

**GB** Instructions for use/Technical description

**USA** Skin mesh dermatome BA720R

**D** Gebrauchsanweisung/Technische Beschreibung  
Hautnetz-Dermatom BA720R

**F** Mode d'emploi/Description technique  
Dermatome pour trame dermique BA720R

**E** Instrucciones de manejo/Descripción técnica  
Dermátomo para injertos de malla BA720R

**I** Istruzioni per l'uso/Descrizione tecnica  
Estensore di reticoli cutanei BA720R

**P** Instruções de utilização/Descrição técnica  
Dermátomo cutâneo de rede BA720R

**NL** Gebruiksaanwijzing/Technische beschrijving  
Dermatoom BA720R

**S** Bruksanvisning/Teknisk beskrivning  
Huddermatom BA720R

**RUS** Инструкция по применению/Техническое описание  
Кожный перфоратор BA720R

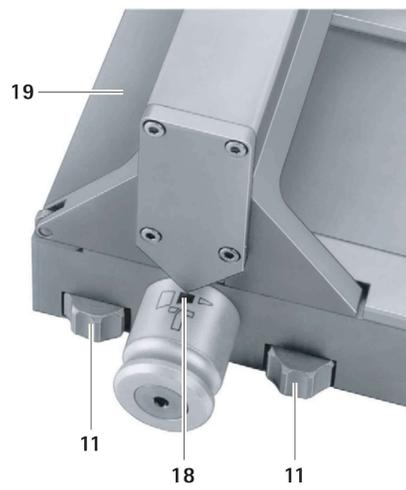
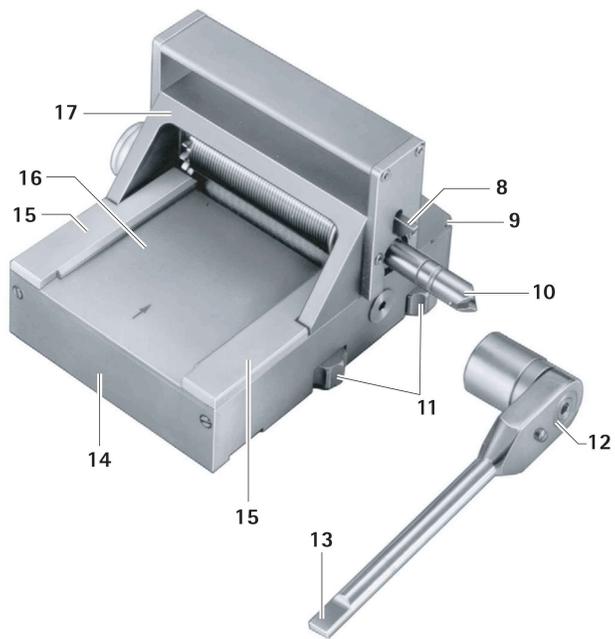
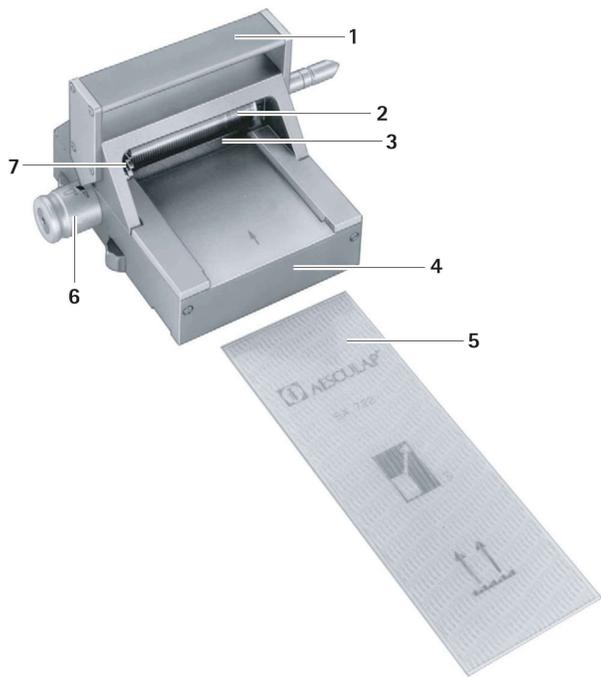
**CZ** Návod k použití/Technický popis  
Síťový kožní dermatom BA720R

