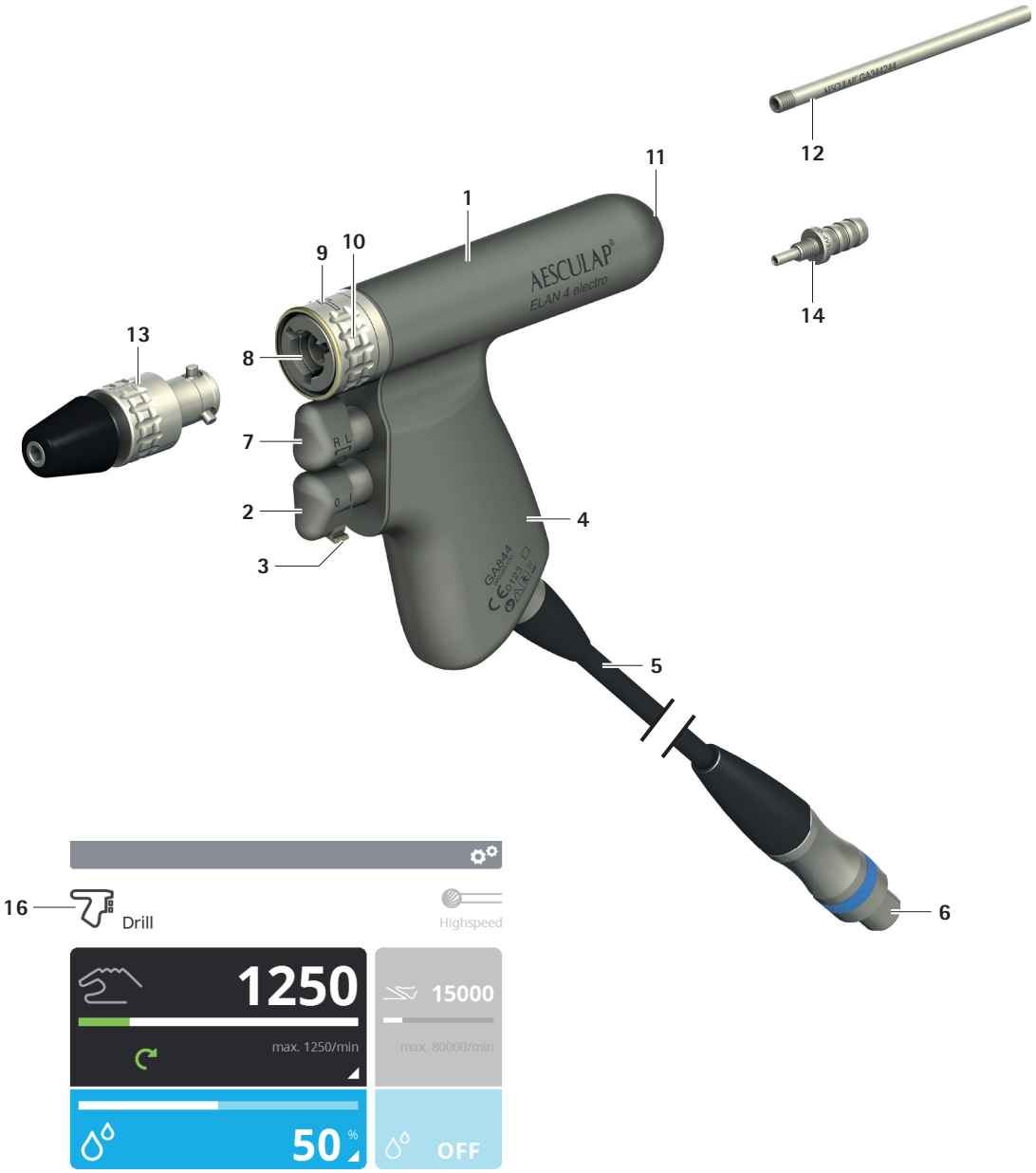
Aesculap®

Effective

USA **Instructions for use/Technical description**
ELAN 4 electro drill GA844

B BRAUN
SHARING EXPERTISE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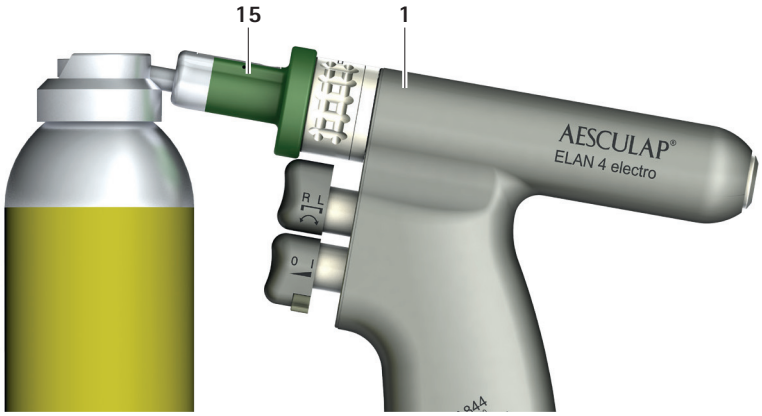
AESCULAP
ELAN 4 electro
Drill
