



GEISTER®

INSTRUCTIONS FOR USE

IRON ASSISTANT™

PNEUMATIC ENDOSCOPE HOLDER





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Read Instruction



Non sterile



Medical device Class I

Article No. 29-5000



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
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Note: All numbers in brackets refer to the appended appendix A

Pictogram in use

(On the device and labelling)

 Attention, see instructions for use	 NON-sterile
 Reference number	 Reusable
 Lot number, serial number	 Operating pressure
 Latex free	



I - INSPECTION OF THE DEVICE AND ACCESSORIES

I-1 Inspection on receipt

As you receive the parcel containing your Pneumatic Endoscope Holder by the forwarding agent, check that packing is in good condition. In case of damages, note the damage on the forwarding agent's receipt before you sign.

Open the parcel containing the device and check it immediately after receipt. Check if it is complete and in good working order.

Any damage, faulty working order, or missing parts have to be notifying to the dealer or the forwarding company immediately (within 48 hours).

Keep the original packaging, in order to send the device back for any service. Please use the form on our website for:

<http://www.geister.com/Seiten/DE/Service/Wartung.php>



The Pneumatic Endoscope Holder and its accessories are delivered non-sterile. Before use, they have to be cleaned and sterilized according to the instructions in section IV of this manual.

I-2 Accessories checklist:

Unless otherwise specified, your Pneumatic Endoscope Holder 29-5000 must be delivered with the following accessories:

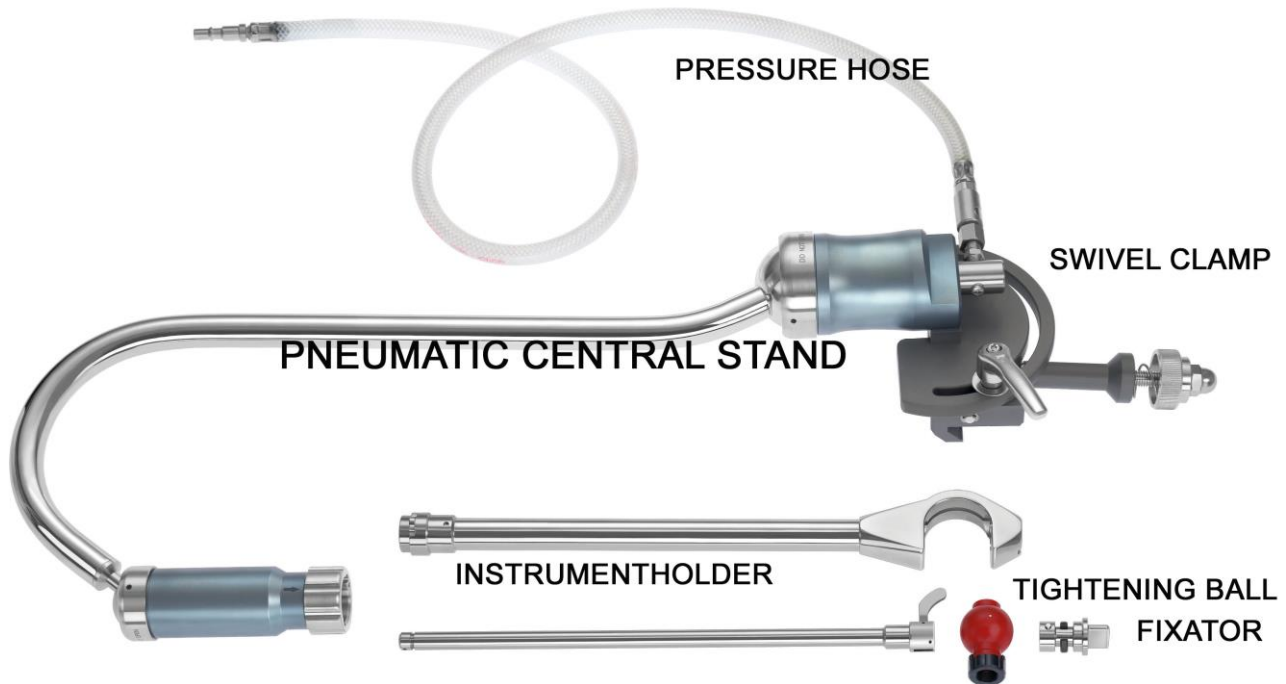
1 Pneumatic Endoscope Holder: (Central stand & Instrument holder). (20/ 21)

1 **A one meter Silicone Hose with quick Stäubli connector. (30)** LT: Vieno metro silikoninė žarna su greita jungtimi.

1 Tightening Ball with inlay for the Instrument. (18)

1 Instruction for use.

2.7



Please refer to the list of accessories at the end of this manual, (see Appendix E).

II - GENERAL INFORMATION – HOW IT WORKS

The Pneumatic Endoscope Holder is a holding and manipulating arm for surgery. It allows the operating team to hold an endoscope in a given position and to change this position immediately with only one hand.

The pressure fixation provides for an easy handling of the Pneumatic Endoscope Holder and a maximal holding power of **5 kg** in case of 7,5 bar. The holding power is related to the gas pressure.

2.3

II-1 Description of parts

The Pneumatic Endoscope Holder consists of:

- The pneumatic central stand, (fixed to the OR table rail) which can either be used below a sterile drape or can be sterilized by autoclaving.
- The instrument holder, which can be completely dismantled and sterilized, may also undergo liquid or ultrasonic cleaning.
- Autoclavable pneumatic tube with quick connector.

II-2 Installation

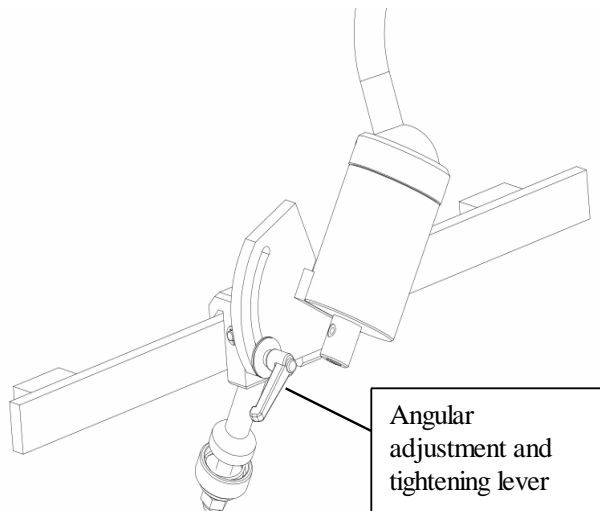
2.4

The central holder has to be mounted with the rail clamp on the OR-table rail. (III-1).

The rail clamp is adaptable to all common sizes of rails found on OR-tables.

The construction allows a 180° turn. The central holder is movable through the lever (40)

LT: Centrinis laikiklis turi būti pritvirtintas su bėgelio spaustuku ant stalo bėgelio. (III-1).
Bėgelio apkaba pritaikoma prie visų įprastų OR stalų dydžių bėgių.



