»ACCESS INSTRUMENTS«

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Content

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In order to keep hazards to patients, users or third parties as low as possible, the instructions for use must be carefully observed. The application, preparation and testing of the instruments may only be carried out by trained specialists.

The access instruments of Tekno-Medical Optik-Chirurgie GmbH are delivered non-sterile and must go through the complete cleaning and sterilization cycle before the first and each subsequent use.

1 SCOPE

MD

The scope of these instructions for use refers to the following products: Access instruments of Tekno Medical Optik-Chirurgie GmbH (see product listing in the last paragraph).
These include, but are not limited to:

- trocars (sleeves, pipes, thorns),
- Shafts (arthroscopic shafts, resectoscope shafts, cysto-urthroscope shafts, diagnostic shafts, nephroscope shafts, albaran levers, permanent irrigation shafts, etc.),
- Hasson attachments, dilators and obturators,
- Optics bridges,
- Veress needles.

2 INSPECTIONS

Before each use of surgical instruments, they must be inspected for fractures, cracks, deformations, damage and functionality. Sensitive areas such as taps, seals, sealing surfaces and all moving parts must be inspected with particular care. Worn, corroded, deformed, porous or otherwise damaged instruments must be sorted out.
The stainless steels used for production form specific passive layers as protective layers. These steels are only partially resistant to the attack of chloride ions and aggressive media and liquids!

Damaged products must not be used!

Instruments must be checked for functionality before each use!

(Instruments with taps, seals, flaps and connections should also be checked for leaks.)

Possible loss of pneumoperitoneum due to leaking taps or missing / damaged seals!

3 HANDLING

The instruments must not be overloaded by twisting or levering, as this may cause damage or breakage of instrument parts. The instruments may only be used by surgically trained medical professionals.
These instruments are not intended for use on the heart or the central nervous and circulatory system!

4 PURPOSES

If used outside the intended purpose, complications or damage to the patient may occur, and a re-operation may be necessary.
Based on his specialist knowledge, the user decides whether the instrument is suitable for the respective application.
Duration of use: Short-term (intended for uninterrupted use for a period of up to 30 days under normal conditions) according to Regulation (EU) 2017/745

4.1 Veress needles (insufflation cannulas)

The Veress needle is used to introduce carbon dioxide or other gases into the abdomen during laparoscopic procedures. The incoming gas raises the abdominal wall and thus minimizes the risk of injury to the internal organs during surgery. It consists of an inner and outer shaft. The inner shaft is pushed back at the time of the incision via a spring, thus exposing the tip of the outer shaft. After that, the blunt, distal end of the inner shaft slides forward again and covers the tip of the outer shaft so as not to injure internal organs.

4.2 Trocars

Trocars are instruments with the help of which an opening is created in a body cavity (e.g., abdomen, chest cavity) and kept open by a tube. Gas (usually CO_2) can also be introduced into the body via the trocar to maintain the surgical field.
For example, the tube and trocar are inserted into the abdomen through the abdominal wall. After pulling the trocar out of the tube, the surgeon then has the option of looking into the abdomen with optics (endoscope) or performing minimally invasive surgery with gripping, cutting and other instruments within the abdomen.

4.3 Shafts

These instruments are used as guides for other surgical instruments or optics (endoscopes). Shafts may also have interfaces (connectors) to other instruments or devices.

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5 INDICATIONS

The access instruments of Tekno-Medical Optik Chirurgie GmbH are used for minimally invasive procedures. These are primarily used to create and maintain access to the surgical field or as guides for other surgical instruments, such as work sockets or optics.

6 CONTRAINDICATIONS

The use of access instruments in the context of minimally invasive procedures is generally contraindicated when the use of other surgical techniques is indicated and in health conditions that inhibit the healing process, such as:

- impaired blood supply,
- extreme obesity,
- acute and chronic, local or systemic infections,
- deep or superficial infections,
- systemic diseases and metabolic dysfunction,
- mental states that make it impossible to participate in the rehabilitation program (Parkinson's disease, alcoholism, drug use, etc.),
- Allergies or other reactions to the material used.

In addition, there are contraindications,

- in case of general inoperability;
- in the absence of readiness on the part of the patient;
- if the technical requirements are not met.

