor.

Note!
The electrical contacts of the plug must be dry and clean. If necessary, wipe them dry and clean with a clean, lint-free disposable cloth! Use compressed air, to blow them dry if necessary.

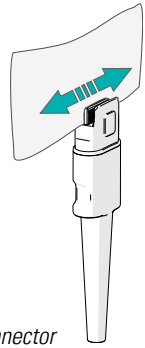


Illustration 12: Cleaning and drying the Spectar Connector

Plug the Spectar Connector into the CAM connector socket located on the front side of the Camera Processor. When establishing the connection with the Camera Processor, align the Spectar Connector in such a way that the coding snug points upwards and is pushed into the coding groove in the connector socket (see figure).

Push the Spectar Connector of the application part carefully into the connector socket until it reaches the stop and snap-locks firmly.

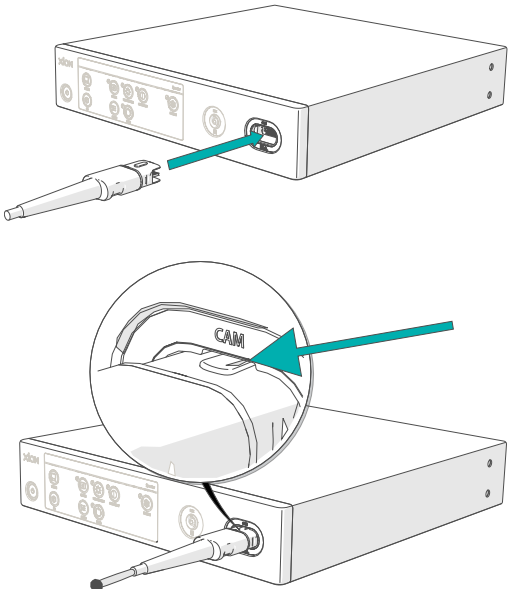
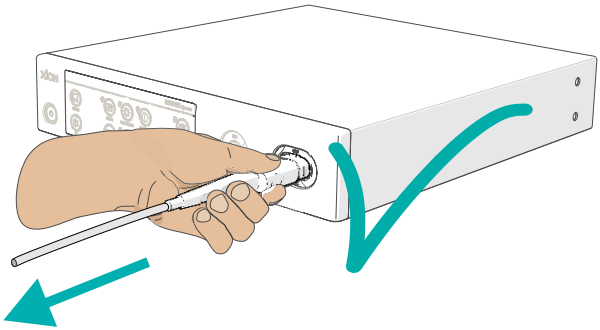
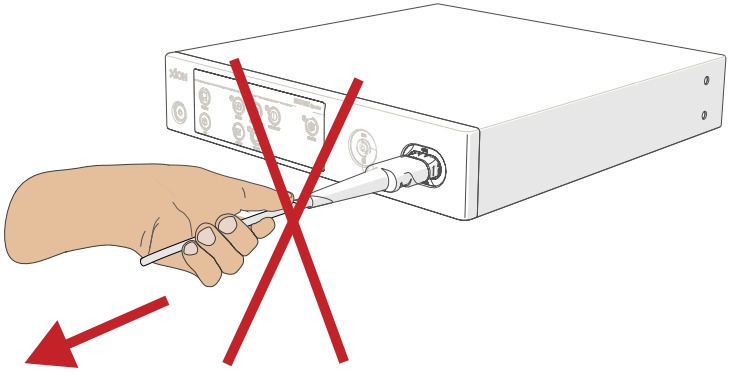


Illustration 13: Spectar Connector and Connector Socket

6.7 Disonnecting

Carefully pull the Spectar Connector out of the connector socket.





6.8 Spectar Connector and Cable

The camera cable and the Spectar Connector are firmly connected to the camera head, and they are equipped with a stable kink-protector. Nevertheless, make sure to avoid mechanical stress. This includes stress from:

- Pulling
- Kinking
- Torsion (twisting),
- Knots and
- Cuts

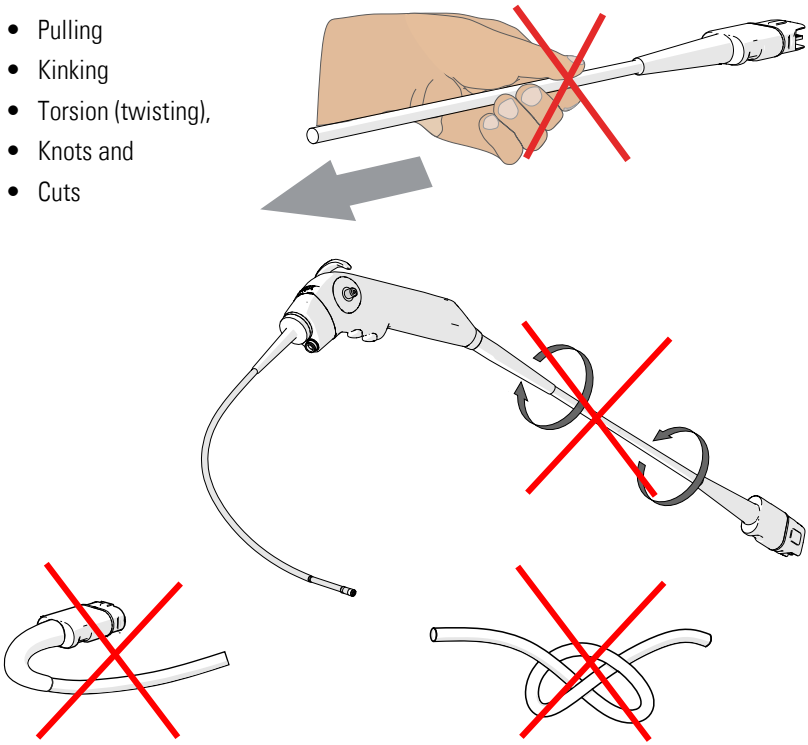


Illustration 14: Forbidden mechanical loads

Note!
Use only cables and connectors that are in a proper working condition. Perform a visual inspection of the Spectar Connector before each use (particularly the contacts). If the cable and/or the plug are damaged, please consult your XION Service Team.

7 Maintenance and Service

7.1 Re-examinations / safety checks

You are required to perform and record repetitive tests / safety checks on your device or application part in accordance with **IEC 62353**. The tests shall be carried out **annually** by a **trained electrician**.

The measurements shall be carried out in accordance with IEC 62353. The enclosed XION test protocol can be used as a guide. Take the limit values from the current standard.

In addition, observe the inspection intervals and accident prevention regulations of the country in which the device or application part is operated.

7.2 Manufacturer's service

XION medical devices shall be repaired only by authorized personnel. Only original spare parts shall be used.

If repairs are required, inform your competent dealer or contact XION GmbH directly.

7.2.1 Address for repairs and return shipments:

XION GmbH
Pankstrasse 8
13127 Berlin
Germany

Fon:	+49 (0)30 / 47 49 87 - 22
Fax:	+49 (0)30 / 47 49 87 - 11
Email:	repair@xion-medical.com
	www.xion-medical.com/en/service

7.2.2 Article numbers and serial numbers

Please state the serial number of your device when you have a query or wish to order spare parts.

- The serial number is located on the metal ring between the handle and the anti-kinking sleeve of the connector cable.

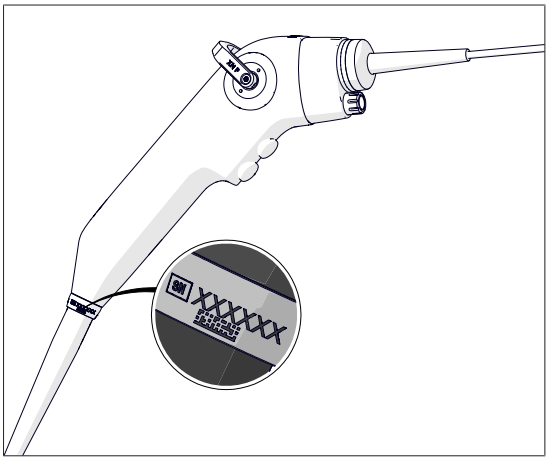
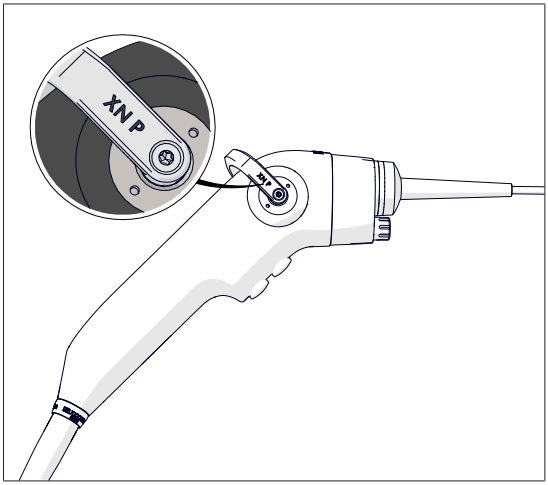


Illustration 15: Location of the serial number

- The article designation is located on the control lever for bending the distal tip.



7.3 Transport

When transporting the Video Nasopharyngoscope, always use its original packaging.

Note!
For transporting, place the ETO ventilation cap (1) on the tester connection (2). Varying air pressure or ambient temperatures (e.g. shipment by air or mail) can harm your equipment.