The Pneumatic Endoscope Holder is operated by use of pneumatic pressure:

2.1.2

LT: Pneumatinis retractorius valdomas naudojant pneumatinį slėgį:

- either from the central compressed air supply
- or from a compressed air cylinder with a pressure regulator (CO₂; AIR; NITROGEN)

LT: * arba iš centrinio suspausto oro tiekimo

* arba iš suslėgtų dujų baliono su slėgio reguliatoriumi (CO₂; ORAS; AZOTAS)

2.1.1

The required pressure is 5 to 8 bar (optimal performance 7-8 bar).

LT: darbinis slėgis nuo 5 iki 8 bar

II-3 Operation

2.2

Pressing the control lever at the distal end with on finger releases all the 3 ball joints simultaneously. Now it is possible to place the endoscope in the desired position only with one hand. The Pneumatic Endoscope Holder will become tightened as soon as the control lever is released.

LT: 3 alkūnės

III – ASSEMBLY AND OPERATION

The assembling, the fixation on the table, the operation with pressure as well as the functional handling should first be practiced outside of an active surgery.

Recommendations about the positioning on the OR-table and maintaining the sterility during the procedure can be found in part (V).

III-1 Mounting the Pneumatic Endoscope Holder on the OR-table:

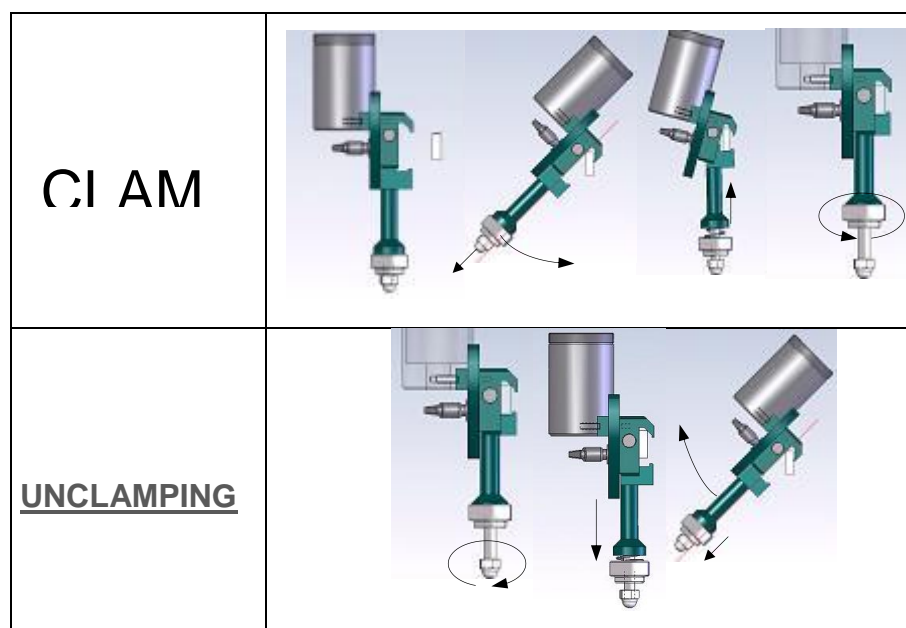
Attach the arm on the OR-table rail; tighten the screw manually (39).
Adjust the swivelling rail clamp to the desired gradient and firmly tighten with the locking handle (40).

IMPORTANT :

Check the tightness of the attachment before holding an instrument (grip on the rail, fixation of the angular adjustment, and the overall stability and rigidity of the rail itself).

Connect the supply hose (30) made from silicone with textile mesh to the “Stäubli”-connector on the base below the central stand. The connector has a check valve (31) and can be swivelled, however **do not remove the connector from the central stand !**

HOW TO FIX the swivelling rail clamp on the OR-table



III-2 Assembly of the instrument holder to the pneumatic central stand

First: Assembling the instrument holder:

Select the proper inlay for the tightening ball and insert it with the threaded end. Fix it with the black ring on the opposite side. Turn the ring four times clockwise to fix the inlay in the thread. Do not overtorque or tighten too much, so it will later allow an easy insertion of the endoscope.

NOTE:

The tightening ball can be inserted or removed anytime once the lever is pressed and the ball spanner (19) is disconnected.

Insert the inner tube (24) into the Instrument Holder; insert the lever into the slot on the closed side. Before doing that, make sure that the spiral spring (23) is placed on its right position inside the Instrument holder.

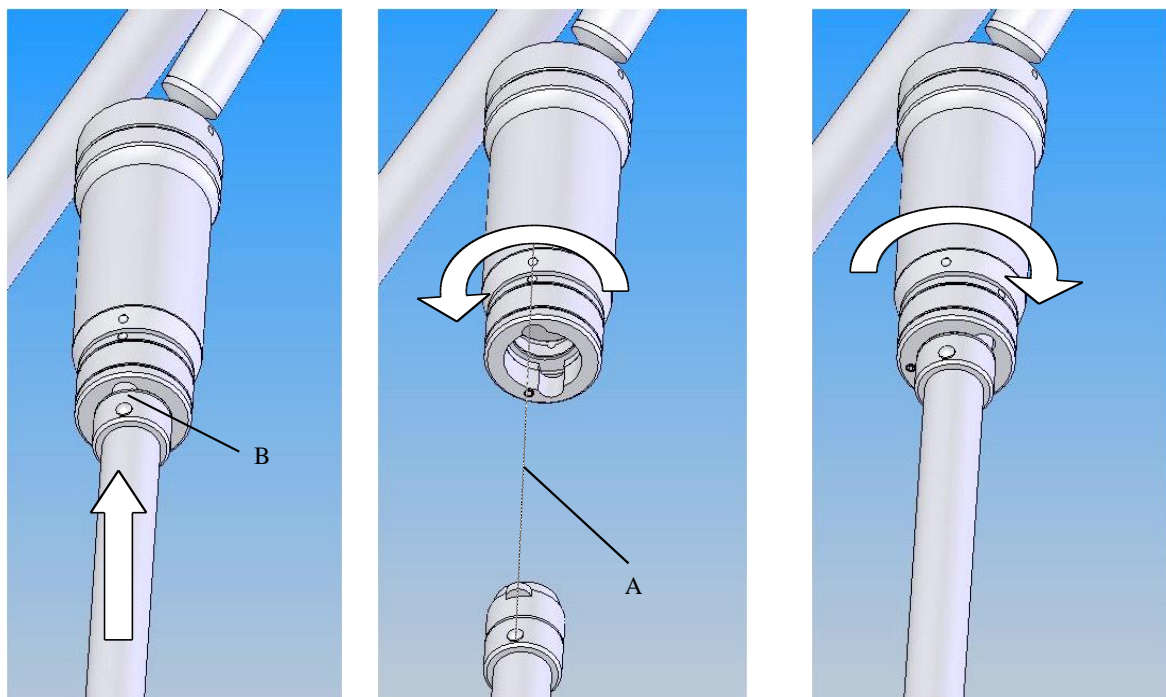
Insert the scope holder (red plastic ball with inlay) into the mount of the inner tube (24). Place the ball spanner with the pins into the slot. Push it to the end, and turn the spanner 90° until the pins are adapted to the slots.

