Aesculap®
MINOP inVent trocar 30°

Legend
1 MINOP inVent Trocar
2 Groove
3 Release button
4 Irrigation connector
5 Endoscope
6 Locking pin endoscope
7 Obturator for the oval working channel
8 Obturator for optical channel
9 Locking pin obturator
10 Wing nut
11 Holding arm adapter

Indications for Use
Aesculap's MINOP system is intended for use in endoscope-assisted microneurosurgery and pure neuroendoscopy (i.e. ventriculoscopy) for direct visualization, diagnostic and/or therapeutic procedures such as ventriculostomies, biopsies and removal of tumors and other obstructions.

Safe handling and preparation
CAUTION
Federal law restricts this device to purchase by, or on instruction by a physician!

Symbols on product and packages

Caution, general warning symbol
Caution, see documentation supplied with the product

Applicable to
► For article-specific instructions for use and information on material compatibility, see also Aesculap Extranet at www.aesculap-extra.net

Note
A specially designed Aesculap endoscope is offered for the MINOP inVent trocar system. For reasons of compatibility, the MINOP inVent trocars may only be used with this special Aesculap endoscope.
Safe operation

- 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 clean the new product, either manually or mechanically, 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.
- Perform a function check of the irrigation channel before each use.
- Perform a function check of the endoscope's stop mechanism before each use.
- To avoid burns when using the MINOP inVent trocar in combination with HF electrodes, ensure that HF current is activated only under visual control.
- When inserting the trocar into the brain/the ventricle, close the working channel with the obturator provided.

**Risk of injury and/or malfunction!**
- Always carry out a function check prior to using the product.

**Risk of injury when using the product beyond the field of view!**
- Apply the product only under visual control.

**Risk of injury caused by protruding 30° endoscope in locked position!**
- Insert the endoscope only when the trocar is in its final position.

**Risk of burns due to high temperature of the instrument-side end of the optical cable of a light source!**
- Apply proper care when operating the light source.
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**WARNING**

Damage to the endoscope due to incorrect handling or operation!
- Insert the endoscope into the trocar only if the trocar is not deformed, bent or kinked.

**Note**
There is an approx. 2 mm marking on the shafts of the MINOP inVent sliding shaft and round shaft instruments. As soon as this marking passes the proximal end of the oval working channel, the instrument emerges from the trocar.

The MINOP inVent trocar 1 is used with a 30° endoscope 5 (MINOP 30° angled endoscope).
- In order to close the working end of the trocar atraumatically,
  - insert obturator for optical channel 8 into the optical channel 14 and
  - insert obturator for the oval working channel 7 into the working channel 12, see Fig. 1.

There is constant irrigation via the irrigation channel.

The irrigation fluid drains out via the large working channel 12 and the small working channel 13, see Fig. 1.

**Fig. 1**
- For freehand operation, attach the MINOP inVent trocar 1 with the holding arm adapter 11 and the wing nut 10 on the holding arm.

**Note**
The endoscopes offered for application with the MINOP inVent system must be used with a light source equipped with a spare bulb.
Camera assembly

Note
Connect the camera only with the endoscope locked in the working trocar!

- Secure the endoscope 5 in the MINOP inVent trocar 1, see Fig. 2.
- When doing so, ensure that the locking pin 6 of the endoscope 5 is on the same side as the release button 3 of the MINOP inVent trocar 1.

- Connect light cable and camera, see Fig. 3-5.
Camera disassembly

*Note*

Extract the endoscope from the working trocar only after the camera has been demounted from the endoscope.

- Disconnect camera and light cable from the endoscope 5, see Fig. 6 and see Fig. 7.
Press release button 3 and remove endoscope 5 from the MINOP inVent trocar 1, see Fig. 8.
Trocar disassembly

Removing the obturator for working/drainage channels

Note
This step is only necessary if the obturator for the working or drainage channel is being used.

- Remove obturator for the oval working channel 7 carefully from the MINOP inVent trocar 1, see Fig. 9.

Removing the obturator for optical channel or endoscope

- Press release button 3 and remove the obturator for the optical channel 8 carefully from the MINOP inVent trocar 1, see Fig. 10.

Fig. 9

Fig. 10
Press release button 3 and remove endoscope 5 from the MINOP inVent trocar 1, see Fig. 11.

