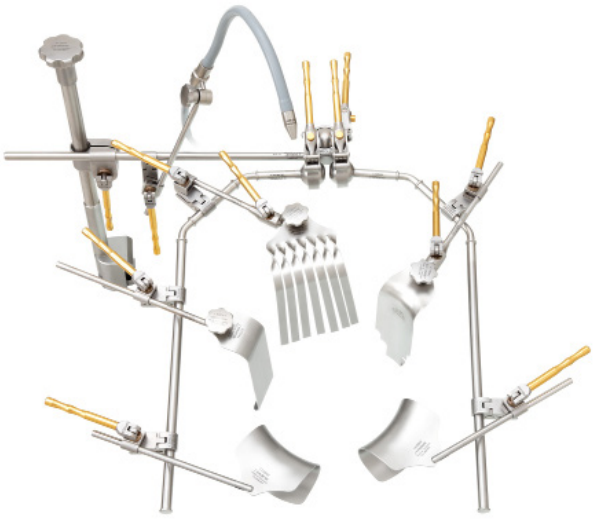
CONDOR® MedTec
EXPAND YOUR POSSIBILITIES



Instructions for Care and Use

Surgical Retractor System Condor GoldLine®

444.GA.GL.EN
Last updated on 11.08.21

0044 CE

Contents

1. Introduction

1.1 About this manual

These instructions for use encompass all the information relevant to use of the Surgical Retractor System Condor GoldLine® This section contains information about the structure of the user manual as well as explanations of the signs and symbols used. These instructions for use contain instructions on handling the retractor system with regard to operation, hygiene, service, maintenance, and disposal.

This user manual may contain inaccuracies or printing errors. The information provided here is updated periodically and changes are incorporated in later issues in the course of product modi cations. Thus, changes or improvements are possible at any time without previous notication.

The latest version of these instructions for use can be found on the Condor website: www.condor-medtec.de.

Should you have further questions, please contact us directly.

These instructions for use are to be read and used by all persons who use or operate the retractor system.
In addition to the instructions in this manual and any binding regulations for the prevention of accidents in the country and at the location of use, observe accepted rules for safe and professional work.

1.2 Symbols used in the text

The following signal words and/or symbols are used in this manual to indicate especially important information.

Danger!
This symbol indicates safety instructions warning of risks to personal health and safety. It indicates imminent danger of death or serious injury.

Caution!
This symbol indicates potentially dangerous situations involving a risk of light injury.

Attention!
This symbol is used with safety instructions indicating a risk of damage to the device or other property.

This symbol indicates additional useful information.

• A dot in front of the text means:
This task is mandatory.

Indented text describes the result of your action.

– A dash in front of the text means:
This is part of a list.

1.3 General safety instructions

The Surgical Retractor System Condor GoldLine® is constructed according to the state of the art and complies with accepted safety rules. However, its use may present risks to the patient or third parties or risk of damage to the device or other property.

Use the Surgical Retractor System Condor GoldLine® only when in proper working condition, within the scope of the intended use, in consideration of safety and potential hazards and in compliance with this user manual. Immediately repair any defects that could possibly affect safety.

Always keep this manual readily accessible at the location of use. In addition to this manual, observe all applicable laws and other regulations on accident prevention and environmental protection.

Do not make any changes, extensions, or conversions to the retractor system without the manufacturer's permission. Spare parts must comply with the requirements stipulated by the manufacturer. Original spare parts always comply with these requirements.

Ensure safe and environmentally-friendly disposal of operating and auxiliary materials, as well as replacement parts!

Summary of the safety instructions

Danger!
The surgical retractor system can loosen from the operating table if the main holder is not completely fastened to the slide rail. Always check that the main holder is fastened securely to the operating table.

Attention!
The main holder is not designed for storing instruments. Do not place any electrosurgical instruments here. Do not approach the distal area of the main holder with an activated electrosurgical device. Do not place any instruments or saturated abdominal cloths on the main holder. This could impede on the electrical insulation.

Danger!
The retractors and instruments can cause tissue damage. Ensure that the choice of instruments meets the surgical requirements and observe necessary tissue release phases.

Danger!
The crossbar can cause injury due to pressure. Make sure that there is sufficient room between the patient and the crossbar.

Danger!
Take care if universal fibre optical cables are damaged or incomplete. Injury to patient, user, or third parties is possible.

Caution!
Instructions that are not properly attached may become loose and patients can be injured. Please always check that the individual instruments are firmly attached to the holder arms.

Caution!
Too short sterile covers and carelessness can lead to contamination of the sterile area. To attach the main holder, touch the upper third if possible.

Caution!
The retainer should be realigned as described. Opening the retainer leads to the complete release of the system from the crossbar.

Caution!
Clamps that are not properly fastened can lead to unstable operation. Ensure that clamps are only attached at suitable positions.

Danger!
Moving and adding retractors can lead to unintended changes in the surgical site. Always check that the instruments are securely attached.

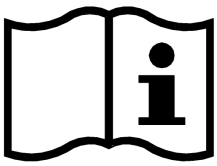
Attention!
Avoid turning the clamping lever in the closed state.
- Turning the clamping lever when the clamp is closed could damage the clamp.
- Open the lock before turning the clamping lever.

Danger!
Check that there is no danger to the patient from operation-related manipulations.

Danger!
Relieve the tissue regularly and ensure that blood circulation at the wound edges is not interrupted.

1.4 Graphical symbols used

The following graphical symbols are used in accordance with DIN ISO 15223-1.

Graphical symbol	Identification
	Identification in agreement with ISO 15223-1 standard. Symbol for 'product number'
	Identification in agreement with ISO 15223-1 standard. Symbol for 'serial number'
	Identification in agreement with ISO 15223-1 standard. Symbol for 'name and address of the manufacturer'
	Identification in agreement with ISO 15223-1 standard. Symbol for „date of manufacture"
	Identification in agreement with ISO 15223-1 standard. Symbol for 'observe instructions for use'
	Identification in agreement with ISO 15223-1 standard. Symbol for 'product not sterile'

Graphical symbol	Identification
	Labelling of medical devices. Symbol for „Medical Device"
	Identification for a data carrier which contains the Unique Device Identifier contains. Symbol for „Unique Device Identifier".
	Labelling of products developed and marketed in accordance with relevant European legal provisions.

2. Basic requirements

2.1 Intended use

The Surgical Retractor System Condor GoldLine® is a class IIa medical product that is used intraoperatively. It is meant exclusively for use in human medicine.

The Surgical Retractor System Condor GoldLine® serves the continuous retraction of the operation area and the positioning of individual organs. The holder arms and instruments can be set flexibly, enabling individual situs adjustment. The GoldLine system takes on tasks, which were previously performed manually by assisting personnel. The systems can be used in individual specialised areas through holder arm and retractor specifications. The surgical retractor system is thus found in general surgery, thoracic surgery, vascular surgery, urology, gynaecology, orthopaedics, etc.