III-3 Connecting the Instrument Holder with the pneumatic central stand

IMPORTANT: The system must be without pneumatic pressure

The Instrument Holder is prepared according to part III-2.

The pneumatic central stands housing ends in a lock nut distally (16). This nut is marked with a dot-point, the housing is marked with an arrow. Turn the nut counter-clockwise until both are in one line. Also the Instrument holder is marked with a dot-





point. If this dot-point is in one line with the dot-point of the nut and the arrow, the Instrument holder can be inserted into the housing. Fix the Instrument Holder by turning the nut clockwise 45°.

NOTE: For dismantling follow the reverse order.

Please read also attachment “ C” carefully.

III-3 Connection to the central pressure supply

The Pneumatic Endoscope Holder can be connected through the extension tube line (33); directly to the central pressure supply of the OR; different adapters (36) are available. A pressure between 7 – 8 bar is considered optimal.

III-4 Connection to pressure cylinders

Make sure that the seal of pressure reducer (3) is in good condition. Visually inspect the hose for wear or damage. Do not use the device if any damage is visible. Then connect the pressure reducer by tightening the screw (2) firmly **by hand**.

Connect the end of the hose (32) directly to the connector of the pressure reducer if the bottle is placed under the OR-table, or use an extension hose with quick connectors (34/33).

Always keep the pressure cylinder in an upright position with the tap facing up.

IMPORTANT:

- **Never use pressure cylinders in horizontal position, or with tap facing down.**
- **Never lubricate the joints or pressure reducer rings**
- **Never try to unscrew the reducer (2) while the tap (1) is open, or while the circuit is under pressure. First, turn off the tap, bring the pressure in the circuit down (by pressing on the Pneumatic Endoscope Holder control lever). Then unscrew the connection (2) by hand.**

III-5 Putting the unit under pressure and testing

Caution:

Avoid putting the Pneumatic Endoscope Holder under pressure when it is not attached properly on the stand.

Bottle supply: turn on the tap (1) and make sure that there is no leakage. For CO₂ the manometer must display a pressure of 50 bar (700psi). If it is under 30 bar (435psi), change or refill the bottle.

Compressed air supply: connect the supply hose to the operating room wall socket.

The Pneumatic Endoscope Holder remains rigid in the selected position. To move the instrument, press the control lever (17) and release it once the desired position is reached.

Insert an instrument or endoscope with a diameter corresponding to the inlay. Press the control lever (17) continuously while introducing the instrument. The control lever (17) should also be pressed while moving the instrument inside the ball, or while taking it out.

Caution:

Repeated manipulation of the Pneumatic Endoscope Holder without an instrument or Endoscope reduces the life expectancy of the ball joint.

***A Instrumentholder can be ordered with
29-5001***



***A Ball set can be ordered with
29-5002***



III-6 End of test

Deflate the gas:

- turn off the tap, or disconnect the hose from the central compressed air supply and disconnect the quick connector (32, 33).
- press the remote lever to deflate the gas circuit.
- remove the instrument holder from the stand, and remove the stand from the OR- table (*Chapter II*)



Warning: Avoid removing the instrument holder from the stand while the unit is still under pressure

IV - CLEANING - DESINFECTION – STERILIZATION

After use the device must be properly cleaned as soon as possible.

IV- 1 Cleaning/disinfecting:

- Dismantle the instrument holder as follows:
Separate the instrument holder from the central stand (turn the nut counter- clockwise),
Turn the tightening ball (19) a quarter of a turn and remove it.
Remove the inner tube (24 and its spring (23)) from the instrument holder. (chapter III) Remove the inlay from the tightening ball.
- The Instrumentholder (16) (Art. No. 29-5001) can be automated cleaning, avoid instructions for use for surgical instruments (Surgical Instruments GA_IFU en_e)

IMPORTANT: Take care of the dismantled components – don't lose them!

- Soak the contaminated instrument holder immediately after use in a cleaning solution (neutral pH detergent), following the manufacturer's instructions concerning concentration and duration. **Do not allow contaminated instrument to dry after use.**
- Use a soft brush to clean incrustated stains.
- Rinse thoroughly with distilled water.
- Dry with compressed air.
- After cleaning, reassemble in reverse order; be sure to include the spring.
- Before sterilizing, verify the condition and functioning of the different parts, particularly the more sensitive parts such as the joints, extension tubing, etc.; lubricate the moving parts such as the control lever (17) with a special lubricant for surgical instruments; do not lubricate the ball joints (13 & 14)
- In case of decontamination with a liquid, first dismantle and soak, and then thoroughly rinse in distilled sterile water.

Pneumatic Central Stand.

- Wipe off any liquid on the device with a gauze pad dipped in alcohol or water.
- Dry with a dry cloth.



- Do not use solvents.

ATTENTION !

Never expose the central stand to liquids that might penetrate the ball joints, never put it in a washing machine or ultra sound cleaning systems as **DAMAGE MAY OCCUR**. The ball joints (13/14) may not be oiled, greased or lubricated with other substances.

IV - 2 Sterilisation

Do not sterilize the Pneumatic Endoscope Holder and accessories over 135°C. Per AAMI TIR 12 1994 "Designing, testing, and Labelling Reusable Medical Device for reprocessing in Health Care Facilities" the following parameter have been chosen for achieving effective sterilization:

2.5

**Steam sterilization by Autoclave for instrument holder and pneumatic central stand
max: 134°C – 18 min – 2 bar**

Follow manufacturer's recommendations for implementation of Asepsis

- If the pneumatic stand is not sterile, see section V-3 Sterile drapes.
- If the pneumatic stand is sterilized, see section V-4.

ATTENTION !

In case of sterilizing the pneumatic central stand with instrument holder, only the part of the hose joined to the stand can be sterilized by autoclave (white translucent woven silicone hose) (30). The rubber extension hose (connection supply hose) is not autoclavable.

The pressure reducer cannot be sterilized or soaked.

DO NOT STERILIZE THE PRESSURE REDUCER OR THE BLACK RUBBER EXTENSION HOSE

V – FITTING FOR SURGERY

The operating and handling of the Pneumatic Endoscope Holder and its accessories should be performed only by trained healthcare professionals familiar with its use, assembly / disassembly and care.

V – 1 Interaction with the instrument being held

The Pneumatic Endoscope Holder is designed to hold endoscopes of various sizes and instruments with a rigid cylindrical shaft that fits with the manual tightening ball



joint. Accordingly it has been classified as a class I medical device according to the EEC/93/42 Directive on Medical Devices. Used for holding an endoscope, the Pneumatic Endoscope Holder should be classified class II according to U.S. FDA.

