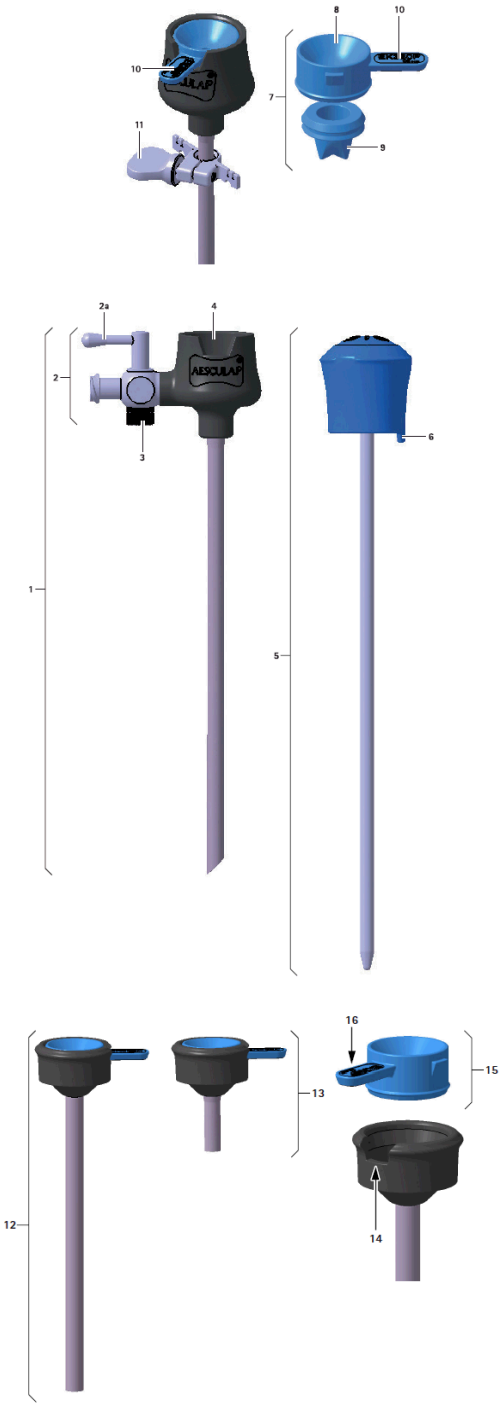
USA Reusable trocar system 3.5 mm, 5mm



USA Reusable trocar system 3.5 mm, 5 mm

Legend

1 Trocar sleeve
2 Insufflation valve (optional, open position)
2a Stopcock
3 Spring cap
4 Recess
5 Trocar obturator
6 Positioning lug
7 Sealing unit
8 Sealing cap
9 Cross slit valve
10 Tab
11 Suture fixation (only for trocar sleeves without insufflation)
12 Reducing sleeve
13 Suture sleeve
14 Recess
15 Sealing cap
16 Tab

Symbols on product and packages

Symbol	Explanation
	Caution, general warning symbol Caution, see documentation supplied with the product
LATEX FREE	Latex-free
	Date of manufacture

Intended use

The reusable trocar system is used in laparoscopic surgery.
It serves to create and maintain an approach to the operating field for instruments and endoscopes in laparoscopic operations.
Endoscopic instruments of up to 3.5 mm and 5 mm diameter can be inserted through the trocars.

Note
Do not use if endoscopic operating techniques are contraindicated.

Available sizes

The reusable trocar system of the EK series is available in the following variants:

Working lengths	60 mm, 110 mm, 150 mm	
Diameter	3.5 mm	blue
	5 mm	red

Safe handling and preparation

CAUTION
Federal law restricts this device to sale by or on order of a physician!

- If laser, ultrasonic or electrosurgical techniques are applied in combination with the trocar system, ensure that the user is sufficiently trained and experienced for these applications. Follow the instructions for use of associated devices and instruments.
- Adhere to the instructions for use of the respective insufflation device/tube.
- Ensure that the product and its accessories are operated and used only by persons with the requisite training, knowledge or experience.
- Read, follow and keep the instructions for use.
- Use the product only in accordance with its intended use, see Intended use.

