



USA Instructions for use/Technical description

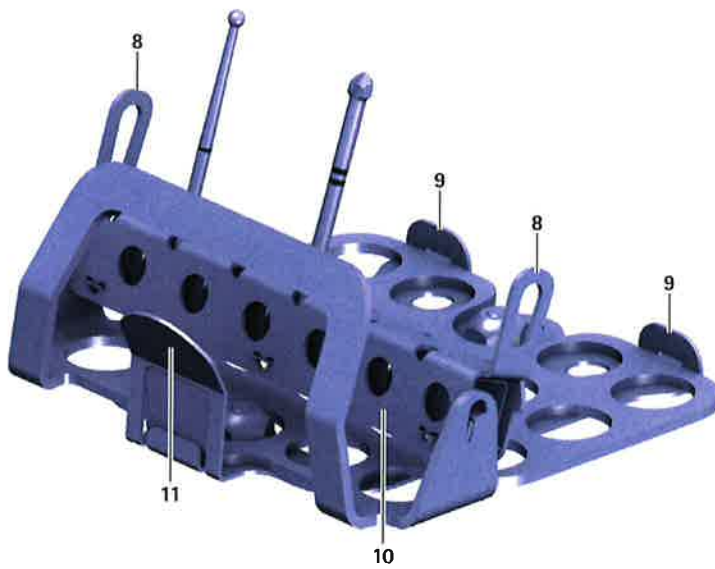
ELAN 4 electro Standard handpiece (1 ring) GA861 to GA864 /
ELAN 4 electro HD handpiece (2 ring) GA865 to GA869

Effective





B



C



D

Aesculap®

ELAN 4 electro Standard handpiece (1 ring) GA861 to GA864 / ELAN 4 electro HD handpiece (2 ring) GA865 to GA869

Legend

- 1 ELAN 4 tool coupling (1 ring or 2 ring)
- 2 Ring marking
- 3 Connector for motor cable
- 4 Slider for tool release
- 5 Symbol of the applied part type in display of ELAN 4 electro control unit
- 6 ELAN 4 tool (1 ring or 2 ring)
- 7 ELAN 4 single-use spray nozzle for 1 ring or 2 ring handpieces
- ELAN 4 ECCOS holder for 12 drills GB718R**
- 8 Side handles
- 9 Holding nibs
- 10 Tool coupling
- 11 Tab

Symbols on product and packages

	Caution Observe important safety information such as warnings and precautions in the instructions for use.
	Maintenance label Recommended date of next service (format: YYYY-MM) by international B. Braun-/Aesculap agents, see Technical Service
	Machine-readable, two-dimensional code The code contains a unique serial number which can be used for electronic tracking of the individual instrument. The serial number is based on the global standard sGTIN (GS1).
	Date of manufacture
	Sterilization using irradiation
	Not for reuse in intended applications as defined by the manufacturer
	Use by
	Manufacturer's batch designation
	Manufacturer's serial number
	Manufacturer's article number
	Temperature limits during transport and storage
	Air humidity limits during transport and storage
	Atmospheric pressure limits during transport and storage

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1. Applicable to

- For item-specific instructions for use and information on material compatibility, see also the Aesculap Extranet at <https://extranet.bbraun.com>

2. Intended use

2.1 Task/function within system

The handheld Highspeed ELAN 4 electro Standard handpiece (1 ring) GA861 to GA864 or ELAN 4 electro HD handpiece (2 ring) GA865 to GA869 is an accessory of the ELAN 4 electro motor system.

The handpiece is connected by an ELAN 4 electro motor cable to the control unit.

The handpiece is used to drive Aesculap ELAN 4 tools (1 ring or 2 ring).

Speed	min. 0 rpm to max. 80 000 rpm
Rotational direction	Right and left rotation
Short interval operation	30 second application, 30 second pause at 60 000 RPM

2.2 Application Environment

Application in the sterile area

2.3 Indications

The ELAN 4 Air Motor System is intended for high speed cutting, sawing, and drilling of bone in the fields of Spine, ENT, Neuro, and Maxillofacial Surgery.

2.4 Contraindications

The ELAN 4 electro motor system is not authorized for use in the central nervous system or central circulatory system.

