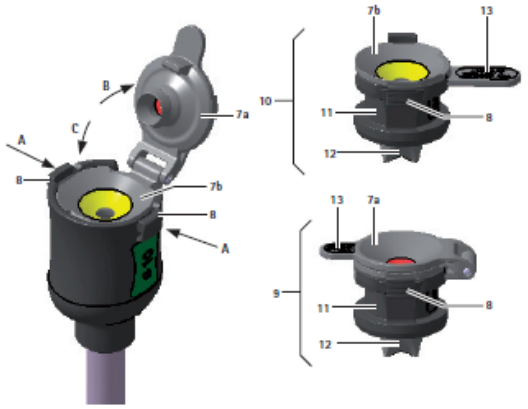
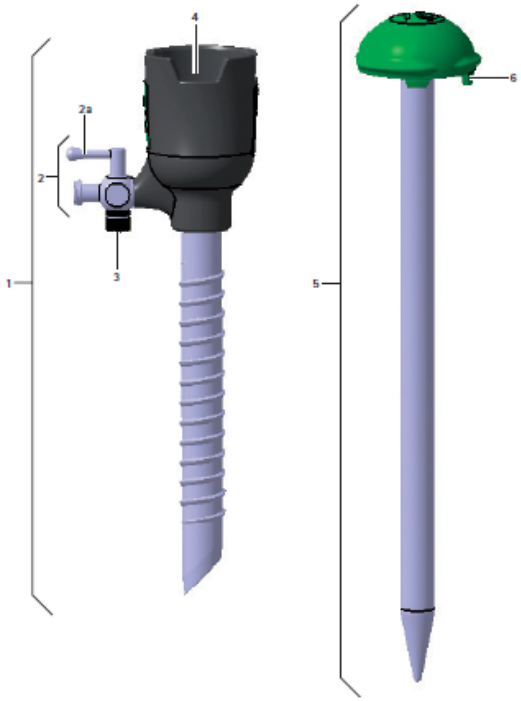
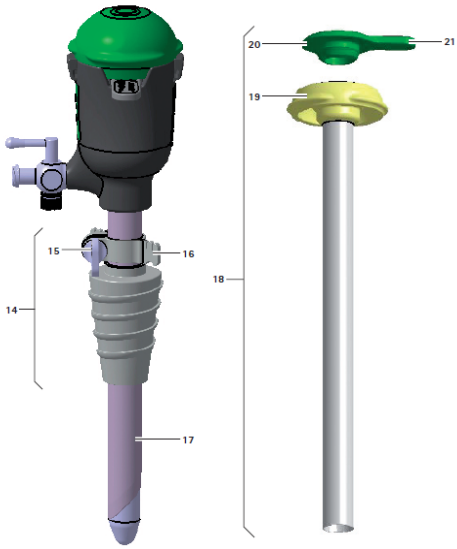
USA Reusable trocar system 10 mm, 12 mm







USA Reusable trocar system 10 mm, 12 mm

Legend

1 Trocar sleeve (with optional thread)
2 Insufflation valve (optional, open position)
2a Stopcock
3 Spring cap
4 Recess
5 Trocar obturator
6 Positioning lug
7a Sealing cap with 5mm reducing converter
7b Sealing cap
8 Locking buttons
9 Sealing unit with 5 mm reducing converter
10 Sealing unit
11 Sealing housing
12 Cross slit valve
13 Tab
14 Stability cone
15 Locking screw
16 Suture fixation
17 Blunt (Hasson) trocar obturator
18 Reducing sleeve
19 Reducing sleeve head
20 Sealing cap
21 Tab

Symbols on product and packages

Symbol	Explanation
	Caution: See documentation supplied with the product
	Date of manufacture
LATEX FREE	Latex-free

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 5–10 mm diameter (10 mm trocar) and 5–12 mm diameter (12 mm trocar) can be inserted.

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	110 mm, 150 mm	
Diameter	10 mm	green
	12 mm	yellow

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 the respective implants and instruments.
- Follow the instructions for use of the insufflation device/tube used with the trocar system.
- 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.
- Only combine Aesculap trocar components of the EK series 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, prepare an abdominal pneumoperitoneum e.g. with a Verress 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.**

- Insert sealing unit **9**/**10** in trocar sleeve **1**, see Assembling.
- When using a trocar sleeve with insufflation valve **2**: Close stopcock **2a** by turning it clockwise by 90°.
- For sealing unit **9** with 5 mm reducing converter: Open sealing cap **7a**, see illustration, arrow **B**.
- 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 rotating movements, applying even and controlled pressure.
- For trocar sleeve **1** with thread: Turn the sleeve clockwise until the thread is fixated.
- Retract trocar obturator **5**.
  Trocar sleeve **1** remains positioned in the patient.
- 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.
- For using 5 mm instruments and sealing unit **9** with 5 mm reducing converter: Engage sealing cap **7a** , see illustration, arrow **C**.
  - or -
- For using 10 mm and 12 mm instruments and sealing unit **9** with 5 mm reducing converter: Disengage sealing cap **7b**, see illustration, arrow **B**.
- Post application of trocar sleeve **1** with thread: Turn the sleeve counterclockwise until the thread is fully released.

Note

Use a reduction sleeve when inserting needles.

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.

Stability cone

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).**
- **Position any further trocars under intra-abdominal visual control.**

- Slide stability cone **14** onto trocar sleeve **1** and tighten locking screw **15**.
- Apply a mini-laparotomy and insert trocar with blunt (Hasson) trocar obturator **17** under visual control.
- Turn clockwise trocar sleeve **1** with stability cone **14** until the thread of stability cone **14** is fixated.
- Retract trocar obturator **1**.
  Trocar sleeve **1** remains positioned in the patient.
- Wind the suture around suture fixation **16** at least twice, into the slots.
- To connect insufflation at insufflation valve **2**: Open insufflation valve **2** and start insufflation.
- Carry out intra-abdominal visual control.
- Post application, unwind the suture thread from suture fixation **16**.
- Turn counterclockwise trocar sleeve **1** with stability cone **14** until the thread of stability cone **14** is released completely.