- Remove the transport packaging and thoroughly clean the new product, either by hand or by a mechanical process, prior to its initial sterilization.
- Store any new or unused products in a dry, clean and safe place.
- Prior to each use, inspect the product for: loose, bent, broken, cracked, worn, or fractured components.
- Do not use the product if it is damaged or defective. Set aside the product if it is damaged.
- Replace any damaged components immediately with original spare parts.
- To avoid damage to the sealing unit: Carefully insert the product through the working channel (e.g. trocar).
- Only combine Aesculap trocar components of the EK line with each other.
- Only combine trocar sleeves and trocar obturators with the same color code (diameter) and the same working length.

Note

All trocar components of the EK series are latex-free.

Safe operation

WARNING

Risk to patients due to inappropriate application!

- **Make certain the user is sufficiently trained and experienced in endoscopic surgical techniques, and familiar with the relevant anatomic features (blood vessels, structures).**
- **Prior to inserting the trocar in the patient, apply an abdominal pneumoperitoneum e.g. with a Veress cannula.**
- **Apply skin incisions in order to obviate excessive application of force.**
- **Position any further trocars under intra-abdominal visual control.**

WARNING

Risk of injury and/or malfunction!

- **Always carry out a function check before using the product.**
- **Replace sealing unit if necessary.**
- **To prevent damage to the sealing unit, apply appropriate care when inserting any instruments.**
- **If possible, insert instruments in their closed position, straight and central through the sealing unit.**

CAUTION

Malfunction due to incompatible instruments!

- **Check for mutual compatibility of the trocar system and instruments. To do this, carefully insert the instrument into the trocar and check for patency.**

Note

The trocar sleeve with insufflation valve may be combined only with the trocar obturator with the stopcock symbol at its head!

- Insert sealing unit **7** in trocar sleeve **1**, see section "Assembling".
- When using trocar sleeve **1** with insufflation valve **2**: Close stopcock **2a** by turning it clockwise by 90°.
- Insert trocar obturator **5** into trocar sleeve **1**. Position positioning lug **6** in recess **4**.
- Insert the trocar into the patient by alternating left/right rotary movements, applying even and controlled pressure.
- Retract trocar obturator **5**.

  Trocar sleeve **1** remains positioned in the patient.
- When using suture fixation **11**: Wind the suture around suture fixation **11** at least twice, into the slots.
- To use an insufflation device connected at insufflation valve **2**: Connect the insufflation device, start the device and open stopcock **2a**.
- Carry out intra-abdominal visual control.
- Post application, unwind the suture thread from suture fixation **11**.

Note

Apply rotary movement to remove hook-shaped instruments.

Note

The sealing unit can be removed from the trocar sleeve for retrieving larger portions of resected tissue. The depressurization caused by this action has to be compensated when re-installing the sealing unit.

Disassembling

Trocars

- With insufflation valve **2**: Unscrew spring cap **3**.
- Remove stopcock **2a**.
- If necessary, open the screw of suture fixation **11** and slide off the suture fixation from trocar sleeve **1**.

Sealing unit

- Grasp tab **10** of sealing unit **7** and extract the sealing unit from trocar sleeve **1**.
- For cleaning, extract cross slit valve **9** from sealing cap **8**.

Assembling

Trocars

- With insufflation valve **2**: Install stopcock **2a** in insufflation valve **2**.
- Screw on spring cap **3**.
- If applicable, slide suture fixation **11** onto trocar sleeve **1** and tighten the screw of suture fixation **11**.

Sealing unit

- Engage cross slit valve **9** in sealing cap **8**.
- Fully press sealing unit **7** into trocar sleeve **1**, with tab **10** in recess **4**.

Validated processing procedure

Note

Adhere to national statutory regulations, international standards and guidelines, and local, clinical hygiene instructions for sterile processing.

Note

Mechanical processing should be preferred over manual cleaning because of the better and more reliable cleaning results of mechanical processing.

Note

Successful processing of this medical product can only be ensured if processing is performed through a validated processing procedure. The user/processor is responsible for the validation.

