Aesculap®
MINOP TR irrigating trocar

Legend
1. Trocar connectors for suction devices and irrigation fluid
2. Release button
3. Flushing channel
4. Foot control switch
5. Infusion stand
6. Irrigation tubing
7. The patient
8. MINOP TR irrigating trocar
9. Suction tube
10. Suction device
11. Irrigation fluid bag

Symbols on product and packages
- Not for reuse in intended applications as defined by the manufacturer
- Caution, general warning symbol
- Caution, see documentation supplied with the product

Scope
- MINOP TR
- For item-specific instructions for use and information on material compatibility, see also the Aesculap Extranet at www.extranet.bbraun.com

Intended use
The MINOP TR irrigating trocar is used exclusively for endoscopic examinations via a transnasal access.

Instrument description

Components

<table>
<thead>
<tr>
<th>Art. no.</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>FH600</td>
<td>Aesculap foot control switch</td>
</tr>
<tr>
<td>FH601R</td>
<td>MINOP TR irrigating trocar, with a suction and a flushing channel as well as an interlocking system, ∅ 4.6 mm, working length 150 mm</td>
</tr>
<tr>
<td>PE184A</td>
<td>Aesculap endoscope 0°, ∅ 2.7 mm</td>
</tr>
<tr>
<td>PE206A</td>
<td>Aesculap endoscope 30°, ∅ 2.7 mm</td>
</tr>
<tr>
<td>FH602</td>
<td>Irrigation tube, sterile (for single use)</td>
</tr>
</tbody>
</table>

Safe handling and preparation

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

Risk of injury caused by incorrect operation of the product!
- Attend appropriate product training before using the product.
- For information about product training, please contact your national B. Braun/Aesculap agency.

- 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.
- 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.
- Read, follow, and keep the TAO 1057 endoscope instructions for use.
- Use the product only in accordance with its intended use, see Intended use.
- Prior to each use, inspect the product for loose, bent, broken, cracked, or fractured components.
- Do not use the product if it is damaged or defective. Set aside the product if it is damaged.

Safe operation

CAUTION
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.

Disassembling

Damage to the endoscope due to incorrect sequence of disassembly!
- First detach the camera from the endoscope, then withdraw the endoscope from the trocar.

CAUTION
- Press unlocking button 2 and carefully pull the endoscope out of the trocar.
- Disassemble the system in reverse order of assembly.

Assembling

- Connect MINOP TR irrigating trocar in accordance with the diagram, see Fig. A. Observe the following:
- Hang the bag with the rinsing fluid on infusion stand 5, at a height of 0.5–1.0m above the trocar, and connect it to the irrigation tube. A pressure cuff may optionally be used.
- Connect irrigation tube 6 to a trocar connector 1 of suction-irrigation trocar 8.
- Insert the irrigation tube 6 into the pedal switch 4 as follows:
  - Actuate the pedal switch.
  - Insert the irrigation tube, see Fig. B.
  - Release the pedal switch.
- Connect suction tube 9 to the other trocar connector 1 of suction-irrigation trocar 8.
- Connect suction tube 9 to suction device 10.

Damage to the endoscope due to incorrect assembly sequence!
- First lock the endoscope in the trocar, then mount the camera.

CAUTION
- Carefully introduce the endoscope into the suction-irrigation trocar until you feel the passive stop.
- Set the vacuum of the suction device to 0.6–0.8bar with continuous suction.
- Install the camera on the endoscope.
- Switch the monitor on.
- Switch on the suction device.
- Press the pedal switch and check that suction and irrigation power are set to the appropriate ratio, see Fig. 1:

Fig. 1 Suction/irrigation ratio

Legend
A. Optimal cleaning effect, suction and flushing performance are in the appropriate ratio if, when the pedal switch is activated, the lens is completely washed with liquid and, after releasing the pedal switch, it is completely dry again.
B. Too much suction, no cleaning effect, as the fluid is sucked off immediately.
Remedy: Reduce suction power and/or increase irrigation flow.
C. Too much irrigation, no cleaning effect, as the lens is not rinsed properly.
Remedy: Reduce irrigation flow and/or increase suction power.

Note
The suction channel of the suction-irrigation trocar only serves for intraoperative lens cleaning and does not replace the intraoperative surgical suction equipment.

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.

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.extranet.bbraun.com.

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

Single-use products

WARNING
- Infection hazard for patients and/or users and impairment of product functionality due to reuse. Risk of injury, illness or death due to contamination and/or impaired functionality of the product!
- Do not reprocess the product!

