Aesculap®
Support arm

Legend
1 Support arm
2 Proximal part of the support arm
3 Fastening element
4 Silicone washer
5 Clamping handle
6 Distal part of the support arm
7 Quick-release coupling
8 Steve
9 Instrument shaft

Symbols on product and packages

Intended use
The support arm is used in minimally invasive surgery to support e.g. optical systems, cameras, instruments and trocars.
Additionally, a fastening element is used at the proximal end of the support arm and an adapter (e.g. Neuropilot®) at the distal end.
The maximum support capacity of the support arm is 40 N.

Safe handling and preparation
CAUTION
Federal law restricts this device to sale by, or on order of a physician!
► 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.
► Clean the new product mechanically after removing its transport packaging and 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.

Safe operation

Injuries caused by unstable fixation of optics, cameras, instruments or trocars!
► Apply appropriate care when supporting and fixing optical systems, cameras, instruments or trocars.
► Tighten the clamping handle and check the fixation of the support arm.
► Do not overload the support arm.

Damage to the joints of the support arm!
► Loosen the clamping handle before changing the position of the support arm.

Disassembling
► Remove any optical systems, cameras, instruments or trocars coupled to the support arm from quick-release coupling 7.
► Turn Steve 8 of quick-release coupling 7 counterclockwise.
Steve 8 of quick-release coupling 7 is unlocked.
► Pull Steve 8 of quick-release coupling 7 towards instrument shaft 9, see Fig. 2.
Instrument shaft 9 is pushed out from quick-release coupling 7.
► Remove fastening element 3 and silicone washer 4 from the support arm.

Assembling

Injuries caused by unstable fixation of optics, cameras, instruments, trocars, support arm and fastening elements!
► Apply appropriate care when supporting and fixing optical systems, cameras, instruments or trocars.
► Tighten the clamping handle and check the fixation of the support arm.
► Do not overload the support arm.
► Ensure that the instrument shaft engages properly.
► With the instrument shaft engaged, turn the sleeve clockwise.
► Firmly tighten the fastening element at the operating table rail and the support arm.
► To separate the sterile region from the unsterile region, slide silicone washer 4 over the rod, starting from the bottom end.
► Fasten holding arm 1 using fastening element 3 FF151RT, PF280RT or RT906RT to the operating table rail, see Fig. 3.
Optional accessory, not part of delivery scope
► Check for correct fixation of support arm 1. Slide the support arm 1 vertically and horizontally.
► Insert instrument shaft 9 into the Steve 8 – see Fig. 4.
Quick-release coupling 7 is locked automatically.
► Position instrument shaft 9 at angles of 60°, see Fig. 5.
► To secure quick-release coupling 7 against inadvertent opening, rotate sleeve 8 clockwise, see Fig. 4.

Validated reprocessing procedure

General safety notes

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

Note
For patients with Cerebral-Infarct disease (CID), suspected CID or possible variants of CID, observe the relevant national regulations concerning the reprocessing of products.

Note
It should be noted that successful reprocessing of this medical device can only be guaranteed following prior validation of the reprocessing method. The operator/reprocessing technician is responsible for this.

Note
For the latest information on reprocessing and material compatibility see also the Aesculap extranet at www.extranet.braun.com
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 2 h. If necessary, pre-cleaning processes are required. Do not use oxidizing process chemicals (e.g. H2O2) as these can cause bleaching or layer loss.
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.
Perform additional drying, if necessary.
Only process chemicals that have been tested and approved (e.g. VWR 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 in 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, cracking, fracturing, premature aging, or swelling.
► Do not use metal cleaning brushes or other abrasives that would damage the product surface and could cause corrosion.
► For further detailed information on hygienically safe and material-preserving/value-preserving reprocessing, see www.a-k-lgc.org, link to Publications, Red Brochure – Proper maintenance of instruments.

Disassembling the product before carrying out the reprocessing procedure
► Disassemble the product immediately after use, as described in the respective instructions for use.
► Tighten the clamping handle by turning it clockwise.

Preparations at the place of use
► If applicable, rinse surfaces that are not accessible to visible inspection (preferably with demineralized water), using a disposable syringe, for example.
► Remove any visible surgical residues as much as possible with a damp, lint-free cloth.
► Place the dry product in a sealed waste container and forward it on for cleaning and disinfection within 2 hours.

Preparation before cleaning
► Carry out non-fixating/NaCl-free pre-cleaning immediately after use.
► Dismantle the product prior to cleaning, see Disassembling.

Cleaning/disinfection

Product-specific safety notes on the reprocessing procedure

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

Damage to the clamping mechanism of the support arm during processing!
► Do not immerse the support arm in any fluid.
► Tighten the clamping handle by turning it clockwise.