Note

The safe and effective use of electrically driven applied parts depends heavily on influences that only the user can control him or herself. Therefore the specifications provided represent framework conditions only.

Note

The clinical success of the use of the ELAN 4 electro motor system is dependent on the knowledge and experience of the surgeon. The surgeon must decide which structures it is sensible to treat and take into account the safety and warning information contained in these instructions for use.

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ELAN 4 electro Standard handpiece (1 ring) GA861 to GA864 / ELAN 4 electro HD handpiece (2 ring) GA865 to GA869

3. Safe handling

CAUTION

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



WARNING

Risk of injury and material damage due to inappropriate use of the product!

- Use the product only in accordance with the intended purpose.



WARNING

Risk of injury and damage to property due to improper handling of the product!

This product is an accessory of the ELAN 4 electro control unit GA800.

- Follow the instructions for use of the ELAN 4 electro control unit GA800 (TA014401).
- Follow the instructions for use of all products used.

- General risk factors associated with surgical procedures are not described in this documentation.
- It is the operating surgeon's responsibility to ensure that the surgical procedure is performed correctly.
- The operating surgeon must have a thorough understanding of both the hands-on and conceptual aspects of the established operating techniques.
- 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.
- Observe "Notes on Electromagnetic Compatibility (EMC)", see TA022130.
- 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.
- Always adhere to applicable standards.
- Ensure that the electrical installations at the premises where the device is to be used meet all requirements acc. to IEC/DIN EN.
- Do not use the control unit and applied part in potentially explosive areas.
- Carry out sterile processing in any reusable applied parts, motor cables and tools prior to use.
- When handling, observe instructions for use that are relevant to Aesculap holder systems TA009721, see Aesculap Extranet at <https://extranet.bbraun.com>

3.1 Sterile ELAN 4 tools

The product is gamma-sterilized and supplied in sterile packaging.

- 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.
- Do not use products from open or damaged sterile packaging.
- 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.
- Do not use the product after its use-by date.

3.2 Sterile ELAN 4 single-use spray nozzles



DANGER

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 reprocess the product.

The product is gamma-sterilized and supplied in sterile packaging.

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.
- Do not use products from open or damaged sterile packaging.
- 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.
- Do not use the product after its use-by date.

4. Product description

4.1 Available sizes

Note

The shaft length can be seen on the shaft of the drill handpiece.

ELAN 4 electro Standard handpiece (1 ring)

Art. no.	Length of shaft
GA861	L4 (approx. 4 cm)
GA862	L7 (approx. 7 cm)
GA863	L10 (approx. 10 cm)
GA864	L13 (approx. 13 cm)

ELAN 4 electro HD handpiece (2 ring)

Art. no.	Length of shaft
GA865	L7 (approx. 7 cm)
GA866	L10 (approx. 10 cm)
GA867	L13 (approx. 13 cm)
GA868	L17 (approx. 17 cm)
GA869	L22 (approx. 22 cm)

4.2 Package includes**ELAN 4 electro Standard handpiece (1 ring)**

Art. no.	Designation
GA861–GA864	ELAN 4 electro Standard handpiece (1 ring)
TA014443	Instructions for use of ELAN 4 electro Standard handpiece (1 ring) GA861 to GA864 / ELAN 4 electro HD handpiece (2 ring) GA865 to GA869 (leaflet)

ELAN 4 electro HD handpiece (2 ring)

Art. no.	Designation
GA865–GA869	ELAN 4 electro handpiece HD (2-Ring)
TA014443	Instructions for use of ELAN 4 electro Standard handpiece (1 ring) GA861 to GA864 / ELAN 4 electro HD handpiece (2 ring) GA865 to GA869 (leaflet)

4.3 Components required for operation

- Operation-ready ELAN 4 electro control unit GA800, see TA014401
- ELAN 4 tool (1 ring or 2 ring)

4.4 Operating principle*Note*

The ring marking 2 shows the shaft diameter of the tool to be used. ELAN 4 tools can be only coupled to the applied part if the ring markings (1 ring/2 ring) of the applied part and tool match.

The drill handpiece is fitted with an ELAN 4 tool coupling (1 ring or 2 ring). It is used with ELAN 4 electro foot controls/manual controls.

With the drill handpiece, the coupled tool rotates at the set motor speed. The motor speed of the drill handpiece can be adjusted continuously by the manual/foot control.