Highspeed
1250
max. 1250/min
15000
max. 80000/min
50 %
OFF

A



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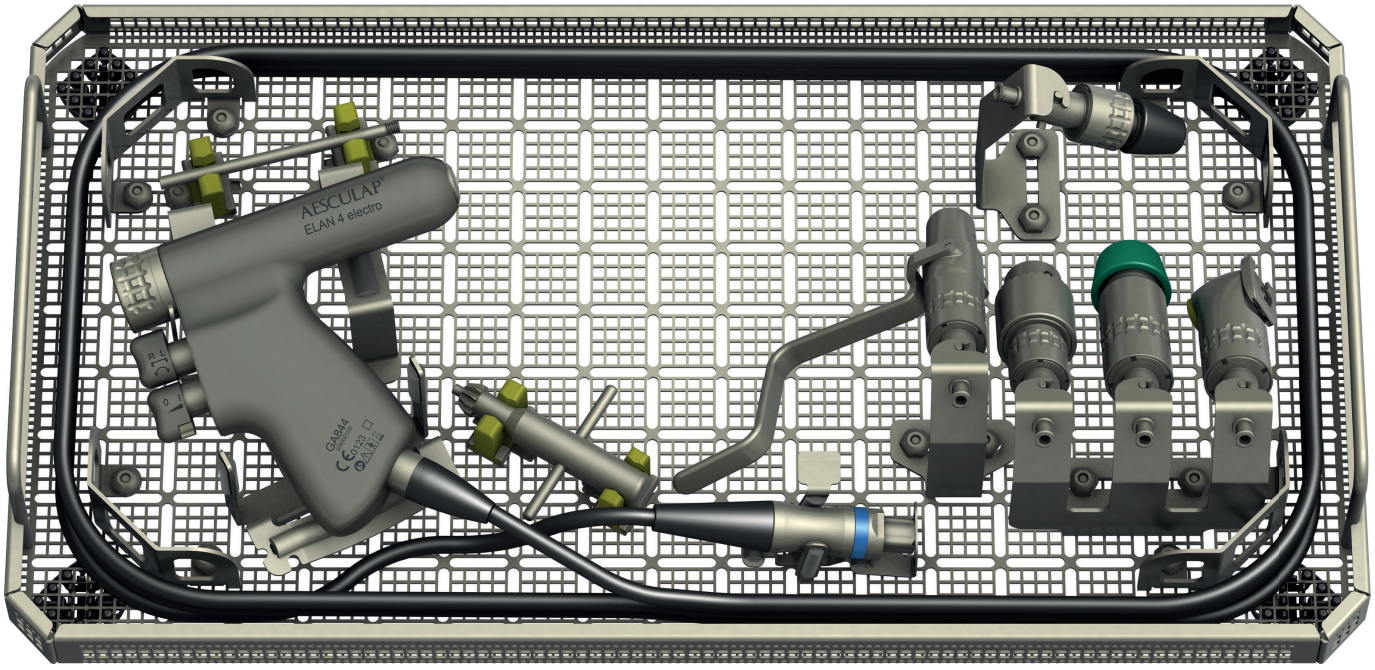


USA

Effective

Aesculap®

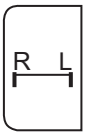
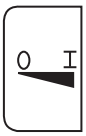
ELAN 4 electro drill GA844