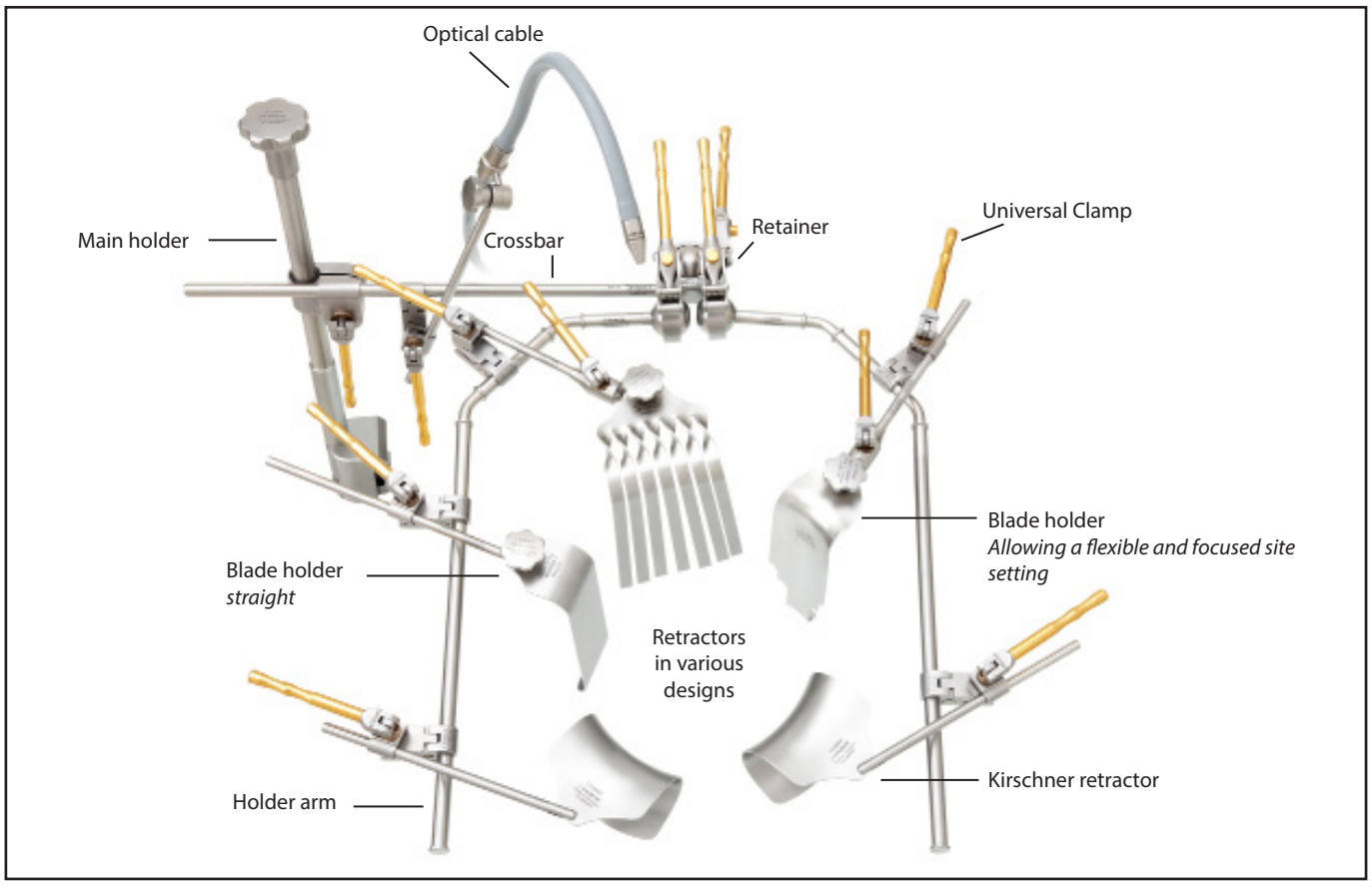
When put together in a certain way, instruments such as light guides and cameras can also be held.

The Surgical Retractor System Condor GoldLine® may only be operated by personnel who have familiarised themselves with the product through these instructions for use. We cannot undertake any liability for damage to persons or the product that has been caused by external accessories or subsequent deviation from the intended purpose.

The intended purpose is the use as specified. This is described completely for the operator or user on the labelling and the instructions for use. The Surgical Retractor System Condor GoldLine® may only be used in full accordance with the instructions for use.

- Intended use also means following the instructions for use and adhering to the inspection and maintenance conditions.
- The Surgical Retractor System Condor GoldLine® may only be used by medically trained personnel.
- Before use, always check that the product is intact.

2.2 Device description



Example of the Condor GoldLine® retractor system for abdominal surgery

3. Storage

The Surgical Retractor System Condor GoldLine® may only be used in a sterile state.
Observe the instructions for use and preparation when storing, preparing, and sterilising the system.

The instruments should always be

– Stored in a clean, cool and dry place.

– Protected against mechanical damage.

– Protected against falling and handled carefully

The generally valid directives and recommendations apply, for example:

– DIN EN ISO 17664:2018-04

– RKI recommendations

– AKI – Correct instrument preparation for storage of re-sterilisable instruments.

4. Operation

Please read the instructions for use carefully before starting to use the Surgical Retractor System Condor GoldLine®!

The Surgical Retractor System Condor GoldLine® can be attached to all operating tables that have a slide rail.

4.1 Attaching main holder to operating table

The main holder is attached to the operating table above the sterile cover. The position of the main holder is oriented on the operation technology of the specialist department.

You can find suggestions on setting up the Condor® system in the instructions for use in the Condor® catalogue. The latest version is available on our website.

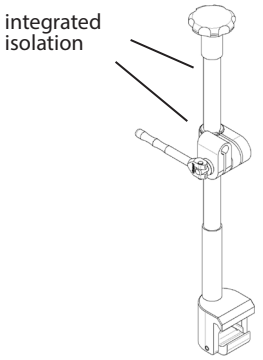
In order to tighten the main holder, always make sure that the clamp at the bottom end of the main holder is completely open. Place the main holder on the slide rail.

Turn the hand-wheel to the right to fasten the main holder to the slide rail.

Danger!
The surgical retractor system can loosen from the operating table if the main holder is not completely fastened to the slide rail. Always check that the main holder is fastened securely to the operating table.

Attention!
The main holder is not designed for storing instruments. Do not place any electrosurgical instruments here. Do not approach the distal area of the main holder with an activated electrosurgical device. Do not place any instruments or saturated abdominal cloths on the main holder. This could impede on the electrical insulation.

Always before use, make sure that the main holder is fixated securely and sterilely. Ensure that only one layer of the sterile cover is between the sterile cover and the main holder.



Youtube
Tutorial

4.2 Main holders of the latest generation

Ref. 100.060.060 E , Ref. 100.060.060 EL, etc.

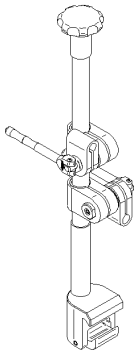
Main holders of the latest generation can be disassembled. The integrated insulation provides additional protection against electric currents.
They can be identified by the "Z" contained in their serial number (e.g. 0100 Z). Along with the main holder foot, the assemblies "Clamp" and "Threaded rod" are equipped with the serial number.

In order to disassemble the main holder, unscrew the hand wheel in a counter-clockwise direction.

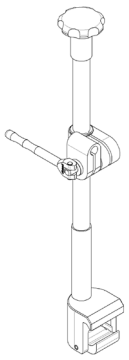
There is a thread inside the main holder foot to tension the compensator when attaching the main holder to the operating table. There is a further safety thread at a somewhat higher position in the main holder tube. These devices prevent the main holder from being disassembled completely when removing it from the operating table.

After the hand wheel is unscrewed together with the threaded rod, the assembly "Clamp" can also be removed from the main holder tube. When re-installing the main holder please observe that only the components of the same serial number are assembled.

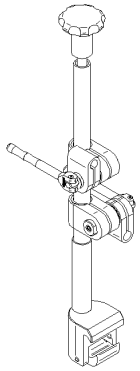
Assembly/disassembly using the example of 100.060.060 E and 100.060.060 EL:



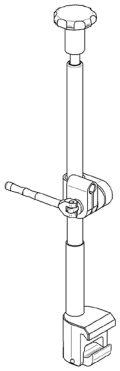
Main holder EL



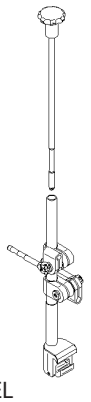
Main holder E



Main holder EL

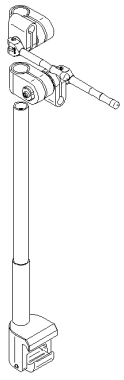


Main holder E

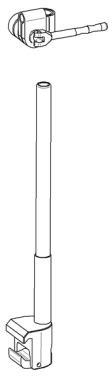


Main holder EL

Main holder E



Main holder EL



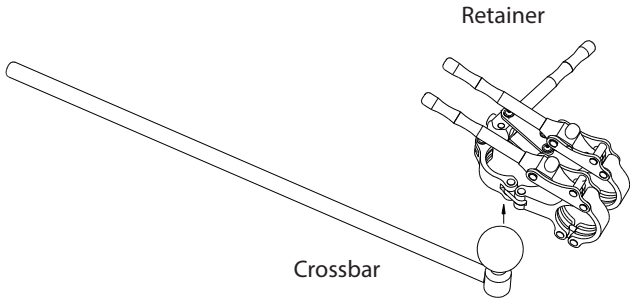
Main holder E

Ensure that the main holders are equipped with a sufficient number of clamps. For example:
100.060.060 E „Main holder with eccentric closure and integrated isolation, incl. one clamp".
100.060.060 EL „Main holder with eccentric closure and integrated isolation, incl. two clamps".