The drill handpiece can be operated in right or left (clockwise or counter-clockwise) rotation mode.

5. Preparation

Non-compliance with these rules will result in complete exclusion of liability on the part of Aesculap.

- ▶ Do not use products from open or damaged sterile packaging.
- ▶ Prior to use, inspect the product and its accessories for any visible damage.
- ▶ Use the products and their accessories only if they are in perfect technical condition.

6. Working with the applied part**WARNING****Risk of infection and contamination!**

Applied parts and motor cable are delivered unsterile!

- ▶ Carry out sterile processing of the applied parts and motor cable prior to use, in accordance with the instructions for use.

**WARNING****Risk of injury and material damage due to inadvertent activation of the applied part!**

- ▶ Secure applied parts that are not actually used against inadvertent activation ("Off" position), see instructions for use for ELAN 4 electro control unit GA800 (TA014401).

**WARNING****Risk of injury and material damage due to inappropriate use of tools!**

- ▶ Always follow the safety advice and information given in the instructions for use.
- ▶ When coupling/uncoupling, handle tools with cutting edges with care.

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WARNING

Damage to the product if dropped!

- Use the products only if they are in perfect technical condition, see Function check



WARNING

Risk of burns to skin and tissue due to blunt tools/ lack of maintenance of the applied part!

- Use tools only if they are in perfect condition.
- Replace blunt tools.
- Ensure correct maintenance of the applied part, see Maintenance.

6.1 System set-up

Note

Operating elements on the system components of the ELAN 4 electro motor system are labeled with a gold marking.

Connecting the accessories

Combinations of accessories that are not mentioned in the present instructions for use may only be employed if they are specifically intended for the respective application, and if they do not compromise the performance and safety characteristics of the products.

All configurations must comply with basic standard IEC/DIN EN 60601-1. Any individual connecting devices with one another is responsible for such configuration and must ensure compliance with basic standard IEC/DIN EN 60601-1 or applicable national standards.

- Follow the instructions for use of individual accessories.
- Please contact your B. Braun/Aesculap Partner or Aesculap Technical Service (address: see Technical Service with any inquiries in this respect).

Removing ELAN 4 ECCOS holder for 12 burrs GB718R from the tray

The insert of the ELAN 4 ECCOS holder for 12 burrs GB718R can be removed from the tray together with the tools.

- Pull the tab 11 and remove the insert of the holder, see Fig. C.

Coupling the tool to the applied part



WARNING

Risk of injury when coupling/uncoupling tools in the "On" position due to accidental activation of the applied part!

- Only couple/uncouple tools in the "Off" position.



WARNING

Risk of injury due to small parts in the operation site!

- Do not couple/uncouple tools over the operation site.

- Lock applied part ("Off" position), see instructions for use of ELAN 4 electro control unit GA800 (TA014401).

- Push tool shaft 6 as far as it will go into ELAN 4 tool coupling (1 ring or 2 ring) 1, see Fig. A.

The tool engages. The tool is correctly coupled when the ring marking 2 on the tool is no longer visible.

- Pull at tool 6 to check that it is securely coupled.

Uncoupling the tool from the applied part



WARNING

Risk of injury when coupling/uncoupling tools in the "On" position due to accidental activation of the applied part!

- Only couple/uncouple tools in the "Off" position.



WARNING

Risk of injury due to small parts in the operation site!

- Do not couple/uncouple tools over the operation site.

- Lock applied part ("Off" position), see instructions for use of ELAN 4 electro control unit GA800 (TA014401).

- Pull back slider for tool release 4 on the applied part and remove tool 6 from ELAN 4 tool coupling (1 ring or 2 ring) 1, see Fig. A.

Mounting the spray nozzle and tube set

- Connect tube set GA395SU to pump of ELAN 4 electro control unit GA800, see TA014401.

- Push application-side tube end onto tube connection of the ELAN 4 single-use spray nozzle for 1 ring or 2 ring handpieces 7.

- Push single-use spray nozzle for ELAN 4 1 ring or 2 ring handpieces 7 onto the shaft of the applied part and push/turn into the desired position, see Fig. A.

Note

The spray tube of the ELAN 4 single-use spray nozzle for 1 ring or 2 ring handpiece is bendable by hand and can be adapted to the requirements of application (e.g. aligned to tool head).