General notes

To avoid unnecessary, excessive contamination of the complete instrument tray during operations, take care that contaminated instruments are collected separately and not put back into the instrument tray.

Encrusted or fixated residues from surgery can make the cleaning process more difficult or ineffective, and can cause corrosion of stainless steels. Therefore the time interval between application and cleaning should not exceed 6 h, and neither potentially fixating pre-cleaning temperatures >45 °C nor any fixating disinfectants (active ingredient: aldehyde, alcohol) be used.

Excessive doses of neutralizers or basic detergents can cause chemical degradation and/or fading and obliteration of laser inscriptions on stainless steel surfaces, regarding visual reading and machine-readability of the inscriptions.

Residues containing chlorine or chlorides e.g. in surgical residues, medicines, saline solutions and in the service water used for cleaning, disinfecting and sterilization will cause corrosion damage (pitting, stress corrosion) and result in the destruction of stainless steel products. To remove such residues, the products must be rinsed sufficiently with fully desalinated water and dried thoroughly.

Only use process chemicals that have been tested and approved (e.g. VAH/DGHM or FDA approval or CE mark) and which are compatible with the product's materials according to the chemical manufacturers' recommendations. All process parameters specified by the chemical's manufacturer, such as temperatures, concentrations and exposure times, must be strictly observed. Failure to do so can result in the following problems:

- Material damage, e.g. corrosion, cracks, fracturing, premature aging or swelling.
- Do not use process chemicals that would cause stress cracking or brittleness of plastics.
- Clean the product immediately after use.

For further detailed advice on hygienically safe and material-/value-preserving reprocessing, see www.a-k-i.org

- Use suitable cleaning/disinfecting agents if the product is put away in wet condition. To prevent foam formation and reduced effectiveness of the process chemicals: Prior to mechanical cleaning and disinfecting, rinse the product thoroughly with running water.

Preparations at the place of use

- Disassemble the product immediately after use, as described in the respective instructions for use.
- With insufflation valve **2**: Open stopcock **2a**.
- Remove visible surgical residues as completely as possible, using a lint-free wet wipe.
- Put the dry product into a closed disposal container and have it transferred to cleaning and disinfecting within 6 h.

Preparation prior to cleaning

- Present the product in dry condition in a disposal container for cleaning and disinfecting within 30 min after use.

Cleaning/Disinfecting

CAUTION

Damage to the product due to inappropriate cleaning/disinfecting agents and/or excessive temperatures!

- **Use cleaning and disinfecting agents according to the manufacturer's instructions. The cleaning and disinfecting agents must**
  - **be approved e.g. for plastic materials and high-grade steel**
  - **not attack softeners (e.g. silicone).**
- **Observe specifications regarding concentration, temperature and exposure time.**
- **Do not exceed the maximum allowable cleaning temperature of 94 °C.**

- Carry out ultrasound cleaning:
  - as an effective mechanical supplement to manual cleaning/disinfecting,
  - as a pre-cleaning procedure for products with encrusted residues, in preparation for mechanical cleaning/disinfecting,
  - as an integrated mechanical support measure for mechanical cleaning/disinfecting,
  - for additional cleaning of products with residues left after mechanical cleaning/disinfecting.

Manual cleaning/disinfecting

- Inspect visible surfaces for residual contamination after manual cleaning/disinfecting.
- Repeat the cleaning process if necessary.

Manual cleaning with immersion disinfection

Stage	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemical
I	Cleaning	RT (cold)	15	2	D-W	BBraun Stabimed; aldehyde-free, phenol-free and QAV-free
II	Intermediate rinse	RT (cold)	1	-	D-W	-
III	Disinfecting	RT (cold)	15	2	D-W	BBraun Stabimed; aldehyde-free, phenol-free and QAV-free
IV	Final rinse	RT (cold)	1	-	FD-W	-
V	Drying	RT	-	-	-	-

D-W: Drinking water
FD-W: Fully desalinated water (demineralized)
RT: Room Temperature

