AESCULAP®

en **Instructions for use/Technical description**
Ring-type scissors and spring-type scissors

USA Note for U.S. users
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de **Gebrauchsanweisung/Technische Beschreibung**
Ring- und Federscheren

fr **Mode d'emploi/Description technique**
Ciseaux à anneau et à ressort

es **Instrucciones de manejo/Descripción técnica**
Tijeras anulares y elásticas

it **Istruzioni per l'uso/Descrizione tecnica**
Forbici ad anello e a molla

pt **Instruções de utilização/Descrição técnica**
Tesouras com anéis e de mola

nl **Gebruiksaanwijzing/Technische beschrijving**
Ring- en veerscharen

da **Brugsanvisning/Teknisk beskrivelse**
Ring- og fjedersakse

nb **Bruksanvisning/Teknisk beskrivelse**
Ring- og fjærsakser

sv **Bruksanvisning/Teknisk beskrivning**
Ring- och fjädersaxar

fi **Käyttöohje/Tekninen kuvaus**
Rengas- ja jousisakset

et **Kasutusjuhend/Tehniline kirjeldus**
Rõngas- ja vedrukäärid

lv **Lietošanas instrukcijas/tehniskais apraksts**
Šķēres ar apaļiem rokturiem un atsperšķēres

lt **Naudojimo instrukcija/techninis aprašas**
Žiedinės ir spyruoklinės žirklės

ru **Инструкция по примению/Техническое описание**
Изогнутые и пружинные ножницы

cs **Návod k použití/Technický popis**
Kroužkové a pružinové nůžky

pl **Instrukcja użytkowania/Opis techniczny**
Nożyczki chirurgiczne i mikrochirurgiczne

sk **Návod na použitie/Technický opis**
Nožnice s okami a pružinové nožnice

hu **Használati útmutató/Műszaki leírás**
Gyűrűs és rugós ollók

sl **Navodila za uporabo/Tehnični opis**
Škarje z okroglim ročajem in vzmetne škarje

hr **Upute za uporabu/Tehnički opis**
Škare s prstenom i oprugom

ro **Manual de utilizare/Descriere tehnică**
Foarfeci cu inel și arc

bg **Упътване за употреба/Техническо описание**
Пръстеновидни и пружинни ножици

tr **Kullanım Kılavuzu/Teknik açiklama**
Halka ve yaylı makaslar

el **Οδηγίες χρήσης/Τεχνική περιγραφή**
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AESCULAP®

Ring-type scissors and spring-type scissors

1. About this document

Note

General risk factors associated with surgical procedures are not described in these instructions for use.

1.1 Scope

These instructions for use apply to ring-type and spring-type scissors in nearly all surgical disciplines.

Note

The applicable CE mark for the product can be seen on the label or packaging of the product.

► For article specific instructions for use and material compatibility and lifetime information, see B. Braun eIFU at eifu.bbraun.com

1.2 Safety messages

Safety messages make clear the dangers to patient, user and/or product that could arise during the use of the product. Safety messages are labeled as follows:

⚠WARNING

Indicates a possible threat of danger. If not avoided, minor or moderate injury may result.

⚠CAUTION

Indicates a possible threat of material damage. If not avoided, the product may be damaged.

2. Clinical use

2.1 Areas of use and limitations of use

2.1.1 Intended use

Surgical scissors
The instruments are used to cut tissue and/or medical materials and supplies.

Dissecting scissors
The instruments are used to cut and/or dissect tissue.

Nail scissors
The instruments are used to cut or split finger nails and toe nails and/or cuticles.

Bandage scissors and material scissors
The instruments are used to cut medical materials and supplies and/or clothing.

Micro scissors
The instruments are used to cut and/or dissect tissue during micro surgical procedures.

2.1.2 Indications

The instruments are used in a multitude of surgical procedures and interventions in almost all surgical disciplines, see Intended use.

2.1.3 Contraindications

No contraindications for the product are currently known.

2.2 Safety information

2.2.1 Clinical user

General safety information
To prevent damage caused by improper setup or operation, and to not compromise the manufacturer warranty and liability:

► Use the product only according to these instructions for use.
► Follow the safety and maintenance instructions.
► Ensure that the product and its accessories are operated and used only by persons with the requisite training, knowledge and experience.
► Store any new or unused products in a dry, clean, and safe place.
► Prior to use, check that the product is in good working order.
► Keep the instructions for use accessible for the user.