6.2 Function check

- Prior to each use, check that all products to be used are in good working order.

- Check the secure connection of all products to be used.

- Check that the tool is coupled properly. To do this, pull on the tool.

- Check that the cutting edges of the tools are not showing any mechanical damage.

- Briefly run the applied parts at maximum speed.

- Do not use the product if it is damaged or defective. Set aside the product if it is damaged.

6.3 Operation



WARNING

Coagulation of patient tissue or risk of burns for patients and users from hot applied part/tool!

- ▶ Cool the tool during operation.
- ▶ Put down the applied part/tool beyond reach of the patient.
- ▶ Allow the applied part/tool to cool down.
- ▶ Use a cloth to protect against burns when changing the tool.



WARNING

**Risk of infection from aerosol formation!
Risk of injuries caused by particles coming loose from the tool!**

- ▶ Take appropriate protective measures, e.g. watertight protective clothing, face mask and protective goggles, suction extraction.



WARNING

Risk of injury and/or malfunction!

- ▶ Always carry out a function test prior to each use of the product.



WARNING

Risk of injury due to application of the product outside the field of view!

- ▶ Only use the product under vision.



WARNING

**Risk of injury and damage to the tool/system!
The rotating tool may catch cover drapes (textile or other).**

- ▶ Never allow the tool to touch cover drapes (textile or other) during operation.



WARNING

Danger of injury from foreign body reactions (e.g. inflammation, encapsulation) if particles remain in the body!

- When using diamond tools, it is always possible for diamond grains/nickel particles to break away/off.**
- ▶ Carefully rinse and vacuum while and after working with diamond tools.

It is only possible to operate the applied part and change the setting parameters on the control unit if:

- the applied part is connected to the control unit,
- there is no second applied part released ("On" position) at the same time and
- the applied part type 5 is shown in the display of the control unit.

Note

For further information, see instructions for use of ELAN 4 electro control unit GA800 (TA014401).

7. Validated reprocessing procedure

7.1 General safety notes

Note

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

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

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.

The recommended chemical was used for validation.

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 also the Aesculap Extranet at <https://extranet.bb.raun.com>

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

7.2 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 neutralizing agents or basic cleaners may result in a chemical attack and/or fading and the laser marking becoming unreadable either visually or by machine.

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 damage to metallic products. These must be removed by rinsing thoroughly with demineralized water and then drying.

Perform additional drying, if necessary.

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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:

- 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 surface and could cause corrosion
- ▶ For further detailed information on hygienically safe and material-preserving/value-preserving reprocessing, see www.a-k-i.org, link to Publications, Red Brochure – Proper maintenance of instruments.

7.3 Preparations at the place of use

- ▶ Separate the products from each other immediately after use.
- ▶ 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 6 hours.

7.4 Preparation before cleaning

Applied part

- ▶ Prior to first mechanical cleaning/disinfection process: Mount ECCOS holder GB082R/GB083R in a suitable tray (e.g. JF222R).
- ▶ Place the product in the correct position in the ECCOS holder GB082R/GB083R, see Fig. B.

Tools

- ▶ Thoroughly rinse the product with running, cold water.
- ▶ Prior to first mechanical cleaning/disinfection process: Mount the bottom part of the ECCOS holder GB718R in a suitable tray (e.g. JF222R).
- ▶ Place the tools in the correct position in the tool holder 10 of the ECCOS holder GB718R, see Fig. C.
- ▶ Engage the insert of the holder in the bottom part. When doing so, ensure that the holding nibs 9 on the top part are inserted in the recesses in the bottom part.

7.5 Cleaning/disinfection

Product-specific safety guidelines on the reprocessing procedure



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

- ▶ Following the manufacturer's instructions, use cleaning and disinfecting agents which
 - be approved for plastic material and high-grade steel,
 - do not attack softeners (e.g., in silicone).
- ▶ Do not use cleaning agents that contain acetone.
- ▶ Observe specifications regarding concentration, temperature and exposure time.
- ▶ Do not exceed the maximum temperature of 60 °C during chemical cleaning and/or disinfection.
- ▶ Do not exceed the maximum temperature of 90 °C during thermal disinfection with DI water.
- ▶ Dry the product for at least 10 minutes at a maximum of 120 °C.