Not for use on the heart and on the central circulatory and nervous system.
The doctor in charge must decide on the basis of the patient's general condition whether the intended application can be carried out.

7 PATIENT POPULATION

Apart from the contraindicated uses listed in these instructions for use, there are no restrictions on the patient population.

8 COMBINATIONS

The products of this group can be connected to insufflators or suction devices via standardized Luer-Lock connections. The access instruments are usually used in combination with other minimally invasive instruments, such as optics, work shafts, retaining pliers, scissors, etc. These combination products are not part of this product group, so the use and combination (with side effects and interactions) cannot be described in this instruction.
The responsibility for the use of our access instruments in combination with third-party instruments lies solely with the attending physician.
The compatibility of the instruments and devices with each other must be checked before each procedure.

9 DISPOSAL

If the instruments can no longer be repaired and reconditioned, the instruments must be disposed of in accordance with the applicable country-specific regulations and laws.

10 WARNINGS

Instruments made of stainless steel must not be placed in physiological saline solution (NaCl), prolonged contact can lead to pitting or stress corrosion. Instruments may only be sterilized after prior cleaning and disinfection. **Do not** touch sharp edges and tips.

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11 REPROCESSING

In general, surgical instruments may only be reprocessed by persons who have the necessary expertise for the intended activities. Detailed information on the reprocessing of surgical instruments can be found in the "**Red Brochure**" of the AKI. Under www.a-k-i.org you will also find links to laws, standards and publications of processing expert committees. Due to the product design and the materials used, no defined limit of maximum feasible applications can be set. The service life of medical devices is determined by their function and gentle handling. Frequent reprocessing has little effect on the product. The end of product life is usually determined by wear and damage caused by use. The legibility of the marking has been verified over 200 preparations.

11.1 On-site preparation

Remove coarse dirt from the instruments immediately after use. Do not use fixing agents or hot water (>40°C), as this can cause residues to set and negatively affect cleaning results. Rinse cavities with cold water.
If rinsing with cold water is not possible, the instrument must be wrapped in a damp cloth to prevent residue from drying on the instrument.

11.2 Transport

Safe storage in a closed container and transport of the instruments to the reprocessing site to avoid damage to the instruments and contamination to the environment.

11.3 Preparation for decontamination

If possible, the instruments must be disassembled or opened for reprocessing. The instruments must be stored on machine-compatible instrument carriers in a dishwasher-safe manner. The condition of the instrument panels must not impair the subsequent cleaning and disinfection by means of sound or rinsing shadows.

11.4 Manual pre-cleaning

11.4.1 General

Immerse instruments in cold deionized water for at least 5 minutes. If possible, disassemble the instruments and clean them under cold running water with a soft brush until no residue is visible. Rinse cavities, bores, and threads with a pressure washer for at least 10 seconds (pulsed method, minimum pressure 2 bar). Place instruments in an ultrasonic bath at 40°C with a 0.5% alkaline or enzymatic cleaner and sonicate for 15 minutes. Remove instruments and rinse with cold water. The cleaning solution should be changed at least once a day, and more often if necessary. Excessive soiling impairs the cleaning effect and increases the risk of corrosion. National laws and regulations must be observed.

11.4.2 Veress needles

Veress needles, due to their long and thin lumens, may still contain internal contaminants after manual pre-cleaning. Therefore, they must be rinsed several times with the tap open before disassembly and machine cleaning. Rinsing solution or demineralized water should preferably be used for this purpose.

11.5 Automated cleaning

Place open instruments in a sieve tray on the trolley and start the cleaning process. Disassemble instruments into their individual parts as much as possible (see instrument-specific instructions). Instruments with a flushing or Luer-lock connection must be connected to the washer-disinfector's flushing port using a flushing adapter.

