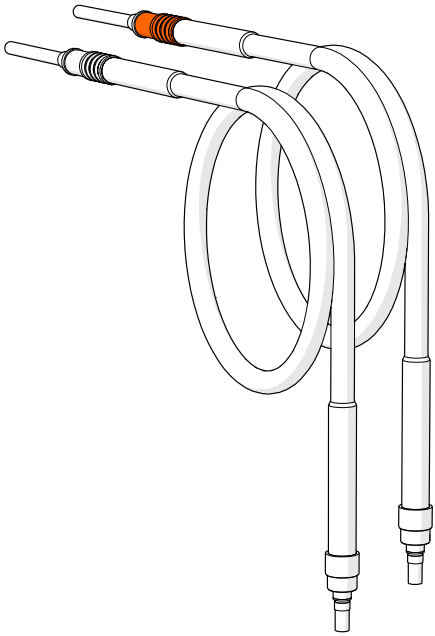
Light Guide Cable



Instruction for Use

High-performance fibre-optic light conducters (orange)
LED high-performance fibre-optic light conducters (white)

Ver.05 en • 04.03.2022

General

CE

This medical device is CE marked in accordance with Regulation (EU) 2017/745 on medical devices.

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1 Directions for Using the Manual

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

Before using the medical device, please read the complete User Manual. Keep the User Manual within reach of the medical device. If you pass the medical 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
	**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
	Article number
	Serial number
	Temperature limit
	Keep away from sunlight
	Keep dry

3 Intended Purpose

3.1 Intended use

Fibre-optic light conductors provided by XION GmbH are used to pick up light from a light source at one end, conduct it through to the other end and then selectively switch it on and off into an endoscope or other optical medical device.

Fibre-optic light conductors provided by XION GmbH are not intended for direct application on the patient.

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

XION GmbH fibre-optic light conductors are intended for use in combination with endoscopes using halogen, xenon or LED-based cold light sources during medical endoscopic examinations and treatments.

CAUTION!
Applications in conjunction with laser light sources and high-frequency devices is not permitted.

3.4 Contraindication

Contraindications that relate directly to the medical device, are currently unknown. The use of fibre-optic light conductor 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.
- All ELECTRICAL devices located in the vicinity of patients must comply with the requirements of standards family IEC60601-1 for medical electrical devices. Only devices or accessories that have been tested to this standard shall be connected to the signal inputs / signal outputs of the control unit.
- Follow the instructions given in the Instructions for Use of the respective application parts and components.
- Any serious incidents occurring in connection with the medical device must be reported to the manufacturer and the competent authority.
- Mechanical stresses shorten the service life of the fibre-optic light conductor. Therefore, avoid pulling, knotting, twisting, and cuts on the cable, and also avoid damage to the optical surfaces of the end faces of the fibre-optic light guide.

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.
- 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.

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.

High-energy light at the exit area of the fibre-optic light conductor

High-energy light can exit from the output area of the fibre-optic light conductor. Deposits in the fibre-optic output area or direct tissue contact can result in high temperatures above 41°C and possible tissue damage due to thermal absorption. Heat-sensitive or flammable surfaces may be damaged or they may ignite!

- You must prevent any person from looking directly into the light exit.
- Always prevent direct contact with tissue in the light exit area!

- Keep the light exit clean.
- Switch off the light source when the endoscope is not being used.
- Applications in conjunction with laser light sources and high-frequency devices is not permitted.

4.4 Reprocessing

- Before cleaning at any time, disconnect the fibre-optic light conductor from the camera processor.
- Before reprocessing, remove the fibre-optic cable adapters.
- Do **NOT** clean the fibre-optic light conductor in an ultrasonic bath.
- Do **NOT** reprocess the fibre-optic light conductor by means of hot-air sterilisation.

5 Product description

Please note that there are two versions of the fibre-optic light conductors.

LED high-performance fibre-optic light conductors are marked white on the light entry side; they are optimised for LED light sources and ensure particularly high light output.

High performance fibre-optic light conductors are marked orange on the light entry side and are intended for xenon, halogen and LED light sources.

Both ends of the fibre-optic light conductors are equipped with threads for adapters with which they can be adapted to almost all existing cold light sources and endoscopes.

Light source connector

On delivery, the light source output (LED) of the XION light sources has a STORZ type adapter connected to it. You must also attach an appropriate STORZ connector adapter to the connector stud of the fibre-optic light conductor.

Connecting endoscopes

You can connect XION fibre-optic light conductors directly to XION endoscopes because XION endoscopes are delivered with STORZ and WOLF type adapters.

