Trocar system

ENGLISH

Trocar system

INSTRUCTIONS FOR USE

REF

85530000, 85530001,
85530002, 85530003,
85530500

CE 0297

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⚠ Please read all information contained in this insert attentively.
Incorrect handling and care, as well as misuse, can lead to premature wear of surgical instruments or risks to patients and users.

Intended Use
The trocar system is developed to be used in minimally invasive surgery, particularly laparoscopy, paediatric surgery and gynaecology. By using a trocar an access to a body cavity (e.g. Abdomen, chest cavity) can be created and kept open through the tube. After pulling out the trocar the surgeon will be able to insert grasping, cutting and other instruments through the tube and operate minimally invasive in the appropriate body cavity.

⚠ *Instruments for electrosurgery must only be used by persons who have been specially trained or instructed in this.*

Contraindications
Incidents which have been reported in connection with the use of trocar systems:
Damage of blood vessels caused by inaccurate positioning and/or excessive force during penetration, inadequate insufflation of abdomen, Infections, Coagulopathy.

Use and safety instructions
The non-observance of the present use and safety instructions may lead to injuries, malfunctions or other unexpected incidents.
- Before initial use and any other use, all instruments have to be completely cleaned, disinfected and sterilised and their functioning has to be checked.
- It is very important to check each surgical instrument for visible damage and wear, such as sufficient function and visual inspection of the sealing caps and valves. Especially the condition of the silicone gasket after several times of reprocessing must be checked.
- Never use damaged instruments.
- When temporarily not in use, the instrument must be placed electrically insulated from the patient.
- Observe the use and safety instructions of the manufacturer of the high-frequency surgical device.

Assembly and Operation
For assembly and disassembly of the instrument follow the pictogram, which is available upon request, or can be downloaded on www.bissinger.com.
After skin disinfection in the area of the puncture site and setting the local anesthetic penetration of the abdominal wall and the advancement of the trocar into the abdominal cavity may occur. After pulling out the trocar a gripping, cutting and other instruments can be inserted through the tube/ trocar to operate minimally invasive within the abdominal cavity. Solely instruments with a nominal diameter of ≤ 3 mm may be imported the tube.

⚠ When used in combination with other instruments the appropriate working instructions have to be noted.

Reprocessing
Due to the product design, the raw materials used and the intended purpose it is not possible to determine a precise limit with regard to the maximum possible number of reprocessing cycles. The serviceable life of the instruments is determined by their function as well as by a careful handling. Instruments for electro surgery are by nature subject to increased wear depending on the type and time of use.

Caused by reprocessing, the silicone components (Sealing cap, slotted silicone valve, sealing cap for Luer Lock) will show increased wear. If there is visible brittleness or visually recognizable damage, the corresponding component must be replaced.

Preparation and transport
Immediately after each use, clean the instruments with a soft brush under cold tap water until all visible contamination is removed. Pre-cleaning of the trocar system should take place only assembled. Do not use fixation agents or hot water (>40°C). Storage and transport of the instruments to the reprocessing location must be ensured in a sealed container.

Machine reprocessing
Before machine reprocessing, the trocar must be disassembled completely according to disassembly instruction.
Cleaning
Trocar sleeve, trocar and silicone valves and fittings have to be inserted in the washer-dissinfector and connected to the respective rinsing connectors.
1. Prerinse. with cold water for 1 min
2. Discharge
3. Prerinse with cold water for 3 min.
4. Discharge
5. Wash at 55°C with a 0.5% alkaline or at 45°C with an enzymatic cleaning agent for 5 min.
6. Discharge
7. Neutralise with warm tap water (>40°C) and a neutralising agent for 3 min.
8. Discharge
9. Rinse with warm tap water (>40°C) for 2 min.
10. Discharge

Disinfection
Machine-operated thermal disinfection must be carried out under observation of the national requirements regarding the A0 value (see ISO 15883).

Drying
Dry the outside of the instruments by carrying out a drying cycle of the cleaning/disinfection machine.
If necessary, manual drying may additionally be carried out using a lint free cloth. Dry cavities by blowing with sterile compressed air.

Manual reprocessing
Ultrasonic pre-cleaning
1. The instruments are placed in an ultrasonic bath with 0.5% enzymatic cleaning detergent and treated with ultrasound for 15 minutes at 40°C/104°F.
2. Remove the instrument and rinse them completely with cold water to remove the cleaning detergent.