Step	Parameter	
Pre-rinsing 1	Rinsing-temperature + water quality	Cold tap water
	Exposure time	60 s
Pre-rinsing 2	Rinsing-temperature + water quality	Cold tap water
	Exposure time	180 s
Cleaning	Cleaning-temperature	45°C
	Water quality	Tap water
	Exposure time	300 s (worst case condition) / RKI Recommendation: 600 s
	Detergent	Neodisher Medizym
	Concentration	0,50 %
Neutralization	Rinsing-temperature	40°C
	Water quality	Tap water
	Exposure time	180 s
	Neutralizing detergent	Neodisher Z
	Concentration	0,10 %
Post-rinsing	Rinsing-temperature	40 °C
	Water quality	Deionized water
	Exposure time	120 s

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11.6 Automated (thermal) disinfection

Step	Parameter	
Thermal Disinfection	Disinfection-temperature	90°C (A_0 3000)
	Water quality	Deionized water
	Exposure time	300 s
Dry	Drying of the outside of the instruments by the drying cycle of the washer-disinfector. If necessary, manual drying can also be achieved with the help of a lint-free cloth. Dry cavities and channels of the instruments with sterile compressed air. Allow products need to cool down to room temperature.	

For UK: The washer disinfection cycle should run at a minimum of 90°C for a minimum of 1 minute.

11.7 Functional testing

Visual inspection of cleanliness; if necessary, assembly of the instruments, maintenance and functional test according to the operating instructions. If necessary, repeat the reprocessing process until the instrument is optically clean. All plastic parts and seals must be checked after sterilization to ensure that they are not cracked, brittle or worn. If damaged, these parts must be replaced with new original parts. Treat instruments with moving parts with care oil, e.g.: TK95100-00. Taps and valve pistons must be greased before sterilization (we recommend our tube grease Z0000128110). Defective or damaged instruments must be discarded immediately. (Further information can be found in DIN 96298-4.)

11.8 Maintenance of the instruments

"Maintenance" basically means the application of instrument oil or instrument milk (emulsion of white oil in water). Products with movable jaws, joints, joints or with metallic sliding surfaces must be treated with steam-sterilizable care products based on paraffin oil. The paraffin oil must comply with the applicable pharmacopoeia and be physiologically harmless. (Further information can be found in DIN 96298-4.)

11.9 Packaging

Select standard-compliant packaging of the instruments for sterilization according to DIN EN ISO 11607-1, DIN EN 868-2 and DIN EN 868-8.

11.10 Sterilization

Sterilization of the products using a fractionated vacuum process (according to DIN EN ISO 17665), taking into account the respective national requirements.

Pre-vacuum	3 times
Sterilization temperature	134 °C
Sterilization time	5 min
Drying time	20 min.

The use of other sterilization methods is beyond our responsibility.

Sterilization parameters UK:

Sterilization of the instruments by applying a fractionated pre-vacuum process (according to Health Technical Memorandum 01-01 Part C):

- Heat up to a minimum sterilization temperature of 134° - 137°C (maximum temperature 137°C).
- Minimum holding time: at least 3 min.

11.11 Storage

The sterilized instruments must be stored in suitable packaging in a dry, clean and dust-free environment and at a constant level of humidity. The distance between the floor and the shelf should be at least 30cm.
The storage period is to be determined by the user himself.
Protect from sunlight!

11.12 Information on the validation of the reprocessing

The following materials and machines were used in the processing process:

Detergent	Neodisher Medizym 0,5 % (v/h)
Neutralisator	Neodisher Z 0.1% (v/v)
Washer-disinfector (RDG)	Miele PG 8535
Steam-autoclave	Lautenschläger ZentraCert
For details see test reports: 23277 / 23278 / 23279 (CleanControlling Medical GmbH & Co. KG, 08-2021)	

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12 ADDITIONAL INSTRUCTIONS

If the chemicals and machines described above are not available, it is up to the user to validate his process accordingly.
It is the responsibility of the user to ensure that the remanufacturing process, including resources, materials and personnel, is suitable to achieve the required results.
The state of the art and national laws require the following of validated processes.

During reprocessing, the temperature acting on the instrument should **not** exceed **140°C**.
In principle, mechanical cleaning and disinfection are always preferable to manual cleaning. With mechanical cleaning and disinfection, there is greater safety in the process.
Never use metal brushes, metal sponges or abrasive cleaning agents for manual cleaning/pre-cleaning. Strongly alkaline cleaning agents damage plastics and anodized coatings.
The instruments must not be sterilized in hot air sterilizers.
Do not use caustic cleaning agents. Do not use strong oxidizing cleaning agents. Agents with a neutral pH value (7.0) are best suited.