Note

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

Validated cleaning and disinfection procedure

Product	Validated procedure	Reference
Applied part	Manual cleaning with immersion disinfection	see Manual cleaning with immersion disinfection – applied part
	Manual pre-cleaning with brush and subsequent mechanical alkaline cleaning and thermal disinfection	see Mechanical cleaning/disinfecting with manual pre-cleaning – applied part
Tools	Manual pre-cleaning with ultrasound and brush, and subsequent mechanical alkaline cleaning and thermal disinfection	see Mechanical cleaning/disinfecting with manual pre-cleaning – tools

7.6 Manual cleaning with immersion disinfection – applied part

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemicals
I	Pre-cleaning	RT (cold)	-	-	D-W	-
II	Cleaning	RT (cold)	>5	1	D-W	pH-neutral, pH ~ 9*
III	Intermediate rinse	RT (cold)	-	-	D-W	-
IV	Disinfection	RT (cold)	>15	2	D-W	Concentrate-free, aldehyde-free, phenol-free, QUAT-free, pH ~ 9**
V	Final rinse	RT (cold)	-	-	C-W	-
VI	Drying	RT	-	-	-	-

D-W: Drinking water

C-W: Critical water

RT: Room temperature

*Recommended: BBraun Helizyme

**Recommended: BBraun Stabimed

- Follow the instructions for use of the ELAN 4 rinsing devices and rinsing adapters TAO14447 and TAO14448.
- Do not clean the applied part in an ultrasound bath.

Phase I

- Clean the product under running water, using a suitable cleaning brush until all visible residues have been removed from the surfaces.
- Mobilize non-rigid components, such as release button, unlocking sleeve, etc. during cleaning.
- Rinse the applied part through the rinsing adapter GB698R at least 3 times for 5 seconds with a water gun.

Phase II

- Using a disposable syringe, fill the inside of the applied part with cleaning solution through the rinsing adapter GB698R.
- Place the applied part, with rinsing adapter connected, fully in enzymatic cleaning solution for 5 minutes.

Phase III

- Rinse the entire product (all accessible surfaces) under running water.
- Mobilize non-rigid components, such as release button, unlocking sleeve, etc. during rinsing.
- Rinse the applied part through the rinsing adapter GB698R at least 3 times for 5 seconds with a water gun.

Phase IV

- Prior to manual disinfection, allow rinsing water to drain off the product for a sufficient length of time and use compressed air to blow all liquid out of the product through the rinsing adapter GB698R in order to prevent dilution of the disinfecting solution.
- Using a disposable syringe, fill the inside of the applied part with disinfectant solution through the rinsing adapter GB698R.
- Place the applied part, with rinsing adapter connected, fully in disinfectant solution for 15 minutes.

Phase V

- Rinse the entire product (all accessible surfaces) under running water.
- Mobilize non-rigid components, such as release button, unlocking sleeve, etc. during cleaning.
- Rinse the applied part through the rinsing adapter GB698R at least 3 times for 5 seconds with a water gun.

Phase VI

- Dry the product in the drying phase with suitable equipment (e.g. cloth, compressed air).
- After manual cleaning/disinfection, check visible surfaces visually for residues.
- Repeat the cleaning/disinfection process if necessary.

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7.7 Mechanical cleaning/disinfecting with manual pre-cleaning – applied part

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.

Manual pre-cleaning with a brush

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemicals
I	Brushes	RT (cold)	–	–	D–W	–
II	Rinsing	RT (cold)	5	–	D–W	–

D–W: Drinking water
RT: Room temperature

- ▶ Follow the instructions for use of the ELAN 4 rinsing devices and rinsing adapters TA014447 and TA014448.
- ▶ Do not clean the applied part in an ultrasound bath.

Phase I

- ▶ Clean the product with a suitable cleaning brush until all discernible residues have been removed.
- ▶ Mobilize non-rigid components, such as release button, unlocking sleeve, etc. during cleaning.