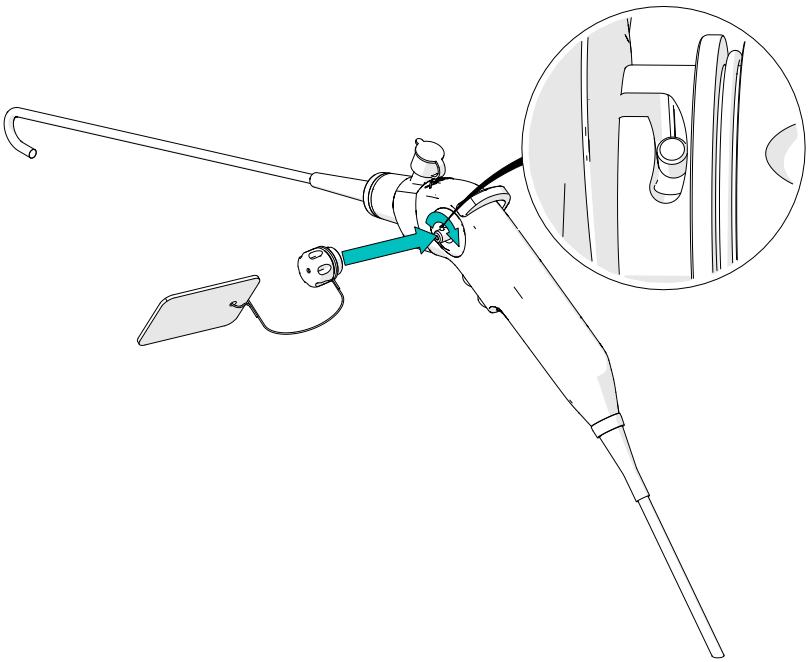


Illustration 16: Attaching the ETO ventilation cap

Note!
Follow the instructions on the instruction label of the ETO cap.

7.4 Repair process

1. Service Document
Report the defective device to XION together with this completed Service Document.

2. RMA Number
XION will send an RMA Number to you; note this number on the adhesive label provided.

3. Packaging & Shipping
Pack the cleaned device into the protective film provided, and store it safely in its original packaging. Now attach the completed adhesive shipping note and the RMA number label to the package

4. Sterilization (instruments and endoscopes only)
To protect our employees, instruments and endoscopes are only accepted in a decontaminated condition. The reprocessing procedure must be verified by means of a Decontamination Certificate. You can receive this certificate directly with the Return Service Card or at www.xion-medical.com. A completed Declaration of Decontamination is a prerequisite for our acceptance and further processing of the returned goods. If the returned goods are not accompanied by a corresponding declaration, we will perform decontamination at your expense, or we reserve the right to refuse acceptance.

The manufacturer may reject repairing a contaminated product.

5. Cost estimate
The device will be professionally inspected and you will receive from XION a cost estimate for your approval of the repair.

6. Approval
If approved, please send the signed cost estimate back to XION by fax.

7. Repair
Following your approval, repair work will begin immediately.

8. Shipment
Your repaired device including information documents for returns will be sent back to you in a new protective film.

7.5 Responsibility

The manufacturer guarantees that the device and accessories have been carefully checked before leaving the factory. The manufacturer will only be responsible for the technical safety features within the framework of legal provisions when all work on the product is performed by service personnel authorized by the manufacturer, and the device and accessories are only used according to the intended use of the device. Authorized service personnel may only be trained and certified by the manufacturer.

7.6 Warranty

For a period of one year from the date of delivery to the final customer, we shall without cost replace verifiably faulty material or improper workmanship. This does not include shipping costs or shipment risks.

7.7 Disclaimer

As soon as you yourself or any other non-authorized person/s open the device and/ or perform repairs or modifications, XION GmbH is released from any and all liability for the operational safety of the device. At the same time, all and any warranty claims become void.

7.8 Disposal

Defective or decommissioned products shall be disposed of as electronic waste in accordance with the EU Directive Waste of Electrical and Electronic Equipment – WEEE Directive 2012/19/EU.

Ask your local specialist dealer for the responsible collection point or return your device to XION GmbH.

7.9 Service Adress

XION GmbH
Pankstrasse 8
13127 Berlin
Germany
Fon: +49 (0)30 / 47 49 87 – 32
Fax: +49 (0)30 / 47 49 87 – 11
Email: service@xion-medical.com
www.xion-medical.com/en/service

7.10 Accessories

Article	Article number
Adapter for leak tester, OLYMPUS/XION type	130 009 013
Leak tester	130 009 012
Leak tester for OLY valve*	327 009 212
ETO ventilation cap	130 009 010
ETO cap for OLY valve*	130 009 011
connector kit for XION endoscopes to CDD-E	130 009 014
Connection set for Video Nasopharyngoscope EV-NC 2 and endoscopes with OLY valve* on washing machine (CDD-E)	327 009 214
reprocessing stopper for microphone connector	327 009 006
Microphone for video nasopharyngoscopes	327 009 020
For flexible endoscopes with working channel	
Sealing cap for working channel	200 009 005
Rinsing hose for working channel	200 009 006
stop cock attachment for working channel Luer-Lock	130 009 015
three-way stop cock attachment for working channel	130 009 016

Table 3: Accessories for video nasopharyngoscopes

* OLYMPUS compatible connector

7.11 Troubleshooting

This device was tested and is in compliance with the EMC requirements

In spite of this it cannot be excluded that the device may be radiating high-frequency energy, so that other equipment in the vicinity is being disturbed; this may be the case if the equipment was not installed properly.

Try to eliminate faults as follows:

- Connect the device to a power circuit that is separate from the one to which the disturbed device is connected.
- Increase the distance between the devices, or place them differently.

If the above steps and recommendations for resolving errors were not successful, contact the service technician.

8 Declarations concerning EMC

Guidelines and Manufacturer Declaration

Electric medical devices are subject to particular precautionary measures with regard to electromagnetic compatibility (EMC) and must be installed and commissioned according to EMC guidelines.

The device is intended for use in the following specified electromagnetic environments. The customer or user should ensure that it is only used in these environments.