Stage I

- Fully immerse the product in the cleaning/disinfecting solution. Make certain that all accessible surfaces are moistened.
- Clean the product under running tap water, using a suitable cleaning brush if necessary, until all visible residues have been removed from the surfaces.
- Brush through surfaces not accessible to visual inspection, e.g. in products with hidden crevices, lumens or complex geometries, for at least 1 min or until no more residues can be removed, using an appropriate cleaning brush (brush head length: 30 mm/∅: 4.5 mm, e.g. TA 011944).
- Mobilize non-rigid components, e.g. set screws, links, etc. during cleaning.
- After cleaning, thoroughly (at least five times) rinse through these components with the cleaning/disinfecting solution, using a disposable syringe (20 ml).
- Do not use metal cleaning brushes or other abrasives that would damage the product surfaces and could cause corrosion.

Stage II

- Rinse the product completely (all accessible surfaces) under running water.
- Allow water to drip off for a sufficient length of time.

Stage III

- Fully immerse the product in the disinfecting solution. Make certain that all accessible surfaces are moistened.

Stage IV

- Carry out a full rinse of the product (all accessible surfaces) under running water.
- Allow water to drip off for a sufficient length of time.

Stage V

- Dry the product with lint-free tissue or medical-quality filtered compressed air.

Mechanical cleaning/disinfecting with manual pre-cleaning

Note
The disinfector must be of tested and approved effectiveness (e.g. DGHM or FDA approval or CE mark according to DIN EN ISO 15883).
Note
For thermal disinfection, always use fully desalinated (demineralized) water. Ensure that Ao is >3 000 for the process.

Note
The disinfector used for processing must be serviced and checked at regular intervals.

Note
Manual pre-cleaning with a brush is necessary for all trocar sleeves and sealing units. Trocar obturators can be cleaned mechanically, without manual pre-cleaning.

Manual pre-cleaning with brush

Stage	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemical
I	Disinfecting cleaning	RT (cold)	15	2	D-W	BBraun Stabimed; aldehyde-free, phenol-free and QAV-free
II	Irrigation	RT (cold)	1	-	D-W	-

D-W: Drinking water
RT: Room Temperature

Stage I

- Fully immerse the product in the cleaning/disinfecting solution. Make certain that all accessible surfaces are moistened.
- Clean the product with a suitable cleaning brush until all visible residues have been removed from the surface.
- Brush through surfaces not accessible to visual inspection, e.g. in products with hidden crevices, lumens or complex geometries, for at least 1 min or until no more residues can be removed, using an appropriate cleaning brush (brush head length: 30 mm/∅: 4.5 mm, e.g. TA 011944).
- Mobilize non-rigid components, e.g. set screws, links, etc. during cleaning.
- After cleaning, thoroughly rinse through these components (at least five times) with the cleaning solution, using a disposable syringe (20 ml).
- Do not use metal cleaning brushes or other abrasives that would damage the product surfaces and could cause corrosion.

Stage II

- Rinse the product completely (all accessible surfaces) under running water.

Mechanical alkaline cleaning and thermal disinfecting

Machine type: Single-chamber washer/disinfector without ultrasound

- Place the product on a tray that is suitable for cleaning (avoid rinsing blind spots).
- With insufflation valve **2**: Connect insufflation stopcock **2** or Luer valve directly to the special connector at the injector carriage.

Stage	Step	T [°C/°F]	t [min]	Water quality	Chemical/Note
I	Prerinse	<25/77	3	D-W	-
II	Cleaning	55/131	10	FD-W	BBRAUN HELIMATIC CLEANER ALCALINE with tensides; application solution 0.5 %
III	Intermediate rinse	>10/50	1	FD-W	-
IV	Thermal disinfecting	90/194	5	FD-W	-
V	Drying	-	-	-	According to disinfector program

D-W: Drinking water
FD-W: Fully desalinated water (demineralized)

Inspection, maintenance and checks

- Allow the product to cool down to room temperature.
- Slightly lubricate the set screw and thread of the suture fixation with maintenance oil suitable for the respective sterilizing process (e.g. Aesculap STERILIT® I oil spray JG600 or STERILIT® I drip lubricator JG598).
- After each complete cleaning, disinfecting and drying cycle, check that the product is: dry, clean, operational, and free of damage (e.g. broken insulation or corroded, loose, bent, broken, cracked, worn or fractured components).
- Dry the product if it is wet or moist.
- Repeat cleaning and disinfecting of products that still show impurities or contamination.
- Check the product for proper functioning.
- Immediately sort out damaged or inoperative products and have them sent to Aesculap Technical Service, see Technical Service.
- Assemble the separable product, see Assembling.
- Check for compatibility with associated products.