Phase II

- ▶ Connect the connector for motor cable 3 with ELAN 4 electro rinsing device GB692R.
- ▶ Rinse the applied part:
 - For 5 min with a tap/hose or
 - 3 times for 5 seconds with a water gun

Mechanical alkaline cleaning and thermal disinfection

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

Phase	Step	T [°C/°F]	t [min]	Water quality	Chemicals
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 disinfection	90/194	5	FD-W	-
V	Drying	-	-	-	In accordance with the program for the cleaning and disinfecting machine

D-W: Drinking water

FD-W: Fully desalinated water (demineralized, low microbiological contamination)

*Recommended: BBraun Helimatic Cleaner alkaline

- ▶ Connect the connector for motor cable **3** with ELAN 4 electro rinsing device GB692R.
- ▶ Place the rinsing device on a wire basket suitable for cleaning.
- ▶ Connect the rinsing device to the rinsing connection of the rinsing cart.
- ▶ After the mechanical cleaning/disinfection process:
 - Remove any residual rinsing water from the applied part using a compressed-air gun, see instructions for use ELAN 4 rinsing device and rinsing adapter TA014447 and TA014448.
 - Check visible surfaces for residues.

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7.8 Mechanical cleaning/disinfecting with manual pre-cleaning – tools

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.

Manual pre-cleaning with ultrasound and brush

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemicals
I	Immersion	RT (cold)	>30	50	D-W	Enzymatic detergent*
II	Rinsing	RT (cold)	-	-	D-W	-
III	Ultrasonic cleaning	55/131	>15	2	D-W	Concentrate-free, aldehyde-free, phenol-free, QUAT-free, pH ~ 9**
IV	Cleaning with brush	RT (cold)	-	-	D-W	-

D-W: Drinking water

RT: Room temperature

*Recommended: BBraun Helizyme

**Recommended: BBraun Stabimed

- Only perform ultrasound cleaning in the ECCOS holder GB718R to prevent any damage to the cutting edges.

Phase I

- Fully immerse the product in enzymatic cleaning solution for at least 30 minutes. Ensure that all accessible surfaces are moistened.

Phase II

- Rinse the entire product (all accessible surfaces) under running water.

Phase III

- Tilt up the tool holder **10** of the ECCOS holder GB718R by the side handles **8**, see Fig. C.
- Clean the product in an ultrasonic cleaning bath (frequency 35 kHz) for at least 15 minutes. Ensure that all accessible surfaces are immersed and acoustic shadows are avoided.

Phase IV

- Clean the product with a suitable cleaning brush until all discernible residues have been removed.

Mechanical alkaline cleaning and thermal disinfection

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

Phase	Step	T [°C/°F]	t [min]	Water quality	Chemicals
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 disinfection	90/194	5	FD-W	-
V	Drying	-	-	-	In accordance with the program for the cleaning and disinfecting machine

D-W: Drinking water

FD-W: Fully desalinated water (demineralized, low microbiological contamination)

*Recommended: BBraun Helimatic Cleaner alkaline

- ▶ Place the tools in the correct position in the tool holder **10** of the ECCOS holder GB718R, see Fig. C.
- ▶ Check visible surfaces for residues after mechanical cleaning/disinfecting.

7.9 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.
- ▶ ELAN 4 electro Connect oil spray adapter GB600860 (gray) to connector for motor cable **3** and spray through the applied part for approx. 2 seconds with Aesculap-STERILIT oil spray GB600, see Fig. D.
- ▶ Check the product for any damage, abnormal running noise, overheating or excessive vibration.
- ▶ Inspect tools for broken, damaged or blunt edges.
- ▶ Set aside the product if it is damaged.

7.10 Packaging

- ▶ Always follow the instructions for use of the respective packaging and storage devices (e.g. instructions for use TA009721 for Aesculap-ECCOS holder system).
- ▶ Place the applied part in the correct position in the ECCOS holder GB082R/GB083R, see Fig. B.
- ▶ Place the tools in the correct position in the ECCOS holder GB718R, see Fig. C.
- ▶ Pack trays appropriately for the intended sterilization process (e.g. in Aesculap sterile containers).
- ▶ Ensure that the packaging will prevent a recontamination of the product.

7.11 Steam sterilization

Note

For further information, see Technical Data.

- ▶ Make certain that all external and internal surfaces of the product will be exposed to the sterilizing agent.
- ▶ Validated sterilization process
 - Steam sterilization using fractional vacuum process
 - Steam sterilizer according to DIN EN 285 and validated according to DIN EN ISO 17665
- ▶ When sterilizing several instruments 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.