**PL** Instrukcja użytkowania/Opis techniczny  
Siatkownica do dermatomu BA720R

**SK** Návod na používanie/Technický opis  
Dermatóm BA720R pre kožnú sieťku

**TR** Kullanım Kılavuzu/Teknik açıklama  
Cilt ağı dermatomu BA720R





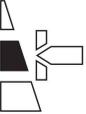
# Aesculap®

## Skin mesh dermatome BA720R

### Legend

- 1 Carrying handle
- 2 Cutting cylinder
- 3 Counter cylinder
- 4 Cutting device
- 5 Carrier plate for skin graft
- 6 Setting wheel for cutting depth
- 7 Gearwheel transmission
- 8 Cutting cylinder lock
- 9 Hinge
- 10 Shaft of cutting cylinder 2
- 11 Fastening screws for upper part 17
- 12 Hand ratchet for driving the cutting cylinder
- 13 Screwdriver end for screws 11 and shaft 10
- 14 Lower part
- 15 Guide strips for carrier plates
- 16 Insertion tray for carrier plates 5
- 17 Upper part, hinged
- 18 Scale of the setting wheel
- 19 Removal tray for carrier plates

### Symbols on product and packages

	Caution, general warning symbol Caution, see documentation supplied with the product
	Scale symbol for "Skin graft cutting"
	Date of manufacture

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### 1. Applicable to

- For item-specific instructions for use and information on material compatibility, see also the Aesculap Extranet at [www.extranet.bbraun.com](http://www.extranet.bbraun.com)

## 2. Safe handling

### CAUTION

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



The operation and reprocessing instructions for the skin mesh dermatome may differ from these instructions for use!

These instructions for use describe only the operation and reprocessing of the skin mesh dermatome as of series number 4000.

- ▶ For upgrades, please contact your national B. Braun/Aesculap agency.

- ▶ Remove the transport packaging and clean the new product, either manually or mechanically, prior to its initial sterilization.
- ▶ Prior to use, check that the product is in good working order.
- ▶ To prevent damage caused by improper setup or operation, and in order not to compromise warranty and manufacturer liability:
  - Use the product only according to these instructions for use.
  - Follow the safety and maintenance instructions.
  - Only combine Aesculap products with each other.
- ▶ Ensure that the product and its accessories are operated and used only by persons with the requisite training, knowledge, or experience.
- ▶ Keep the instructions for use accessible for the user.

## 3. Product description

### 3.1 Scope of supply

Designation	Art. no.
Skin mesh dermatome, complete with hand ratchet	BA720R
Carrier plate for expansion factor 1.5; sterile	BA721
Carrier plate for expansion factor 3; sterile	BA722
Carrier plate for expansion factor 6; sterile	BA723

### 3.2 Intended use

The skin mesh dermatome BA720R is used for the cutting of skin grafts in general, burns and plastic surgery.

## 3.3 Operating principle

The cutting cylinder 2 is turned anticlockwise with hand ratchet 12. The carrier plate 5 transports the skin graft between cutting cylinder 2 and counter cylinder 3. During this transport, the skin graft is cut.

The cutting depth is set with setting wheel 6, using scale 18. The staggered slits in the skin graft allow expanding the graft to rhombic skin mesh.

The skin mesh can be used for covering defects of up to six times the size of the grafting site.

## 4. Preparation

Non-compliance with the following instructions will preclude all responsibility and liability in this respect on the part of Aesculap.

- ▶ Prior to use, inspect the skin mesh dermatome BA720R and its accessories for visible damage.
- ▶ Only use the skin mesh dermatome BA720R and its accessories if they are in perfect condition.
- ▶ Be certain that the skin mesh dermatome is set up on a sufficiently stable support (e.g. table, equipment cart, etc.).

## 5. Working with the skin mesh dermatome BA720R

### 5.1 System set-up



Risk of infection and contamination!

The device and its accessories are delivered in unsterile condition.

- ▶ Sterilize the device and accessories before use.

- ▶ Slide hand ratchet 12 on shaft 10 so that it clicks into position.

### 5.2 Function checks

Carry out a trial run of the skin mesh dermatome BA720R prior to each use:

- ▶ Verify that gearwheel transmission 7 is moved when turning hand ratchet 12.
- ▶ Make certain that setting wheel 6, once engaged, can be easily rotated through the range of scale 18.
- ▶ Only use the device if it is in perfect condition.