4.3 Attaching and removing retainer and crossbar

Ref. 100.170.080 K, Ref. 100.440.040 K

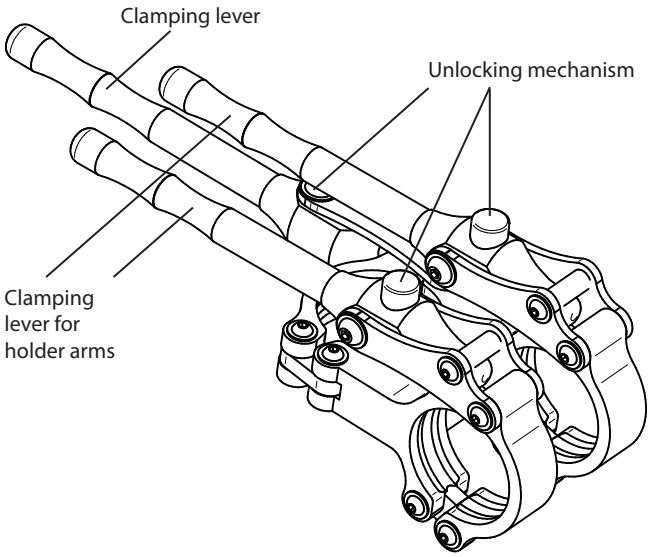
The Surgical Retractor System GoldLine contains a crossbar and a retainer.
Together, the crossbar and retainer form the initial position for the holder arms.



Attaching and removing the crossbar

- In order to fasten the crossbar, open the clamp on the main holder. For this, turn the clamping lever. The "OPEN" inscription can now be read on the eccentric lock.
- Fixate the crossbar with the clamp on the main holder. The ball of the crossbar points upwards.
- Align the crossbar in such a way that there is sufficient space between crossbar and patient.
- To fasten the crossbar, turn the clamping lever on the main holder. The "CLOSED" inscription can now be read.
- Remove the crossbar by turning the clamping lever on the main holder..

Danger!
The crossbar can cause injury due to pressure. Make sure that there is sufficient room between the patient and the crossbar.



Always before use, make sure that the main holder is fixated securely and sterilely.

Attaching and removing the retainer

- To attach the retainer, open the clamping lever on the side by pressing the release and simultaneously pulling the clamping lever.
- Now turn the opened joint of the retainer around the ball of the crossbar.
- Close the joint with the retainer's clamping lever. The retainer is now fixated to the crossbar.
- To remove the retainer from the crossbar, press the release button and gently open the clamping lever.

The height of the surgical retractor system can also be adjusted.

- A Distance holder is fixed in front of the sterile cover using a radial clamp.
- The Distance holder can increase/reduce the height and length by around 30 cm.

Areas of application are, for example:

– Thyroid gland surgeries

– Operations in paediatric surgery

– Bariatric surgery

– Upper abdomen/transplant surgery

Adjusting the retainer

- Use the clamping lever to adjust the alignment of the retainer.
- Only actuate the clamping lever. In this way, the retainer remains connected to the crossbar.
- Fixate the clamping lever as soon as you are satisfied with the alignment.

Caution!
The retainer should be realigned as described. Opening the retainer leads to the complete release of the system from the crossbar. If holder arms and instrument are attached to the crossbar, hold against them in this case.

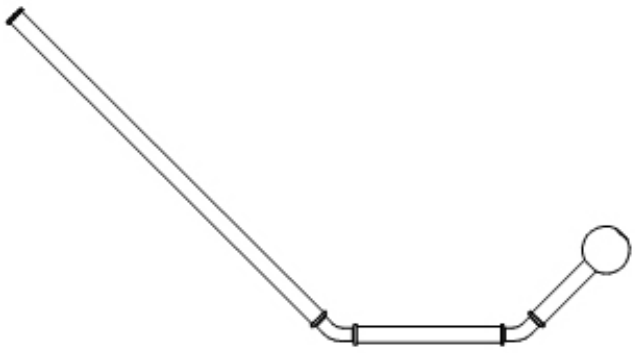
Youtube
Tutorial

4.4 Attaching holder arms

Ref. 100.170.080 K, Ref. 100.440.040 K

The holder arms enable clamps and instruments to be fastened during an operation
For this, they must be fi rmly attached to the retainer

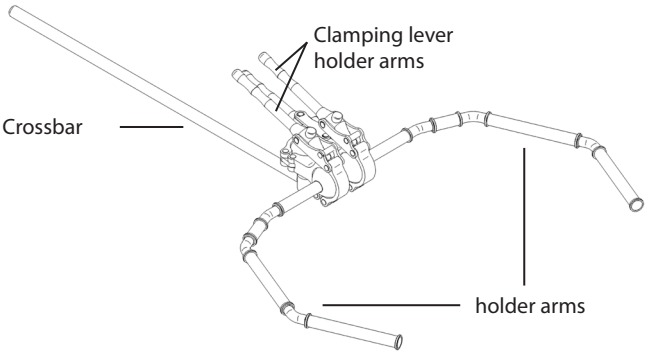
- Open the respective eccentric lock at the retainer by means of traction on the clamping lever
- Actuate the release and open the clamping lever
- Place the holder arm with the ball in the open retainer
- Close the retainer
- Check the fi rm seating of the holder arms
- Press the release and open the clamping lever to remove the holder arms.



Example for holder arm

Adjusting the holder arms

- The holder arms with ball can be set individually and adapted to the operation situs
- For this, open the clamping lever on the desired side, bring the holder arm into position and close the clamping lever
- Fixate the clamping lever as soon as you are satisfi ed with the alignment
- Only actuate the clamping lever In this way, the holder arm remains connected to the retainer

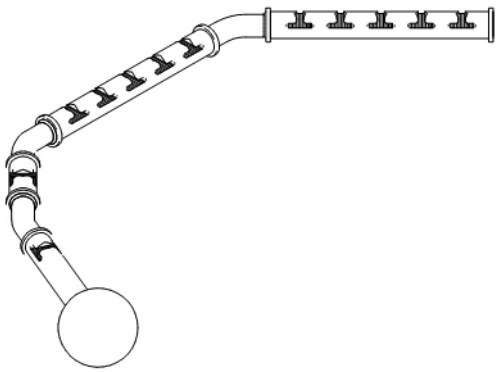


Crossbar, Retainer and holder arms

4.5 Holder arms Mini - multifunctional

Ref. 100.220.012 K-ML, Ref. 100.220.012 K-MR,
Ref. 100.220.040 K-ML und Ref. 100.220.040 K-MR

The holder arms enable the combined use of reusable retractors and single-use retractors When using the retractors, please observe the relevant manufacturer's information Only ever use retractors with CE marking.
When preparing the Mini M holder arms, observe in particular the additional visual check for residues in the notches

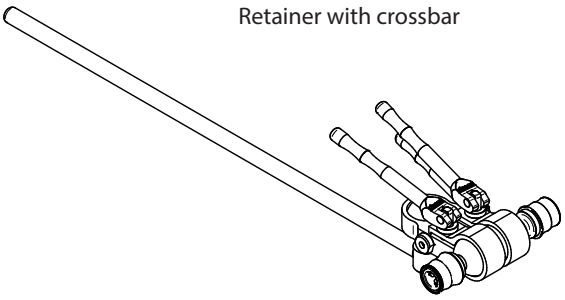


Example for Holder arm Mini multifunctional

4.6 Attaching and removing retainer with crossbar

Ref. 100.120.060 K

Retainer with crossbar



The Surgical Retractor System Condor GoldLine® contains, as a further option, a crossbar including a retainer.