Consequently, the choices of the type of instrument held by the Pneumatic Endoscope Holder as well as its applications are the sole responsibility of the surgeon. This is of primary importance when it is used with instruments that are likely to entail particular risks.

The specifications described below could help in evaluating possible device compatibilities.

The compression resistance of instruments held by the Pneumatic Instrument Holder:
Supplied with 8 bars, the linear force which can be applied to the articulated DISTAL joint can reach **1000 N (10kg)**.

This strength could cause the elastic ball joint to break if the Pneumatic Endoscope Holder is put under pressure without an instrument or endoscope installed.

With normal usage and if the appropriate ball joints are used, all force is evenly distributed by the ball joints and there is no risk of damage to the instruments, particularly standard endoscopes.

In case there is a doubt upon instrument resistance, use a lower pressure (5/6 bar).

Electrical risk

In certain conditions, especially when all the articulations of the arm are in a locked/stopped position, there could be electrical conduction between the instrument holder (distal part) and the operating table rail. In this case, the instrument holder ball joints in Plastic continue to assure electric insulation of the instrument being held.

ATTENTION!

However, if using electrical or electromagnetic active instruments or devices sensitive to electrostatic discharges, the user should make sure there are no conductive part of the instrument to come into contact with a metal part of the arm (e.g., handle, part of an endoscope, etc.).



Unintended emission of substances or energy:

The Pneumatic Endoscope Holder is operated by pressurized gas. If the system is not deflated by pushing the lever no gas is emitted.

Only in case the ball joints are released by pressure deflation, gas will be emitting. The volume in case of simple repositioning under normal atmospheric pressure is between 2 to 3 litres per minute.

When using a sterile cover the emitted gas will float to the rail clamp.

Energy emission:

No emission at all from electromagnetic energy (no power supply, consumption or emission).

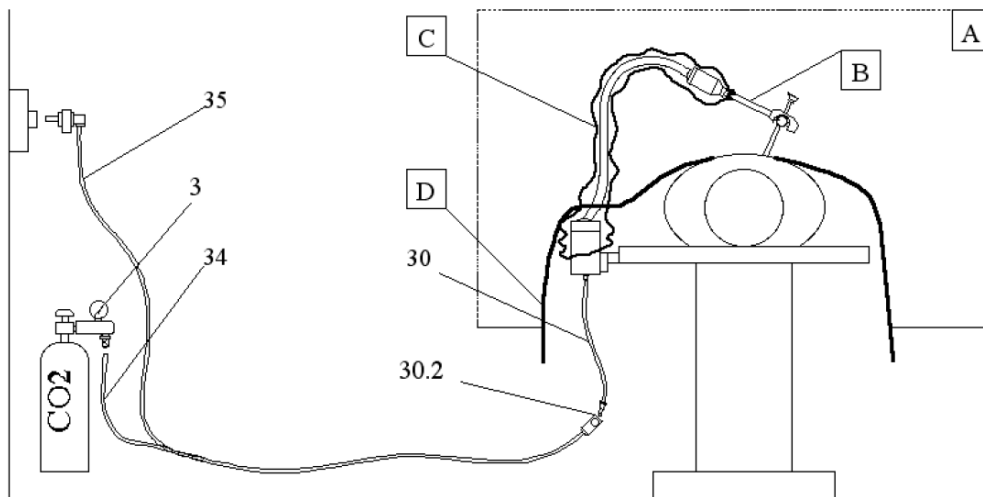
V - 2 Positioning of the Pneumatic Endoscope Holder

The easiest way to manipulating and using it is achieved by placing the Pneumatic Central Stand on the rail opposite or lateral to the surgeon.

IMPORTANT: Avoid reducing or entirely obstructing the working space of the surgical team.

V – 3 sterile positioning with pneumatic central stand are unsterile

Not sterile pneumatic central stand – sterile instrument holder



Pressure reducer on CO ₂ bottle (quick connector) (35)	A	Sterile field
Supply hose, autoclavable part (length –1m) (non-sterile) (30)	B	Sterile instrument holder
Wall gas supply (6-8 bar) CO ₂ or air	C	Non-sterile stand, use of a single use sterile tube or camera cover.
	D	Operating drapes

ATTENTION

surgeon are sterile – assistant are non-sterile !

After positioning of patient and anaesthesia, the assistant fixing the rail clamp on the table in position described in V-2. The arm of the pneumatic central stand has to be move in the farthestmost position from the patient. This is limited by the working space of the distal ball point (13).

The surgeon is placing the sterile covers in a common way. On the side, where the Pneumatic Endoscope Holder is mounted, the cover has to be placed on the base over the distal ballpoint.

The Assistant now moves the pneumatic central stand to a vertical position, the proximal ball point should be directed towards the surgeon.

The surgeon puts the instrument holder into a suitable sterile tube cover. Now he is able to connect the instrument holder with the pneumatic central stand. The nut will be turned by the assistant to fix the connection (III-3) and appendix C.

The surgeon put the sterile tube cover over the Pneumatic Endoscope Holder to cover the pneumatic central stand completely. The distal end of the sterile tube cover has to be properly connected with sterile covering of the table. The proximal

end has to be fixed on the instrument holder. The assistant starts the pressure supply.

The Pneumatic Endoscope Holder is now ready for use.

The surgeon selects the lever (17) position, down or on top, before he places the endoscope in the tightening ball. The positioning is to realize by a half turn.

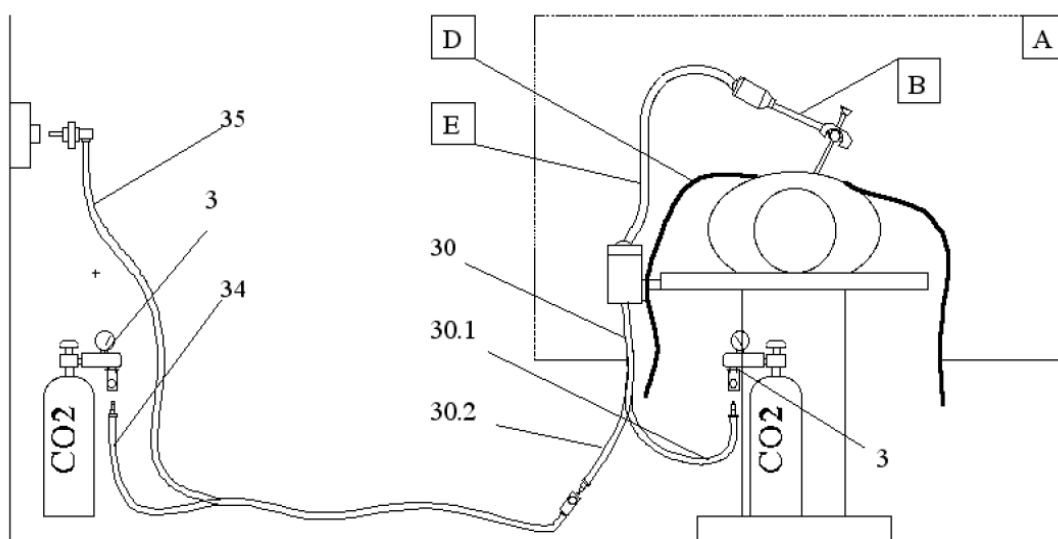
IMPORTANT!