# Aesculap®

## Skin mesh dermatome BA720R

### 5.3 Safe operation



**Risk of injury and/or malfunction!**

- ▶ Always carry out a function check prior to using the product.

#### Setting the cutting cylinder



**Damage to the cutting cylinder! The cutting cylinder can only be set when running freely.**

- ▶ Make certain that the carrier plate is not engaged under the cutting cylinder.

- ▶ Slightly pull out setting wheel 6 until it disengages.
- ▶ Turn setting wheel 6 to the required position.

Skin graft cutting	
Possible settings at the setting wheel	Scale symbols
extremely thick skin graft	
normal setting for cutting <span style="color: red; font-weight: bold;">1.4.1</span>	
reserve setting for cutting	

- ▶ Slightly push in setting wheel 6 until it engages.

#### Processing the skin graft

*Note*

Only place individual carrier plates on the insertion tray, one after the other.

For long skin grafts, sequentially insert several carrier plates.



**Coiling of the skin graft! The skin graft can be lifted off from carrier plate as soon as it has been cut into by the cutting cylinder!**

- ▶ Press the skin graft onto the carrier plate, using fine tweezers, directly behind the cut-in line.
- ▶ If the cutting cylinder has been turned too far already, turn back the cutting cylinder, using the screwdriver end of the ratchet.

- ▶ Position the required carrier plate 5, with the grooved surface facing up, on insertion tray 16.
- ▶ Position the skin graft on carrier plate 5.
- ▶ Push carrier plate 5 between guide strips 15 under cutting cylinder 2 until the cutting cylinder engages.

- ▶ Turn hand ratchet 12 anticlockwise. The carrier plate is transported.
- ▶ Keep turning hand ratchet 12 until the complete carrier plate 5 is in position on removal tray 9. This completes the processing of the skin graft.

#### Changing the cutting cylinder

*Note*

The cutting cylinder cannot be sharpened.

#### Dismounting the cutting cylinder



**Cuts on hands or other body parts, caused by sharp edges on the cutting cylinder!**

- ▶ Touch the cutting cylinder only at the shaft.

- ▶ Turn cutting device 4 upside down so that the four screws 11 are visible, see Fig. 1.

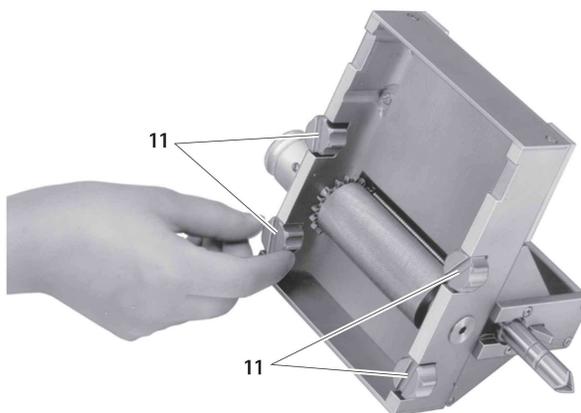


Fig. 1

- ▶ Loosen screws 11 by hand or, if they are difficult to turn, with the screwdriver end 13 of hand ratchet 12.
- ▶ Return cutting device 4 to its upright position.

- ▶ Open upper part 17, see Fig. 2.

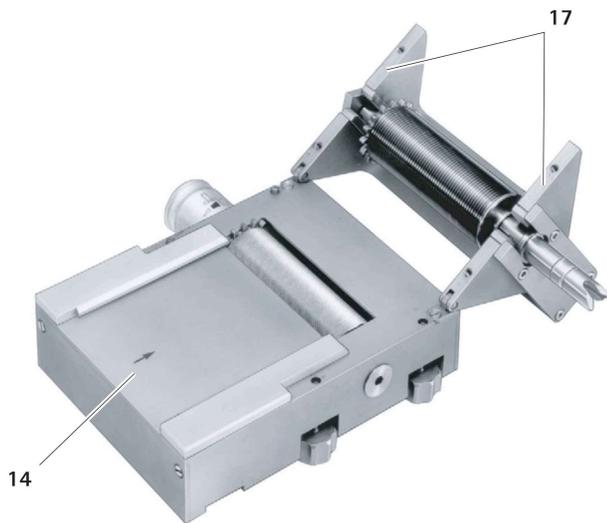


Fig. 2

- ▶ Hold down lock 8 and, at the same time, pull at shaft 10 to decouple cutting cylinder 2, see Fig. 3.