Attaching and removing the crossbar

- In order to fasten the crossbar, open the clamp on the main holder. For this, turn the clamping lever. The "OPEN" inscription can now be read on the eccentric lock.
- Fixate the crossbar with the eccentric lock at the main holder so that the ball at the crossbar points upwards.
- Align the crossbar in such a way that there is sufficient space between crossbar and patient.
- To fasten the crossbar, turn the clamping lever on the main holder. The "CLOSED" inscription can now be read.
- Remove the crossbar by turning the clamping lever on the main holder.

Attaching and removing the retainer

- There is a clamping lever on the side that is used to stabilise the retainer. Turn this for fastening.
- Now place the opened joint of the retainer around the ball of the crossbar.
- The retainer cannot be removed from the crossbar, and also remains connected with the crossbar during cleaning, disinfection, and sterilisation.

Danger!
The crossbar can cause injury due to pressure. Make sure that there is sufficient room between the patient and the crossbar.

Adjusting the retainer

- Use the clamping lever to adjust the alignment of the retainer.
- No device is provided here to support the weight of the system and facilitate the adjustment of the system.
- Fixate the clamping lever as soon as you are satisfied with the alignment.

The height of the surgical retractor system can also be adjusted.

- A Distance holder is fixed in front of the sterile cover using a radial clamp.
- The Distance holder can increase/reduce the height and length by around 30 cm.

Areas of application are, for example:

– Thyroid gland operations

– Operations in paediatric surgery

– Bariatric surgery

– Upper abdomen/transplant surgery

Always before use, make sure that the main holder is fixated securely and sterilely.

4.7 Attaching holder arms

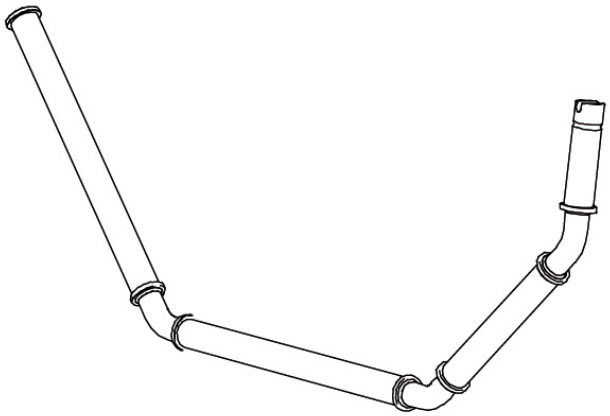
Ref. 100.400.012 K, Ref. 100.480.012 K,
Ref. 100.220.012 K, Ref. 100.360.012 OT

The holder arms enable clamps and instruments to be fastened during an operation. For this, they must be firmly attached to the retainer.

- Open the respective eccentric lock at the retainer. The ball element can now move freely.
- Push back the coupling slider with two fingers.
- Insert the holder arm according to the two black markings. The black markings are on the holder arm and the coupling.
- To connect the holder arm firmly to the retainer, release your fingers from the coupling slider. This goes back to its initial position and the holder arm is locked in the coupling.
- Check the firm seating of the holder arms.
- To remove the holder arms, open the eccentric lock at the clamping lever and push the coupling slider back with two fingers. Pull out the holder arm.

Adjusting the holder arms

- Use the respective clamping lever to adjust the alignment of the holder arms.
- Fixate the clamping lever as soon as you are satisfied with the alignment.

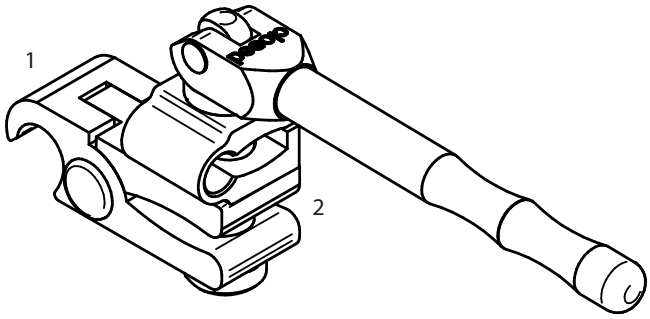


Example holder arm

4.8 Fastening and removing the universal clamp

Ref. 100.050.020 ES, Ref. 100.050.020 DC

The clamps of the Surgical Retractor System Condor GoldLine® are used to connect the holder arm and the instrument in the operation area.



- Open the eccentric lock. The "OPEN" inscription can now be read. For simple attachment of the clamp, place your thumb (1) above the clamp. At the back part of the clamp, place your index or middle finger (2) between the clamp jaws and
- spread them apart.
- The clamp can only be fastened at the intended position.
- The simple attachment of the clamp is enough to protect the clamp from falling down.
- Push the clamp to find the suitable position for holding the instruments.
- Insert the required instrument into the clamp.
- Turn the eccentric lock to close the clamp so that it can no longer be moved. The "CLOSED" inscription can now be read.

Attention!
Avoid turning the clamping lever in the closed state.
- Turning the clamping lever when the clamp is closed could damage the clamp.
- Open the lock before turning the clamping lever.

Removing clamps

- Open the eccentric lock of the clamp to remove from the holder arm. Turn the clamping lever.
- Remove the instrument from the clamp and operation area.
- Place your thumb (1) above the clamp again.
- At the back part of the clamp, place your index or middle finger (2) between the clamp jaws and spread them apart.
- Now pull the clamp down from the holder arm.

Youtube
Tutorial

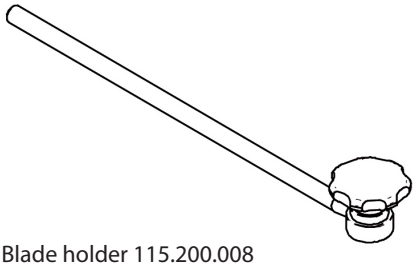
4.9 Blade holder variants

Retractors may be swivel. This means that a holding bar is directly attached to the retractor. They can also be mounted on the blade holder. The holding bar of the blade holder can then be inserted in the clamp and positioned in situs.

Blade holder
Ref. 115.200.008

- Select the suitable instrument / blade for the operation.
- Remove the screw head from the blade holder by turning to the left.
- Insert the appropriate instrument with the provided opening on the blade holder.
- Fasten the screw head by turning to the right with the blade holder.

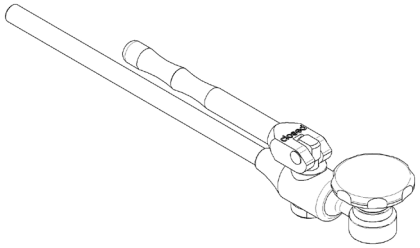
Always insert the blade holder in such a way that the head screw points upwards. In this way, it is quicker to change, move, or re-tighten instruments.



Blade holder 115.200.008

Blade holder with ball- and socket joint
Ref. 115.200.008 E

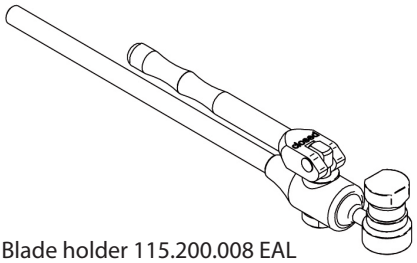
- The blade holder with ball joint ensures precise setting possibilities such as the tip-focused setting in the operation area.
- Remove the screw head from the blade holder.
- Insert the appropriate instrument with the provided opening on the blade holder.
- Fasten the screw head with the blade holder.
- Open the eccentric lock with the clamping lever so that "OPEN" can be read.
- Select the desired position and turn the clamping lever again. "CLOSED" can now be read.