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 should be approved for plastic material and high-grade steel,
► do not attack sufferers (e.g. in silicone).
► Observe specifications regarding concentration, temperature and exposure time.
► Do not exceed the maximum allowable temperature of 55 °C.
► Do not use oxidizing process chemicals (e.g. H2O2), as these can cause bleaching or layer loss.
Validated cleaning and disinfection procedure
For mechanical cleaning:

Use appropriate (neutral, enzymatic and mild-alkaline) detergents on this product with its aluminum components.

### Mechanical neutral or mild alkaline cleaning and thermal disinfecting

<table>
<thead>
<tr>
<th>Validated procedure</th>
<th>Specific requirements</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanical neutral or mild alkaline cleaning and thermal disinfecting</td>
<td>- Position the product in such a way that water will not enter the product (e.g. through coupling interfaces). - Tighten the clamping handle by turning it clockwise.</td>
<td>Chapter Mechanical cleaning/disinfecting and sub-chapter: Chapter Mechanical neutral or mild alkaline cleaning and thermal disinfecting</td>
</tr>
</tbody>
</table>

### Mechanical cleaning/disinfecting

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

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

### Mechanical neutral or mild alkaline cleaning and thermal disinfecting

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

#### Phase | Step | T [°C/°F] | t [min] | Water quality | Chemicals |
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>II</td>
<td>Pre-rinse</td>
<td>&lt;25/77</td>
<td>3</td>
<td>D–W</td>
<td>Neutral:</td>
</tr>
<tr>
<td>II</td>
<td>Cleaning</td>
<td>55/131</td>
<td>10</td>
<td>FD–W</td>
<td>- Concentrate: - pH neutral - &lt;5% anionic surfactant - 0.5% working solution Milder alkaline: - Concentrate: - pH = 9.5 - &lt;5% anionic surfactant - 0.5% solution</td>
</tr>
<tr>
<td>III</td>
<td>Intermediate rinse</td>
<td>&gt;10/50</td>
<td>2</td>
<td>FD–W</td>
<td>-</td>
</tr>
<tr>
<td>IV</td>
<td>Thermal disinfection</td>
<td>93/199</td>
<td>10</td>
<td>FD–W</td>
<td>- In accordance with the program for the cleaning and disinfecting machine</td>
</tr>
<tr>
<td>V</td>
<td>Dry</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

D–W: Drinking water
FD–W: Fully deionized water (demineralized, low microbiological contamination: drinking water quality at least)

*Recommended: BBraun Hemoclean Cleaner Neutral

- Check visible surfaces for residues after mechanical cleaning/disinfecting.
- Repeat the cleaning/disinfecting process if necessary.

#### 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 clean, dry, operational, and free of damage (e.g. broken insulation or corrodied, 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.
- Open the clamping handle of the support arm by turning it counterclockwise as far as it will go.
- 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.
- Open the clamping handle of the support arm by turning it counterclockwise as far as it will go.

#### Steam sterilization

- 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 285 and validated according to DIN EN ISO 17665
    - Steam sterilization using fractional vacuum process at 114 °C (heating time 5 min)
    - 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>Aesculap Orga Tray/Sterile container (perforated bottom)</th>
<th>Minimum cycle parameters*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization method</td>
<td>Temp.</td>
</tr>
<tr>
<td>Prevacuum</td>
<td>270 °F/138 °C</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 Crohn’s Disease (CD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination.

#### Storage

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

#### Maintenance

This product is maintenance-free.

In cases of damage, stiffness or insufficient clamping force, please contact your national B. Braun/Aesculap agency, see Technical Service.

### 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 Tutlingen / Germany
Phone: +49 (7461) 16-1602
Fax: +49 (7461) 16-5621
E-Mail: ats@aesculap.de
Or in the US:
Aesculap Technical Services
615 Lambert Pointe Drive
Hazelwood, MO 63042
Aesculap Repair Hotline
Phone: +1 (800) 214-3392
Fax: +1 (314) 695-4420
Other service addresses can be obtained from the address indicated above.

### Accessories/Spare parts

#### Art. no. | Designation
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>FF260R</td>
<td>Flexible fastening element with ball joint</td>
</tr>
<tr>
<td>RT060R</td>
<td>Flexible fastening element with tooth rim</td>
</tr>
<tr>
<td>FF151R</td>
<td>Rigid fastening element</td>
</tr>
<tr>
<td>RT046P</td>
<td>Adapter for endoscope holder</td>
</tr>
<tr>
<td>RT079R</td>
<td>Adapter for fixation on endoscope body/eye piece</td>
</tr>
<tr>
<td>RT099R</td>
<td>MINOP TRENDAdapter for holding arm</td>
</tr>
<tr>
<td>RT081R</td>
<td>Adapter for attaching RT055P</td>
</tr>
<tr>
<td>RT060R</td>
<td>Neuropilot® IV+EA</td>
</tr>
<tr>
<td>RT068R</td>
<td>MINOP InVent adapter for holding arm</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