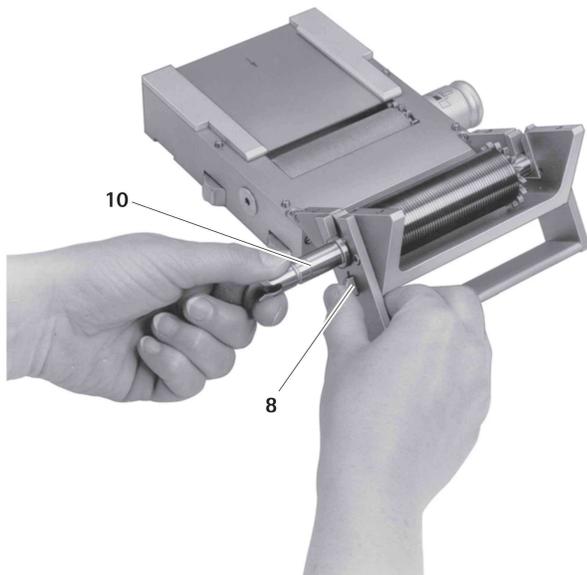


Fig. 3

- ▶ Turn cutting cylinder 2 while pulling it out of bearings 20, see Fig. 4. This completes the dismounting of cutting cylinder 2.

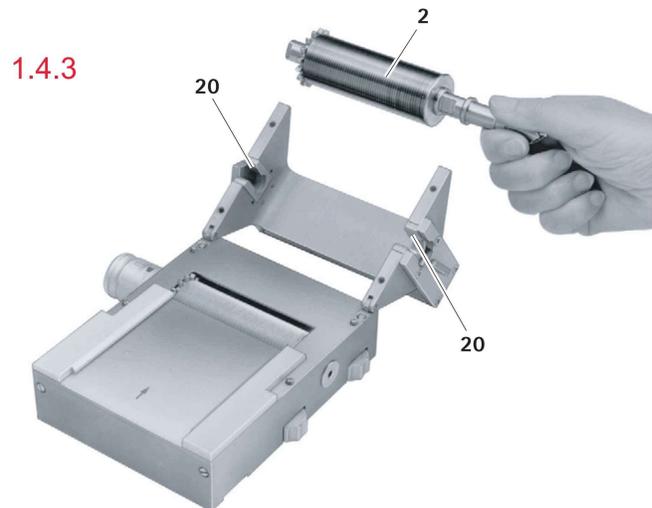


Fig. 4

#### Mounting the cutting cylinder

1.4.2

##### Note

To prevent transport damage, cutting cylinder 2 is protected by a piece of cardboard on delivery. Remove the cardboard protection only after cutting cylinder 2 has been mounted completely.

- ▶ Insert the cutting cylinder 2 into the two bearings 20, see Fig. 4.
- ▶ Hold cutting cylinder 2 at shaft 10 and press it into bearings 20 until it clicks into position, see Fig. 3.
- ▶ Turn shaft 10 and check cutting cylinder 2 for correct seating.
- ▶ Close upper part 17 on lower part 14, see Fig. 2.
- ▶ Turn cutting device 4 upside down so that the four screws 11 are visible, see Fig. 1.
- ▶ Tighten screws 11 by hand.
- ▶ Return cutting device 4 to its upright position.
- ▶ Remove the piece of cardboard from cutting cylinder 2. This completes the mounting of cutting cylinder 2.

### 6. Validated reprocessing procedure



The reprocessing instructions for the skin mesh dermatome may differ from these instructions for use!

These instructions for use describe only the operation and reprocessing of the skin mesh dermatome as of series number 4000.

- ▶ For upgrades, please contact your national B. Braun/Aesculap agency.

#### 6.1 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.

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](http://www.extranet.bbraun.com)

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

#### 6.2 Single-use products



**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!

Designation	Article no.
Carrier plate	BA721
	BA722
	BA723

#### 6.3 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](http://www.a-k-i.org), link to Publications, Red Brochure – Proper maintenance of instruments.

#### 6.4 Preparations at the place of use

- ▶ 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.

## 6.5 Preparation before cleaning

- ▶ Carry out non-fixating/NaCl-free pre-cleaning immediately after use.

### Note

The indicated drying temperature is a guide temperature only. It must be checked taking into account the specific conditions (e.g. load) and if applicable adjusted.