13 REPORTING PRODUCT ISSUES

In accordance with the requirements of Regulation (EU) 2017/745 on medical devices and our quality management system, all product problems must be reported to the manufacturer.
During business hours you can reach us by phone at +49 (0) 07461 / 1701-0.
Outside of regular business hours, please send an email to safety@tekno-medical.com.
Serious incidents must also be reported to the competent authority in their locality.

14 WARRANTY

The products are made of high-quality materials and undergo quality control before delivery. If errors still occur, please contact our service. Tekno-Medical cannot guarantee that the products are suitable for the respective procedure. This must be determined by the user himself. Tekno-Medical assumes no liability for incidental or resulting damages. Tekno-Medical accepts no liability if it is proven that these instructions for use have been violated.
Attention: In the case of the use of the instruments in patients with Creutzfeldt-Jakob disease, Tekno-Medical declines any responsibility for reuse.

15 SERVICE AND REPAIR

Do not carry out any repairs or modifications to the product on your own. Only authorized personnel of the manufacturer are responsible and provided for this.
Defective products must have gone through the entire remanufacturing process before being returned for repair.
For returns, use our RMA application form and the decontamination certificate.
You can find the forms on our homepage: https://www.tekno-medical.com/de/service/reparaturservice/

16 SYMBOLS

The symbols used in this instruction and on the label have the following meaning according to DIN EN ISO 15223-1:

	Attention!		Manufacturer
MD	Medical device		Date of manufacturing
NON STERILE	Non-sterile		Read the instructions for use
REF	Catalogue number		Protect from sunlight
LOT	Lot-number		Store in a dry place
UDI	Unique device identification		
CE 0483	CE mark with the number of the notified body: **mdc – medical device certification GmbH** Kriegerstrasse 6, D – 70191 Stuttgart		

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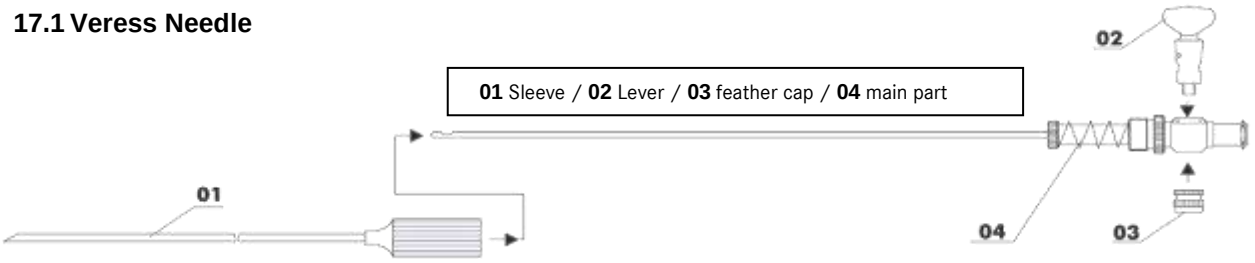
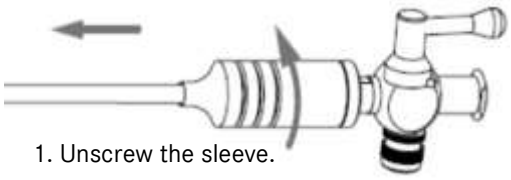
17 ASSEMBLY & DISASSEMBLY