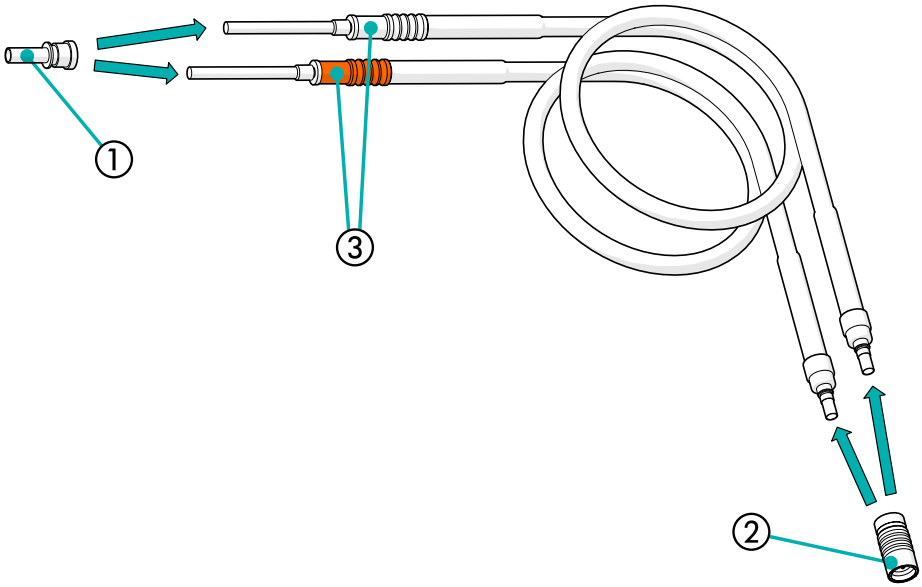


Illustration 1: XION fibre-optic light conductor variants and corresponding adapters

The adapters that may be required - both on the light entrance side as well as on the light exit side - are not part of the standard scope of delivery of the fibre-optic light conductors; they must be ordered/requested separately if required.

The article numbers for the appropriate adapters are listed in Section Accessories.

1. Adapters for light entry side (light source)
   Available adapters:
   STORZ / WOLF / OLYMPUS / ACMI / PENTAX / FUJINON
2. Adapters for light exit side (application part)
   Available adapters:
   STORZ / OLYMPUS / WOLF / ACMI
3. Colour marking
   to distinguish the XION fibre-optic light conductor:
   white = LED high-performance fibre-optic light conductor
   orange = high-performance fibre-optic light conductor

5.1 Performance features

- Optimal temperature resistance
- For use with all high-performance light sources
- Significantly increased light transmission
- Long service life
- Very flexible
- Universal adapter system

5.2 Combination with Other Medical Devices

Use the medical device only as intended in compliance with the relevant national and local requirements and regulations, and within in the system environment delivered and installed by XION GmbH, for which XION GmbH has issued a System Declaration.

Using the device outside of the XION environment does not constitute the intended purpose of the device.

Connecting endoscopes

You can connect XION fibre-optic light conductors directly to XION endoscopes because XION endoscopes are delivered with STORZ and WOLF type adapters.

Light source connector

On delivery, the light source output (LED) of the XION light sources has a STORZ type adapter connected to it. You must also attach an appropriate STORZ connector adapter to the connector stud of the fibre-optic light conductor.

- Follow the instructions given in the Instructions for Use of the respective application parts and components.

CAUTION!
Do not use fibre-optic light conductors in conjunction with laser light sources or high-frequency devices!

5.3 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
High-performance fibre-optic light conductor, Ø 3.5 mm, 1.8 m	310 723 318
High-performance fibre-optic light conductor, Ø 3.5 mm, 2.3 m	310 723 323
High-performance fibre-optic light conductor, Ø 3.5 mm, 3.0 m	310 723 330
High-performance fibre-optic light conductor, Ø 3.5 mm, 3.5 m	310 723 335
High-performance fibre-optic light conductor, Ø 3.5 mm, 4.0 m	310 723 340
High-performance fibre-optic light conductor, Ø 4.8 mm, 1.8 m	310 723 518
High-performance fibre-optic light conductor, Ø 4.8 mm, 2.3 m	310 723 523
High-performance fibre-optic light conductor, Ø 4.8 mm, 3.0 m	310 723 530
High-performance fibre-optic light conductor, Ø 4.8 mm, 3.5 m	310 723 535
High-performance fibre-optic light conductor, Ø 4.8 mm, 4.0 m	310 723 540
LED high-performance fibre-optic light conductor, Ø 3.5 mm, 1.8 m	310 724 318
LED high-performance fibre-optic light conductor, Ø 3.5 mm, 2.3 m	310 724 323
LED high-performance fibre-optic light conductor, Ø 3.5 mm, 3.0 m	310 724 330
LED high-performance fibre-optic light conductor, Ø 4.8 mm, 2.3 m	310 724 523
LED high-performance fibre-optic light conductor, Ø 4.8 mm, 3.0 m	310 724 530

Table 1: Available XION fibre-optic light conductors

6 Product Application

Fibre-optic light conductors shall be used only in a properly reprocessed condition and only by authorized personnel.

