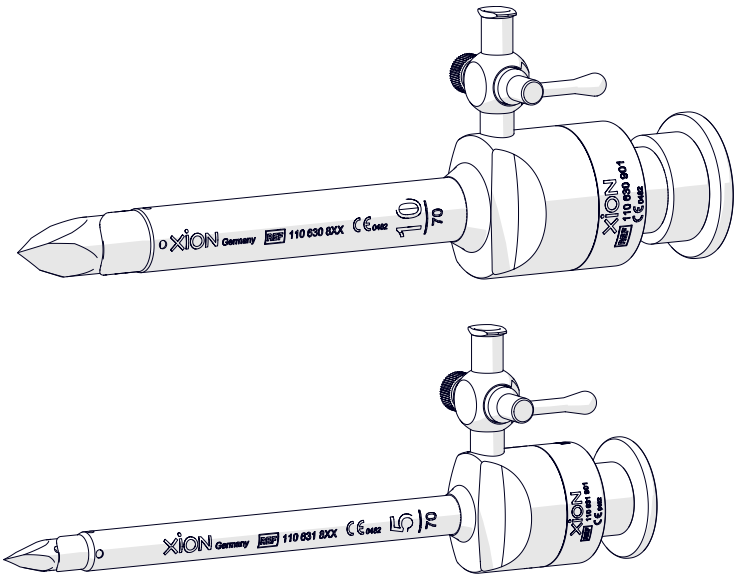
TRINOX Trocar system



Instruction for Use

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General

CE 0482

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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 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.

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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
	Collect separately
CE 0482	CE Notified Body

3 Intended Purpose

3.1 Intended use

The TRINOX Trocar System is used in minimally invasive surgery to open an access channel into visceral cavities for inserting endoscopic instruments.

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 TRINOX Trocar System is used in laparoscopic and thoracoscopic interventions.

3.4 Contraindication

Contraindications that relate directly to the medical device are currently unknown. Using TRINOX Trocar Systems 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.
- Only insert appropriate endoscopes into the shaft/sleeve. Pay attention to the diameter and length.
- Follow the instructions given in the Instructions for Use of the respective application parts and components.
- Mechanical stresses shorten the service life of the device. It is thus important to avoid shocks, blows and bending loads.
- Any serious incidents occurring in connection with the medical device must be reported to the manufacturer and the competent authority.

Side effects trocars:

Potential complications of trocar insertion techniques include infection, bleeding, organ injury and hernias. These adverse effects are only described in rare cases.

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.
- Before reprocessing the first time, remove the protective cap. If the protective cap is not removed, this would prevent the distal end from being properly reprocessed. After reprocessing, it would again contaminate the reprocessed distal end. Therefore, replace the protective cap on the distal only for transporting purposes (return shipment).
- 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.
- The device is **NOT** suitable for operating in MRT rooms due to the ferromagnetic interactions encountered there.
- When using RF electrodes, it is important to ensure that the active electrode is always in the field of view, and that it has no contact with metal parts.
- Only insert appropriate endoscopes into the shaft/sleeve. Pay attention to the diameter and length.
- In laser surgery interventions, the laser beam must not impinge on the trocar.

4.4 Reprocessing

- Dismantle the trocar system before reprocessing.
- Remove the protective cap (trocar mandrel) before reprocessing.

5 Product Description

The TRINOX Trocar System consists of a trocar sleeve (1), a trocar mandrel (5) and obturators (6).

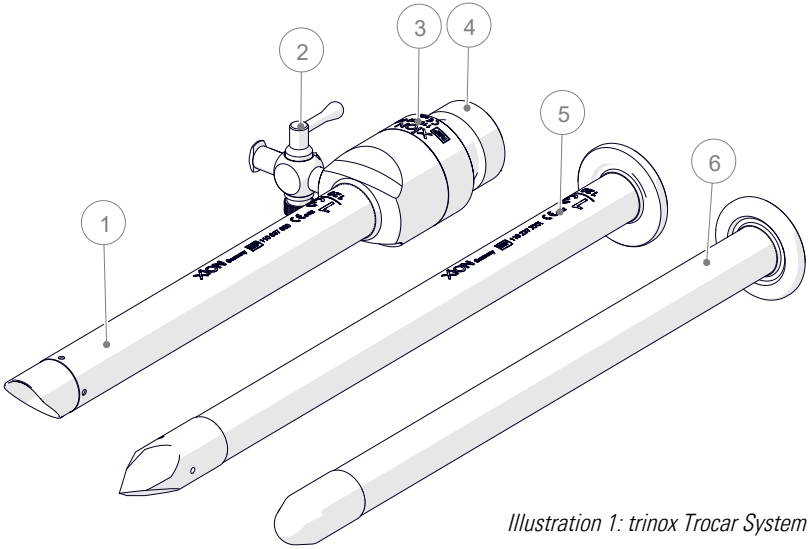


Illustration 1: trinox Trocar System

The trocar sleeve incorporates an automatic magnetic flap valve (3) which prevents gas loss when inserting the instrument. The absence of any mechanical joints or springs ensures a high level of functional safety as well as simple and effective instrument reprocessing in clinical operations.