Removing irrigation tube
> Remove tube from irrigation connector 4, see Fig. 12.
Removing the holding arm adapter

- Unscrew the wing nut 10.
- Remove holding arm adapter 11, see Fig. 13.

Trocar assembly

Inserting the endoscope/obturators

- Insert the endoscope 5/obturator for optical channel 8 carefully into the MINOP inVent trocar axially 1.
- When doing so, ensure that the locking pin 6 of the endoscope 5 or the locking pin 9 of the obturator for the optical channel 8 is on the same side as the release button 3 of the MINOP inVent trocar 1, see Fig. 14 and see Fig. 15.
Inserting the obturator for the oval working channel

- Hold the obturator for the oval working channel 7 at the distal end and carefully insert it into the working channel 12 as far as the stop, see Fig. 16. Due to friction in the channel, the obturator is secured from falling out.

Fig. 15

- Insert the endoscope 5/obturator for optical channel 8 as far as the stop or until the locking pin 6 or 9 clicks into place, so that the endoscope 5/obturator for optical channel 8 can only be removed by activating the release button 3.

Fig. 16
Assembling the holding arm adapter
► Unscrew the wing nut 10 of the holding arm adapter 11, see Fig. 17.

► Insert the holding arm adapter 11 laterally into the hole (either right or left), until the flange engages in the appropriate groove 2 that secures the holding arm in place, see Fig. 18.
- Screw on the wing nut 10 until the holding arm adapter 11 is fixed in place, see Fig. 19.
- MINOP The inVent trocar 1 is now ready to be fitted to the holding arm.

**Connecting the irrigation tube**

- Connect the irrigation tube with the irrigation connector 4, see Fig. 20.
- Check the irrigation function.
**Validated reprocessing procedure**

**General safety instructions**

*Note*
Adhere to national statutory regulations, national and international standards and directives, 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 products.

*Note*
Mechanical reprocessing should be favored over manual cleaning as it gives better and more reliable results.

*Note*
Successful processing of this medical device can only be ensured if the processing method is first validated. The operator/sterile processing technician is responsible for this. The recommended chemistry was used for validation.

*Note*
If there is no final sterilization, then a virucidal disinfectant must be used.

*Note*
For the latest information on reprocessing and material compatibility see also the Aesculap extranet at www.aesculap-extra.net

The validated steam sterilization procedure was carried out in the Aesculap sterile container system.

**General information**

Dried or affixed surgical residues can make cleaning more difficult or ineffective and lead to corrosion. Therefore the time interval between application and processing should not exceed 6 h; also, neither fixating pre-cleaning temperatures $>$45 °C nor fixating disinfecting agents (active ingredient: aldehydes/alkohols) should be used.

Excessive measures of neutralizing agents or basic cleaners may result in a chemical attack and/or to fading and the laser marking becoming unreadable visually or by machine for stainless steel.

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. These must be removed by rinsing thoroughly with demineralized water and then drying.

Additional drying, if necessary.

Only process chemicals that have been tested and approved (e.g. VAH 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 the chemical manufacturer’s application specifications must be strictly observed. Failure to do so can result in the following problems:

- Optical changes of materials, e.g. fading or discoloration of titanium or aluminum. For aluminum, the application/process solution only needs to be of pH $>$8 to cause visible surface changes.
- Material damage such as corrosion, cracks, fracturing, premature aging or swelling.
Do not use metal cleaning brushes or other abrasives that would damage the product surfaces and could cause corrosion.

Further detailed advice on hygienically safe and material-/value-preserving reprocessing can be found at www.a-k-i.org, link to Publications, Red Brochure – Proper maintenance of instruments.

**Cleaning/disinfection**

**Product-specific safety notes on the reprocessing procedure**

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 which
  - are approved for the material in question (e.g., aluminum, plastics, high-grade steel),
  - do not attack softeners (e.g. in silicone).

- Observe specifications regarding concentration, temperature and exposure time.

- Do not exceed the maximum permitted cleaning temperature of 55 °C.

- Do not use oxidizing chemicals (e.g. H₂O₂), which could cause bleaching/layer loss of the product.

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

**Disassembling the product before carrying out the reprocessing procedure**

- Disassemble the product immediately after use, as described in the respective instructions for use.