Maintenance and service shall be performed exclusively by the manufacturer or by service centres authorized by the manufacturer.

6.1 Visual and Functional Inspection

Always check the fibre-optic light conductor and accessories before using them.

6.1.1 Checking the fibre-optic light conductor

Perform a visual inspection, paying particular attention to the following points:

- The device must be free of any type of damage (sharp edges, rough surfaces).
- The device must show no discernible contamination.
- The device must show no residues of cleaning agents and/or disinfectants.
- There must be no parts loose or missing.
- Labels and markings, which are necessary for safe and proper use, must be legible.

Be careful when handling damaged and incomplete products. These may cause injuries to the patient, users or third parties.

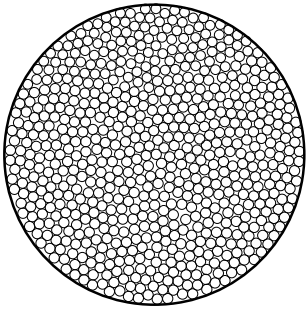
The conductor cross-sections must be matched to the light entrance diameter of the endoscope, so that there are no reflections that could cause damage to the light exit of the fibre-optic light conductor.

6.1.2 Visual inspection

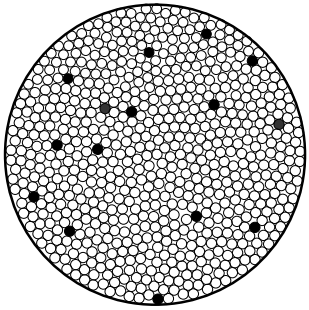
Hold one side of the fibre-optic light conductor towards a light source (e.g. window) and perform a visual inspection for:

- Deposits on the glass surfaces,
- the number of black spots.

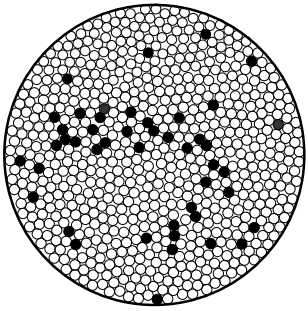
The black spots indicate broken light fibres. The proportion of these should not exceed 30%, otherwise transmission will be substantially affected.



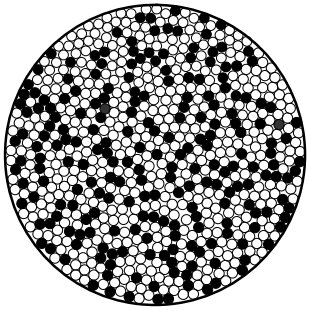
Flawless fibre-optic light conductor



Fibre-optic light conductor with a few broken light fibres



Borderline fibre-optic light conductor with almost 30% broken light fibres



Fibre-optic light conductor with more than 30% broken light fibres - do not use!

Table 2: Visual inspection for fibre-optic light conductors

In case of doubt, compare the light transmission of the fibre-optic light conductor with the light transmission of another fibre-optic light conductor.

6.1.3 Checking the conductor ends (light entrance and exit)

- Check the conductor ends for damage (sharp edges, rough surfaces, etc.).
- Select the adaptor system, i.e. which adapters are to be used at the light entrance and the light exit.
- Functional test, i.e. remove and mount the adapters at the light entrance and light exit:

1. To remove the adapters, turn them counter-clockwise from the respective conductor end.
2. To mount the adapters, turn them clockwise on to the respective conductor end.

7 Maintenance and Service

The device is maintenance free.

7.1 Manufacturer's Service

XION medical devices shall be repaired only by authorized personnel (commissioned by Messrs. XION GmbH). Use only original spare parts.

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

7.1.1 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

7.1.2 Article numbers and serial numbers

Please always state the serial number [SN] and the article number [REF] with your return shipments, queries or spare part orders.