Electromagnetic environment

The device uses HF energy exclusively for its internal function. For this reason, its RF emissions are very low and it is improbable that neighbouring electronic devices are affected.

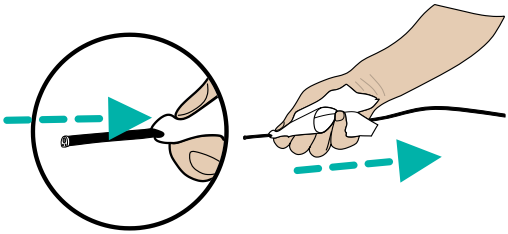
The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

9 Reprocessing

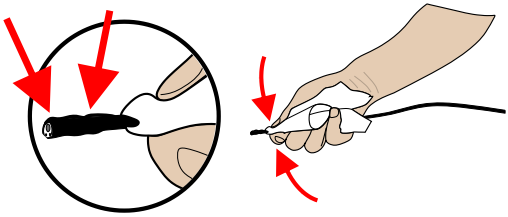
9.1 Pre-cleaning at the point of use - Insertion shaft

Note!
Clean the insertion shaft carefully. Strong mechanical pressure can damage the surface.

Please clean/wipe the insertion shaft with a damp cloth (e.g. water) – apply moderate pressure only!



Too much pressure when wiping compresses the shaft sleeve and causes damage.



If the shaft sleeve gets compressed: Carefully applying slight pressure, pull the compressed shaft sleeve back until it is lying smoothly on the shaft.

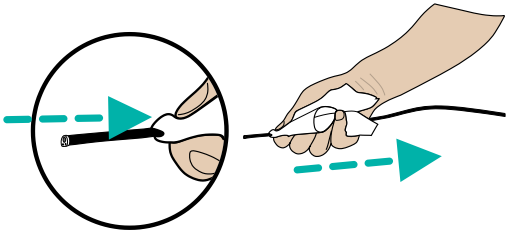


Illustration 17: Careful handling of the insertion shaft

Note!
After cleaning the insertion shaft, it is essential to perform a leak test. See Leak test [▷ 41].

9.2 Leak test

Note!
A leak test must always be performed before immersing the device for processes like cleaning and disinfection.

The leak test described hereinafter is intended exclusively for the leak test that is to be performed within the framework of reprocessing, and it is not intended for the function test during the application!

9.2.1 Checking the components

Checking the leak tester:

1. Check the leak tester for cracks, scratches, defects damage and residues.
2. Actuate the hand pump (1) and ensure that air exits from the tester-connection cap (2) of the leak tester.

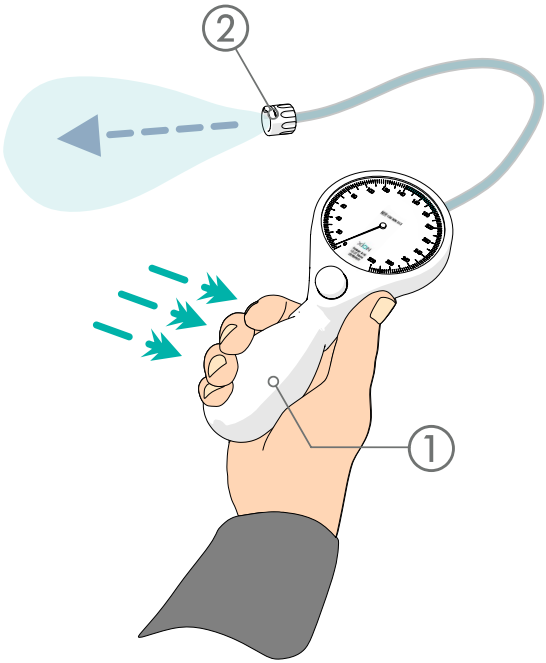


Illustration 18: Checking the leak tester

9.2.2 Performing a leak test

Note!
Never connect or disconnect the leak tester under water, otherwise moisture may penetrate the device and damage it.
The tester connection cap (1) of the leak tester and the tester connection (2) on the application part must be dry.

Place the tester connection cap (1) firmly on the tester connection (2) and turn the cap clockwise by a quarter turn. The tester is now firmly connected with the nasopharyngoscope and can no longer be pulled off.