**Preparations at the place of use**

- If applicable, rinse non-visible surfaces preferably with deionized water, with a disposable syringe for example.

- Remove any visible surgical residues to the extent possible with a damp, lint-free cloth.

- Transport the dry product in a sealed waste container for cleaning and disinfection within 6 hours.

**Preparation before cleaning**

- Disassemble the product prior to cleaning, see Trocar disassembly.
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► Carry out ultrasound cleaning:
  - as an effective mechanical supplement to manual cleaning/disinfection.
  - as a pre-cleaning procedure for products with encrusted residues, in preparation for mechanical cleaning/disinfection.
  - as an integrated mechanical support measure for mechanical cleaning/disinfection.
  - for additional cleaning of products with residues left after mechanical cleaning/disinfection.

► Clean and disinfect microsurgical products mechanically if they can be placed securely in the machine or on the positioning aids.

Validated cleaning and disinfection procedure

<table>
<thead>
<tr>
<th>Validated procedure</th>
<th>Specific requirements</th>
<th>Reference</th>
</tr>
</thead>
</table>
| Manual pre-cleaning with ultrasound and brush, and subsequent mechanical alkaline cleaning and thermal disinfection | ■ Cleaning brush: for small working channel e.g. TA013543  
■ 20 ml disposable syringe  
■ Place the instrument in a tray that is suitable for cleaning (avoiding rinsing blind spots).  
■ Connect components with lumens and channels directly to the rinsing port of the injector carriage.  
■ Keep working ends open for cleaning. | Chapter Mechanical cleaning/disinfection with manual pre-cleaning and sub-chapter:  
■ Chapter Manual pre-cleaning with ultrasound and brush  
■ Chapter Mechanical alkaline cleaning and thermal disinfecting |
Manual cleaning/disinfection

⚠️ DANGER

Risk to patients!
- The product must only be cleaned mechanically!

Mechanical cleaning/disinfection with manual pre-cleaning

Note
The cleaning and disinfection device must be of tested and approved effectiveness (e.g. FDA approval or CE mark according to DIN EN ISO 15883).

Note
The cleaning and disinfection device used for processing must be serviced and checked at regular intervals.

Manual pre-cleaning with ultrasound and brush

<table>
<thead>
<tr>
<th>Phase</th>
<th>Step</th>
<th>T [°C/°F]</th>
<th>t [min]</th>
<th>Conc. [%]</th>
<th>Water quality</th>
<th>Chemical</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Ultrasonic cleaning</td>
<td>RT (cold)</td>
<td>&gt;15</td>
<td>2</td>
<td>D-W</td>
<td>Aldehyde-free, phenol-free, and QUAT-free concentrate, pH ~ 9*</td>
</tr>
<tr>
<td>II</td>
<td>Rinsing</td>
<td>RT (cold)</td>
<td>1</td>
<td>-</td>
<td>D-W</td>
<td>-</td>
</tr>
</tbody>
</table>

D–W: Drinking water
RT: Room temperature

*Recommended: B.Braun Stabimed

- Note the information on appropriate cleaning brushes and disposable syringes, see Validated cleaning and disinfection procedure.

Phase I
- Clean the product in an ultrasonic cleaning bath (frequency 35 kHz) for at least 15 min. Ensure that all accessible surfaces are immersed and acoustic shadows are avoided.
- Clean the product with a suitable cleaning brush in the solution until all discernible residues have been removed from the surface.
- If applicable, brush through non-visible surfaces with an appropriate cleaning brush for at least 1 min.

- Mobilize non-rigid components, such as set screws, links, etc. during cleaning.
- Thoroughly rinse through these components with the cleaning disinfectant solution (at least five times), using a disposable syringe.