Legend

1 Product (ELAN 4 electro drill)
2 Rotational speed control button
3 Safety catch
4 Screw handle
5 Cable
6 Connector for control unit
7 Knob for left-rotation
8 Coupling
9 Arrow
10 Rotating sleeve
11 Adapter (for Kirschner wire protection sleeve and rinsing adapter)
12 Kirschner wire protection sleeve
13 Attachment
14 Rinsing adapter
15 Oil spray adapter
16 Symbol of the application part type in the display of the ELAN 4 electro control unit

Symbols on product and packages

	Caution Observe important safety information such as warnings and precautions in the instructions for use.
 YYYY-MM	Maintenance label Indication of the next maintenance appointment (Date: Year-Month)
	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).
	Manufacturer
	Date of manufacture
	Follow the instructions for use
	Labeling of electrical and electronic devices pursuant to directive 2002/96/EG (WEEE)
	Classification Type BF

	Reverse button clockwise/counterclockwise rotation + oscillation mode switch
	Motor speed control
LOT	Manufacturer's batch designation
SN	Manufacturer's serial number
REF	Manufacturer's article number
QTY	Delivery quantity
	Non-sterile medical device
	According to US federal law, this product may only be sold by a physician or by the order of a physician
	Temperature limits during transport and storage
	Air humidity limits during transport and storage
	Atmospheric pressure limits during transport and storage

Contents

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1. About this document

Note

General risks of surgical intervention are not described in these instructions for use.

1.1 Scope

These instructions for use apply to the ELAN 4 electro drill tool GA844.

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

1.2 Warnings

Warnings indicate risks to patients, users, and/or products which may develop during the use of the product. Warnings are marked as follows:

⚠ **DANGER**

Indicates a potential danger. If it is not prevented, death or severe injuries may result.

⚠ **WARNING**

Indicates a potential danger. If it is not prevented, minor or moderate injuries may result.

⚠ **CAUTION**

Indicates a potential damage to property. If it is not prevented, the product may be damaged.

2. General information

2.1 Intended use

Task/Function

The ELAN 4 electro drill GA844 is an accessory of the ELAN 4 electro motor system.

The drill is connected to the control unit.

The ELAN 4 electro drill GA844, combined with the corresponding attachment and tool, is used for processing hard tissue, cartilage and the like, as well as bone replacement material, to screw bone pins in and out, to drive screw tools and to set transfixion wires.

2.2 Main functions and design characteristics

Speed

min. 0 min^{-1} to max. 1 250 min^{-1}

Rotational direction

Right and left rotation, oscillation

Short-time interval operation

Drilling (clockwise/counterclockwise rotation):

- 60 second application, 60 second pause
- 6 repetitions
- 30 min cooling time
- Max. Temperature 48 °C

Medullary reaming (clockwise/anti-clockwise rotation):

- 30 second application, 30 second pause
- 8 repetitions
- 30 min cooling time
- Max. Temperature 48 °C

Drilling (oscillation):

- 15 s application, 15 s pause
- 3 repetitions
- 30 min cooling time
- Max. temperature 48 °C

Saw operation with GB891R:

- 30 second application, 60 second pause
- 4 repetitions
- 30 min cooling time
- Max. temperature 48 °C

Saw operation with GB892R:

- 30 second application, 60 second pause
- 5 repetitions
- 30 min cooling time
- Max. Temperature 48 °C

Screws with GB896R and GB897R:

- 10 s machine application, 10 s manual application, 30 s pause
- 30 repetitions
- 30 min cooling time
- Max. Temperature 48 °C

Electrical systems generally heat up during continual operation. It is advised to give the system a break after use to cool down, as listed in the table on operating mode.

Heating depends on the tool used and the load. After a certain number of repetitions, the system should cool down. This procedure prevents system overheating as well as possible injury to the patient or user.

The user is responsible for the use and adherence to the pause sequence described.

2.3 Application environment

Use in sterile and non-sterile areas

Sterile separation at the control unit.

2.4 Indications for Use

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

2.5 Contraindications

The product is not licensed for use on the central nervous system or central circulatory system.

Note

The safe and effective use of the product greatly depends on influences which can only be controlled by the user. Therefore the specifications provided represent framework conditions only.

Clinically successful use of the product 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.

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 if this product is not used as intended!

► **Use the product only for its intended purpose.**

⚠ WARNING

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

► **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.