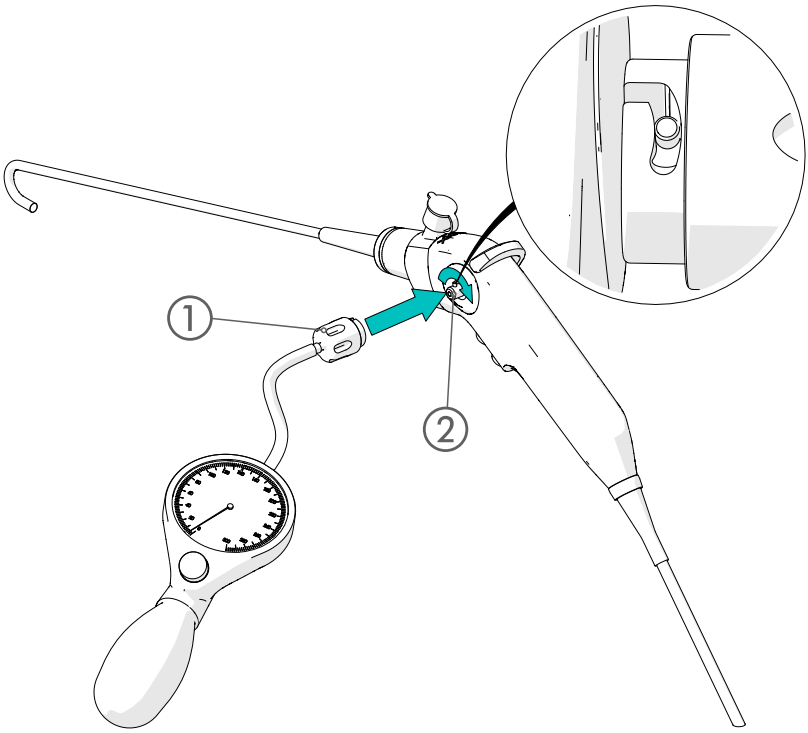


Illustration 19: Attaching the leak tester

By pumping the leak tester, generate a pressure at the top of the green zone as shown in the illustration here.

If the needle is above this range, adjust by opening the drain valve (1).

If the pressure drops by less than 10 divisions within one minute, this means that you can reprocess the application part.

Illustration 20: Scale of the leak tester

Note!
If the pressure drops by 10 divisions or more within one minute, this means that the application part is leaking! In this case it must not be used or immersed in a liquid!

In this case:

- Wipe the outer casing with a suitable instrument disinfectant (e.g. 70 % isopropyl alcohol),
- Wrap the application part in a protective film sleeve,
- Pack it in the original packaging and
- Send it to our Service Adress [▸ 37].

9.3 Disassembly

9.3.1 Removing the microphone

Note!
Remove the microphone before reprocessing the application part! The integrated microphone of the application part is not suitable for immersion in liquids or for machine reprocessing!

Note!
If you are using compressed air to dry the microphone opening after reprocessing, you do **NOT** need to use the reprocessing plug. Use the plug if you are not using compressed air for drying.

- Turn the microphone counter-clockwise and then pull it off.

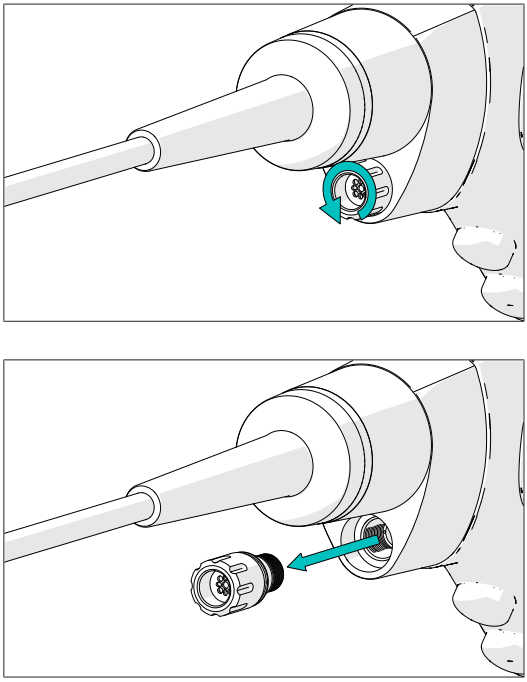
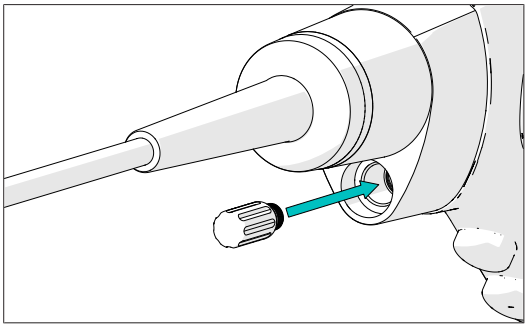


Illustration 21: Removing the integrated microphone

- Place the reprocessing plug from the front into the microphone opening of the device.
- Turn the reprocessing plug until it is firmly hand tight.



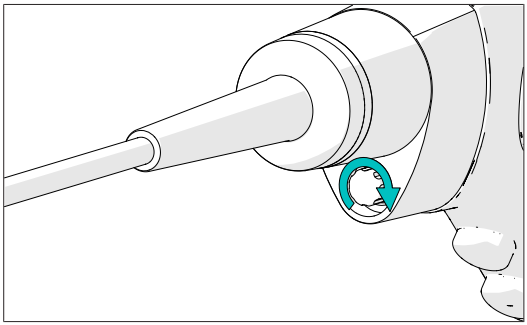


Illustration 22: Screw the reprocessing plug into the application part

9.3.2 Removing and mounting the channel attachment

Before any further reprocessing, remove any channel attachment that may be mounted; it will be cleaned/disinfected separately.

1. Pull the protective cap (1) off from the channel attachment (2).
2. Loosen the union nut on the channel attachment (2) by turning it in the direction of the arrow. Next pull the channel attachment (2) off upwards.
3. Loosen the knurled nut (3) on the tap body (4) by turning it in the direction of the arrow.
4. Pull the plug (5) upwards out of the tap body.
5. After completing cleaning/disinfection, reassemble in the reverse order. Lubricate the stopcock plug (5) with a suitable stopcock grease.