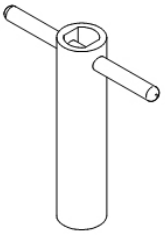
Blade holder 115.200.008 E

Blade holder with ball- and socket joint and handle nut for translucent retractors Ref. 115.200.008 EAL with socket wrench Ref. 122.020.100

- The blade holder with ball joint is distinguished by its special field of application.
- It is specially designed for translucent retractors so that the retractors do not interfere with the requirements for intraoperative radiography.
- Use the socket wrench to fasten the retractor.
- The blade holder with ball joint ensures precise setting possibilities such as the tip-focused setting in the operation area.
- Select the desired position and turn the clamping lever again. "CLOSED" can now be read.



Blade holder 115.200.008 EAL

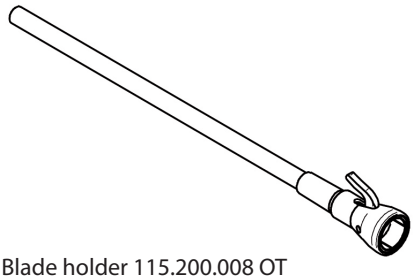


Socket wrench
122.020.100

Youtube
Tutorial

Blade holder with ball pivot
Ref. 115.200.008 OT

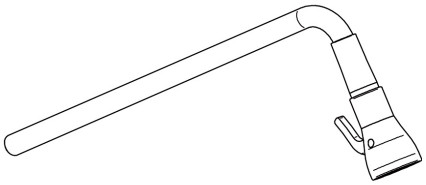
- This blade holder enables the clamping of instruments that are equipped with a ball for fastening.
- Press the toggle opening and insert the instrument with ball device.
- Let go of the toggle opening. The clamped instrument and the blade holder are now firmly connected.
- Special feature: Through the connection via a ball joint, movements in the operation field can be compensated and optimal setting positions achieved.



Blade holder 115.200.008 OT

Blade holder 90° with ball pivot
Ref. 115.200.090 OTG

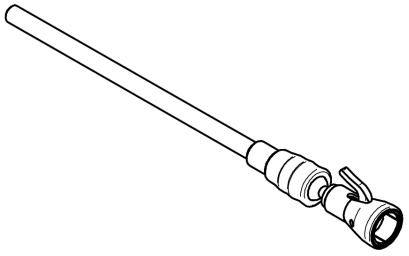
- This blade holder enables the clamping of instruments that are equipped with a ball for fastening.
- Press the toggle opening and insert the instrument with ball device.
- Let go of the toggle opening. The clamped instrument and the blade holder are now firmly connected.
- Special feature: The 90° bend resists high holding forces and helps you to execute adjustment positions that are otherwise very inaccessible.



Blade holder 115.200.008 OTG

Flexible blade holder with ball pivot
Ref. 115.200.008 OTF

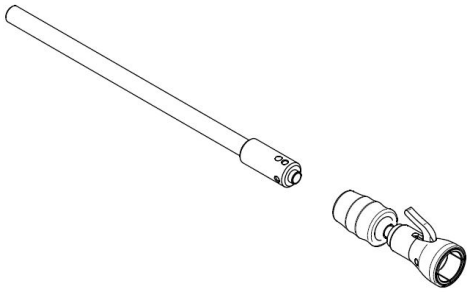
- This blade holder enables the clamping of instruments that are equipped with a ball for fastening.
- Press the toggle opening and insert the instrument with ball device.
- Let go of the toggle opening. The clamped instrument and the blade holder are now firmly connected and form a ball joint.
- Special feature: Through the connection via two ball joints, many movements in the operation field can be compensated and optimal setting positions achieved.



Blade holder 115.200.008 OTF

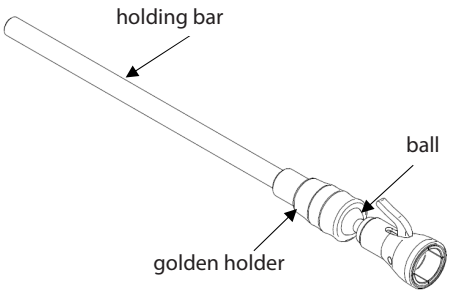
Flexible blade holder with ball pivot
Ref. 115.200.008 OTF

Mounting



- Press the ball towards the holding bar.
- Then pull the golden holder towards the holding bar.
- Let go of the golden holder. The blade holder has been mounted.
- Preparation should be done in dismantled state.

Dismantling



- The OTF blade holder has a ball joint.
- Press the ball towards the holding bar.
- Then push the golden holder on the holding bar towards the ball.
- The blade holder is now dismantled into two parts and can be prepared.

4.10 Traction device for Rochard system

Ref. 140.260.400

Mounting

- Assemble the handle with the pusher element and the pull bar.
- Insert both into the guide block.
- Allow some space for the interlocking bolts to latch in.
- Place the interlocking bolts in the provided openings.
- Make sure that the bolts are fully secured.

Dismantling

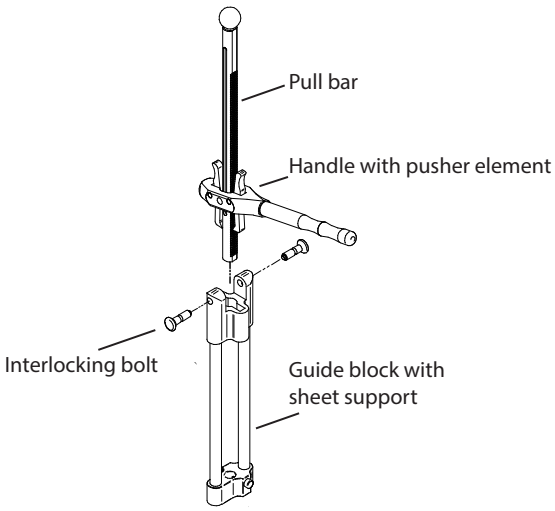
- Remove the interlocking bolts at the side.
- Remove the handle with the pusher element and the pull bar from the guide block.

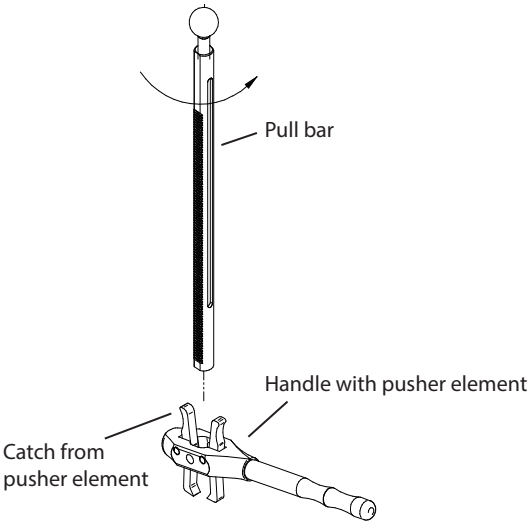
Mounting / Dismantling of the pull bar from the pusher element

- Turn the pull bar 90°. (See illustration).
- Pull the pull bar from the handle with pusher element.
- OR: Squeeze the catches of the pusher element and then pull the pull bar out of the handle with pusher element.

For cleaning and sterilisation

Please dismantle all individual parts. When doing so, the interlocking bolts should be stored in a wire basket.