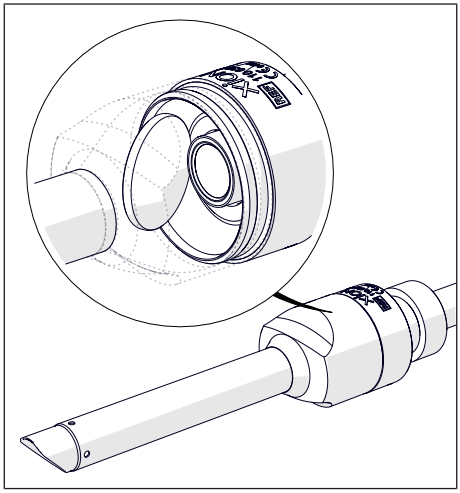


Illustration 2: Solenoid valve with open flap

A cap seal at the end of the valve seals the inserted instrument when the flap is open.

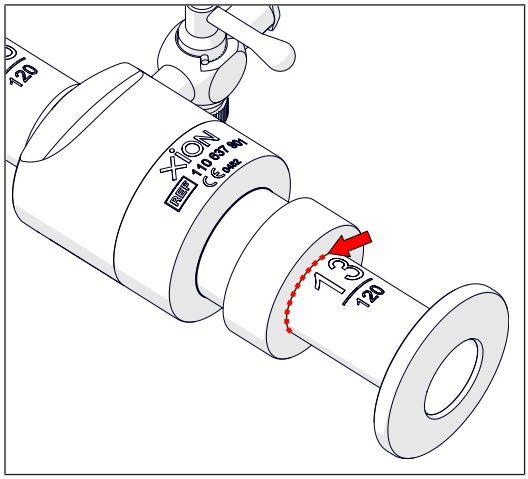


Illustration 3: Cap seal on the trocar sleeve

The trocar sleeves are available:

- with different working lengths,
- with or without tap (including Luer-Lock connection)
- the smallest size Ø 3.5 with and without insufflation connection (including Luer-Lock).

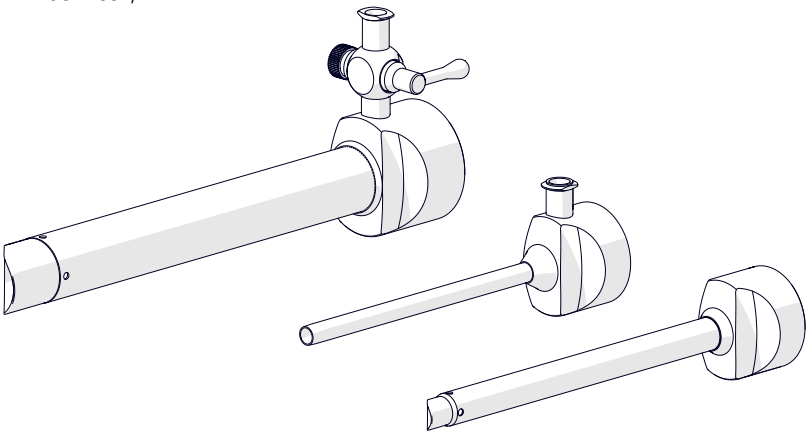


Illustration 4: Trocar sleeves with/without tap and without insufflation connection (from left to right).

Trocar mandrels are available with different tip forms: cone (1), pyramidal (2), as shielded trocars (3), with an internal perforation shield and also as filling mandrels/obturators (4) with a rounded end for mini-laparotomy.

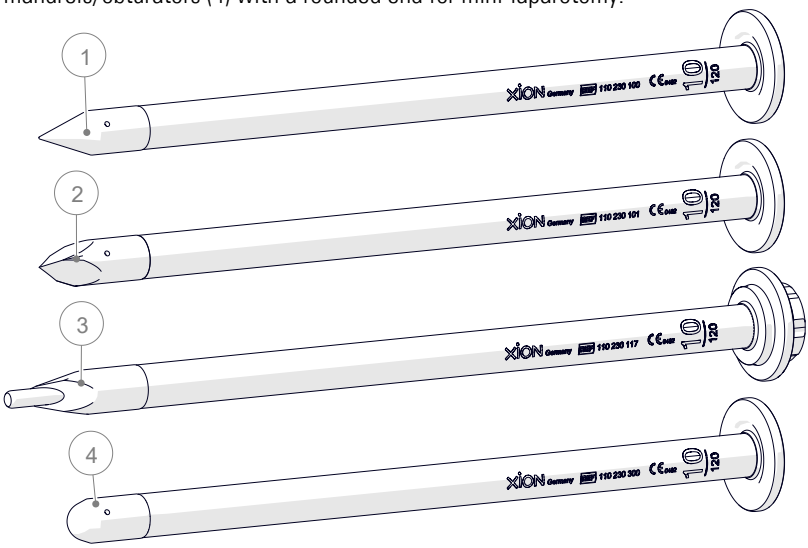


Illustration 5: XION Trocar Mandrels

5.1 Accessories

The extensive range of accessories available for the Trocar system includes:

- **Extraction sleeves**: these facilitate safe retrieval of tissue and are helpful when inserting delicate smaller-diameter instruments, moving swabs or mesh into the surgical site, and make endoscopic suturing easier.