## 6.6 Cleaning/disinfection

### Product-specific safety instructions for the reprocessing procedure



CAUTION

Damage to the product due to inappropriate cleaning/disinfecting agents!

- ▶ Only use cleaning/disinfecting agents approved for surface cleaning. Follow the manufacturer's instructions for the respective cleaning/disinfecting agent.



CAUTION

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 plastic material and high-grade steel,
  - do not attack softeners (e.g. in silicone).
- ▶ Observe specifications regarding concentration, temperature and exposure time.
- ▶ Do not exceed the maximum permitted cleaning temperature of 60 °C.

- ▶ Dry the product for at least 10 minutes at a maximum of 120 °C.

### Validated cleaning and disinfection procedure

Validated procedure	Special features	Reference
Manual cleaning and wipe disinfection	<ul style="list-style-type: none"> <li>■ When cleaning products with movable hinges, ensure that these are in an open position and, if applicable, move the joint while cleaning.</li> <li>■ Drying phase: Use a lint-free cloth or compressed air for medical purposes</li> <li>■ Ensure that the product is positioned in such a way that water will not enter the product e.g. through coupling interfaces. (Immediately remove any fluid that entered the product inadvertently.)</li> <li>■ To avoid damage to cutting cylinder 2, clean the cutting cylinder with a soft brush.</li> </ul>	Chapter Manual cleaning/disinfecting and subsection: <ul style="list-style-type: none"> <li>■ Chapter Manual cleaning and wipe disinfecting</li> </ul>
Mechanical alkaline cleaning and thermal disinfecting	<ul style="list-style-type: none"> <li>■ Install Eccos holder GB688R in a suitable wire basket (e.g. JF214R).</li> <li>■ Insert the product in its proper position in Eccos holder GB682R.</li> </ul>	Chapter Mechanical cleaning/disinfecting and subsection: <ul style="list-style-type: none"> <li>■ Chapter Mechanical alkaline cleaning and thermal disinfecting</li> </ul>

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## Skin mesh dermatome BA720R

### 6.7 Manual cleaning/disinfecting

- ▶ 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.

#### Manual cleaning and wipe disinfecting

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemical
I	Cleaning	RT (cold)	-	-	D-W	-
II	Drying	RT	-	-	-	-
III	Wipe disinfection	-	>1	-	-	Meliseptol HBV wipes 50 % Propan-1-ol
IV	Final rinse	RT (cold)	0.5	-	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

#### Phase I

- ▶ Clean the product under running faucet water, using a suitable cleaning brush until all visible residues have been removed from the surfaces.
- ▶ Mobilize non-rigid components, such as set screws, links, etc. during cleaning.

#### Phase II

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

#### Phase III

- ▶ Wipe all surfaces of the product with a single-use disinfectant wipe.

#### Phase IV

- ▶ After the specified exposure time (at least 1 min), rinse the disinfected surfaces under running FD water.
- ▶ 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.

## 6.8 Mechanical cleaning/disinfecting

### 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.

### 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/Note
I	Prerinse	<25/77	3	D-W	-
II	Cleaning	55/131	10	FD-W	<ul style="list-style-type: none"> <li>■ Concentrate, alkaline:               <ul style="list-style-type: none"> <li>- pH = 13</li> <li>- &lt;5 % anionic surfactant</li> </ul> </li> <li>■ 0.5 % working solution               <ul style="list-style-type: none"> <li>- pH = 11*</li> </ul> </li> </ul>
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.

## 6.9 Inspection, maintenance and checks

- ▶ Allow the product to cool down to room temperature.
- ▶ Inspect the product after each cleaning and disinfecting cycle to be sure it is: clean, functional, and undamaged.
- ▶ Set aside the product if it is damaged.

## 6.10 Packaging

- ▶ Follow the instructions for use for the applied packaging and storage systems (e.g. instructions for use TA009721 for Aesculap Eccos storage system).
- ▶ Insert the product in its proper position in the Eccos holder, or put it on a tray in such a way that the product is protected against damage. Ensure that all cutting edges are protected.
- ▶ Pack trays appropriately for the sterilization process (e.g. in Aesculap sterile containers).
- ▶ Ensure that the packaging will prevent a recontamination of the product.

## 6.11 Steam sterilization 1.4.3

### Note

The carrier plates BA721, BA722 and BA723 are gamma-sterilized single-use products. These products must not be steam-sterilized and are intended for single use only.