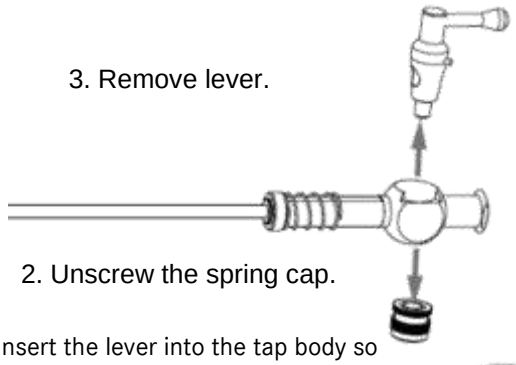
17.1 Veress Needle



Disassemble the instrument



1. Unscrew the sleeve.

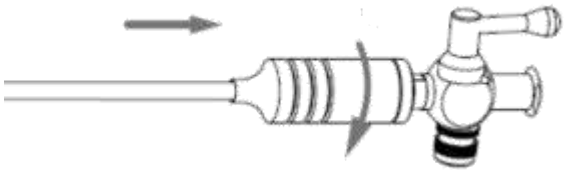


2. Unscrew the spring cap.

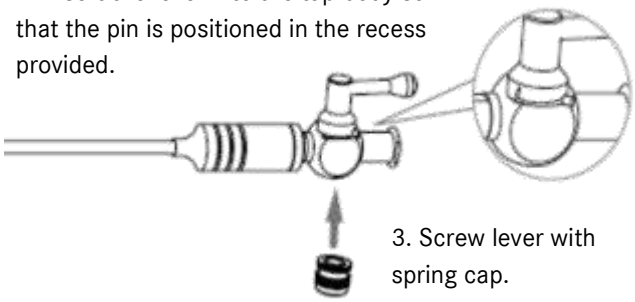
3. Remove lever.

Assembling the instrument

1. Insert the sleeve and screw it tight.



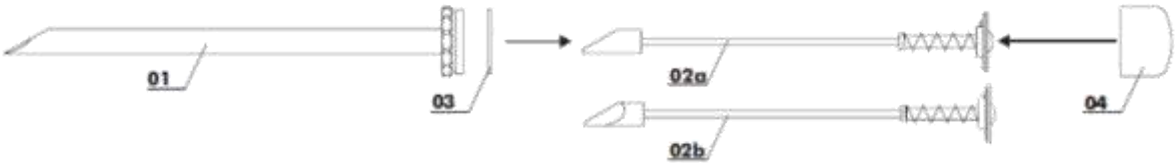
Outer and inner shafts of the same Veress cannulas **do not** exchange with each other!



2. Insert the lever into the tap body so that the pin is positioned in the recess provided.

3. Screw lever with spring cap.

17.2 Safety trocars



01 Piercing Sleeve / **02a** Spring Rod / **2b** Spring Rod Safety Trocar / **3** O-ring / **04** Cap

Assembling the instrument

Insert the piercing sleeve **01**over the spring rod **02a** or **02b** and rotate it until the guide pin is in the guide slot. Hold the grommet **01** by the knurling and screw it to the cap **04**.
Check the instrument for proper functioning.

17.2.1.1.1.1.1

Disassemble the instrument

Please only dismantle pre-cleaned instruments!
Unscrew the cap **04** from the grooving sleeve **01** and tighten the spring rod **02a** or the spring rod. **02b**.
The safety trocar is now completely dismantled.

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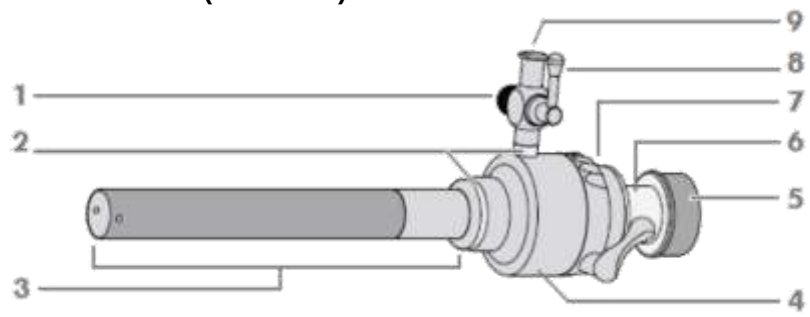
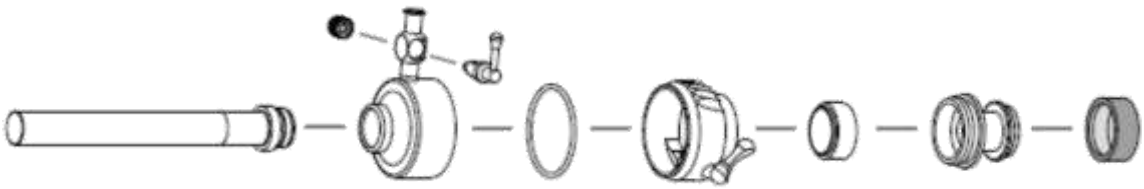
17.3 Trocar sleeve (automatic)