► 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 installation of the room is consistent with the requirements of IEC/DIN EN.

► Do not operate the product in explosion-hazard areas.

► Sterilize product before use.

► When using the ECCOS holder system, observe the pertinent instructions for use for TA009721, see Aesculap Extranet at https://extranet.bbraun.com

Note

The user is obligated to report all serious incidents occurring in connection with the product to the manufacturer and to the competent authority of the country in which the user is registered.

4. Product description

4.1 Scope of supply

Art. no.	Designation
GA844	ELAN 4 electro drill
GA344244	Kirschner wire protection sleeve
GA344211	Rinsing adapter
GB600880	Oil spray adapter for GA344/GA844
TA011944	Cleaning brush
TA014437	Instructions for use for GA844 (flyer)

4.2 Components required for operation

- Operationally ready ELAN 4 electro control unit GA800, see TA014401 (from software: V3.00)
- Attachment (depending on the indication, see also instructions for use TA014552 or TA014553)
- Tool (depending on indication)

4.3 Operating principle

The product **1** has an electric motor which is connected to the ELAN **4** control unit and supplied with voltage by means of a permanently connected cable 5.

The output speed is controlled electronically and can be continuously regulated with the knob for speed control **2**.

The direction of rotation can be changed from right to left again using the knob for left rotation **7**. The product can also be operated in an oscillation mode.

On the output side, the product **1** has a coupling **8**, which enables the coupling of various drilling, medullary reamers, sawing, and screw attachments. These attachments lock themselves when plugging into the product.

By actuating a rotating sleeve **10** the attachment **13** can be loosened.

Gearing in the various attachments changes the tool speed and enable operation of the motor at an ideal operating point.

The attachments have various integrated couplings on the working end, to receive corresponding tools, with adapters as applicable.

The product is equipped with a cannulation to receive guide spears or the like.

5. Preparation

Aesculap assumes no liability if the following rules are not followed:

- ► 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 device

⚠ WARNING

Risk of infection and contamination!

Product is delivered unsterilized!

- ► **Sterilize the product before use according to the operating instructions.**

⚠ WARNING

Risk of injury and material damage due to accidental activation of the product!

- ► **Products which are not being actively used must be secured against accidental activation (position OFF).**

⚠ 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.**

⚠ 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 through blunt tools or if product has not been maintained properly!

- ► **Use tools only if they are in perfect condition.**
- ► **Replace blunt tools.**
- ► **Maintain the product properly, see Maintenance.**

⚠ WARNING

Damage to the product due to incorrect handling!

- ► **Do not kink, jam, crush, and pull on the motor cable, also do not damage it using sharp objects.**

6.1 System set-up

⚠ WARNING

Risk of injury due to small parts that could enter the surgical field!

- ► **Do not couple/uncouple tools and attachments over the surgical field.**

6.1.1 Connecting the accessories

Do not use accessories in combinations that are not mentioned in these instructions for use.

- ► Follow the instructions for use of individual accessories.
- ► Please address your B. Braun/Aesculap partner or Aesculap Technical Service with any inquiries in this respect; for a contact address, see Technical Service.

6.1.2 Protection against inadvertent activation

Note

The safety catch at the ELAN 4 electro drill tool GA844 is only used for mechanical protection against an unintentional actuation of the speed control pusher **2**. *When the safety catch is activated there is no communication with the control unit and it is not shown in the display.*

To prevent the product being inadvertently activated when changing a tool or accessory, the knob for speed control can be locked.

To lock rotational speed control button **2**:

- ► Twist the safety catch **3** to position OFF.

  The speed control knob **2** is blocked and the product **1** cannot be operated.

Unlocking the knob for speed control **2**:

- ► Twist the safety catch **3** to position ON.

  The speed control knob **2** is unlocked and the product **1** can be operated.

6.1.3 Attaching and removing product attachments

Note

For additional information on the attachments, see TA014552 and TA014553 (flyer).

⚠ WARNING

Risk of injury when attaching/removing attachments/tools in the ON position through inadvertent activation of the product!

- ► **Only attach/remove attachments/tools in the OFF position.**
- ► Secure product **1** from inadvertent activation with the safety catch **3**, see Protection against inadvertent activation.

Coupling

- ► Push attachment **13** into coupling **8** until it clicks into place.
- ► Pull on the attachment **13** to ensure a secure fit.