Note

The user is obligated to report all severe events in connection with the product to the manufacturer and the responsible authorities of the state in which the user is located.

Notes on surgical procedures
It is the user's responsibility to ensure that the surgical procedure is performed correctly.
Appropriate clinical training as well as a theoretical and practical proficiency of all the required operating techniques, including the use of this product, are prerequisites for the successful use of this product.
The user is required to obtain information from the manufacturer if there is an unclear preoperative situation regarding the use of the product.

2.2.2 Sterility

The product is delivered in an unsterile condition.

► Clean the new product after removing its transport packaging and prior to its initial sterilization.

2.3 Application

⚠WARNING

Risk of injury and/or malfunction!

► **Prior to each use, inspect the product for loose, bent, broken, cracked, worn, or fractured components.**
► **Always carry out a function test prior to each use of the product.**

3. Validated reprocessing procedure

3.1 General safety information

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.

Note

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

Note

For up-to-date information about reprocessing and material compatibility, see B. Braun eIFU at eifu.bbraun.com

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

3.2 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 precleaning temperatures >45 °C nor fixating disinfecting agents (active ingredient: aldehydes/alcohols) 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 "AKI-Brochures", "Red brochure".

3.3 Reusable products

Influences of the reprocessing which lead to damage to the product are not known.

A careful visual and functional inspection before the next use is the best opportunity to recognize a product that is no longer functional, see Inspection.

3.4 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.

3.5 Cleaning/Disinfection

3.5.1 Product-specific safety information on the reprocessing method

Damage to or destruction of the product due to inappropriate cleaning/disinfecting agents and/or excessive temperatures!

► Use cleaning agents and disinfectants according to the manufacturer's instructions.
► Observe specifications regarding concentration, temperature and exposure time.
► Do not exceed a disinfection temperature of 96 °C.

For products with plasma layers (e. g. Noir instruments), the layer can be damaged or worn if special cleaning procedures with oxidising chemicals (e. g. hydrogen peroxide H_2O_2) are used.

► Do not use oxidizing chemicals for cleaning.
► For wet disposal, use suitable cleaning agents/disinfectants. To prevent foam formation and reduced effectiveness of the process chemicals: Prior to mechanical cleaning and disinfection, rinse the product thoroughly under running water

3.5.2 Validated cleaning and disinfection procedure

Validated procedure	Specific requirements	Reference
Manual cleaning with immersion disinfection	► Use a suitable cleaning brush. ► Keep working ends open when cleaning. ► Clean products with movable hinges in the open position or while moving the joints. ► Drying phase: Use lint free cloth or medical compressed air	Chapter Manual cleaning/disinfection and subsection: ■ Chapter Manual cleaning with immersion disinfection
Mechanical alkaline cleaning and thermal disinfection	► Place product on screen basket suitable for cleaning (make sure all areas will be reached by water jets). ► Keep working ends open when cleaning. ► Placing the product on the sterilization tray with the hinge open.	Chapter Mechanical cleaning/disinfection and subsection: ■ Chapter Mechanical alkaline cleaning and thermal disinfection

3.6 Manual cleaning/disinfection

► Prior to manual disinfecting, allow water to drip off for a sufficient length of time to prevent dilution of the disinfecting solution.
► After manual cleaning/disinfection, check visible surfaces visually for residues.
► Repeat the cleaning/disinfection process if necessary.

3.6.1 Manual cleaning with immersion disinfection

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemical
I	**Disinfecting cleaning**	RT (cold)	>15	2	D-W	Aldehyde-free, phenol-free, and QUAT-free concentrate, pH ~ 9*
II	**Intermediate rinse**	RT (cold)	1	-	D-W	-
III	**Disinfection**	RT (cold)	5	2	D-W	Aldehyde-free, phenol-free, and QUAT-free concentrate, pH ~ 9*
IV	**Final rinse**	RT (cold)	1	-	FD-W	-
V	**Drying**	RT	-	-	-	-

D-W: Drinking water
FD-W: Fully desalinated water (demineralized, low microbiological contamination: drinking water quality at least)
RT: Room temperature
*Recommended: BBraun Stabimed fresh

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

Phase I

► Fully immerse the product in the cleaning/disinfectant for at least 15 min. Ensure that all accessible surfaces are moistened.
► 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.
► Drain any remaining water fully.