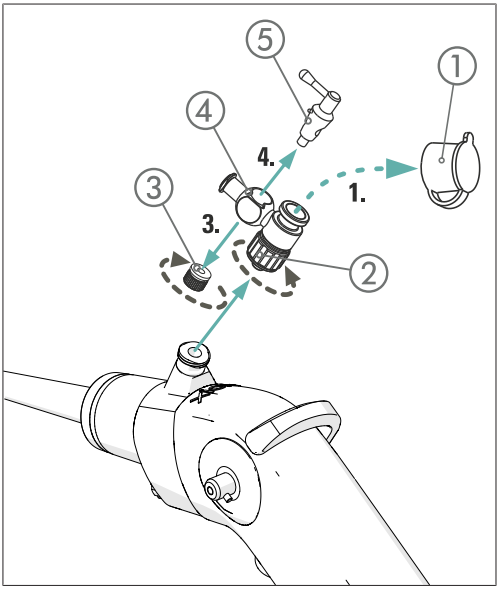


Illustration 23: Disassembling the duct attachment for nasopharyngoscopes

Note!
Always use the union nut to mount/dismount the channel attachment. When you turn the channel attachment, the leverage is too great: The threaded insert in the device may come loose. Your device then leaks.

9.4 Cleaning/disinfecting the microphone

- Clean/disinfect the microphone with a clean, lint-free disposable cloth, which has been dipped into the prepared cleaning/ disinfectant solution.
- Avoid too much wetting. The disposable cloth should only be slightly moist.

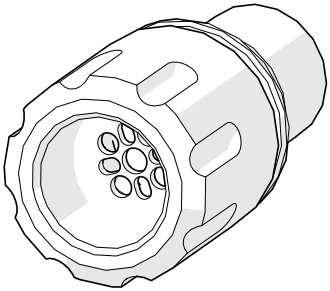


Illustration 24: Microphone of the XION video nasopharyngoscope

Note!
Make sure that no liquid penetrates into the microphone!

9.5 Connector kit for working channel to CDD-E

Use the rinsing hose for working channel (1) to connect the working channel to a rinsing hose of the CDD-E.

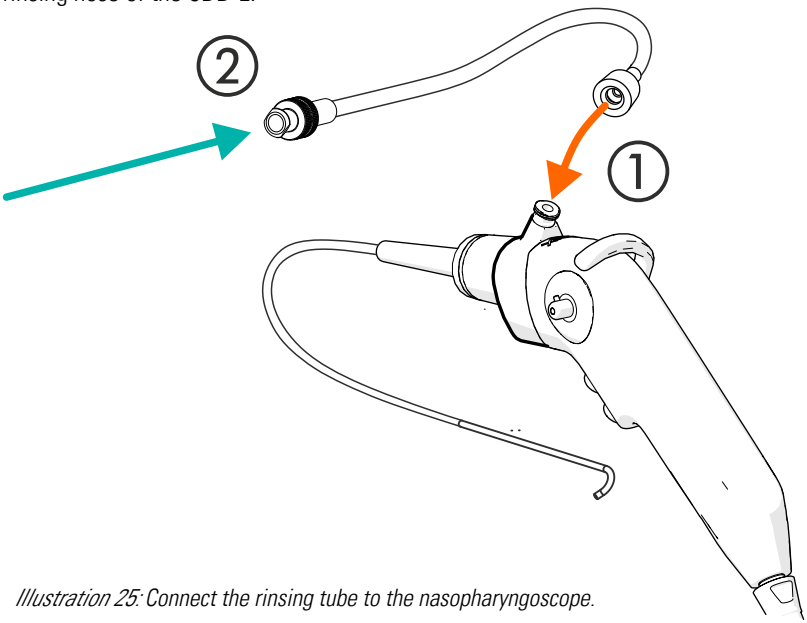


Illustration 25: Connect the rinsing tube to the nasopharyngoscope.

9.6 Connector Kit for XION endoscopes to CDD-E

1. Connect the connector plug (2) of the connector kit to the tester connector (3) of the application part.
2. Rotate the connector plug one-quarter of a turn clockwise. The connector kit and the application part are now firmly connected to each other.
3. Connect the end of the silicone connector tube (1) to your CDD-E according to the instructions.