Uncoupling

- ► Turn the sleeve **10** in the direction of the arrow **9** and simultaneously remove the attachment **13** from the product **8**.

Attach the Kirschner wire protection sleeve

Note

The special Kirschner wire chuck is recommended for the placement of guide wires.

⚠ WARNING

Risk of injury when using long guide wires!

- ► **Use Kirschner wire protection sleeve when using long guide wires.**
- ► Screw on the Kirschner wire protection sleeve **12** into attachment **11**.

Attach the tool to the attachment

Note

Attachment of the tools is described in operating instructions TA014552 and TA014553 (leaflet).

6.2 Function checks

A function check must be carried out prior to each use and attachment change.

- ► Check the secure connection of all products to be used.
- ► Check that the attachment is coupled properly. To test this, pull on the attachment.
- ► Check that the tool is coupled properly. To do this, pull on the tool.
- ► For GB891R: check that the tool attachment has locked into place. To do this, turn the tool attachment.

- ► Ensure that the tool blades are not mechanically damaged.
- ► Release product for use (ON position).
- ► Run the product shortly at maximum speed in right and left rotation.
- ► Make certain that the rotational direction is correct in each case.
- ► Check the product for damage, abnormal operation noises, heavy vibration and excessive heat.
- ► Do not use the product if it is damaged or defective.
- ► Set aside the product if it is damaged.

6.3 Safe operation

⚠ WARNING

Coagulation of patient tissue or risk of burns for patients and user through hot product!

- ► **Do not use products for acetabulum milling.**
- ► **Cool the tool during operation.**
- ► **Keep product/tool out of the reach of patients.**
- ► **Let the product/tool 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!

- ► **Use suitable protection (such as waterproof protective clothing, face mask, safety gases, suction).**

⚠ WARNING

Risk of injury and/or malfunction!

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

⚠ WARNING

Risk of injury when using the product beyond the field of view!

- ► **Apply the product only under visual control.**

⚠ WARNING

Risk of injury and damage to the tool/system!

The rotating tool may get caught in drapes (such as textiles).

- ► **Do not let the tool come into contact with drapes (such as textiles) during operation.**

The application part can only be used and the setting parameters at the control unit can only be altered if:

- the application part is connected to the control unit,
- there is no second application part activated (position "On") at the same time and
- the application part type 16 is shown in the display for the control unit.

Note

When two ELAN 4 electro drill tools GA844 are connected to the ELAN 4 electro control unit GA800, the drill tool whose speed control safety catch is actuated first is active.

Note

For additional information, see the operating instructions for the ELAN 4 electro control unit GA800 (TA014401).

Note

The product drive motor is operated using a magnetic sensor system. In order to prevent inadvertent activation of the motor, the product may not be exposed to any magnetic fields (such as magnetic instrument pads).

6.3.1 Normal Operation

Product operating in right rotation mode:

- ► Activate the knob for speed control **2**.

  The speed of the product **1** is continuously regulated pursuant to the attachment utilized.

Product operating in left rotation mode:

- ► Press the knob for left rotation **7** completely in and keep it depressed.
- ► Activate the knob for speed control **2**.

  The speed of the product **1** is continuously regulated pursuant to the attachment utilized.

6.3.2 Oscillating operation or thread cutting operation

Note

Check that the oscillation mode is set to "ON" at the control panel on the ELAN 4 control unit (GA800).

Enable oscillating operation or thread cutting operation:

- ► Keep the knob for left rotation **7** pressed for 3 seconds.

  There will be multiple signal tones.

Oscillating operation:

- ► Press the knob for speed control **2** in all the way.

  Product **1** will rotate clockwise and counterclockwise in alternation.

Tapping operation:

- ► Depress the speed control knob **2** up to a maximum of half-way.

  Product **1** will gradually turn counterclockwise and clockwise, whereby the rotational angle in the clockwise direction is greater than that of the counterclockwise direction.

To activate left rotation:

- ► Press the speed control knob **2** in addition to the knob for left rotation **7**.

  The product **1** will rotate counterclockwise.

Disable oscillating operation or thread cutting operation:

- ► Keep the knob for left rotation **7** pressed for 3 seconds.

  There will be multiple signal tones.

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.

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.bbraun.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 precleaning 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.