<table>
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<td>FH602</td>
<td>Irrigation tube, sterile (for single use)</td>
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</table>
General information

Dried or oiled 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 freezing pre-cleaning temperatures ≥+45 °C nor freezing disinfecting agents (active ingredients: aldehydes/alcohols) should be used. Excessive measures of neutralizing agents or basic cleaners may result in a chemical attack and/or to fogging 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 (etching, 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. VHM or FDA approval or CE mark) and which are compatible with the product’s materials according to the chemical manufacturer’s 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/processing solution only needs to be of pH >8 to cause visible surface changes.

Material damage such as corrosion, cracks, fraying, 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-safe processing reprocessing can be found at www.a-

Disassembling the product before carrying out the reprocessing procedure

Disassemble the product immediately after use, as described in the respective instructions for use. Remove the sealing cap from the laser link connector.

Preparations at the place of use

If applicable, rinse non-visible surfaces preferably with deionized water, with a disposable spray 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

Dispose of the product prior to cleaning, see Disassembling. Disassemble the product prior to cleaning.

Cleaning/disinfection

Product-specific safety notes on the reprocessing procedure

Risk to patients!

The product must only be cleaned mechanically!

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 (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 allowable temperature of 55 °C.

Cleaning/sterilization

Mechanical cleaning/disinfection with manual pre-cleaning

Note

The endoscopes have their own instructions for use for these. Take the applicable, validated cleaning procedures from this.

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.

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>
<tbody>
<tr>
<td>Manual pre-cleaning with ultrasonic and brush, and subsequent manual mechanical cleaning and thermal disinfection</td>
<td>Cleaning brush, e.g. PF893800</td>
<td>Chapter Mechanical cleaning and disinfection with manual pre-cleaning and sub-chapter: Chapter Manual pre-cleaning with ultrasonic and brush Chapter Mechanical alkali cleaning and thermal disinfecting</td>
</tr>
<tr>
<td></td>
<td>20 ml disposable syringe</td>
<td></td>
</tr>
<tr>
<td></td>
<td>When cleaning products with movable hinges, ensure that these are in an open position and, if applicable, move the joint while cleaning.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Place the product in a tray that is suitable for cleaning (avoiding rimming blind spots).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Connect components with lumens and channels directly to the rinsing part of the injector carriage.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Keep working ends open for cleaning.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Place products in the tray with their hinges open.</td>
<td></td>
</tr>
</tbody>
</table>

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>Alcohol-free, phenol-free, and QUAT-free concentrate, pH ~ 9*</td>
</tr>
<tr>
<td>II</td>
<td>Rinsing</td>
<td>RT (cold)</td>
<td>-</td>
<td>-</td>
<td>D-W</td>
<td>-</td>
</tr>
</tbody>
</table>

D-W: Drinking water

RT: Room temperature

*Recommended: BBraun Stabimed

Note

The information on appropriate cleaning brushes and disposables syringes, see Validated cleaning and disinfection procedure.

Phase 1

Clean the product in an ultrasonic cleaning bath (frequency 35 kHz) for at least 15 min. Ensure that all accessible surfaces are immersed and that the joints are filled with liquid for at least 5 min.

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 8

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>T [°C/°F]</th>
<th>t [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: pH = 13 – ≤ 5% anionic surfactant 0.5% working solution 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 (deionized, low microbiological contamination: drinking water quality at least)

Recommended: BBraun Helimatic Cleaner alkaline

Note

Check visible surfaces for residues after mechanical cleaning/disinfecting.

Inspection, maintenance and checks

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® I oil spray J0600 or STERILIT® I drip lubricant J0598).

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. 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 disassembled products, see Assembling.

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 Aesculap sterile containers).

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

Steam sterilization

Note

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

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:

– Steam sterilization using fractional vacuum process

– Steam sterilizer according to DIN EN 265 and validated according to DIN EN ISO 17685

– Steam sterilizer is immersed and acoustic shadows are avoided.

When sterilizing several products 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.
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 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**

► 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 Tuttlingen / Germany

Phone: +49 (7461) 96-1602
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>
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<tr>
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<tbody>
<tr>
<td>FH602</td>
<td>Irrigation tube, sterile $\varnothing$ 4 mm, length 8 m (for single use)</td>
</tr>
<tr>
<td>GN093</td>
<td>Pressure cuff</td>
</tr>
<tr>
<td>PF93800</td>
<td>Cleaning brush</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

TA-Nr. 011205 11/12  V6 Änd.-Nr. 45489