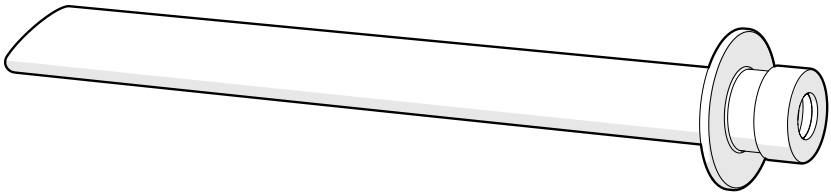


Illustration 6: Extraction sleeve, example figure 16/13 mm, length 120 mm

- **Fixation sleeves with thread**: for affixing the trocar sleeve in the abdominal wall

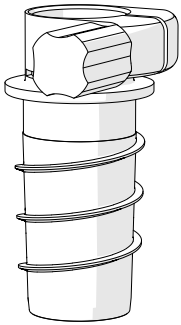


Illustration 7: Fixation sleeve Ø 13 mm

- **HASSON-type cone attachments**: these allow fixation of a standard trocar sleeve during mini-laparotomy

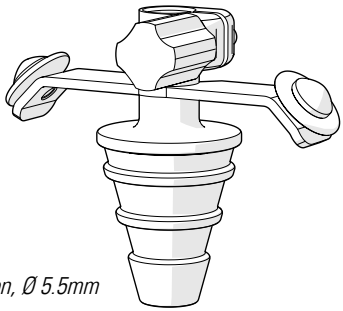


Illustration 8: Cone attachment according to Hasson, Ø 5.5mm

- **Reducing adapters** and **flap reducers**: these facilitate the insertion of smaller diameter instruments without gas loss

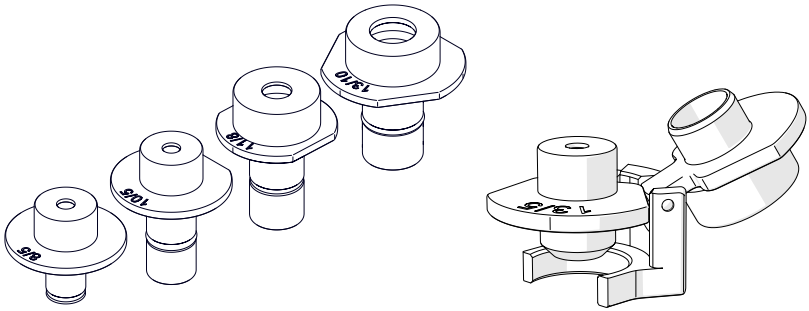


Illustration 9: Reducer inserts and double flap reducer using the example of 13/5.5 +10 mm

5.2 Performance features

- Made of stainless steel
- Available in many variants and designs for instrument diameters from 2.7 mm to 16 mm
- with/without insufflation tap resp. with/without insufflation connection at Ø 3.5 mm
- Can be autoclaved

5.3 Technical Data

- Application lengths of trocar sleeves: 70 / 100/ 120 / 150 / 200 mm
- Diameters of trocar mandrels: 3.5 / 5.5 / 8.0 / 10.0 / 11.0 / 13.0 / 16.0 mm
- Operating temperature: +10°C to +40°C
- Storage and transport temperature: -10°C to + 60°C

5.4 Scope of delivery

The scope of delivery of your TRINOX Trocar System includes various system components that vary depending on the agreed purchase order.

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.

Based on your delivery note, check that the items delivered are complete and intact.

5.5 Combination with other medical devices

The diameters and lengths of endoscopic instruments may vary depending on the manufacturer. When endoscopic instruments and accessories provided by different manufacturers are used in a medical intervention, make sure that these instruments are compatible.

Use appropriate accessories to avoid pressure losses

If the endoscopic instrument has a smaller diameter than the trocar sleeve being used, this can result in a loss of pressure during the surgical intervention. You should thus use suitable accessories such as reducing adapters or flap reducers.

Example: To switch from a size 10 instrument (size 10 trocar sleeve) to a size 5.5 instrument during surgery, you need a size 10 to size 5.5 reducer adapter or a size 10 to size 5.5 flap reducer.