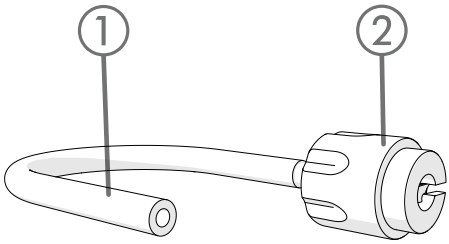


Illustration 26: Connector kit endoscopes to CDD-E

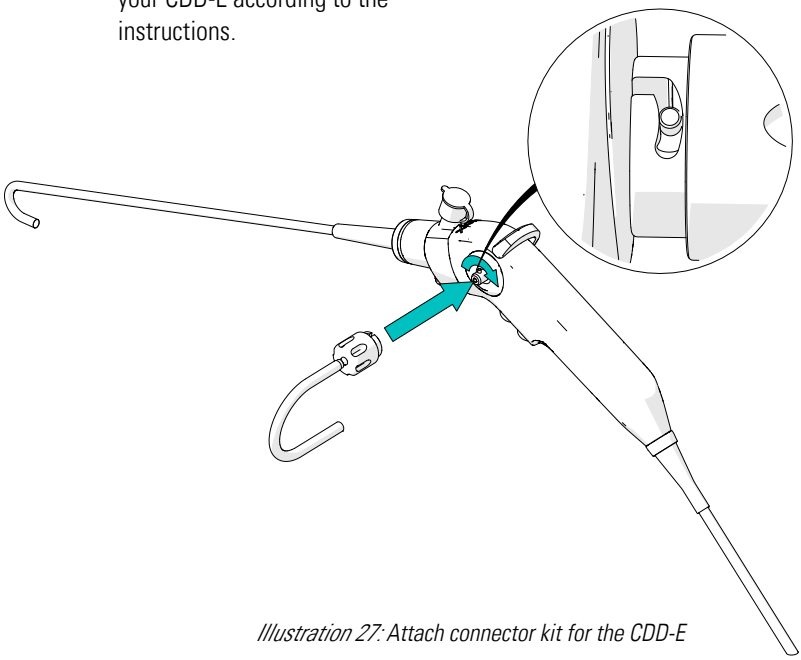


Illustration 27: Attach connector kit for the CDD-E

9.7 CDD-E Olympus-XION adapter

XION offers an Adapter for leak testers, type OLYMPUS/XION, as an optional accessory.

1. Connect the OLYMPUS leak tester (1) from the cleaning and disinfection device (CDD-E) to the OLYMPUS-to-XION adapter (2) and tighten it in a clockwise direction.
2. Connect the unit thus created to the tester connection.

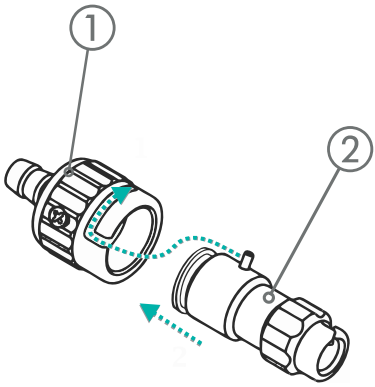


Illustration 28: Connection adapter, OLYMPUS/XION type, optional

9.8 Perform the reprocessing

The medical device can be cleaned and disinfected either manually OR by machine. We recommend machine cleaning/disinfection.

 **WARNING NOTES**	• **Not** steam-sterilizable! • Do **NOT** clean in an ultrasonic bath! • Before reprocess, remove the microphone. Do **not** immerse the microphone and do **not** reprocess by machine. • Perform a leak test! Before each submersion process, cleaning/disinfection. • Before reprocessing: Attach the plug-protection cap • Before immersing in liquids: Remove the ETO cap. • Before sterilization (packaging): Attach the ETO cap. • Avoid considerable force, particularly while cleaning the insertion shaft; do not use coarse abrasives, metal brushes and cotton swab sticks made of metal. • Do not use physiological saline solutions for immersing and/or rinsing. Use de-ionized water. • Maximum temperature during reprocessing 60°C. • When immersing the instrument, the air should be able to pass out of the hollow spaces, so that all instrument surfaces are entirely wetted.

INSTRUCTIONS:

Pre-cleaning at the point of use	Use a damp disposable cloth (dipped in water or non-fixing liquid) to remove surface contamination from the device (endoscope shaft and distal tip [▷ 40]). Disconnect the flexible endoscope from the camera processor. Where applicable, flush the existing working channel with water.

Storage and transport:	Do not kink, twist or knot the endoscope shaft and cable. Avoid tensile stresses. Do not transport the endoscope hanging by its cable. When transporting devices, make sure that they are secured against slipping. Always use a closed container with a lid. Perform reprocessing as soon as possible after the instrument has been used.
Disassembly:	Remove and separate the adapter and the channel attachment (if present) from the flexible endoscope. Unscrew the microphone from the video nasopharyngoscope and separately reprocess manually. Before reprocessing, screw in the reprocessing plug.
Leak test:	Remove the ETO cap. Perform a leak test [▶ 42]. If the unit is leaking: DO NOT REPROCESS!

Do you want to machine reprocess?
Then continue with "Machine Cleaning/Disinfection" [▶ 54].
Otherwise, continue with "Manual Cleaning/Disinfection".

Manual Cleaning/ Disinfection:	**Note!** The procedure described here assumes subsequent sterilization. If you wish to dispense with sterilisation, select a **virucidal disinfection process** process. It is essential to closely follow the manufacturer's instructions concerning concentration and immersion duration of the cleaning/disinfecting agent! Perform all described work below the surface of the liquid to prevent spraying/splashing the contaminated liquid! Equipment: Disposable gloves, disposable cloth, deionised water, soft brush, running water, neodisher Endo® CLEAN (0.5%) and neodisher® Septo 3000 (2%) both from Dr. Weigert.