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7.12 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^{-6} , 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	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.

7.13 Storage

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

8. Maintenance

To ensure reliable operation, the product must be maintained in accordance with the maintenance labeling or at least once a year.



e.g. 2016-07

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

9. Troubleshooting

Note

For further information, see instructions for use of ELAN 4 electro control unit GA800 (TA014401).

10. Technical Service



Danger to life of patients and users if the product malfunctions and/or protective measures fail or are not used!

- Do not perform any servicing or maintenance work under any circumstances while the product is being used on a patient.
- Do not modify the product.

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

- 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 14-939

E-Mail: ats@aesculap.de

Or in the US:

Aesculap Inc.

Attn. Aesculap Technical Services

615 Lambert Pointe Drive

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.

11. Accessories/Spare parts

Art. no.	Designation
GA261SU	ELAN 4 single-use spray nozzle for 1 ring handpiece L4
GA262SU	ELAN 4 single-use spray nozzle for 1 ring handpiece L7
GA263SU	ELAN 4 single-use spray nozzle for 1 ring handpiece L10
GA264SU	ELAN 4 single-use spray nozzle for 1 ring handpiece L13
GA265SU	ELAN 4 single-use spray nozzle for 2 ring handpiece L7
GA266SU	ELAN 4 single-use spray nozzle for 2 ring handpiece L10
GA267SU	ELAN 4 single-use spray nozzle for 2 ring handpiece L13
GA268SU	ELAN 4 single-use spray nozzle for 2 ring handpiece L17
GA269SU	ELAN 4 single-use spray nozzle for 2 ring handpiece L22
GA395SU	ELAN 4 electro single-use tube set
GB082R	ELAN 4 electro ECCOS holder for reamer handpiece GA861 to GA869, 1 handpiece
GB083R	ELAN 4 electro ECCOS holder for reamer handpiece GA861 to GA869, 3 handpieces
GB600	STERILIT Power Systems oil spray
GB600860	ELAN 4 electro oil spray adapter
GB692R	ELAN 4 electro rinsing device
GB698R	ELAN 4 electro rinsing adapter
GB718R	ELAN 4 ECCOS holder for 12 burrs
GP111R-GP243R	ELAN 4 tools (1 ring), single use
GP301R-GP397R	ELAN 4 tools (2 ring), single use
GP398SU GP399TC-SU	ELAN 4 tools (2 ring), single use
TA014442	Gebrauchsanweisung für ELAN 4 electro Handstück Standard (1-Ring) GA861 bis GA864 / ELAN 4 electro Handstück HD (2-Ring) GA865 bis GA869 (A4 für Ringordner)
TA014443	Instructions for use of ELAN 4 electro Standard handpiece (1 ring) GA861 to GA864 / ELAN 4 electro HD handpiece (2 ring) GA865 to GA869 (leaflet)

12. Technical Data

12.1 Classification acc. to Directive 93/42/EEC

Art. no.	Designation	Class
GA861-GA864	ELAN 4 electro Standard handpiece (1 ring)	IIa
GA865-GA869	ELAN 4 electro HD handpiece (2 ring)	IIa
GP111R-GP243R	ELAN 4 tools (1 ring), single use	IIa
GP301R-GP397R	ELAN 4 tools (2 ring), single use	IIa
GP398-SU GP399TC-SU	ELAN 4 tools (2 ring), single use	IIa

12.2 Performance data, information about standards

Max. power	approx. 140 W
Max. torque	approx. 2,2 Ncm
Max. motor speed	80 000 rpm
Tool connection	ELAN 4 1 ring (GA861 to GA864) ELAN 4 2 ring (GA865 to GA869)
Applied part	Type BF
EMC	IEC/DIN EN 60601-1-2
Conforming to standard	IEC/DIN EN 60601-1

Art. no.	Weight	Dimensions (Ø x L)
GA861	80 g ± 10 %	16 mm x 152 mm ± 5 %
GA862	83 g ± 10 %	16 mm x 177 mm ± 5 %
GA863	87 g ± 10 %	16 mm x 206 mm ± 5 %
GA864	91 g ± 10 %	16 mm x 237 mm ± 5 %
GA865	89 g ± 10 %	16 mm x 176 mm ± 5 %
GA866	95 g ± 10 %	16 mm x 206 mm ± 5 %
GA867	100 g ± 10 %	16 mm x 236 mm ± 5 %
GA868	108 g ± 10 %	16 mm x 276 mm ± 5 %
GA869	118 g ± 10 %	16 mm x 326 mm ± 5 %

The product can be reprocessed 350 times. This was proved after 350 reprocessing cycles by a high voltage test at 1,6 kV.

