

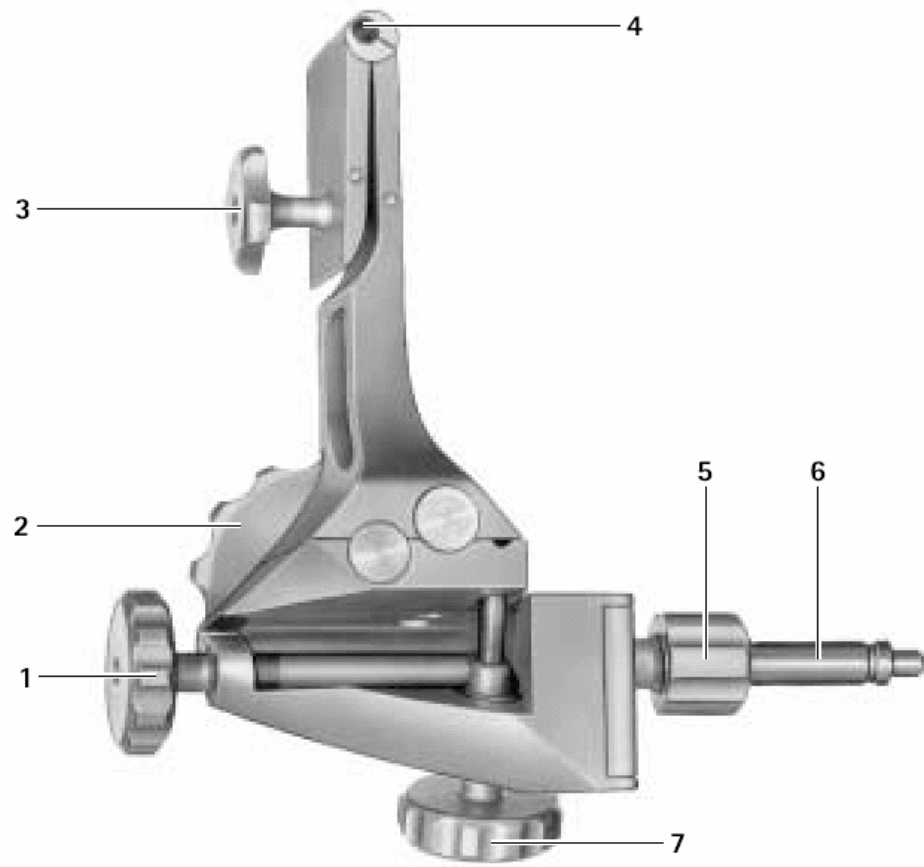
# AESCULAP®



**QB** Instructions for use  
**USA** Neuropilot IV + EA

**B | BRAUN**

**CE**



**Legend**

- 1 Adjustment knob (direction X)
- 2 Adjustment knob (direction Z)
- 3 Adjustment knob (fixation)
- 4 Reduction sleeve
- 5 Nut
- 6 Adapter
- 7 Adjustment knob (direction Y)
- 8 Sleeve of the UNITRAC support arm

**Intended use**

Neuropilot IV + EA is a holder that is used in neurosurgery to fix, and fine tune the position of, endoscopes or trocars. It is designed especially for endoscope-assisted (EA) surgery, but can also be used for fully endoscopic intraventricular (IV) procedures.

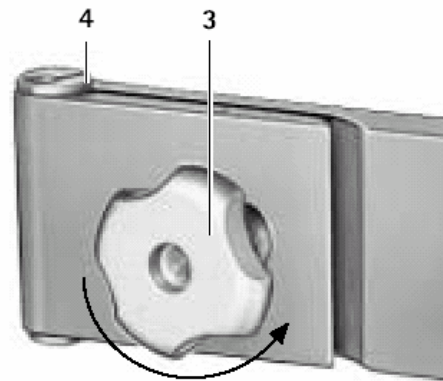
Neuropilot IV + EA may only be used in conjunction with the UNITRAC support arm (RT 040 R). Adjustment knobs allow the position of the endoscope or trocar to be fine tuned in three different directions in Neuropilot IV + EA.