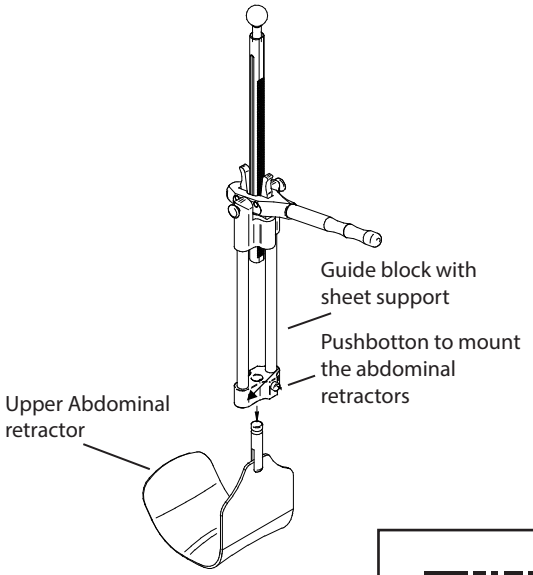
Upper Abdominal retractor
Ref. 114.060.085 UA, etc.

Mounting upper abdominal retractor

- Keep the pushbutton pressed.
- Push the abdominal retractor through the guide block.
- Release the pushbutton.
- To let the abdominal retractor latch in, pull the retractor a little back again.

Dismantling upper abdominal retractor

- Press the pushbutton on the bottom end of the guide block.
- Pull the abdominal retractor from the sheet support with the pushbutton pressed..



Youtube Tutorial

4.11 Traction device for Thorax

Ref. 140.260.400 TX, Ref. 140.260.400 TXW, etc.

Mounting (See sequence of images on p.18)

- Assemble the handle with the pusher element and the pull bar.
- Insert both into the guide block.
- Allow some space for the interlocking bolts to latch in.
- Place the interlocking bolts in the provided openings.
- Make sure that the bolts are fully secured.

Dismantling (See sequence of images on p.18)

- Remove the interlocking bolts at the side.
- Remove the handle with the pusher element and the pull bar from the guide block.

Mounting / Dismantling of the pull bar from the pusher element

- Turn the pull bar 90°. (See illustration).
- Pull the pull bar from the handle with pusher element.
- OR: Squeeze the catches of the pusher element and then pull the pull bar out of the handle with pusher element.

For cleaning and sterilisation
Please dismantle all individual parts. When doing so, the interlocking bolts should be stored in a wire basket.

The TX traction device is frequently used in the area of the costal arches and is for retracting the intercostal space. For this, smaller abdominal retractors can be connected with the TX traction device.
Make sure to apply the traction slowly and evenly.

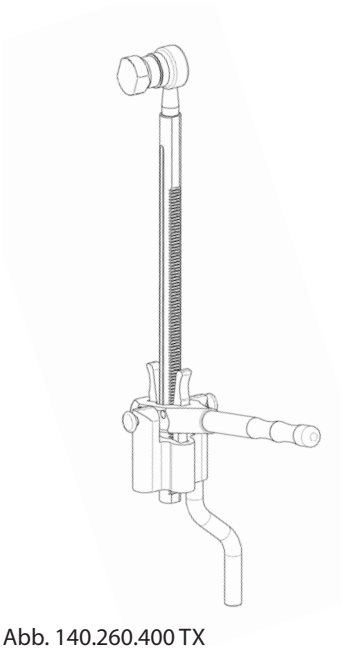


Abb. 140.260.400 TX

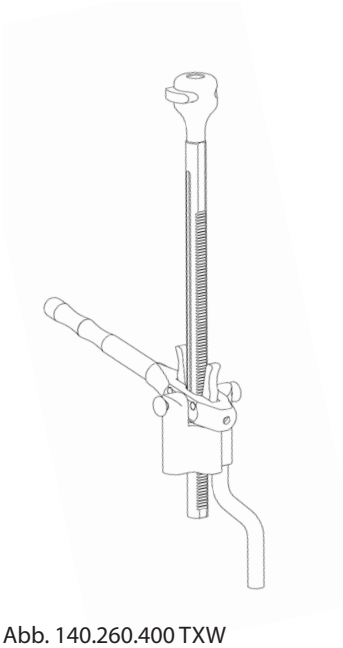


Abb. 140.260.400 TXW

4.12 Camera and instrument holder

Ref. 115.250.008 F

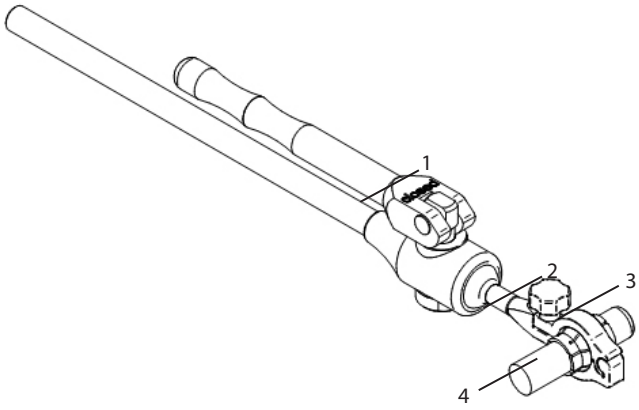
The “flex” camera and instrument holder with eccentric lock and double ball is used for the sterile holding of optics during an operation. This instrument is frequently used in minimally invasive surgery (MIS).

Open the eccentric lock (1). The “OPEN” inscription can now be read and the ball (2) can move freely in the joint.

As soon as you are satisfied with the alignment, close the eccentric lock (1) again. The “CLOSED” inscription can now be read and the ball is fixated.

Open the setting screw (4) to open and close the instrument holder (ball 3).

For various instruments, different balls are available in sizes 3 mm, 4 mm, 5 mm and 10 mm.



5. Situs adjustments

The situs adjustment is decisive for an operation to go smoothly. The right blade holders and instruments must also be selected. Use all retractors so that the surgeon is not impaired and there is no danger to the patient. Also take the time to position the instruments according to your requirements. This saves you from losing time unnecessarily when repositioning instruments.

Check that there is no danger to the patient from operationrelated manipulations.

The positioning, repositioning, and removal of the retractor should only be done under visual control.

This applies to both invasive and minimally invasive operations.

Danger!
Check that there is no danger to the patient from operation-related manipulations.

Danger!
Relieve the tissue regularly and ensure that blood circulation at the wound edges is not interrupted.

Count control:
Count controls before, during, and after the operation are recommended. The components of the Condor® GoldLine system may enter the situs unobserved.

Danger!
Forgotten count controls and visual inspections of the instruments can lead to post-operative retention of foreign bodies. Always carry out count controls. Document the count controls.

Further general information

Attention!
The Surgical Retractor System Condor GoldLine® may not be used when magnetic resonance tomography (MRT) is used simultaneously, as they could impair the functioning of the MRT. Only components that have been approved by Condor MedTec GmbH may be used.

Danger!
Anaesthetic incidents (e. g. pressing) can lead to damage to the parenchymatous organs of the upper abdomen. If anaesthetic incidents occur, loosen retractors or remove the entire barrier.

Danger!
In the event of resuscitation, the surgical retractor system should be removed immediately when no longer needed.

6. Instructions for care and use Surgical Retractor System Condor GoldLine®

Service Life

The Surgical Retractor System Condor Goldline® and the Leg support are related to the product line of „re-usable surgical instruments". The end of the product service life is principally determined by wear and damages due to use. With increasing service life instruments get passive layers subject to material composition, surface condition and cleaning conditions. Passive layers on the instruments neither show quality defects nor affect the functions of the system. And from experience the corrosion risk rather decreases with an increasing passive layer.

In order to ensure long-lasting functionality and safety as weil as accordance with your quality requirements, we recommend you to carry out the foilowing steps when processing the instruments supplied unsterile and reprocessing the contaminated instruments

Pretreatment

It is recommended to carry out reprocessing of the contaminated instruments as soon as possible after use. They should be transported in closed containers. After the use of recyclable instruments, attention should be paid to them not being damaged du ring transport. Prior to cleaning, the instruments have to be disassembled as far as possible.