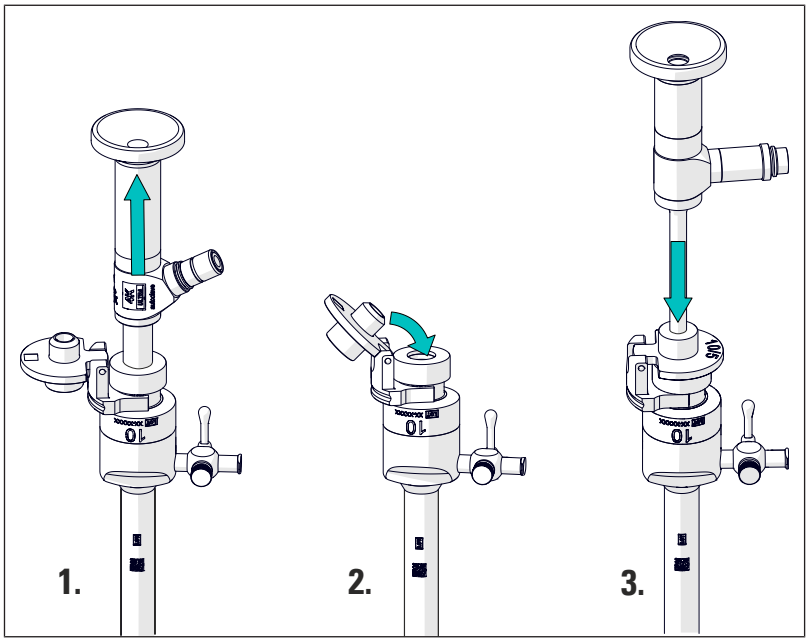


Illustration 10: Switching a laparoscope from 10 to 5.5 mm with the help of the flap reducer

Compatible with Luer-Lock

XION Trocar Sleeves can be combined with CO_2 insufflators via the Luer-Lock connection.

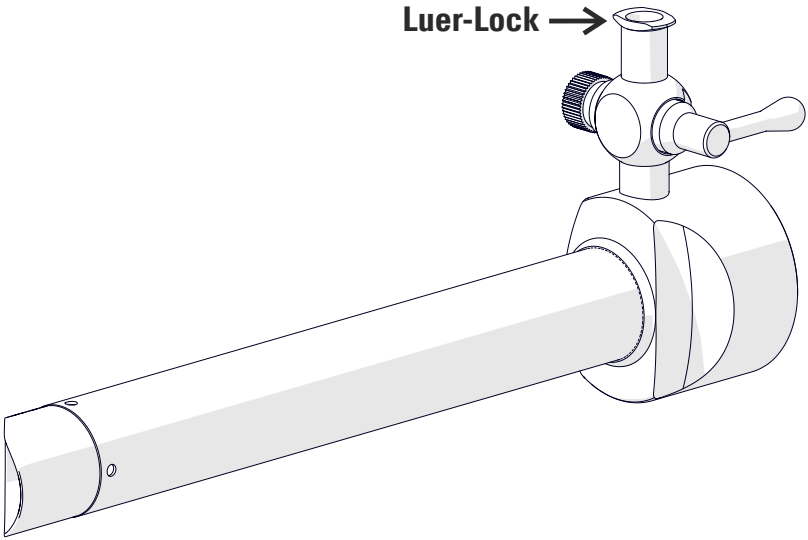


Illustration 11: Luer lock connection on the trocar sleeve

Note!
When combining your TRINOX Trocar System with optional components, please make sure to also observe the respective information and safety instructions provided by the respective instrument manufacturer.

6 Application

6.1 Select a suitable trocar mandrel

Select the trocar mandrel that is suitable for use with the trocar sleeve. The diameters and lengths must match.

The diameter and length are marked both on the trocar sleeve as well as on the trocar mandrel. The diameter is indicated on the solenoid flap valve.

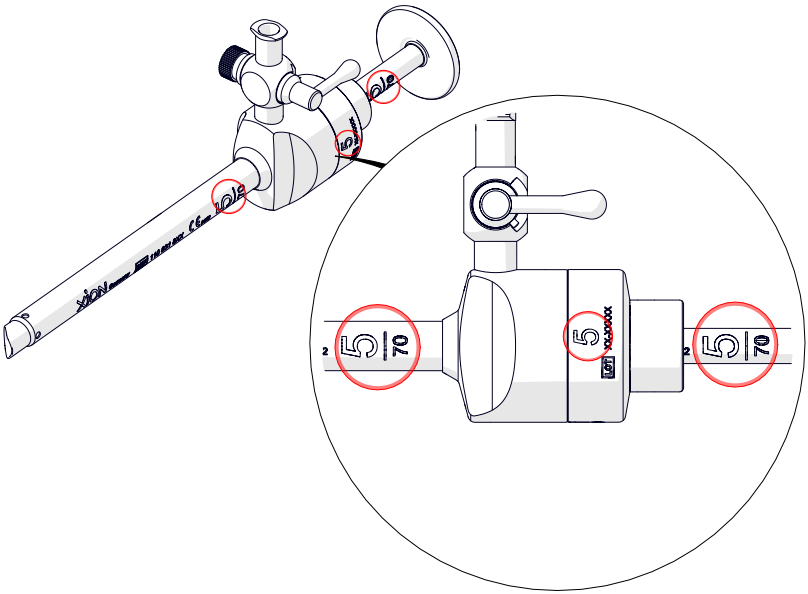


Illustration 12: Specification of diameter and length on trocar sleeve and trocar mandrel, diameter on solenoid flap valve

Determine the appropriate length by inserting the trocar mandrel into the trocar sleeve as far as it will go. The non-cylindrical part of the trocar mandrel – in the case of triangular mandrels, the polished area – must protrude completely out of the trocar sleeve.