Manual Cleaning/ Disinfection:	**Microphone:** Remove and clean/disinfect with disposable cloth (immerse in solutions for cleaning and disinfection) **Video nasopharyngoscope:** **1. Cleaning:** a) Place the nasopharyngoscope and all disassembled parts completely in the cleaning bath (neodisher Endo® CLEAN 0.5 %) (25° ± 5°C). b) Below the surface of the liquid, use a brush (soft bristles) to clean – especially the channel inlet, cavities and plug contacts. Actuate the lever and clean the hidden parts. Working channel: • Insert a suitable brush into the working channel via the channel inlet. Carefully push the brush forward until it completely exits at the distal end and then pull it back (until it completely exits from the channel inlet). Carry out the procedure at least 3 times. • Clean the channel opening and the distal end with a soft brush. Channel attachment: • Use a suitable brush to clean all lumens of the dismantled channel attachment. To do this: Push the brush through each lumen until it exits and then pull it back completely. Carry out the procedure at least 3 times. • Use a suitable brush to clean the outer surfaces of the channel attachment. c) 15 min. immersion time **2. Intermediate rinsing:** • Rinse the entire endoscope and all individual parts with deionised water for at least 1 min. Working channel: • Connect the working channel with a flushing hose and flush. Alternatively, use the syringe. Channel attachment: • Rinse all lumens with running water

Manual Cleaning/ Disinfection:	**3. Disinfection:** • Place the nasopharyngoscope and all disassembled parts completely in the disinfection bath (neodisher® Septo 3000 2%) (25° ± 5°C). • Under liquid surface: Working channel use a syringe to fill with disinfectant solution. • 15 min. holding time **4. Final rinsing:** • Rinse the entire endoscope and all individual parts with deionised water for at least 1 min. Working channel: • Connect the working channel with a flushing hose and flush. Alternatively, use the syringe. Channel attachment: • Rinse all lumens with deionized water **5. Drying:** • Dry external surfaces, preferably with compressed air. Alternatively with a clean disposable cloth. • Dry the working channel and channel attachment, preferably with compressed air (max. 0.5 bar). Alternatively, use an air-filled syringe to blow over the Luer-Lock connector until no more moisture comes out of the distal end of the working channel or the lumen of the channel attachment. • Use a cotton swab soaked in alcohol to finalize cleaning the glass surfaces, dry off. **Continue from work step "Assembly"**

Machine Cleaning/ Disinfection:	**Warning!** Before performing machine cleaning, it is necessary to do preliminary manual cleaning (see Manual cleaning/disinfection, points 1. through 2.) • Plug the connector kit onto the tester connection. Turn clockwise a quarter of a turn. • Connect the Connector kit to the CDD-E Working channel: • Connect working channel to the CDD-E via a flushing hose Channel attachment: • Assemble channel attachment; connect to CDD-E via Luer-Lock connection. Stopcock must be open! **Machine (CDD):** Endoscope WD BHT INNOVA® E3 CMS DC **Cleaning:** • 0.5% neodisher EndoCLEAN® (Dr. Weigert) 6 min. at 37°C and 6 min. holding time at 43°C **Disinfection**: • 1% neodisher endo® SEPT PAC (Dr. Weigert) with 10 min: Holding time at 25°C **Drying:** • If necessary, with compressed air. • Use a cotton swab soaked in alcohol to finalize cleaning the glass surfaces, dry off.

Mounting:	Unscrew the reprocessing plug. Screw microphone in.
Inspection and functional test:	Check for completeness, hygienic condition, damage, surface texture and correct operation. Warning! Replacement elements must be disinfected.

Do you want to sterilize?

Then continue from the heading titled "Packaging".

Otherwise, conclude your reprocessing with "Storage (in disinfected condition)".

Storage (in disinfected condition):	At room temperature, in a dry place protected against dust and direct sunlight. Preferably hanging in a suitable storage cabinet.

Packaging:	Use suitable packaging for the respective sterilization process. The bag must be large enough (seal must not be stretched or under tension). Sets: Place in intended trays or appropriate general-purpose sterilization trays. Devices must not be in contact with each other. A suitable method must be used for packaging. Package the*channel attachment* separately.
Sterilization:	**LTSF:** Webeco FA95, program "60°C", Temperature: 60°C for 30 minutes. holding time.
Storage (after sterilisation):	Store in the sterile packaging; at room temperature, dry and protected against dust and direct sunlight.

The above instructions were provided by the medical-devices manufacturer and validated as being SUITABLE for preparing a medical device for its use. The specifications (concentration/action time) for cleaning and disinfection apply in the event of subsequent sterilisation.
The reprocessor is responsible for ensuring that the actually conducted reprocessing treatment using the specified equipment, materials and personnel in the reprocessing facility fully achieves the desired results. This normally requires that the method is validated and routinely monitored. Similarly, any deviation by the reprocessor from the instructions provided must be carefully evaluated for its efficacy and potential adverse consequences.

Manufacturer and Distributor

XION GmbH
Pankstrasse 8
13127 Berlin
Germany
Fon: +49 (0)30 / 47 49 87 - 0
Fax: +49 (0)30 / 47 49 87 - 11
Email: info@xion-medical.com
www.xion-medical.com/en