On stainless steel, residues containing chlorine or chloride (such as surgical residues, drugs, saline solutions in water for cleaning, disinfection and sterilization) may lead to corrosion (pitting corrosion, tensile corrosion) and thus to the destruction of the product. These must be removed by rinsing thoroughly with demineralized water and then drying.

Perform 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:

- Visual material changes (such as fading or color changes in titanium or aluminum). For aluminum, the application/process solution only needs to be pH >8 to cause visible surface changes.
- Material damage (such as corrosion, cracks, breaks, 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 Reusable products

The service life of the product is limited by damage, normal wear, type and duration of the application, handling, storage and transportation of the product.

Careful visual and functional testing prior to next use is the best way to identify a malfunctioning product.

7.4 Preparations at the place of use

► Remove all attached components from the product (tool an accessories).

► 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.

7.5 Preparation before cleaning

► Prior to first mechanical cleaning/disinfection process: Install the Aesculap ECCOS holder system in a suitable tray.

► Insert products in the correct position into the Aesculap ECCOS holder system, see Fig. **B**.

7.6 Cleaning/disinfection

7.6.1 Product-specific safety instructions for the reprocessing procedure

⚠ 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).**

► **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 maximum temperature when using 95°C DI water for thermal disinfection.**

► **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.

7.7 Manual cleaning with wipe disinfection

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemicals
I	**Pre-cleaning**	RT (cold)	≥2	-	D-W	Until visually clean
II	**Cleaning with enzyme solution**	RT (cold)	≥2	0.8	D-W	pH-neutral*
III	**Intermediate rinse**	RT	≥5	-	D-W	-
IV	**Drying**	RT	-	-	-	-
V	**Wipe disinfection**	-	>1	-	-	Meliseptol HBV wipes 50 % Propan-1-ol
VI	**Final rinse**	RT (cold)	0.5	-	FD-W	-
VII	**Drying**	RT	-	-	-	-

DW: Drinking water
FD-W: Fully desalinated water (demineralized, microbiological, at least of drinking water quality)
RT: Room temperature
* Suitable enzyme solution: Helizyme, Cidezyme (the latter being used for validation purposes)

► Do not clean the product in a ultrasonic bath and do not immerse the product in any fluids. Let any fluid incursions drain out immediately, otherwise there is a danger of corrosion and loss of function.

Phase I

► Move flexible components (such as sleeves) during cleaning.
► Clean the product under running water, using a suitable plastic cleaning brush until all visible residues have been removed from the surfaces.
► Brush cannulation with cleaning brush TA011944 and difficult to access surfaces with a suitable plastic cleaning brush for at least 1 min.

Phase II

► Follow the operating instructions of the enzyme cleaner with regard to correct concentration, dilution, temperature and water quality.
► Spray products with a pH neutral enzyme solution, let soak in for at least 2 minutes and then wipe off.

Phase III

► Move flexible components (such as sleeves) during cleaning.
► Rinse product under running tap water for at least 5 minutes.
► Follow the operating instructions of the enzyme cleaner with regard to correct concentration, dilution, temperature and water quality.
► Remove contamination with a lint-free cloth or soft brush moistened with enzyme cleaner.
► Rinse flexible components (such as sleeves) and cannulations for 20 seconds with the water pistol (cold water, at least 2.5 bar).
► After manual cleaning, check visible surfaces and areas of flexible components for residues.
► If necessary, repeat the cleaning process (phase 1 to 3).

Phase IV

► Dry the product in the drying phase with suitable equipment (such as lint-free cloths, pressurized air).

Phase V

► Wipe all surfaces of the product with a single-use disinfecting wipe.

Phase VI

► Rinse disinfected surfaces after the prescribed reaction time for at least 1 minute under running demineralized water.
► Drain any remaining water fully.

Stage VII

► Dry the product in the drying phase with suitable equipment (such as lint-free cloths, pressurized air).

7.8 Automatic cleaning/disinfection with manual pre-cleaning

Note

The cleaning and disinfection device must fundamentally have a tested efficacy (such as FDA approval or CE label pursuant to DIN EN ISO 15883).

Note

The cleaning and disinfection machine used for processing must be serviced and checked at regular intervals.