The following applies for trocar mandrels with ventilation holes: You should only see two ventilation holes of the trocar mandrel. The third one should be concealed by the trocar sleeve.

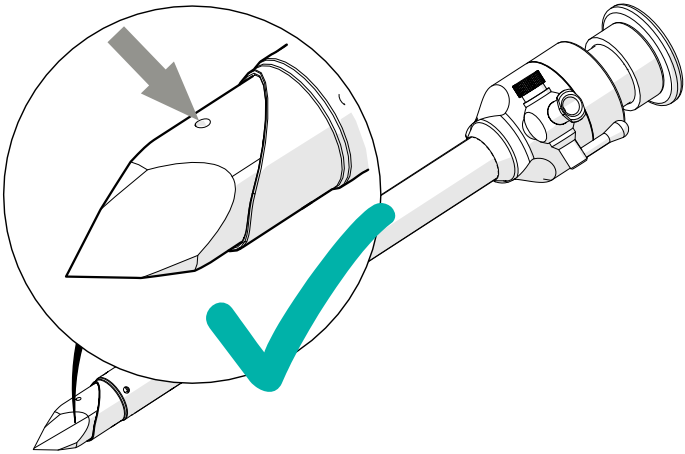
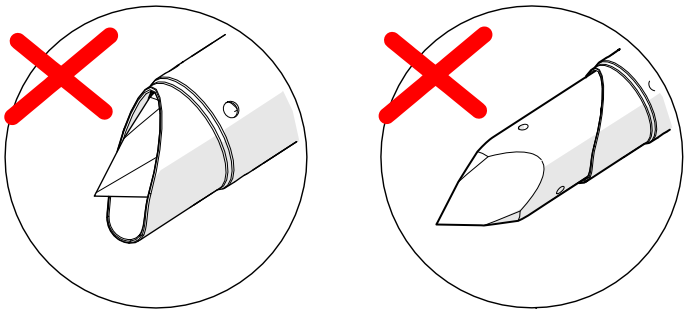


Illustration 13: Matching, too short and too long trocar mandrel



Caution!
If the trocar mandrel is too short, this could cause tissue to be cut, punched or torn out of the skin during insertion. The body orifice would thus become significantly larger.
On the other hand, a trocar mandrel that is too long would penetrate into the body more deeply than is necessary for the treatment.

When applying trocar mandrels with a smaller diameter, flap reducers or reducing adapters must be used.

6.2 Visual Inspection

Perform a visual inspection as follows:

- Check instruments and accessories for damage, hygienic condition and completeness,
- Check the distal end for deformation and sharp edges,
- Check the sealing rings for damage,
- Check the cap seals for embrittlement and/or fissures in the borehole.

6.3 Functional test

Perform a functional inspection as follows:

- Check the valve function of the flap while an instrument is inserted,
- Check the insufflation tap for mobility and firm position of the spring nut,
- In the case of a shielded trocar mandrel: check the spring mechanism.

Caution
Do NOT use the instrument in the event of actual or presumed defects that could endanger the patient, users or third parties!

Caution
Before inserting the trocar, use suitable techniques to prepare the abdomen, the thorax or the joint for the intervention.

6.4 Application on the Patient

Caution!
The components of the TRINOX Trocar System including all optional accessories must be checked every time before using them on the patient!

1. Guide the appropriate trocar mandrel into the trocar sleeve up to the stop.
2. Pierce the entire trocar system into the body. Insufflation is now possible.
3. Pull the trocar mandrel out of the trocar sleeve.
4. Insert the required instrument.

6.5 Disassembly

Caution!
Dismantle the instruments before cleaning.

Trocar sleeve with tap

- Unscrew the solenoid valve (3) out of the trocar sleeve (1)
- Remove the sealing cap (4)
- Remove the valve flap (5)
- Remove the sealing ring (6)
- Dismantle the tap (2)