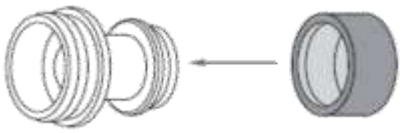


1 Spring Cap
2 Color coding
3 Shaft Tube
4 Housing
5 Sealing cap
6 Sealing cap holder
7 Main part with lever
8 Tap
9 LL connection

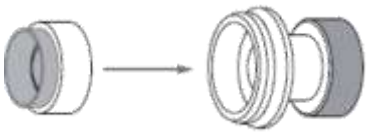


Assembling the instrument

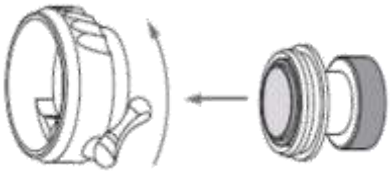
1. Put on the sealing cap.



2. Insert the gasket so that the sealing lip protruses.

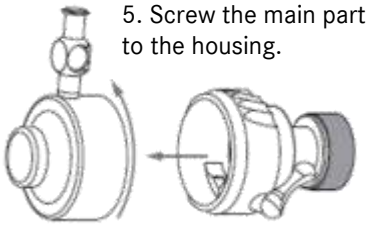


3. Screw the sealing cap holder to the main part.



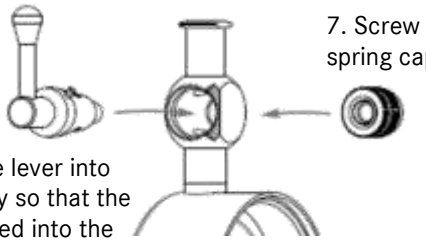
4. Put on the O-ring.

5. Screw the main part to the housing.



6. Insert the lever into the tap body so that the pin is inserted into the gap.

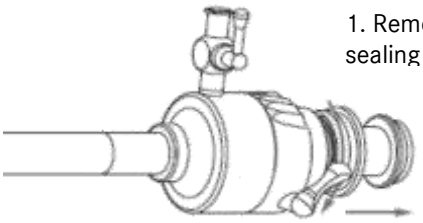
7. Screw lever with spring cap.



8. Screw on the shaft tube.

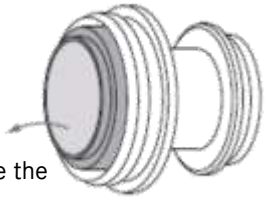
Disassemble the instrument

1. Remove the sealing cap.



2. Unscrew the sealing cap holder.

3. Unscrew the main part.
4. Remove the O-ring.



5. Remove the seal.

6. Unscrew the spring cap,
7.Remove levers.
8. Unscrew the shaft tube.

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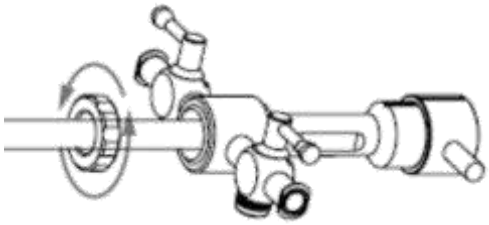
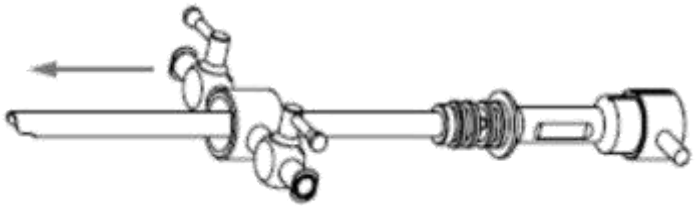
17.4 Arthroscopy shaft

Disassemble the instrument



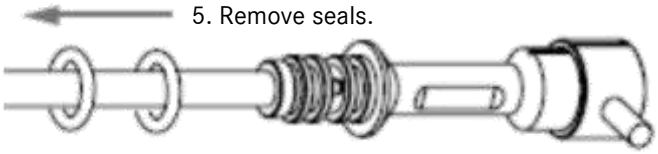
1. Loosen and remove the connection nut.