Disassembling

Trocars with insufflation valve

- Unscrew spring cap **3**.
- Remove stopcock **2a**.

Sealing unit

- Press both locking buttons **8** at sealing housing **11** and remove sealing unit **9**/**10** from trocar sleeve **1**
- With sealing unit **9**: Open sealing cap at tab **14** and remove it upwards from sealing housing **11**.
- With sealing unit **10**: Remove sealing cap **7b** at tab **14** upwards from sealing housing **11**.
- Remove cross slit valve **12** downwards and out of sealing housing **11**.

Stability cone

- Undo locking screw **15** and slide off stability cone **14** from trocar sleeve **1**.

Assembling

Trocars with insufflation valve

- Install stopcock **2a** in insufflation valve **2**.
- Screw on spring cap **3**.

Sealing unit

- Check seals for cracks and other damage; replace if necessary.
- Press sealing cap **7a** or **7b** downwards into sealing housing **11**. Position the link or tab in recess **4**.
- Press cross slit valve **12** upward into sealing housing **11**.
- Insert sealing unit **9** or **10** in trocar sleeve **1**.
- Press centrally on sealing cap **7a**/**7b** until both locking buttons **8** click into position in trocar sleeve **1**. When doing this, position the link of sealing unit **9** or tab **13** of sealing unit **10** in recess **4**.

Stability cone

- Slide stability cone **14** onto trocar sleeve **1** and tighten locking screw **15**.

Validated processing procedure

Note

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

Note

For patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants of CJD, observe the relevant national regulations concerning the reprocessing of the products.

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.

Due to process tolerances, the manufacturer's specifications can only serve as an approximate guide for assessing the processing procedures applied by the individual operator/processors.

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. To avoid this, the time interval between application and processing should not exceed 6 h, and neither fixating pre-cleaning temperatures >45 °C nor any fixating disinfecting agents (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, disinfection 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 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 may be used for processing the product. 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 cause stress cracking or brittleness of plastics.
- Clean the product immediately after use.
- Further detailed advice on hygienically safe and material-/value-preserving reprocessing can be found at www.a-k-i.org, Publications Red Brochure – Proper maintenance of instruments.
- 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.
- For sealing unit **9** with 5 mm reducing converter: Open sealing cap **7a** at the link.
- Remove visible surgical residues as completely as possible, using a lint-free wet wipe.

Preparation prior to cleaning

- Have the product dry in a disposal container and ready for immediate cleaning and disinfecting within 30 min after use.

Cleaning/Disinfecting

WARNING

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 for plastics (thermoplastics, silicone) 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

- Clean hinged or jointed products in open and closed positions.
- Check visible surface for residues 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 phenol and QAV-free
II	**Intermediate rinse**	RT (cold)	1	-	D–W	-
III	**Disinfecting**	RT (cold)	15	2	D–W	BBraun Stabimed; aldehyde phenol and QAV-free
IV	**Final rinse**	RT (cold)	0.5	-	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, if necessary with a suitable cleaning brush (e.g. TA no. 007747), until all visible residues have been removed from the surface.
- Brush through all surfaces that are not accessible to visual inspection, e.g. in products with hidden crevices, lumens or complex geometry, for at least 1 min or until no more residues can be removed. Mobilize non-rigid components, such as set screws, links, etc. during cleaning.
- After cleaning, thoroughly rinse through these components (at least five times) 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

Categorically, 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, phenol 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 (e.g. TA no. 007747) until all visible residues have been removed from the product surface.
- Brush through all surfaces that are not accessible to visual inspection, e.g. in products with hidden crevices, lumens or complex geometry, for at least 1 min or until no more residues can be removed. Mobilize non-rigid components, such as 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 suitable tray (avoiding rinsing blind spots) in such a way that the inner lumens will be rinsed well and the cleaning solution can drain off easily.
- Connect the insufflation stopcock or Luer valve directly to the special connector at the injector carriage.
- Place the sealing cap with its joint on the tray in such a way that the links are kept open.

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 alkaline 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.
- After each complete cleaning, disinfecting and drying cycle, check that the product is: dry, clean, operational, and free of damage (e.g. 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.
- Sort the product into its appropriate storage device or put it on a suitable tray. Make certain that all cutting edges are protected.
- 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

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

Note

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

Note

The stability cone can be sterilized either separately or mounted on the trocar sleeve.

CAUTION

Damage or leaking of the cross slit valve caused by incorrect handling during sterilization!

- **Sterilize trocar obturators separately (not in the trocar sleeve).**

- Position the sealing cap with its joint in such a way that the joint is kept open.
- 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 and 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.

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.

Storage

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

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
EK083P	Sealing unit 10/12 mm with reducing converter (box of 1), consisting of:
EK084P	- Cross slit valve 10/12 mm (box of 20)
EK087P	- Sealing cap with reducing converter 10/12 mm (box of 5)
EK088P	- Sealing housing 10/12 mm (box of 1)
EK086P	Sealing unit 10/12 mm (box of 1), consisting of:
EK084P	- Cross slit valve 10/12 mm (box of 20)
EK085P	- Sealing cap 10/12 mm to 5 mm (box of 5)
EK088P	- Sealing housing 10/12 mm (box of 1)

Disposal

➢ Adhere to national regulations for disposal of the products.

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

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

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