Because of the corrosion risk and also cleaning factors, long intervals between use and treatment for reuse should be avoided, e. g. overnight or over the weekend. This applies to both „wet" and „dry disposal". The Instrument Preparation Working Group (www.a-k-i.org) recommends, wherever possible, the method of „dry disposal" to be preferred. In case of „dry disposal" intervals of over 6 hours should be avoided.

A mechanical process must be used for cleaning and disinfection. When selecting the cleaning agent to be used, attention must be paid to material compatibility, suitability and effectiveness for cleaning medical devices. The concentrations, temperatures and exposure times specified by the manufacturer of the cleaning agent or detergent and disinfectant as weil as the specifications for rinsing must be observed.

6.1 Cleaning

Cleaning comprises 3 steps:

1. **Precleaning**
   - **1.1. Manual precleaning**
   - **1.2. Precleaning in the ultrasonic bath**
2. **Automatie cleaning according to DIN EN ISO 158833-1 and -2 (in a washer-disinfector unit)**

We recommend the use of detergents that are effective against prions (please take notice of the manufacturer's instructions for application). Current studies analysing decontamination of infectious prions show that a consecutive cleaning with an alkaline detergent (pH value > 10) and disinfection or sterilisation is the most effective method. Please carry out the cleaning steps according to the instructions of the cleaning agent manufacturer! The following points refer to the alkaline cleaner Deconex 28 Alka One from Borer Chemie, with which our products were validated.

1. Precleaning

1.1 Manual precleaning

Saak the contaminated components in cold water (at least drinking water quality) for at least 10 minutes. Please note: The instruments should not, however, lie in water and / or cleaning and disinfection agents over a langer period of time, e. g., overnight / over the weekend.

- Submerse the components and clean them with a soft brush for at least 1 min, making sure that all surfaces are treated. In case of heavy contamination, the duration of the pre-cleaning may differ from those indicated. Cannulings and blind holes should be treated specifically with a brush suited for this purpose.

- Thoroughly rinse the components in running water (at least drinking water quality). The water has to run through the cannulings; blind holes have to be filled and emptied repeatedly.

1.2. Precleaning in the ultrasonic bath

Place the pretreated components in an ultrasonic bath (frequency: 35 to 40 kHz) heated to approx. 40°C, containing cleaning agent (e.g., Deconex 28 Alka One, Barer Chemie) according to the manufacturer's instructions for use and then sonicate the instruments for 10 minutes. After cleaning in the ultrasonic bath, rinse the instruments for 1 min under cold running water (at least drinking water quality).

2. 2. Automatic cleaning (in a washer-disinfector unit cleaning according to DIN EN ISO 158833-1 and -2)

Before you start with the machine cleaning, you should have carried out a pre-cleaning according to point 1. For the automatic cleaning the instruments have to be placed in perforated baskets suited for cleaning (avoid areas that cannot be reached by the water).

Hollow-body instruments must be connected to hollow-body rinsing systems of washer-disinfectors. An alkaline cleaner (pH > 10) should be used according to the manufacturer's instructions for use. Pay attention to the correct dosage! The products are validated for alkaline cleaning. Acidic cleaning agents and disinfectants must not be used.

Also observe the instructions of the equipment manufacturer. A typical cycle should include the following steps and should be carried out according to the instructions to the cleaning manufacturer's instructions:

Example of a cleaning cycle incl. disinfection:
(please note the specifications of the cleaning agent manufacturer)

- at least 2 minutes of pre-washing using cold water (drinking water quality and max. 45°C)
- treat with alkaline cleaning agent for the appropriate exposure time, concentration and temperature as specified by the detergent manufacturer (e.g. at least 5 min with Deconex 28 Alka One, Barer Chemie at 70°C).
- Carry out intermediate rinse(s) according to the detergent manufacturer's instructions (e.g. 1 min with 40-45°C warm drinking water, then 1 min with deionised water (DI water)).

- Thermal disinfection with DI water and max. 93°C - A_o Value ≥ 3000 (e.g. 5 min at 90°C)
- drying cycle (max. 120°C)

The information given above may vary depending on loading and programme.

The information given above may vary depending on loading and programme.

- After disinfection, check all components for visible contaminations (especially in the cannulings and blind holes). If necessary, repeat the cycle or clean manually.

- All parts, especially hinges must be dried with clean compressed air after disinfection.

Caution!
Insufficient drying can lead to corrosion of the instruments! Therefore, make sure that the instruments are completely dry after disinfection.

After disinfection, store the product under the following conditions: completely dry, protected from dust, in a closed container, under low-germ conditions (see section Storage).

Caution!
When storing for several days, disinfect the product again before sterilisation!

The medical devices must be sterilised in the context of reprocessing after disinfection (chapter 6.4). Inspect parts for damage that may affect their functionality.

Damaged and defective instruments have to be sorted out and replaced. Instruments that are to be returned to Condor for repair must also be sterilised beforehand (individual packaging, see section Sterilisation). Please use our form for returns at the end of these instructions for use.

After the instruments have been cleaned and cooled down, areas such as joints, threads, etc. have to be treated with appropriate care products (medical white oil) according to the manufacturer's range of application.

6.2 Sterilisation

The instruments can be sterilised packaged individually (in standard sterilisation bags), in dedicated container systems or all-purpose sterilisation containers. Containers should not be overloaded (please take notice of the manufacturer's instructions).

Sterilisation should be carried out applying a validated method with steam and fractionated prevacuum. (e.g. steriliser according to EN 285 and validated according to DIN EN ISO 17665-1). A residence time of 5 minutes must be adhered to at a temperature of 134°C. All joints and eccentric catches must be in open position during sterilisation.

After sterilisation, store the product in sterile packaging protected from moisture, temperature fluctuations, direct sunlight and dust.

Caution!
Improper storage can lead to lass of sterility - the manufacturer accepts no liability in this respect. The manufacturer accepts no liability in this respect.

Concluding advice
The instructions given above have been validated by the Condor® GmbH as being suitable for the pretreatment of the reusable Surgical Retractor System Condor GoldLine®.
It is the reprocessing person's responsibility to make sure that the reprocessing actually carried out yields the desired results with the equipment, materials, and personnel used in the reprocessing facility. Normally, the procedure has to be validated and monitored routinely for this purpose. In the same fashion, any deviation from the provided instructions by the reprocessing person has to be carefully evaluated as regards effec-tiveness and potential disadvantageous impacts!

We finally confirm that none of the products leave our house prior to passing an appropriate quality control procedure. Nevertheless, complaints are possible. Please examine the articles for completeness and operability and notify us immediately in case of any flaws. Please do not use any flawed articles

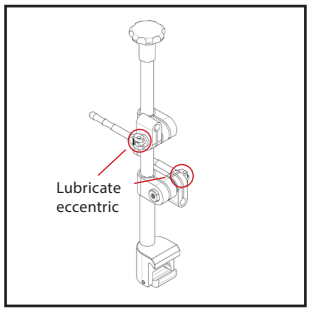
Instruments returned to Condor for repair should also be sterilised before being dispatched (packaged individually, refer to item “sterilisation”). For this, please use our template (form) at the end of these instructions for use. Condor® MedTec GmbH verifies that the above instructions are suitable for the preparation of instruments for reprocessing.