For laparoscopic procedures:

Before fixing the endoscope with the Pneumatic Endoscope Holder all trocars should be on place, otherwise this activity can destroys the endoscope.

V - 4 Pneumatik Endoskope Holder used as a sterile device: the whole arm is autoclaved

Sterile pneumatic central stand and sterile instrument holder



Pressure reducer for medical CO ₂ bottle (3)	A Sterile field
Autoclavable gas supply hose (1 m) (30)	



30.1: Connection to pressured CO ₂ bottle 30.2: Connection to a non-sterile extension hose Extension hose for connection to CO ₂ bottle (34) Extension hose for connection to wall gas (35) .CO ₂ or air connectors (6-8 bar) The pressure supply of gas can be alternative from wall connector or an medical pressure cylinder with pressure regulator	B Sterile Instrument Holder (autoclaved) D Sterile operating drapes E Sterile stand (whole Endoboy autoclaved) set up over operating drapes
--	---

ATTENTION

surgeon are sterile – assistant are non-sterile !

After positioning of patient and anaesthesia; the surgeon drapes the table with sterile covers in a common way.

The surgeon is mounting the sterile Pneumatic Endoscope Holder on the rail, passing through the sterile cover. Now he can give out the sterile gas supply hose (30) to the non-sterile assistant.

Surgeon is fixing the instrument holder (16) on the proximal ball point.

(15) (III-3) and appendix C.

The assistant starts the pressure supply. The Pneumatic Endoscope Holder is now ready for use.

The surgeon select the lever (17) position, “down or on top”, before he places the endoscope in the tightening ball. The positioning is to realize by a half turn.

The Pneumatic Endoscope Holder is now ready for use.



The surgeon select the lever (17) position, “down or on top”, before he place the endoscope in the tightening ball. The positioning is to realize by a half turn.

IMPORTANT!

For laparoscopic procedures:

Before fixing the endoscope with the Pneumatic Endoscope Holder all trocars should be on place, otherwise this activity can destroys the endoscope.

V - 5 On the end of the procedure

- Stop the pressure supply. Close the swivel valve on the pressure cylinder or disconnect the wall connector. Press the lever (17).
- Open the tightening ball fixation and remove the endoscope.
- Disconnect the instrument holder from the pneumatic central stand.
- Disassemble the instrument holder and the tightening ball, clean it and prepare it for sterilization. The pneumatic central stand then to be processes according to chapter IV.
- Suitable preparation according to chapter IV.

VI - TECHNICAL SPECIFICATIONS - CARE/MAINTENANCE

VI-1 Specifications

Class I medical device classified according to the EEC/93/42 Directive on Medical Devices

In compliances with FDA 510K, class II product.

CO₂ or compressed air pressure supply from 5 to 8 bar.

The resistance and torque depends on the pressure of the gas.

Main materials used:

- Mechanical parts: stainless steel 316L, aluminium 2017A + hard anodization (rail clamp)
- Screws, pins, springs: stainless steel 302



- Seals, hoses: Viton, PTFE, and silicone
- Elastic ball joints: POM (Delrin) medical grade

No part or accessory is composed by latex



VI-2 Care - Maintenance

The essential care and maintenance of the Pneumatic Endoscope Holder consists of following cleaning instructions (see section IV) and regular inspection of all sensitive parts such as seals, mobile parts, and pneumatic hoses.

IMPORTANT:

An annual general inspection by the manufacturer is necessary to keep the device in good working order. This maintenance procedure includes a complete inspection of the device, replacement of worn parts, and the final factory inspection is repeated.

Only by this, proper function is guaranteed for every 12 month past of general inspection.

In the absence of this annual inspection, the manufacturer ceases to guarantee that the Pneumatic Endoscope Holder's operation conforms to specifications.

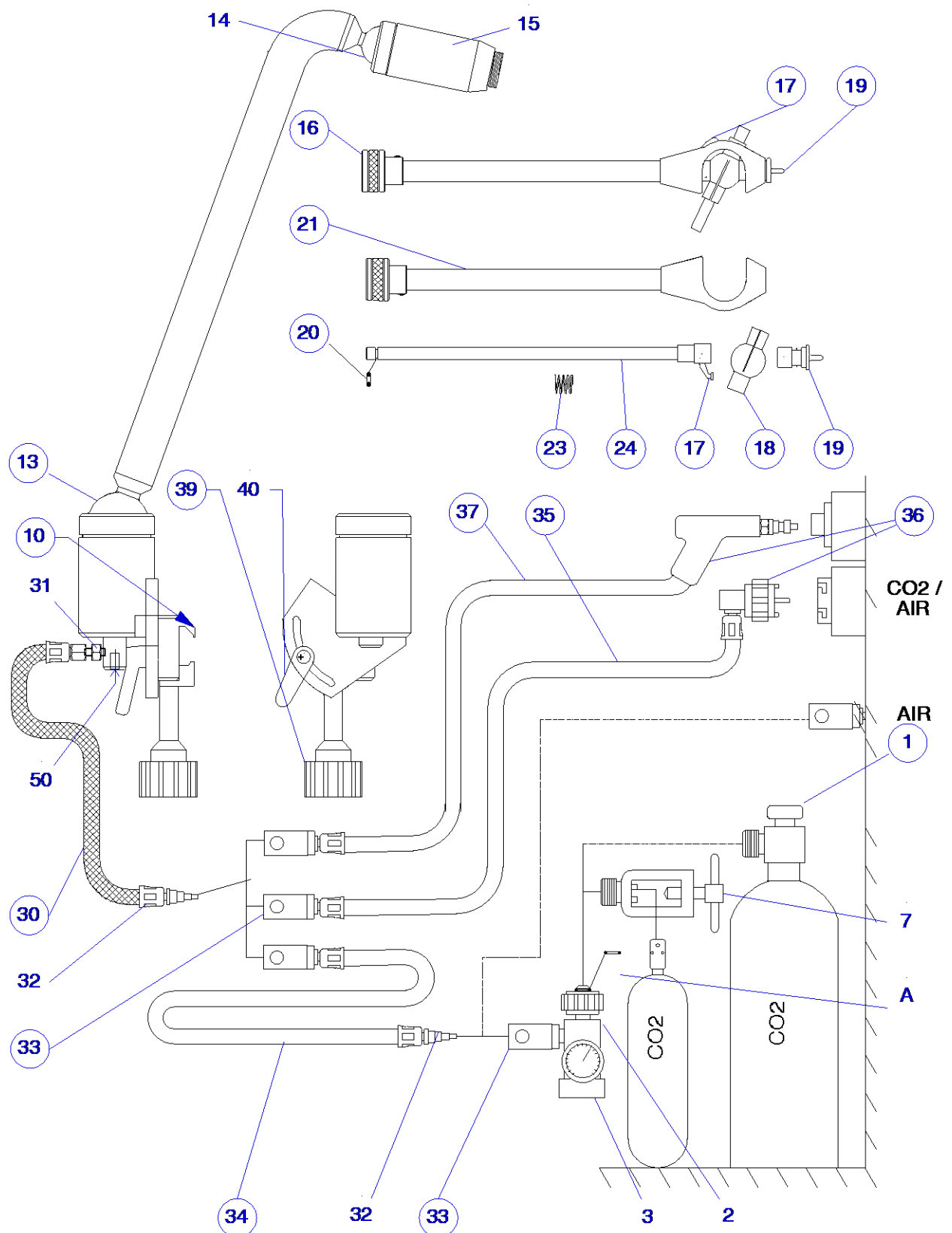
A service manual including technical information on the product is available on request. All the maintenance and repair operations have to be performed by people trained and qualified for repairing the Pneumatic Endoscope Holder, as well as **using only original spare parts.**