Cleaning
Prepare a cleaning bath according to the manufacturer's instructions.
1. Rinse products with cold tap water (<40°C) until all visible contamination has been removed. Remove adhering dirt by using a soft brush.
2. Place products in the prepared cleaning bath so that they are completely submersed. Observe residence time according to the manufacturer's instructions.
3. Clean the instrument in the bath manually using a soft brush. Brush all surfaces several times.
4. *The following step only applies to channels and the insides of tubes:* Push the brush into and out of the tubes at least six times. Rinse the tubes with DI water. Repeat the procedure.
5. Rinse the products thoroughly with DI water to remove the cleaning agents without residue.

Disinfection
Prepare a disinfectant bath according to the instructions of the disinfectant manufacturer. Place the instruments in the disinfectant bath and observe the specified residence time. Rinse the products thoroughly with fully demineralised water to remove the disinfectant without residue.

Drying
Manual drying is carried out using a lintfree cloth and, in particular, for drying cavities and channels, sterile compressed air.

Functional test and packaging
Perform visual inspection for cleanliness; if required, perform an assembly and functional test according to the operating instructions.
If necessary, repeat the reprocessing process until the instrument is optically clean.
Packaging has to comply with ISO 11607 and EN 868 standards for packaging for sterilised instruments.

Sterilisation
Sterilisation of the products with fractional pre-vacuum procedure (in accordance with ISO 13060 / ISO 17665) under observation of the respective national requirements.
- 3 pre-vacuum phases with a pressure of at least 60 mbar.
- Heating up to a sterilisation temperature of at least 132°C and at most 137°C
- Exposure time: at least 3 min.
- Drying time: at least 10 min.

⚠ In case of suspected contamination with prions (CJD) differing national guidelines and possibly longer holding times (e. g. 15 min.) are to be followed.

Storage
Sterilised instruments must be stored in a dry, clean and dust-free environment. The applicable national guidelines must be followed.

Repairs
The silicone gaskets (slotted sealing valve, sealing cap and sealing cap for Luer connector) can be replaced if necessary by the user. The corresponding components are available as spares.

Never attempt to perform repairs yourself. Service and repair work may only be performed by persons qualified and trained accordingly. For any question on these matters, please contact either the manufacturer or your medico-technical department.

⚠ *Defective products must complete the entire reprocessing process before being returned for repair.*

Replacement parts for 85530000:
85530070 Sealing cap for Luer-Lock
85530051 Silicone valve slit (transparent)
85530050 Sealing cap red

Replacement parts for 85530002:
85530070 Sealing cap for Luer-Lock
85530091 Seal for Luer connection (transparent)
85530091 Silicone valve (white)

Information on the validation of the reconditioning
The following testing instructions, materials and equipment have been used for validation:

Cleaning agents (for machine use):
Neodisher FA by Dr. Weigert (alkaline)
Endozime by Ruhof (enzymatic)
Cleaning agents (manual cleaning):
Cidezyme, Enzol Enzym detergent, Johnson&Johnson
Disinfectants (manual disinfection):
Cidex OPA, Johnson&Johnson
Neutralising agent:
Neodisher Z by Dr. Weigert
Cleaning and disinfection device:
Miele Desinfector G 7735 CD
Miele insert module E 327-06
Miele MIS module E 450

For details, see report.
SMP GmbH # 01707011901 (machine cleaning)
MDS GmbH # 135196-10 (man. cleaning/disinfection)
Nelson Labs # 200432706-02 (sterilisation)
MDS GmbH Testbericht 084183-10 (sterilisation)

If the chemicals and machines described above are not available, the user has to validate the used process accordingly.

Handling
During transport, cleaning, care, sterilisation and storage, all surgical instruments should be handled with maximum care.
This applies particularly to blades, fine tips and other sensitive areas.

Disposal
Disposal must be carried out in accordance with the respective applicable local and national laws and regulations.

Warranty
Günter Bissinger Medizintechnik GmbH exclusively supplies tested and faultless products to its customers. All products are designed and manufactured to comply with maximum quality requirements. We refuse any liability for products which have been modified as compared to the original product, misused or handled or used improperly.

Explanation of symbols

LOT	Batch code
NON STERILE	Unsterile
REF	Reference number
⚠	Attention
	Refer to instructions for use
CE 0297	CE-Mark and registration number of the Notified Body DQS Medizinprodukte GmbH August-Schanz-Straße 21 60433 Frankfurt, Germany
	Manufacturer Production date
Rx ONLY	Attention:According to US-laws, this device must only be sold by a doctor or on the instruction of a