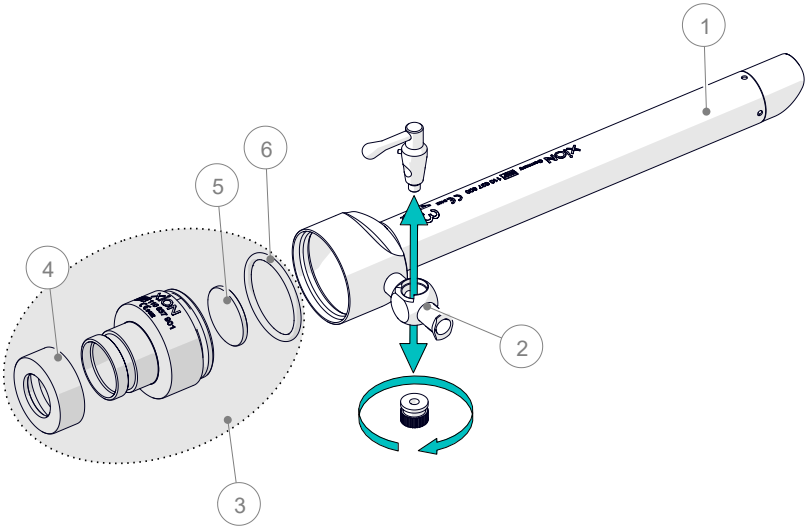


Illustration 14: Disassembling the TRINOX Trocar System

Shielded trocar

All XION shielded trocars consist of the mandrel tube (1), the cover (2), the compression spring and the rod. There are two variants:

1. **On the shielded trocars with Ø 5.5 mm, the insert is complete.**

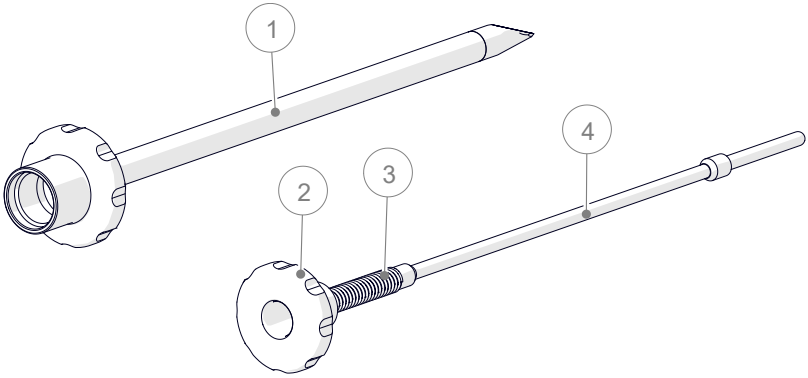


Illustration 15: Shielded trocar Ø 5.5 mm, disassembled

2. **On the shielded trocars <u>upwards from</u> Ø 8 mm, the insert consists of individual parts.**

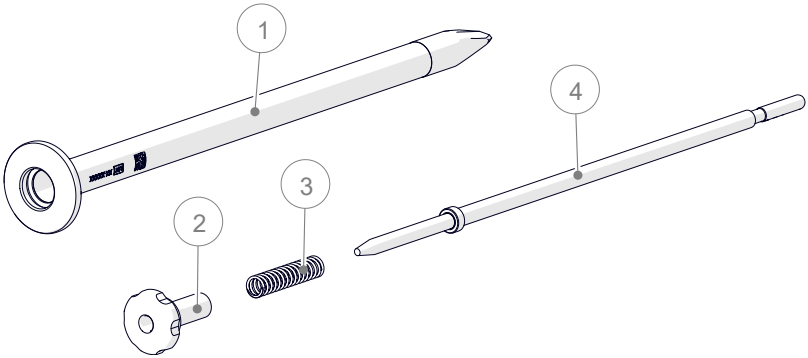


Illustration 16: Shielded trocar Ø 10 mm, disassembled

Procedure for disassembling both variants.