The manufacturer declines responsibility in case of accident or if the device is used without correct maintenance or if it has been modified.

Note:

The firmness of the proximal joint can be adjusted with the help of a screwdriver at the base of the arm (50) to allow more or less free movement of this joint.

APPENDIX: A Index of Spare Parts 29-5000



This drawing shows possible connections of pressure supply are not an part of 29-5000

Appendix B: Installation of pneumatic central stand with swivel clamp on the rail of operation table.

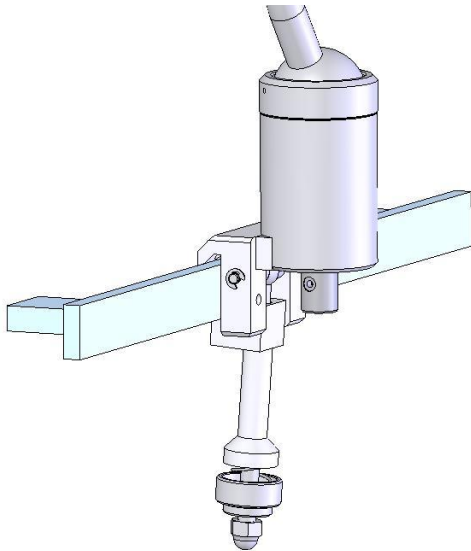
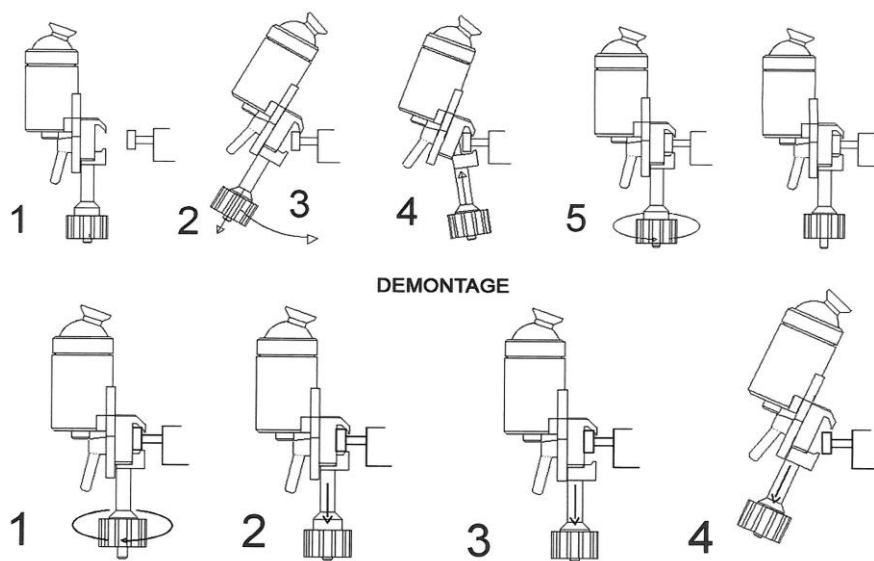
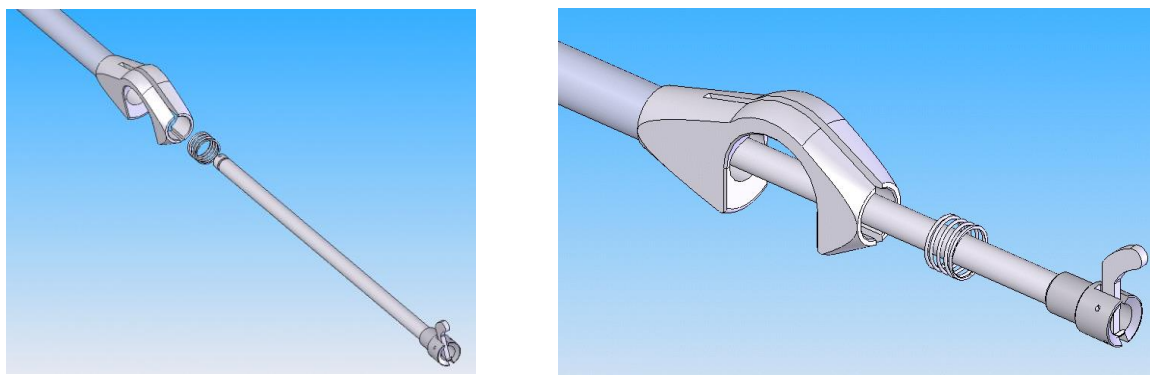