**Safe handling and preparation**

- Read the instructions for use and keep them in a safe place.
- Use the holder only in accordance with professional standards and practices, see Intended use.
- Clean the new holder either manually or mechanically prior to the initial sterilization.
- Store new or unused holders in a dry, clean and safe place.
- Inspect the holder after each cleaning and disinfecting cycle to be sure it is: clean, functioning properly, not damaged, has intact insulation and does not have any loose, bent, broken, cracked, worn, or fractured components.
- Never use damaged or faulty holders.
- Set aside any damaged holders immediately.
- Prior to each use, inspect the holder for: loose, bent, broken, cracked, worn, or fractured components.

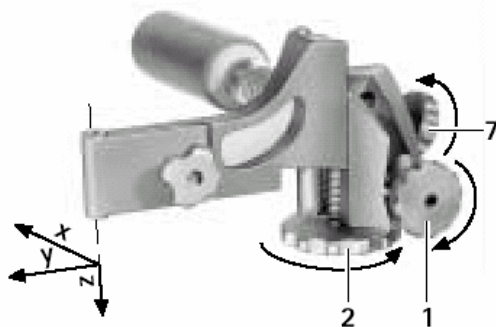
**Safe operation**

- Make certain that the reduction sleeve is compatible with the endoscope or trocar used.
- Follow the instructions for the endoscope or trocar used.
- Rotate the adjustment knob 3 in a counter-clockwise direction as far as it will go.



- Slide the endoscope or trocar from above, into the reduction sleeve 4 in the Neuropilot IV + EA.
- To avoid adverse leverage and breakage of the glass lenses in the endoscope: Insert the endoscope into reduction sleeve 4 as far as it will go.
- Rotate the adjustment knob 3 in a clockwise direction until the endoscope or trocar is seated tightly.  
The endoscope or trocar is now fixed.
- Prior to the operation, rotate the adjustment knobs 1, 2 and 7 in such a way that the trocar spindle of Neuropilot IV + EA is center-positioned in all directions.

- During the operation, use the adjustment knobs 1, 2 and 7 to position the trocar or endoscope in Neuropilot IV + EA:

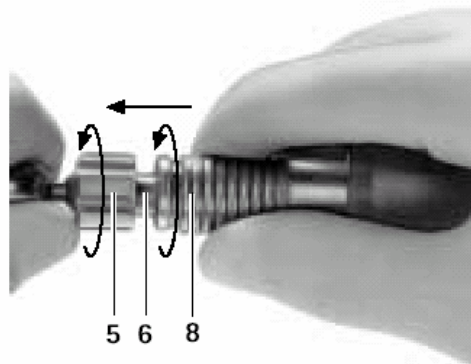


- Use the adjustment knob 1 to fine tune the position in direction X (right-left).
- Use the adjustment knob 7 to fine tune the position in direction Y (forwards-backwards).
- Use the adjustment knob 2 to fine tune the position in direction Z (up-down).

## Disassembly

### Detaching Neuropilot IV + EA from the UNITRAC support arm

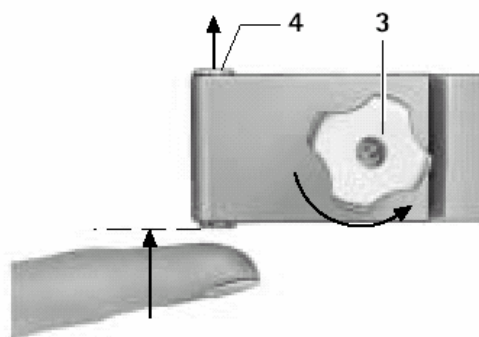
- Follow the instructions for the UNITRAC support arm (TA 009 480/US-doc.no. 476).
- Unscrew the nut 5.