Phase III

► Fully immerse the product in the disinfectant solution.
► Mobilize non-rigid components, such as set screws, joints, etc. during rinsing.
► Rinse lumens at least 5 times at the beginning of the exposure time using an appropriate disposable syringe. Ensure that all accessible surfaces are moistened.

Phase IV

► Rinse/flush the product thoroughly (all accessible surfaces).
► Mobilize non-rigid components, such as set screws, joints, etc. during final rinse.
► Rinse lumens with an appropriate disposable syringe at least five times.
► Drain any remaining water fully.

Phase V

► Dry the product in the drying phase with suitable equipment (e.g. cloth, compressed air), see Validated cleaning and disinfection procedure.

3.7 Mechanical cleaning/disinfection

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.

3.7.1 Mechanical alkaline cleaning and thermal disinfection

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

Phase	Step	T [°C/°F]	t [min]	Water quality	Chemical/Note
I	**Pre-rinse**	<25/77	3	D-W	-
II	**Cleaning**	55/131	10	FD-W	■ Concentrate, alkaline: – pH = 13 – <5 % anionic surfactant ■ 0.5 % working solution – pH = 11*
III	**Intermediate rinse**	>10/50	1	FD-W	-
IV	**Thermal disinfecting**	90/194	5	FD-W	-
V	**Drying**	-	-	-	According to the program for cleaning and disinfection device

D-W: Drinking water
FD-W: Fully desalinated water (demineralized, low microbiological contamination: drinking water quality at least)
*Recommended: BBraun Helimatic Cleaner alcaline

► Check visible surfaces for residues after mechanical cleaning/disinfecting.

3.8 Inspection

► Allow the product to cool down to room temperature.
► Dry the product if it is wet or damp.

3.8.1 Visual inspection

► Make sure all dirt has been removed. In particular, pay attention to, for example, mating surfaces, hinges, shafts, recessed areas and drilled grooves.
► If the product is dirty: repeat the cleaning and disinfection process.
► Check product for damage, e.g., corroded, loose, bent, broken, cracked, worn, heavily scratched or missing parts.
► Check the product for missing or faded labels.
► Check the cutting edges for continuity, sharpness, nicks and other damage.
► Check the surfaces for rough spots.
► Check the product for burrs that could damage tissue or surgical gloves.
► Check the product for loose or missing parts.
► Immediately put aside damaged or inoperative products and send them to Aesculap Technical Service, see Technical service.

3.8.2 Functional test

⚠ CAUTION

Damage (metal cold welding/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: STERILIT® I oil spray JG600 or STERILIT® I drip lubricator JG598).**

► Check that the product functions correctly.
► Check that all moving parts are working property (e.g. hinges, locks/latches, sliding parts etc.).
► Make sure that the scissor blades provide light resistance when closing.
► Immediately put aside inoperative products and send them to Aesculap Technical Service, see Technical service.

3.9 Packaging

► Appropriately protect products with fine working tips.
► Place the product in its holder or on a suitable tray. Ensure that sharp edges are covered.
► Package trays appropriately for the sterilization process (e.g. in Aesculap sterile containers).
► Ensure that the packaging provides sufficient protection against contamination of the product during storage.

3.10 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 in fractionated vacuum process
  – Steam sterilizer in accordance with DIN EN 285 and validated in accordance with DIN EN ISO 17665
  – Sterilization in fractionated vacuum process at 134 °C, holding time 5 min
► If several devices are sterilized at the same time in the same steam sterilizer: Ensure that the maximum permitted load according to the manufacturers' specifications is not exceeded.

3.11 Storage

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

4. Technical service

⚠ CAUTION

Modifications carried out on medical technical equipment may result in loss of guarantee/warranty rights and forfeiture of applicable licenses.

► **Do not modify the product.**
► **For service and repairs, please contact your national B. Braun/Aesculap agency.**

Service addresses

Aesculap Technischer Service
Am Aesculap-Platz
78532 Tuttlingen / Germany
Phone: +49 7461 95-1601
Fax: +49 7461 16-2887
E-Mail: ats@aesculap.de
Other service addresses can be obtained from the address indicated above.

5. Disposal

⚠ WARNING

Risk of infection due to contaminated products!

► **Adhere to national regulations when disposing of or recycling the product, its components and its packaging.**

⚠ WARNING

Risk of injury due to sharp-edged and/or pointed products!

► **When disposing of or recycling the product, ensure that the packaging prevents injury by the product.**

Note

The user institution is obliged to reprocess the product before its disposal, see Validated reprocessing procedure.

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