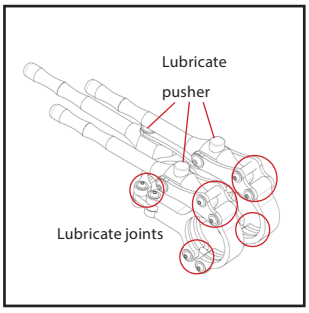
We would like to refer you to further literature:

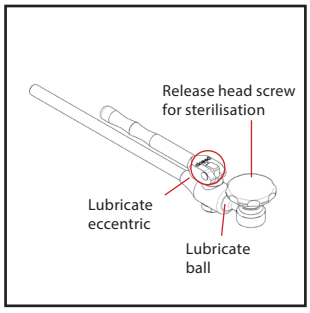
- DIN Taschenbuch 100/1 „Medizinische Instrumente 1“, Beuth Verlag GmbH Berlin, Wien, Zürich, ISBN-13: 978-3-410-20746-7
- DIN Taschenbuch 100/2 „Medizinische Instrumente 2“, Beuth Verlag GmbH Berlin, Wien, Zürich, ISBN-13: 978-3-410-20749-8
- Recommendations of the Robert Koch Institute at www.rki.de/EN
- AKI (Instrument Preparation Working Group) – Proper Maintenance of Instruments (Red Brochure) at www.a-k-i.org

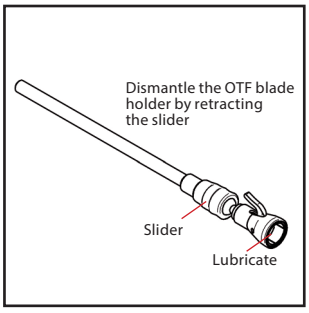
6.3 Care information

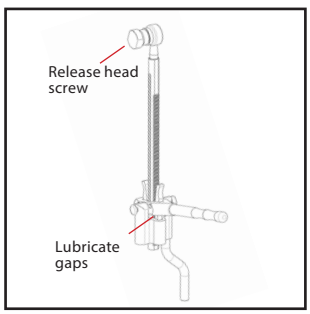
In order to guarantee a long shelf life for the products, some instructions on care should be followed. These are illustrated below as examples for various products, and are to be adopted for similar mechanical components in other items.

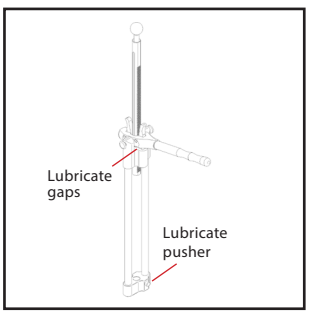


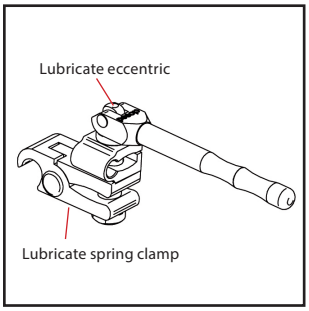


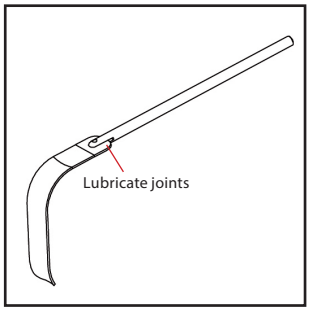


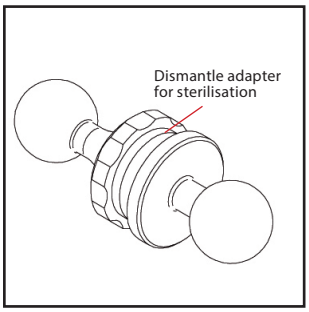


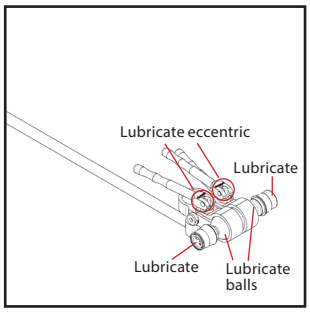


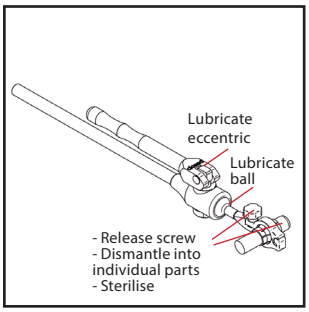


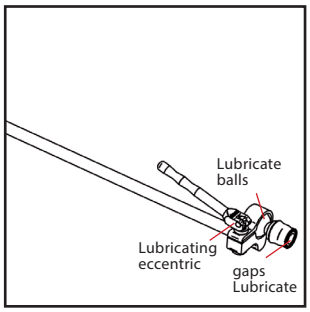




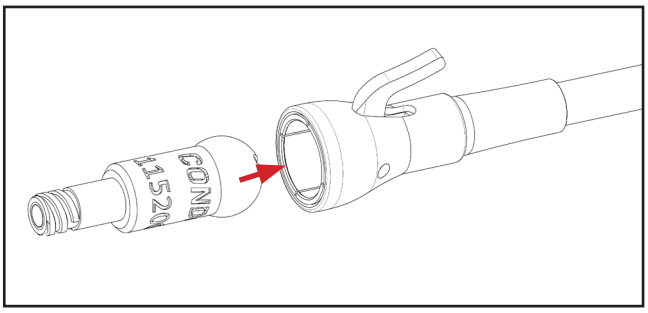








Cleaning adapter for blade holder with ball joint



Connect the cleaning adapter to the water supply, insert it into the blade holder and then rinse it.

7. Maintenance

Careful use, inspections, and maintenance, guarantee functional and operational safety over many years. Inspections are for safety and minimise the risk of malfunctions. We therefore recommend that you perform maintenance / reworking at regular intervals.

Maintenance work should only ever be performed by Condor® MedTec GmbH.

Maintenance improves reliability. It is an essential prerequisite for maintaining functional and occupational safety. We therefore recommend that you preform maintenance at regular intervals. Condor® MedTec GmbH also offers a general overhaul of your systems after expiry of your guarantee.

8. Repairs

In case of malfunctions, please contact the manufacturer Condor® MedTec GmbH exclusively.

The manufacturer will assign an appropriate service provider to you. Please have the article number available, which can be found on the product.

The contact details can be found in chapter 11. technical specification.

Attention!
All serious incidents relating to the product must be notified to the manufacturer and the competent authority of the member state in which the user is located.

9. Replacement parts

Replacement parts you may need should only be acquired from Condor® MedTec GmbH.

Always have the article number available when ordering technica descriptions or replacement parts from the manufacturer. This information is on the laser inscription of the respective product.

10. Disposal

Packaging

Condor® MedTec GmbH will take back the complete packaging on request. Where possible, parts of the packaging will be re-used. If you do not want to make use of this, you can dispose of the packaging via the paper and household waste.

When designing the product, it was ensured that as few composite materials as possible were used. This design concept permits a high level of recycling.

After the product lifespan ends, please dispose of the surgical instruments professionally or use a recycling system.

For all disposal measures, observe the national directives and disposal guidelines.

11. Technical specifications

Manufacturer	
	Condor® MedTec GmbH Dr.-Krismann-Str. 15 33154 Salzkotten GERMANY Tel. +49 5258 9916-0 Fax +49 5258 9916-16 info@condor-medtec.de www.condor-medtec.de

11.1 Classification

The Surgical Retractor System Condor GoldLine® is a class IIa medical device according to Annex IX, rule 7, of the Medical Devices Directive 93/42 EEC, or according to Annex VIII of the Medical Device Regulation (MDR) – (EU) 2017/745, rule 7.

11.2 Applied standards

The Surgical Retractor System Condor GoldLine® fulfils the following standard requirements:

- EN ISO 13485
- 93/42/EWG Appendix II without (4)
- Reg.-Nr./ Reg. No. 44 232 117867
- (EU) 2017/745 (Medical Device Regulation, MDR)

11.3 Certificates

- The current certificates can be downloaded from our homepage (www.condor-medtec.de/downloads).

12. Copyrights

We wish you every success with the Condor GoldLine® wound retractor system and are happy to answer any questions or suggestions you may have.

For reconsignment please note this!

- **Loan instruments back**
- **Instruments back for repair**

Please complete this form and enclose it to your reconsignment.

We hereby confirm the correct desinfection, cleaning and sterilisation of the (loan) instruments enclosed.

Instruments:	Certificate/label:
Hospital (address):	
Department:	
Responsible:	
Date, Stamp, Signature:	

Status: 12.02.2019