### Note

The product may only be sterilized with the upper part 17 open and the cutting cylinder 2 removed.

- ▶ Sterilize the skin mesh dermatome immediately after cleaning.
- ▶ Store the skin mesh dermatome in a suitable wire basket (e.g. JF214R).
- ▶ 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
  - Disassemble the product
  - Steam sterilization through fractionated 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

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## Skin mesh dermatome BA720R

- ▶ 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.

### 6.12 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<sup>-6</sup>, Aesculap recommends the following parameters:

Aesculap Orga Tray/Sterile container (perforated bottom) Minimum cycle parameters*			
Sterilization method	Temp.	Time	Minimum drying time
Prevacuum	270 °F/275 °F	4 min	20 min

\*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.

### 6.13 Storage

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

## 7. Maintenance

In order to ensure reliable operation, the product must be maintained after 300 reprocessing cycles or at least once a year.

For technical service, please contact your national B. Braun/Aesculap agency, see Technical Service.

## 8. Troubleshooting list

Malfunction	Detection	Cause	Remedy
Cutting cylinder 2 fails to rotate	Foreign body in device	Cutting cylinder jammed	Remove foreign body
	-	Hand ratchet 12 not engaged	Engage hand ratchet 12
	Excessive axial slack of cutting cylinder	Cutting cylinder loose	Engage cutting cylinder and secure with lock 8
Cutting cylinder 2 stiff	Strong force required on hand ratchet 12	Defective bearing	Repair by manufacturer
Skin not cut through completely	Incorrect symbol on fine adjustment scale 18	Incorrect setting	Select the required fine adjustment, see Safe operation
	-	Screws 11 loose	Tighten screws by hand or with screwdriver 13
	Cutting tips shiny, hand ratchet 12 stiff	Cutting cylinder 2 worn	Replace cutting cylinder 2, see Safe operation
	Cutting tips broken off	Cutting cylinder 2 defective	Replace cutting cylinder 2, see Safe operation

## 9. Technical Service



**Risk of injury and/or malfunction!**  
▶ Do not modify the product.

- ▶ 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) 95 -1601  
Fax: +49 (7461) 14 -939  
E-Mail: ats@aesculap.de

Or in the US:

Attn. Aesculap Technical Services  
615 Lambert Pointe Drive  
Hazelwood  
MO, 63042 USA  
Aesculap Repair Hotline  
Phone: +1 (800) 214 -3392  
Fax: +1 (314) 895 -4420

Other service addresses can be obtained from the address indicated above.

## 10. Accessories/Spare parts

Art. no.	Designation
BA725R	Replacement cutting cylinder
BA721	Carrier plate factor 1.5
BA722	Carrier plate factor 3 1.4.2
BA723	Carrier plate factor 6
BA726R	Hand ratchet
BA727R	Basket storage aid
GB688R	Eccos holder
TA008023	Instructions for use BA720R

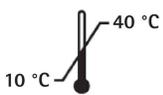
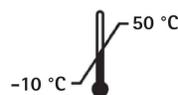
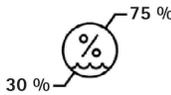
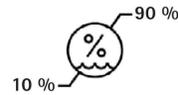
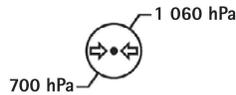
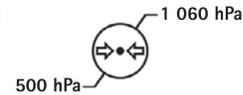
## 11. Technical data

Classification acc. to Directive 93/42/EEC

Art. no.	Designation	Class
BA720R	Skin mesh dermatome	Ila

Dimensions (H x W x D)	150 mm x 195 mm x 105 mm
Weight	4 800 g
Length of carrier plate	220 mm
Width of carrier plate	75 mm

### 11.1 Ambient conditions

	Operation	Storage and transport
Temperature		
Relative humidity		
Atmospheric pressure		

## 12. Disposal

### Note

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

**pagamintas iš nerudijancio plieno 1.4.3**  
The skin mesh dermatome BA720R is made of stainless steel.

- ▶ Dispose of the device with other recyclable metals.
- ▶ Detailed information concerning the disposal of the product is available through your national B. Braun/Aesculap agency, see Technical Service.

## 13. Distributor in the US/Contact in Canada for product information and complaints

Aesculap Inc.  
3773 Corporate Parkway  
Center Valley, PA, 18034,  
USA