2. Remove the cover ring.

3. Unscrew the spring cap(s).

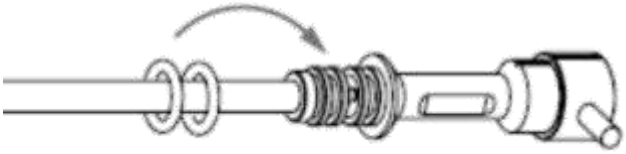
4. Remove levers.



5. Remove seals.

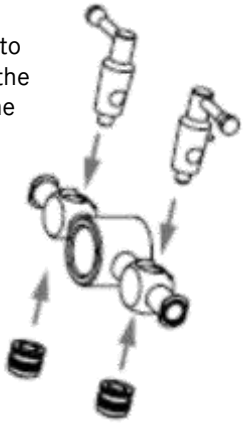
Assembling the instrument

1. Attach the seals.

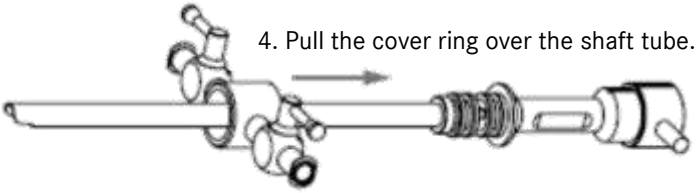


2. Insert the levers into the tap body so that the pin is positioned in the gap.

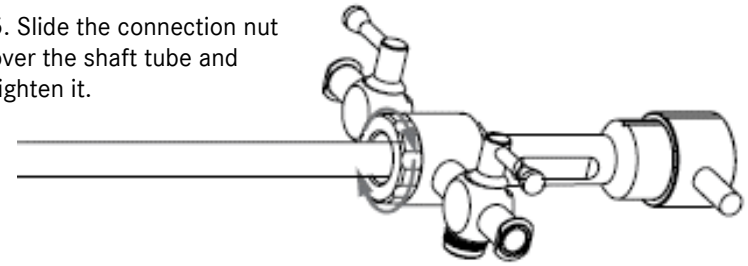
3. Screw levers with spring cap.



4. Pull the cover ring over the shaft tube.



5. Slide the connection nut over the shaft tube and tighten it.



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18 PRODUCT LISTING

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6150-30	704-012*	704-157	704-4025*	730-162	790-531*	791-056	793-024*
6150-35	704-012-15	704-158	704-4026	730-170	790-533*	791-057	793-027*
6150-40	704-013	704-160	704-4027*	730-171	790-535*	791-058	793-028*
6150-45	704-014	704-161	704-4030*	730-172	790-542	791-060	793-040
6150-50	704-015	704-162	704-4033	730-173*	790-543	791-061	793-049
6150-55	704-016	704-170	704-4037	730-210	790-544	791-064	793-050
6150-60	704-016-07	704-171	704-4039	730-220	790-545	791-065	793-052
6152-30	704-016-15	704-172	704-4080	790-040	790-546	791-070	793-121
6152-35	704-016-20*	704-175	704-4081	790-042	790-573	791-072	793-123
6152-40	704-017	704-176	704-4082	790-044	790-574	791-078	793-126
6152-45	704-019	704-177	704-4084	790-046	790-575	791-079	793-127
6152-50	704-020	704-200	704-415	790-047	790-589*	791-130	793-321
6152-55	704-021*	704-203	704-416	790-048	790-615	791-131	793-323
6152-60	704-022	704-204	704-418	790-050	790-617	791-132	794-040
6154-30	704-022-15	704-207	704-419	790-052	790-619	791-133	794-041
6154-40	704-023	704-216	704-435*	790-054	790-621	791-134	794-042
6154-50	704-024	704-217	704-436	790-055	790-623	791-136	794-043
6154-55	704-025	704-218	704-437*	790-059	790-625	791-137	794-044
6154-60	704-026	704-232*	704-438	790-2701Z*	790-642	791-138	797-311
6168-11	704-026-15	704-233*	704-439*	790-316	790-643	791-140	797-311I
6182-24	704-027*	704-238	704-440	790-317	790-644	791-142	797-312
6195-23	704-027-15	704-240	704-450	790-318	790-645	791-143	797-313
6197-23	704-028	704-241	704-451*	790-319*	790-646	791-144	797-314
6200-60	704-029	704-242	704-452	790-321	790-662	791-250	797-321
25224-72	704-030*	704-243	704-452-15	790-322	790-691	791-251	797-321I
39110-01*	704-031	704-244	704-453	790-323	790-696	791-252	797-322
39111-03*	704-032	704-245	704-454*	790-324	790-697	791-253	797-323
39112-01	704-033	704-3002*	704-460	790-324U	790-725	791-256	797-324
39112-02	704-034	704-3006*	704-460-15	790-325	790-726	791-257	797-325
39112-03	704-035	704-3007*	704-461*	790-327	790-727	791-258	797-326
39112-04	704-036*	704-3008*	704-461-15	790-328*	790-807	791-2601	797-327
39112-05*	704-037*	704-3009*	704-462	790-330-XL*	790-808	791-2601A	797-331
39113-01	704-038*	704-3036*	704-462-15	790-331	790-809	791-2601O	797-331I
39113-02	704-060	704-3038*	704-463	790-332	790-810	791-2602	797-332
39113-03	704-061	704-3039*	704-464	790-335*	790-811	791-2604	797-333
39113-04	704-062	704-3052*	704-470	790-337*	790-812	791-2606	797-340
39113-05	704-063*	704-3056*	704-472	790-342*	790-813	791-2608	797-342