- To unlock the fast-action coupling: unscrew the sleeve 8 on the UNITRAC support arm.
- Slide the sleeve 8 forward and remove the adapter 6 from the fast-action coupling on the UNITRAC support arm.

### Removing the reduction sleeve

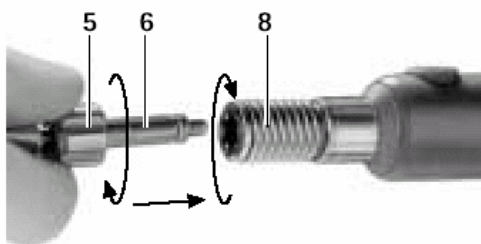
- Rotate the adjustment knob 3 in a counter-clockwise direction.
- Push the reduction sleeve 4 out of the opening from underneath and pull it out from above.



## Assembly

### Mounting Neuropilot IV + EA on the UNITRAC support arm

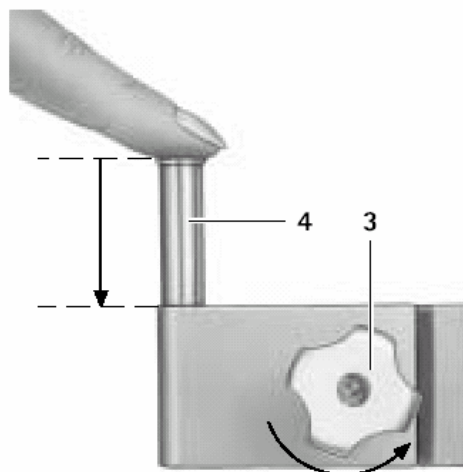
- Follow the instructions for the UNITRAC support arm (TA 009 480/US-doc.no. 476).
- Rotate the adjustment knobs **1**, **2** and **7** in such a way that the trocar or endoscope spindle of Neuropilot IV + EA is center-positioned in all directions.
- Unscrew the nut **5** in the opposite direction of the arrow.



- Slide the adapter **6** into the fast-action coupling of the UNITRAC support arm until the sleeve **8** snaps back.
- To prevent the fast-action coupling from opening adventitiously: screw down the sleeve **8** of the UNITRAC support arm.
- Screw down the nut **5** until Neuropilot IV + EA is seated tightly.

### Inserting the reduction sleeve

- Select a reduction sleeve **4** that is compatible with the trocar or endoscope being used.



- Rotate the adjustment knob **3** in a counterclockwise direction as far as it will go.
- To prevent the reduction sleeve **4** from being pushed into the operating field by accident: always insert the reduction sleeve in a proximal to distal direction.
- Slide the reduction sleeve **4** into the opening from above, until it audibly snaps into place.

## Care and handling

### 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.*

### After each use

- Clean the contaminated holder as quickly as possible.
- For mechanical cleaning, place the holder in a suitable wire basket, and avoid watermarks.
- Preferably put away the holder when it is dry.
- If put away while wet, use an active cleaning disinfectant. Prior to mechanical cleaning and disinfecting, rinse the holder thoroughly in clear running water.
- If ultrasound is needed, carry out the procedure according to the instructions provided by the manufacturer of the apparatus:
  - as an effective mechanical supplement to manual cleaning.
  - for initial cleaning of holders with dried debris on them prior to mechanical cleaning.
- Perform manual or mechanical cleaning. Follow the manufacturer's instructions.

### Manual cleaning and disinfecting

- Lay the holder in a suitable active disinfectant in such a way that all surfaces, cavities, lumina and openings are covered. Follow the disinfectant manufacturer's instructions.
- After disinfecting chemically, always rinse the items thoroughly in plenty of clear running water. Follow the disinfectant manufacturer's instructions.
- Remove encrusted materials with a soft nylon brush. Do not use harsh cleaning agents or metal brushes.
- Dry lumina and channels with a soft round nylon brush.