Packaging

- Protect the tip of the trocar obturator by an appropriate storage holder.
- Package trays appropriately for the sterilization process (e.g. in Aesculap sterile containers).
- Ensure that the packaging provides sufficient protection against recontamination of the product during storage (DIN EN ISO 11607).

Sterilization method and parameters

Note
The product can be sterilized in disassembled or assembled condition.

Note
Aesculap recommends using the Endo Rack for sterilization and storage of the product.

CAUTION

Cross slit valve damaged or leaking due to incorrect handling during sterilization!

- **Sterilize the trocar obturators separately, making certain that they are not inserted in the trocar sleeve or the sealing unit.**

- ➢ Make certain that all external and internal surfaces will be exposed to the sterilizing agent (e.g. by opening all valves and faucets).
- ➢ Validated sterilization process
  - Steam sterilization through fractionated vacuum process
  - Steam sterilizer according to DIN EN 285, validated according to DIN EN ISO 17665
  - Sterilization through fractionated vacuum process at 134 °C/holding time 5 min
- ➢ When sterilizing several products at the same time in one steam sterilizer: Make certain that the maximum allowable load capacity of the steam sterilizer, as specified by the manufacturer, is not exceeded.

Storage

- ➢ Store sterile products in germ-proof packaging under dust protection in a dry, dark and temperature-controlled room.

Sterilization for the US market

- Aesculap does not recommend the device sterilized by flash or chemical sterilization.
- Sterilization may be accomplished by steam autoclave in a standard prevacuum cycle.

To achieve a sterility assurance level of 10^{-6}, Aesculap recommends the following parameters:

Aesculap Orga Tray/sterile container (perforated bottom) Minimum cycle parameters*			
Sterilization method	**Temp.**	**Time**	**Minimum drying time**
Pre-vacuum	270 °F–275 °F	4 min	20 min

*Aesculap has validated the above sterilization cycle and has the data on file. The validation was accomplished in an Aesculap sterile container cleared by FDA for the sterilization and storage of these instruments. Other sterilization cycles may also be suitable, however individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques. Use an FDA cleared accessory to maintain sterility after processing, such as a wrap, pouch,etc.

Technical Service

WARNING

Risk of injury and/or malfunction!

➢ **Do not modify the product.**

➢ For service and repairs, please contact your national B. Braun/Aesculap agency.

Modifications carried out on medical technical equipment may result in loss of guarantee/warranty rights and forfeiture of applicable licenses.

Service addresses

Aesculap Inc.
Attn. Aesculap Technical Services
615 Lambert Pointe Drive
Hazelwood, MO 63042
Aesculap Repair Hotline
Phone: +1 800 214-3392
Fax: +1 314 895-4420

Other service addresses can be obtained from the address indicated above.

Accessories/Spare parts

Art. no.	**Designation**
EK080P	Sealing unit 5 mm (box of 20), consisting of:
EK081P	- Cross slit valve 5 mm (box of 20)
EK082P	- Sealing cap 5 mm (box of 20)
EK097R	- Suture fixation 5 mm (box of 1)
EK380P	Sealing unit 3.5 mm (box of 20), consisting of:
EK381P	- Cross slit valve 3.5 mm (box of 20)
EK382P	- Sealing cap 3.5 mm (box of 20)
EK397R	Suture fixation 3.5 mm (box of 1)

Disposal

➢ Adhere to national regulations when disposing of or recycling the product, its components and its packaging!

Distributor in the US/Contact in Canada for product information and complaints

Aesculap Inc.
3773 Corporate Parkway
Center Valley, PA 18034
USA

SOP-AIC-5000997 Rev.03