1. Unscrew the cover and

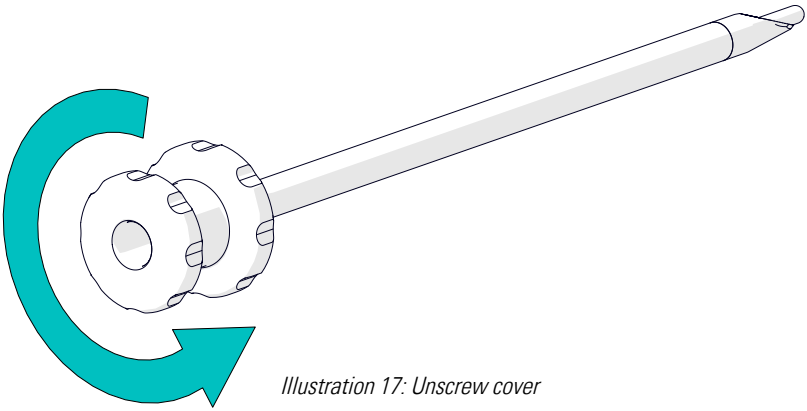


Illustration 17: Unscrew cover

2. Carefully allow the insert to slip out of the mandrel tube.

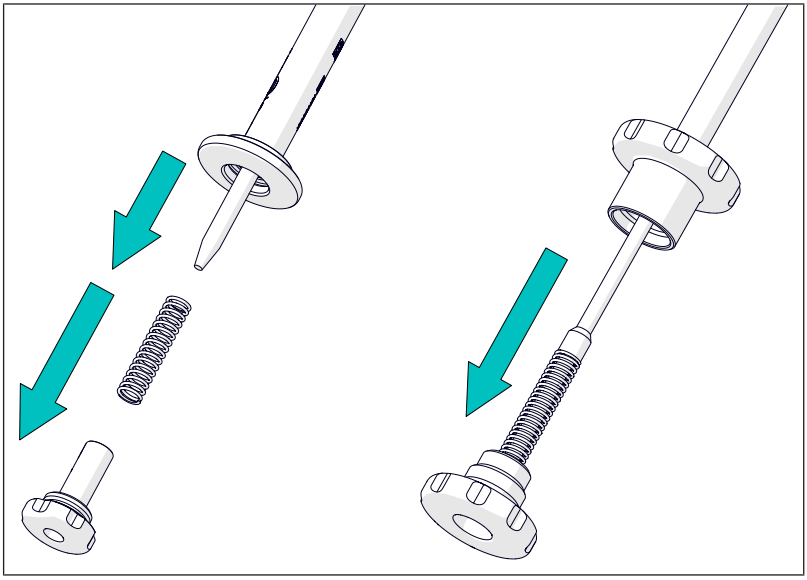


Illustration 18: Insert made of individual parts and complete variant

6.6 Assembly

Trocar sleeve with tap

Before assembling, check the individual parts for damage that may have resulted from cleaning and drying!
After checking the functionality of the components of the TRINOX Trocar System, reassemble them appropriately.
Lightly grease the plug (1) before inserting it into the insufflation tap. Use a suitable tap grease.

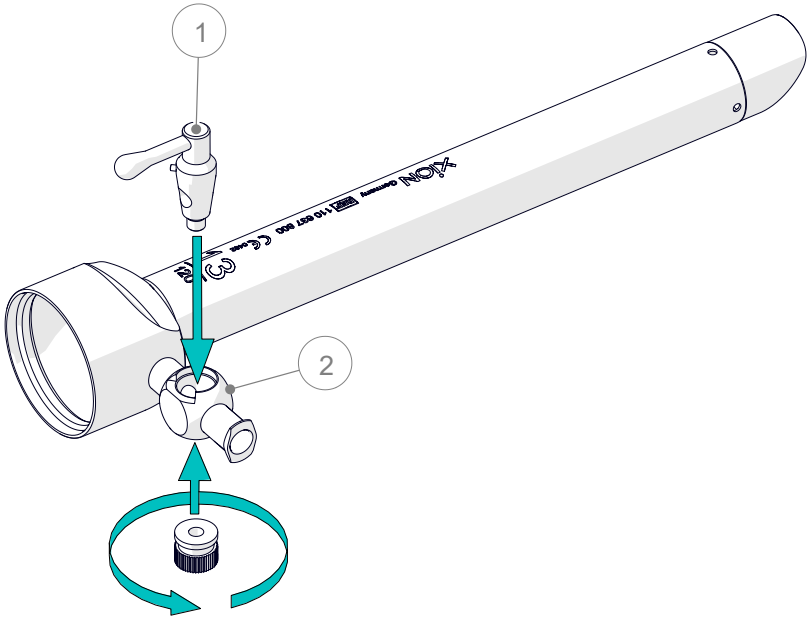
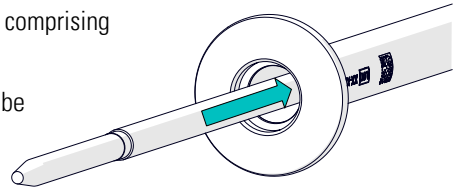


Illustration 19: Mounting the trocar system; greasing the tap

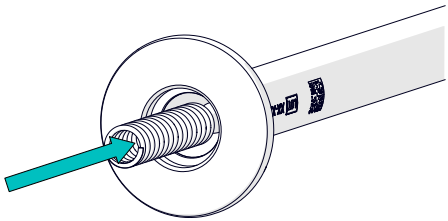
Shielded trocar

Assemble the shielded trocar (insert comprising individual parts) as follows:

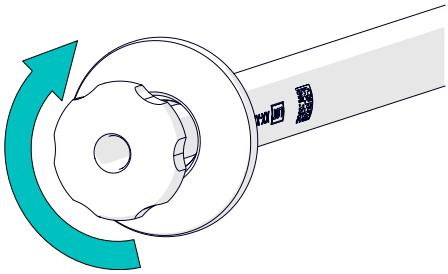
1. Slide the rod into the mandrel tube as far as it will go.



2. Slide the compression spring on to the rod up to the stop.



3. Screw the cover tight



Make sure to insert the rod the right way round. First insert the crowned end into the mandrel tube.