Diagram for fixation of swivel clamp on the rail of operating table

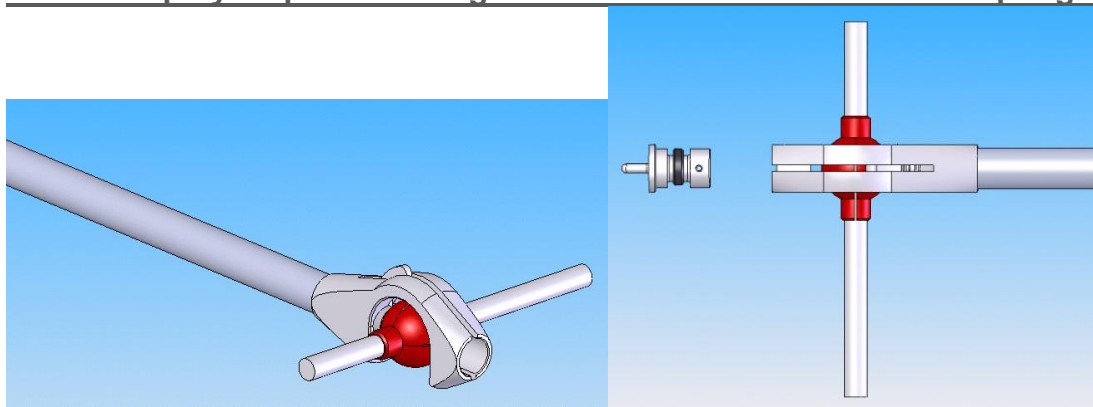
MONTAGE

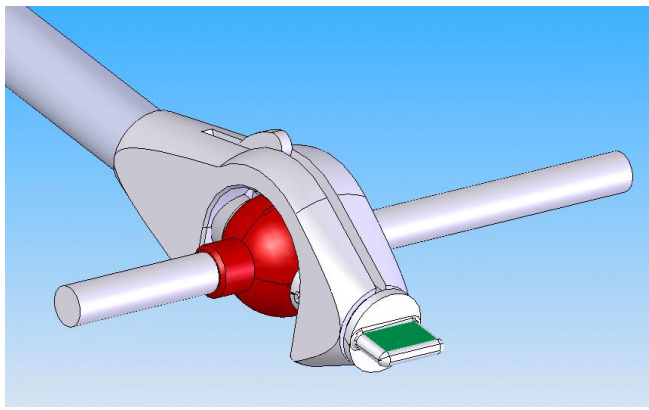
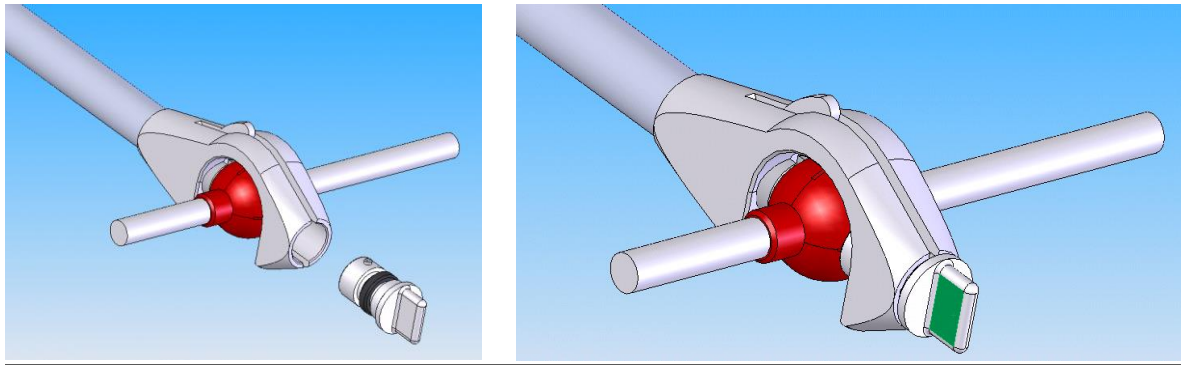


Appendix C: Assembling instrument holder with the pneumatic central stand.



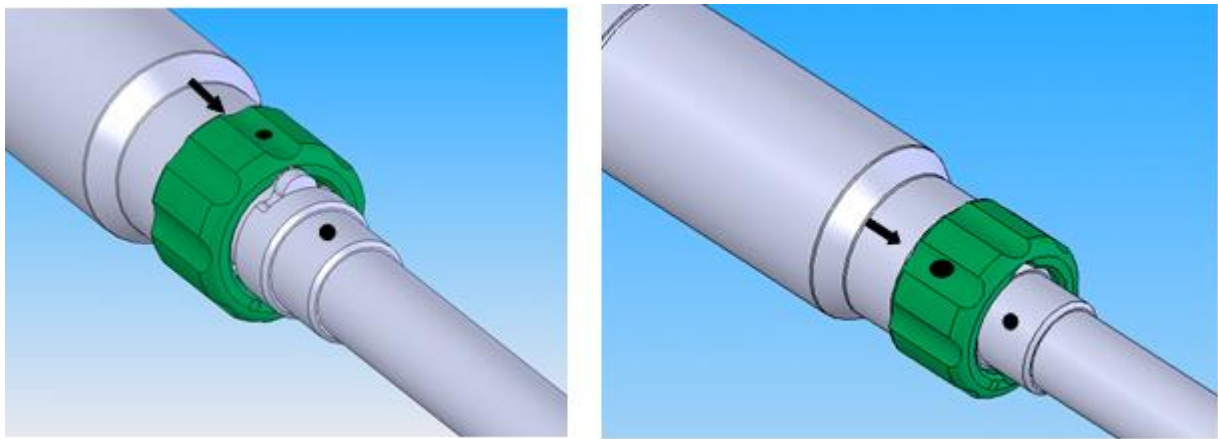
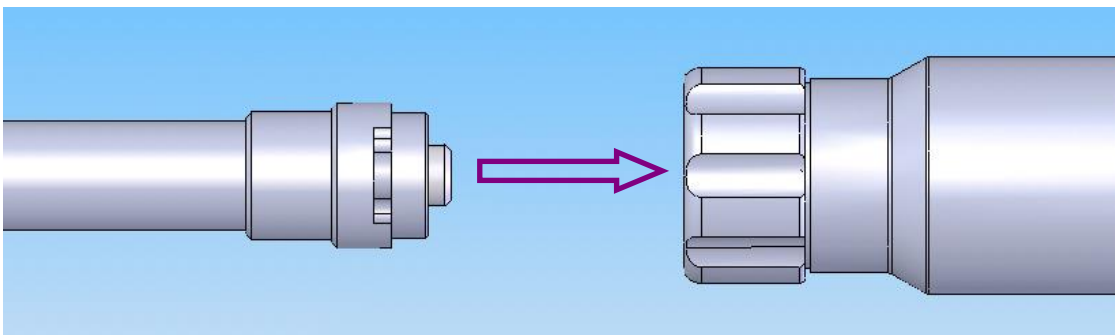
Follow step by step assembling the instrument holder before adapting it.