### Note

*Use brushes that are an appropriate diameter for the lumina they are being used to clean.*

- Carry out the final rinse in distilled or fully demineralized water.
- Dry the holder with an absorbent, soft and lint-free cloth.
- Dry lumina and channels with compressed air.

### Mechanical cleaning and disinfecting

- When choosing a cycle for mechanical cleaning, take into account the materials in the holder to be cleaned (e.g. stainless instrument-grade steel, aluminum). Follow the instructions provided by the manufacturer of the device.
- Carry out the final rinse in fully demineralized water.
- Be sure the drying phase is sufficiently long.
- Remove the holder from the machine as soon as the program is completed.

### Care, checking

- Allow the holder to cool down to room temperature.
- Spray moving parts such as hinges and latches with a sterilizable and moisture-permeable lubricating oil such as AESCULAP STERILIT Spray JG 600 or lubricating oil JG 598.
- Inspect the holder after each cleaning and disinfecting cycle to be sure it is: clean, functioning properly, not damaged, has intact insulation and does not have any loose, bent, broken, cracked, worn, or fractured components.
- Set aside and replace any damaged or defective holders.

### Packing

- Keep the holders in appropriate storage containers.

### Sterilization method and parameters

- Sterilize with steam, taking note of the following: The sterilization has to be done according to a validated steam sterilization procedure (e.g. in a sterilizer in conformance with EN 285/ANSI/AAMI/ISO 11134-1993, ANSI/AAMI ST46-1993, and validated in conformance with EN 554/ISO 13683). In case of application of the fractionated vacuum procedure the sterilization has to be carried out for a minimum of 5 minutes at 134 °C and at 2 bar pressure.

**Sterilization for the US market**

- Sterilization of the device may be accomplished by steam or ethylene oxide (EtO) gas.
- Aesculap does not recommend the device be sterilized by "Flash" or chemical sterilization.
- Surgical instruments may also be placed within an Aesculap rigid sterilization container (Sterilcontainer) for processing under generally accepted hospital in-use conditions.

The recommended sterilization parameters are as follows:

Sterilization method	Temp.	Minimum exposure time	
		Wrapped	In a Steril-container system
Pre-vacuum	270–275 °F	4 min	4 min
Gravity	250–254 °F	15 min	40 min
	270–275 °F	10 min	30 min
Ethylene Oxide (EtO)	125–130 °F	105 min with 12 % EO, 88 % FREON; 45–75 % chamber humidity, reaction of 6 hours	

**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!

**Repairs**

Repairs may be carried out only by persons authorized to do so by Aesculap. Only in this way will warranties and guarantees remain valid.

- If any repairs are needed, please send the instrument to:

AESCULAP Technischer Service  
Am Aesculap-Platz  
78532 Tuttlingen / Germany  
Phone: +49 7461 95 27 00  
Fax: +49 7461 16 28 87  
E-mail: [ats@aesculap.de](mailto:ats@aesculap.de)

Or in the US:

AESCULAP Inc.  
Attn. AESCULAP Technical Services  
615 Lambert Pointe Road  
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**

Reduction sleeve	Inner diameter	Compatible endoscopes and trocars
RT 061 R	4.0 mm	Angled neuroscopes PE 486 A, PE 506 A, PE 526 A
RT 062 R	6.2 mm	Ventriculoscope trocars FF 370 R, FF 372 R
RT 063 R	3.2 mm	Minop trocar FF 397 R
RT 064 R	4.6 mm	Minop trocar FF 398 R
RT 065 R	6.0 mm	Minop trocar FF 399 R
RT 066 R	3.0 mm	PaediScope PF 010 A

**Distributor in the US**

AESCULAP Inc.  
3773 Corporate Parkway  
Center Valley, PA, 18034



CE-Kennzeichnung gemäß Richtlinie 93/42/EWG  
CE marking according to directive 93/42/EEC  
Marquage CE conforme à la directive 93/42/CEE  
Identificación CE en conformidad con la directriz 93/42/CEE  
Marchio CE conforme alla direttiva 93/42/CEE

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