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39113-05S*	704-064*	704-3057*	704-475	790-343	790-814	791-2610	797-343
39113-06*	704-065	704-3058*	704-475-07	790-344	790-815	791-2612	797-345
39114-02*	704-066*	704-3059*	704-475-15	790-345	790-828	791-2614	797-437
39114-03*	704-067	704-359*	704-476	790-345-XL*	790-829	791-2720	797-445
39114-04*	704-068*	704-362	704-477*	790-362	790-833	791-2721	797-493
39115-01	704-070	704-364*	704-478	790-375	790-843	791-2722	797-494
39115-02	704-072	704-366*	704-479	790-376	790-852	791-2723	797-573
39115-03	704-073*	704-366/13*	704-479-15	790-382*	790-862	791-2724	797-574
39117-01	704-076	704-367	704-481	790-416	791-014*	791-2801	797-575
39117-02	704-077	704-368	704-487	790-428*	791-024	791-2801A	797-589
39117-03	704-078	704-389K	704-488	790-429*	791-026	791-2801O	799-311
39117-04	704-087	704-390K	704-489*	790-437*	791-030	791-2802	799-312
39175-01	704-088	704-397K	704-491	790-438*	791-031	791-2802A*	799-313
39175-02	704-090	704-398K*	704-497	790-439*	791-032	791-2805	799-321
39205-10	704-091	704-399G*	704-498	790-473	791-033	791-2806	799-322
39205-12	704-092	704-399K	704-499*	790-474	791-034	791-2900	799-323
39205-14	704-093	704-400*	712-440	790-475	791-035	791-2902	799-324
39205-20*	704-095	704-4001*	712-441	790-491	791-037	791-2904	799-325*
39205-21*	704-096	704-4001K*	712-443	790-492	791-038*	791-2910	799-326
39205-25	704-098	704-4002*	712-450	790-493*	791-040	791-2912	799-327
39205-30	704-099	704-4005*	712-451	790-494*	791-045	791-2914	799-331
39205-31	704-100	704-4006*	712-453	790-498	791-046	791-2919	799-331W*
39205-35	704-101	704-4008*	712-460	790-515	791-047	793-012*	799-332
39205-36	704-102	704-4010*	712-461	790-517	791-048	793-014*	799-333
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704-006-15	704-152	704-4022*	712-473	790-525	791-052	793-018*	Z0000129808
704-006-20*	704-154	704-4023*	730-160	790-527*	791-053	793-019*	Z0000130872
704-010	704-156	704-4024*	730-161	790-529*	791-055	793-020*	

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