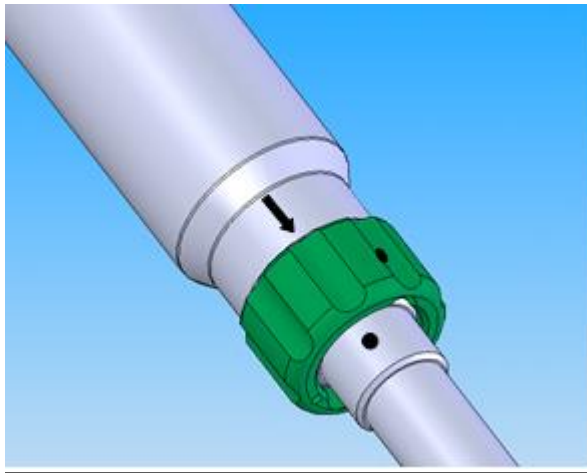




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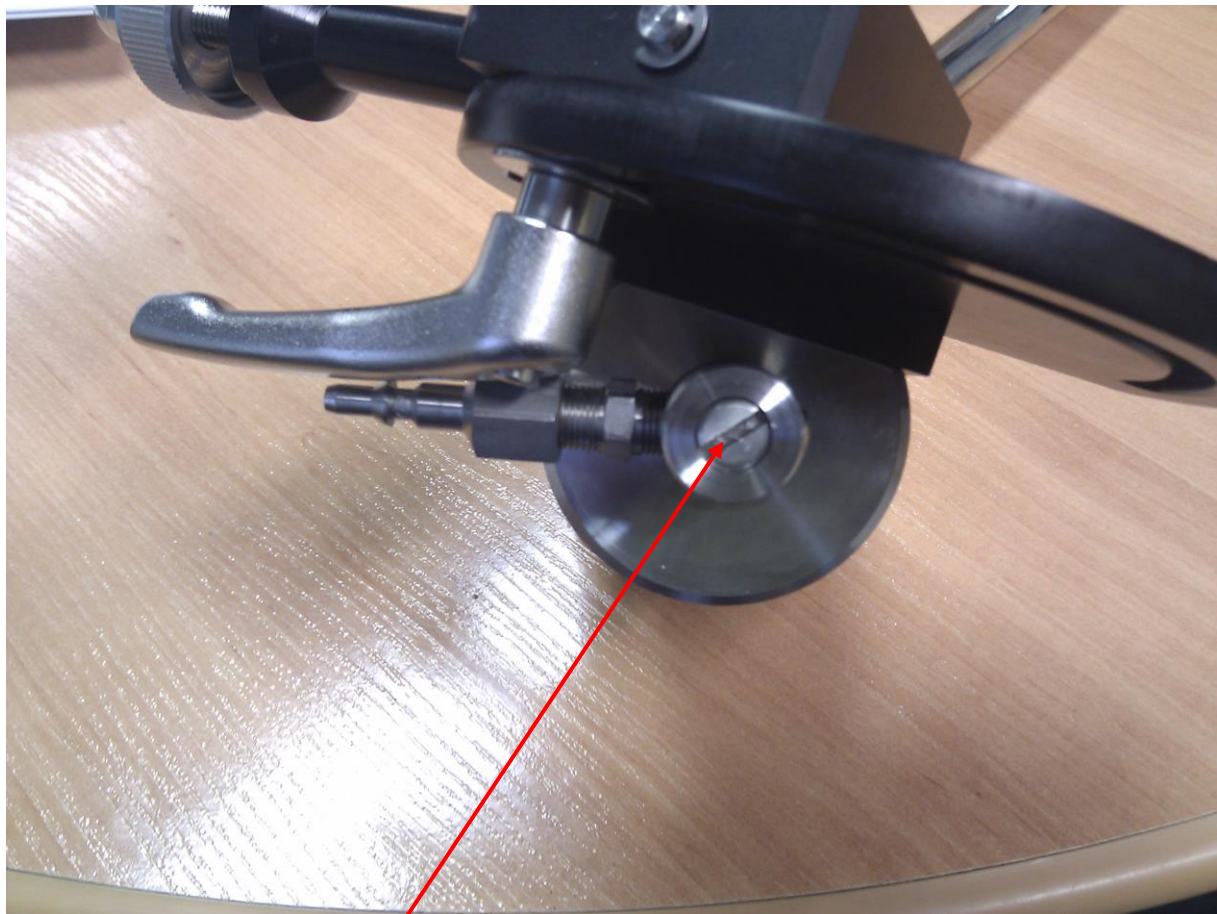
APPENDIX C – PART 2



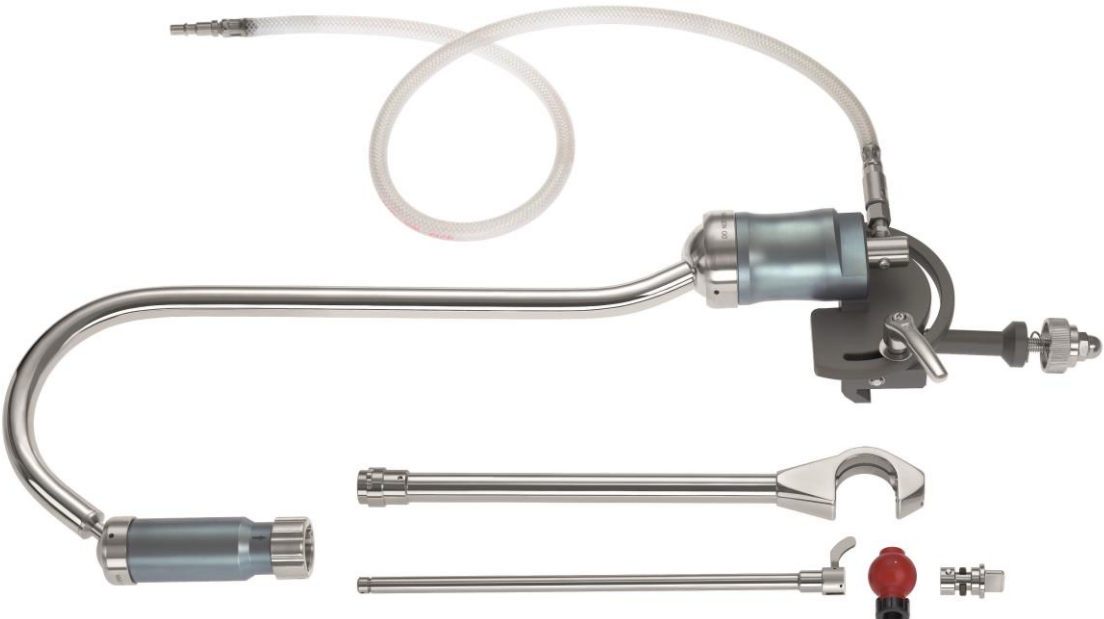






For more details please read chapter III-2 & III-3

APPENDIX D: Adjusting the firmness of the proximal ball joint



APPENDIX E: Spare parts and accessories

29-5000	 <p>IRON ASSISTANT™ Pneumatic Endoscope Holder complete</p>
2.5	 <p>LT: Adapteris skirtas greitai ir steriliai prijungti reikiamą priedą</p> <p>Standard length instrument holder with push to release system.</p>
	 <p>Spring for instrument holder.</p>
2.8	 <p>Manual tightening ball set: One ball with locking nut + 5 mm sheath + 10 mm sheath</p> <p>LT: Adapteris - fiksatorius skirtas endoskopinei 10 mm skersmens optikai</p>
	 <p>10 and 5 mm sheath</p>