

**en Instructions for use/Technical description**

Hemorrhoidal ligator EA992R and ligation rubber ring EA993

USA Note for U.S. users

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da Brugsanvisning/Teknisk beskrivelse

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tr Kullanım Kılavuzu/Teknik açıklama

Hemoroidal ligatör EA992R ve ligasyon lastik halkası EA993

el Οδηγίες χρήσης/Τεχνική περιγραφή

Εργαλείο απολίνωσης αιμορροΐδων EA992R και ελαστικός δακτύλιος απολίνωσης EA993

Legend

- 1 Cone
- 2 Ring with receptacle for ligation rubber ring
- 3 Base unit
- 4 Knurled nut
- 5 Ring for slide rod
- 6 Ligation rubber ring EA993
- 7 Slide rod with release mechanism

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 for the following products:

Art. no.	Designation
EA992R	Hemorrhoidal ligator
EA993	Ligation rubber ring

- For article-specific instructions for use as well as information on material compatibility and lifetime 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

Ligation rubber rings are placed at the base of hemorrhoids using hemorrhoidal ligators. The ligation rubber ring cuts off perfusion so that the tissue (hemorrhoid) dies off after a few days.

2.1.2 Indications

Note

The manufacturer is not responsible for any use of the product against the specified indications and/or the described applications.

Rubber band ligation is indicated for grade 1 and 2 hemorrhoids.
For indications, see Intended use.

2.1.3 Contraindications

Rubber band ligation is contraindicated in the following cases:

- Patient's with Crohn's disease
- Patient is taking anticoagulants.
- Presence of large grade 3 and 4 hemorrhoids.
- Cases of hypertrophied anal papillae and/or chronic anal fissure
- Septic conditions are present in the anorectal region.

2.2 Safety information

2.2.1 Hemorrhoidal ligator EA992R

- 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.

2.2.2 Ligation rubber ring EA993

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 treat the product with cleaning or disinfection procedures.
- Sterilize the product a maximum of one time.

The product is delivered in an unsterile condition.

The product must not be reused.

- 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.
- Sterilize the product before 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.
- Do not use the product after its use-by date.

2.2.3 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.
 - Insert the cone 1 as far as it will go onto the ring with receptacle for ligation rubber ring 2, see Fig. A.
 - Guide the ligation rubber ring 6 over the cone 1 until the ligation rubber ring is securely positioned on the ring with receptacle for ligation rubber ring 2. When doing so, make certain that the slide rod with release mechanism 7 is fully retracted.
 - Remove the cone 1 from the ring with receptacle for ligation rubber ring 2, see Fig. B.
 - Slide the ring with receptacle for ligation rubber ring 2 over the hemorrhoid, see Fig. C.
 - Push the slide rod with release mechanism 7 forward using the ring for slide rod 5, see Fig. C and Fig. D.
- The ligation rubber ring 6 is pushed from the ring with receptacle for ligation rubber ring 2 by the slide rod with release mechanism 7 and it encircles the hemorrhoid.

3. Validated reprocessing procedure

3.1 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.

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 pre-cleaning 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 Single-use products

Art. no.	Designation
EA993	Ligation rubber ring

Risk of infection 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 treat the product with cleaning or disinfection procedures.
- Sterilize the product a maximum of one time.

3.4 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.

3.5 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.

3.6 Preparing for cleaning

- Disassemble the product prior to cleaning, see Disassembly.

3.7 Disassembly

- Remove the cone 1 from the ring with receptacle for ligation rubber ring 2, see Fig. B.
- Undo the ring for slide rod 5 counterclockwise and remove it, see Fig. D.
- Undo the knurled nut 4 counterclockwise and remove it.
- Remove the slide rod with release mechanism 7 from the base unit 3, see Fig. E.

3.8 Cleaning/Disinfection

3.8.1 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!