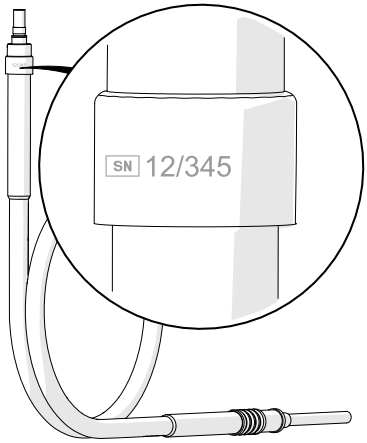


Illustration 2: Serial number on the fibre-optic light conductor

7.2 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.

7.3 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.

7.4 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.

7.5 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.

7.6 Disposal

Devices and accessories that are faulty or out of operation contain a large number of metal, electronic and plastic components which, due to the waste materials and residues involved, can represent an environmental risk if they are improperly disposed of. For this reason, please return components of your XION system whose service life has passed or that have been taken out of service due to irreparable faults to the manufacturer or separate them in commercial waste taking into account national regulations.

7.7 Service Adress

XION GmbH
Pankstrasse 8
13127 Berlin
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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

7.8 Accessories

The conductor cross-sections must be matched to the light entrance diameter of the endoscope, so that there are no reflections that could cause damage to the light exit of the fibre-optic light conductor.

7.8.1 Adapter on light-entrance (LE) side (light source)

Article	Article number
Adapter light entrance, OLYMPUS/ACM type, device side	310 726 341
Adapter light entrance, STORZ type, device side	310 726 310
Adapter light entrance, Wolf type, device side	310 726 320
Adapter LE, ACMI type, device side	310 726 370
Adapter LE, FUJINON type, device side	310 726 360
Adapter LE, PENTAX type, device side	310 726 350
Adapter LE, OLYMPUS type, with connector for insufflation	310 726 342

Table 3: Accessories for fibre-optic light conductors

7.8.2 Adapter on light output (LA) side (instrument)

Article	Article number
Adapter LA, STORZ/OLYMPUS type, endoscope side	310 727 310
Adapter LA, WOLF type, endoscope side	310 727 320
Adapter LA, ACMI type, endoscope side	310 727 370

Table 4: Accessories for fibre-optic light conductors

8 Reprocessing

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

 **WARNING NOTES**	• Do **NOT** clean in an ultrasonic bath! • **DO NOT** use hot air sterilization! • Before reprocessing, remove the adapter and reprocess separately. • Avoid considerable force; 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.
Restrictions in reprocessing	Frequent reprocessing has little detrimental effect on the product itself. The end of the service life of the device is normally determined by the wear and tear encountered during normal usage.

INSTRUCTIONS:

Pre-cleaning at the point of use	Wipe surface contaminants with a lint-free disposable cloth. Lay down the device properly to avoid damage.
Storage and transport:	• Do not kink, twist or knot the cable (narrow radius) or bend it. • Avoid tensile stresses. • Avoid bumping the fused light entrances, because this can destroy the fusion. • When transporting cables, make sure that they are secured against slipping. • Always use a closed container with a lid.

Do you want to machine reprocess?

Then continue with "Machine Cleaning/Disinfection".

Otherwise, continue with "Manual Cleaning/Disinfection".

Manual Cleaning/ Disinfection:	Equipment: Disposable gloves, disposable cloth, de-ionized water, soft brush, running water, Gigasept Instru AF (3%) Schülke & Mayr. 1. Cleaning a) Immerse in the Gigasept Instru AF (3%) cleaning bath (25° ± 5°C). b) 15 min. holding time c) Use a cloth/brush to clean the device below the surface of the liquid – especially cavities and concealed parts. 2. Intermediate rinsing: Rinse with deionised water for at least 1 min. 3. Disinfection: Immerse in the Gigasept Instru AF (3%) disinfection bath for 15 min. (25° ± 5°C). 4. Final rinsing: Rinse with deionised water for at least 1 min. 5. Drying: Use a lint-free cloth to dry the device. If possible dry with compressed air. Blow out the connector ports (with compressed air or by means of an air-filled syringe). **Continue from work step "Inspection and functional test"**

Machine Cleaning/ Disinfection:	Pre-rinsing • Rinse with cold town water for 60s. Machine cleaning: • 0.5% neodisher ® MediClean forte (Dr. Weigert) at 55°C and 10 min holding time. Rinsing: • 60s with cold de-ionized water. Machine disinfection: • Thermal at 90°C with 5 min holding time

Inspection and functional test:	Check for completeness, hygienic condition, damage, surface texture and correct operation.

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

Do you want to sterilize?

Then continue from "Packaging" .

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

Packaging:	Use suitable packaging for the 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. Products must not be in contact with each other. A suitable method shall be used for packaging.
Sterilization:	Steam sterilization: 134°C with 5 min. 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

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