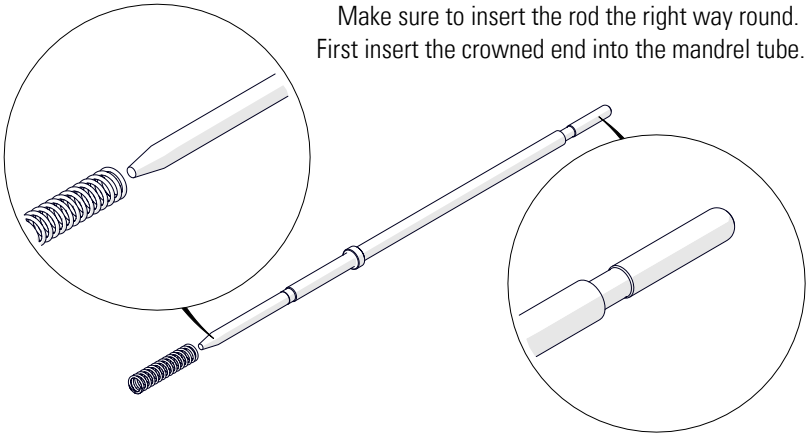


Illustration 20: Tip and end of the shielded trocar

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 number and batch number

When forwarding questions or placing spare part orders, please always state the Article number number [REF] and the batch number [LOT], as shown on the respective trocar (depending on model).

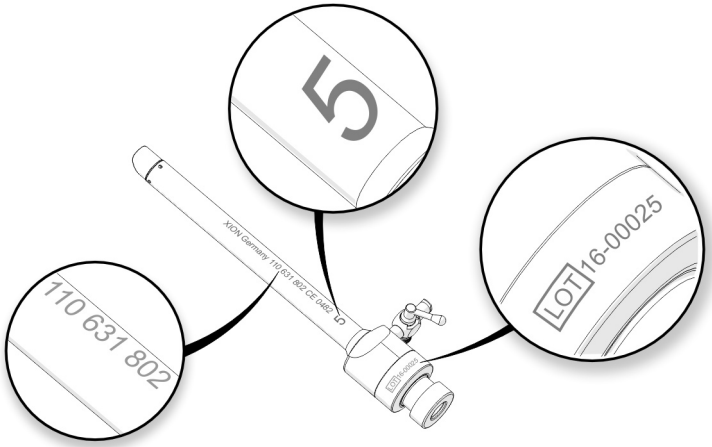


Illustration 21: Specification of article number and diameter on trocar sleeve, batch number on solenoid valve

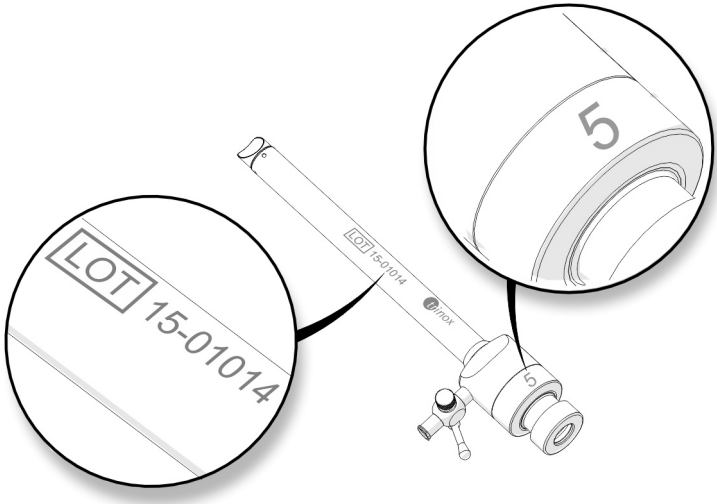


Illustration 22: Batch number on trocar sleeve, diameter on solenoid valve

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
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

8 Reprocessing

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

 **WARNING NOTES**	• Dismantle the trocar system before reprocessing. • Do not use physiological saline solutions for immersing and/or rinsing. Use de-ionized water. • Avoid considerable force, particularly while cleaning the insertion shaft; do not use coarse abrasives, metal brushes and cotton swab sticks made of metal. • When immersing the instrument, the air should be able to pass out of the hollow spaces, so that all instrument surfaces are entirely wetted. • Remove the protective caps before reprocessing (trocar mandrels); do not replace them afterwards. (only delivery/return shipping)
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:

At the location of use:	Pull the endoscope out of the suction rinsing shaft. Remove the connections. Use a moist disposable cloth to remove surface contaminants from the device (shaft and distal tip). Flush with water.
Storage and transport:	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:	Completely disassemble the trocar system. Pack small parts in a suitable container (basket tray).

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

Manual Cleaning/ Disinfection:	**Note!** The procedure described here assumes subsequent sterilization. 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, 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) Below the surface of the liquid, use a brush (soft bristles) to clean – especially cavities and hidden parts **2. Intermediate rinsing:** • Rinse at least 1 min with deionised water. **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:	• Reprocess small parts in a suitable container (basket tray) • Connect the trocar sleeve to a suitable load carrier (rinsing lances, rinsing connections) • Place the trocar mandrel into the basket tray Machine (CDD): Cleaning: 0.5% neodisher MediCLEAN® forte (Dr. Weigert) 10 min. at 55°C Disinfection temperature: 90°C, immersion time 5 min. Drying: with compressed air, where applicable.

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

Mounting:	Mounting individual parts. Where applicable Lubricate the stopcock plug with suitable stopcock grease.

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.

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