- Following the manufacturer's instructions, use cleaning and disinfecting agents that are approved for stainless steel.
- Observe specifications regarding concentration, temperature and exposure time.
- Do not exceed the maximum allowable disinfection temperature of 95 °C.
- Use suitable cleaning/disinfecting agents if the product is disposed of in a wet condition. To prevent foaming and degradation of the efficacy of the process chemicals: prior to mechanical cleaning and disinfection, rinse the product thoroughly with running water

3.8.2 Validated cleaning and disinfection procedure

Validated procedure	Specific requirements	Reference
Manual cleaning with immersion disinfection ■ EA992R	<div><div>■ Suitable cleaning brush</div><div>■ Disposable syringe 20 ml</div><div>■ Drying phase: Use a lint-free cloth or medical compressed air</div></div>	Chapter Manual cleaning/disinfection and subsection: ■ Chapter Manual cleaning with immersion disinfection
Manual pre-cleaning with brush and subsequent mechanical alkaline cleaning and thermal disinfection ■ EA992R	<div><div>■ Suitable cleaning brush</div><div>■ Disposable syringe 20 ml</div><div>■ Place the product on a tray that is suitable for cleaning (avoid rinsing blind spots).</div><div>■ Connect components with lumens and channels directly to the rinsing port of the injector carriage.</div><div>■ To flush the product: Use a flushing nozzle or flushing sleeve.</div></div>	Chapter Mechanical cleaning/disinfection with manual pre-cleaning and subsection: ■ Chapter Manual pre-cleaning with a brush ■ Chapter Mechanical alkaline cleaning and thermal disinfecting

3.9 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.

3.9.1 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, microbiological, at least of drinking water quality)

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.

3.10 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.

3.10.1 Manual pre-cleaning with a brush

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	Rinsing	RT (cold)	1	-	D-W	-

D-W: Drinking water

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.

3.10.2 Mechanical alkaline cleaning and thermal disinfecting

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

Phase	Step	T [°C/°F]	t [min]	Water quality	Chemical
I	Prerinse	<25/77	3	D-W	-
II	Cleaning	55/131	10	FD-W	<div><div>■ Concentrate, alkaline:</div><div><div>- pH = 13</div><div>- <5 % anionic surfactant</div></div><div>■ working solution 0.5%</div><div><div>- pH = 11*</div></div></div>
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 alkaline

- ▶ Check visible surfaces for residues after mechanical cleaning/disinfecting.

3.11 Inspection

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

3.11.1 Visual inspection

- ▶ Ensure that all soiling has been removed. In particular, pay attention to mating surfaces, hinges, shafts, recessed areas, drill grooves and the sides of the teeth on rasps.
- ▶ If the product is dirty: repeat the cleaning and disinfection process.
- ▶ Check the product for damage, e.g. insulation or corroded, loose, bent, broken, cracked, worn or severely scratched and fractured components.
- ▶ Check the product for missing or faded labels.
- ▶ Check the products with long, slim shapes (in particular rotating instruments) for deformities.
- ▶ Check the product for damage to the spiral element.
- ▶ 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.

3.11.2 Functional test

- ▶ Assemble disassembled products, see Assembly.
- ▶ Check that the product functions correctly.
- ▶ Check that all moving parts are working properly (e.g. hinges, locks/latches, sliding parts etc.).
- ▶ Check for compatibility with associated products.
- ▶ Immediately put aside inoperative products and send them to Aesculap Technical Service, see Technical service.

3.12 Assembly

- ▶ Insert the slide rod with release mechanism 7 into the base unit 3, see Fig. E.
- ▶ Screw the knurled nut 4 clockwise onto the slide rod with release mechanism 7, see Fig. D.
- ▶ Screw the ring for slide rod 5 clockwise onto the slide rod with release mechanism 7.
- ▶ Insert the cone 1 as far as it will go onto the ring with receptacle for ligation rubber ring 2, see Fig. A.

3.13 Packaging

- ▶ 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.

3.14 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
 - Sterilization using 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.

3.15 Storage

- ▶ Store sterile products in germ-proof packaging, protected from dust, in a dry, dark, temperature-controlled area.
- ▶ Store sterile single-use products in germ-proof packaging in a dust-protected, dry, dark and temperature-controlled room.

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.

Note

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

TA014814 2020-07 V6 Change No. 62256