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12.3 Tool speed/Setting

Adjustable motor direction	Clockwise/counterclockwise rotation
Adjustable maximum speed setting	10 000 rpm to 80 000 rpm
Step width for maximum speed setting	5 000 rpm
Factory pre-setting for maximum speed setting	75 000 rpm, right rotation

12.4 Short interval operation

Ambient temperature	10 °C to 27 °C
Application cycle	30 second application 30 second pause
Max. application cycles	∞ at 60 000 rpm
Max. temperature	48 °C

12.5 Ambient conditions

	Operation	Storage and transport
Temperature	10 °C to 27 °C	-10 °C to 50 °C
Relative humidity	30 % to 75 %	10 % to 90 %
Atmospheric pressure	700 hPa to 1 060 hPa	500 hPa to 1 060 hPa

13. Disposal

Note

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



Adhere to national regulations when disposing of or recycling the product, its components and its packaging! The recycling pass can be downloaded from the Extranet as a PDF document under the respective article number. (The recycling pass includes disassembling instructions for the product, as well as information for proper disposal of components harmful to the environment.)

Products carrying this symbol are subject to separate collection of electrical and electronic devices. Within the European Union, disposal is taken care of by the manufacturer as a free-of-charge service.

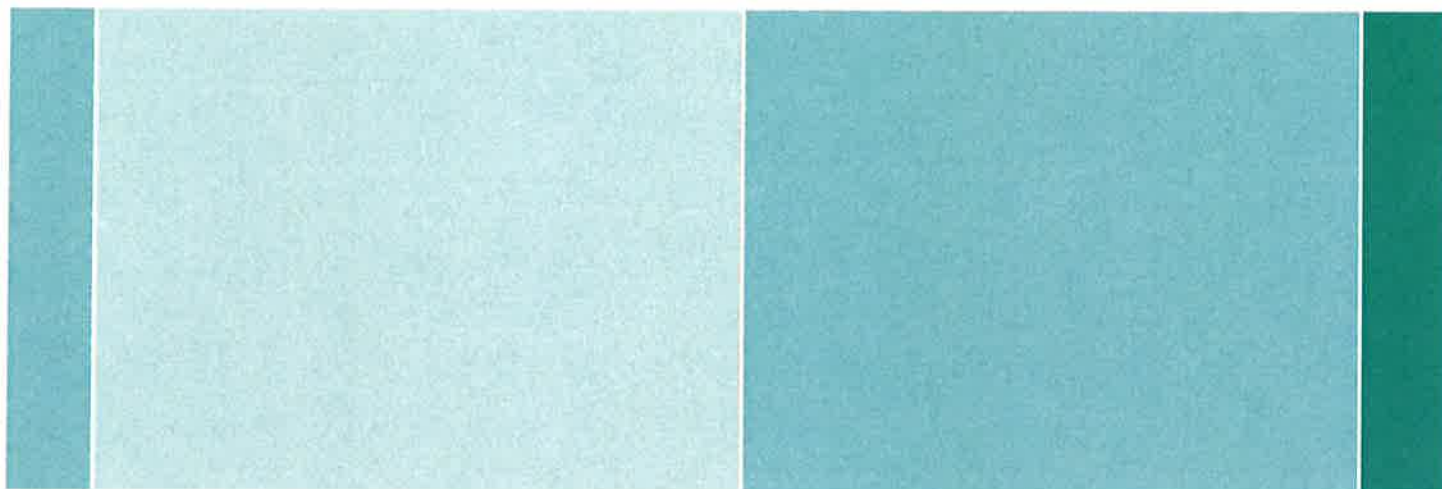
- Detailed information concerning the disposal of the product is available through your national B. Braun/Aesculap agency, see Technical Service.

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

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

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CE 0123 - DIR 93/42/EEC

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