Phase II
- Rinse/flush the product thoroughly (all accessible surfaces) under running water.
- Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.
### Mechanical alkaline cleaning and thermal disinfecting

Machine type: single-chamber cleaning/disinfection device without ultrasound

<table>
<thead>
<tr>
<th>Phase</th>
<th>Step</th>
<th>Temp [°C/°F]</th>
<th>Time [min]</th>
<th>Water Quality</th>
<th>Chemical</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Prerinse</td>
<td>&lt;25/77</td>
<td>3</td>
<td>D–W</td>
<td>-</td>
</tr>
<tr>
<td>II</td>
<td>Cleaning</td>
<td>55/131</td>
<td>10</td>
<td>FD–W</td>
<td>Concentrate, alkaline:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- pH = 13</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- &lt;5 % anionic surfactant</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.5 % working solution</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>- pH = 11*</td>
</tr>
<tr>
<td>III</td>
<td>Intermediate rinse</td>
<td>&gt;10/50</td>
<td>1</td>
<td>FD–W</td>
<td>-</td>
</tr>
<tr>
<td>IV</td>
<td>Thermal disinfecting</td>
<td>90/194</td>
<td>5</td>
<td>FD–W</td>
<td>-</td>
</tr>
<tr>
<td>V</td>
<td>Drying</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>According to the program for cleaning and disinfection device</td>
</tr>
</tbody>
</table>

**D–W:** Drinking water

**FD–W:** Fully desalinated water (demineralized, low microbiological contamination: drinking water quality at least)

*Recommended: B Braun Helimatic Cleaner alkaline*

- Check visible surfaces for residues after mechanical cleaning/disinfecting.
**Inspection, maintenance and checks**

**CAUTION**

Damage (metal seizure/friction corrosion) to the product caused by insufficient lubrication!

- Prior to function checks, lubricate moving parts (e.g. joints, pusher components and threaded rods) with maintenance oil suitable for the respective sterilization process (e.g. for steam sterilization: Aesculap STERILIT® 1 oil spray JG600 or STERILIT® 1 drip lubricator JG598).

- Allow the product to cool down to room temperature.

- After each complete cleaning, disinfecting and drying cycle, check that the instrument 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 damp.

- Repeat cleaning and disinfection of products that still show impurities or contamination.

- Check that the product functions correctly.

- Immediately put aside damaged or inoperative products and send them to Aesculap Technical Service, see Technical Service.

- Assemble separable products, see Trocar assembly.

- Check for compatibility with associated products.

**Packaging**

- Place the product in its holder or on a suitable tray. Ensure that all cutting edges are protected.

- Pack trays appropriately for the intended sterilization process (e.g. in sterile Aesculap containers).

- Ensure that the packaging provides sufficient protection against recontamination of the product during storage.

**Steam sterilization**

*Note*

The product may only be sterilized when dismantled.

- Check to ensure that the sterilizing agent will come into contact with all external and internal surfaces (e.g. by opening any valves and faucets).

- Validated sterilization process
  - Disassemble the instrument
  - Steam sterilization through fractionated vacuum process
  - Steam sterilizer according to DIN EN 285 and validated according to DIN EN ISO 17665
  - Sterilization using fractionated vacuum process at 134 °C/holding time 5 min

- When sterilizing several instruments at the same time in a steam sterilizer, ensure that the maximum load capacity of the steam sterilizer specified by the manufacturer is not exceeded.
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Sterilization for the US market

- Aesculap advises against sterilizing the device by flash sterilization or chemical sterilization.
- Sterilization may be accomplished by a standard prevacuum cycle in a steam autoclave.

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

<table>
<thead>
<tr>
<th>Sterilization method</th>
<th>Temp.</th>
<th>Time</th>
<th>Minimum drying time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevacuum</td>
<td>270 °F-275 °F</td>
<td>4 min</td>
<td>20 min</td>
</tr>
</tbody>
</table>

*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 products. 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.

WARNING

For the US market

If this device is/was used in a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of crosscontamination.

Storage

- Store sterile products in germ-proof packaging, protected from dust, in a dry, dark, temperature-controlled area.

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 Technischer Service
Am Aesculap-Platz
78532 Tuttingen / Germany
Phone: +49 (7461) 95-1602
Fax: +49 (7461) 16-5621
E-Mail: ats@aesculap.de

Or in the US:
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

<table>
<thead>
<tr>
<th>Art. no.</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>FH620R</td>
<td>MiNOP inVent Trocar 30°</td>
</tr>
<tr>
<td>PE204A</td>
<td>MiNOP Endoscope 30°</td>
</tr>
<tr>
<td>RT068R</td>
<td>MiNOP inVent Holding arm adapter</td>
</tr>
</tbody>
</table>

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

3773 Corporate Parkway
Center Valley, PA, 18034, USA