7.8.1 Manual pre-cleaning with a brush

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemistry/Note
I	Rinsing	RT (cold)	-	-	D-W	Until visually clean
II	Brushes	RT (cold)	-	-	D-W	Until visually clean

D-W: Drinking water
RT: Room temperature

► Do not clean the product in a ultrasonic bath and do not immerse the product in any fluids. Let any fluid incursions drain out immediately, otherwise there is a danger of corrosion and loss of function.

Phase I

► Move flexible components (such as sleeves) during cleaning.
► Thoroughly clean the product under running water.

Phase II

► Move flexible components (such as sleeves) during cleaning.
► Brush cannulation with cleaning brush TA011944 and difficult to access surfaces with a suitable plastic cleaning brush for at least 1 min.
► After manual pre-cleaning, check visible surfaces for residue and repeat the pre-cleaning process as required.

7.8.2 Mechanical alkaline cleaning and thermal disinfection

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

Phase	Step	T [°C/°F]	t [min]	Water quality	Chemistry/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 disinfection**	90/194	5	FD–W	-
V	**Drying**	-	-	-	at least 10min at max. 120°C

D-W: Drinking water

FD–W: Fully desalinated water (demineralized, low microbiological contamination: drinking water quality at least)

*Recommended: BBraun Helimatic Cleaner alkaline

- ► Insert product **1** in the correct position in the Aesculap ECCOS holder systems, see Fig. **B**.
- ► Attach the rinsing adapter **14** (GA344211) to the product **1** in the mount **11**.
- ► Then connect the interior rinse device and connect to the rinse connector of the cleaning/disinfection device/rinse cart.
- ► Attach the Kirschner wire protection sleeve **12** to a rinse hose.
- ► After automatic cleaning/disinfection, check visible surfaces for residues and repeat the cleaning/disinfection process as needed.

7.9 Inspection, maintenance and checks

- ► Allow the product to cool down to room temperature.
- ► Spray product after every cleaning and disinfection with Aesculap STERILIT Power Systems oil spray GB600 using the oil spray adapter **15** GB600880 (green) for approx. 2 s, see Fig. **A**.

Note

Aesculap additionally recommends the occasional spraying of moving parts (such as knobs, couplings) with the Aesculap STERILIT Power Systems oil spray.

- ► Check the product after each cleaning and disinfection for the following: cleanliness, damage, function, abnormal operation noise, excessive heat or heavy vibration.
- ► Set aside the product if it is damaged.

7.10 Packaging

- ► Follow the instructions for use of the respective packaging and holders (e.g. instructions for use TA009721 for Aesculap ECCOS holder systems).
- ► Insert products in the correct position into the Aesculap ECCOS holder system, see Fig. **B**.
- ► Pack trays appropriately for the sterilization process (e.g. in Aesculap sterile containers).
- ► Ensure that the packaging will prevent a recontamination of the product.

7.11 Steam sterilization

Note

Remove all attached components from the product (tools, accessories) before sterilization.

- ► Make certain that all external and internal surfaces of the product will be exposed to the sterilizing agent.
- ► Use a validated sterilization method:
  - Steam sterilization using fractional vacuum process
  - Steam sterilizer DIN EN 285 and validated pursuant to DIN EN ISO 17665
  - Sterilization using fractionated vacuum process at 134 °C/holding time 5 min

When sterilizing multiple products in one steam sterilizer:

- ► Ensure that the maximum permitted load specified by the manufacturer for the steam sterilizer is not exceeded.

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/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.

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.

YYYY-MM

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

9. Troubleshooting list

Note

For additional information, see the operating instructions for the ELAN 4 electro control unit GA800 (TA014401).

10. Technical Service

⚠ DANGER

Risk of death to patients and users in case of malfunction and/or failure of protective measures!

- ► **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.**

⚠ CAUTION

Modifications of medical devices may result in a loss of potential guarantee/warranty claims and forfeiture of applicable licenses.

- ► **Do not modify product.**
- ► **Contact national B. Braun/Aesculaprepresentative for service and repair.**

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 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.

11. Accessories/Spare parts

Art. no.	Designation
GA344244	Kirschner wire protection sleeve
GA344211	Rinsing adapter
GB072R	ECCOS winding aid for cables and hoses
GB073R	ELAN 4 electro ECCOS motor cable
GB262R	ECCOS tray with fixations for GA844
GB600	STERILIT Power Systems oil spray
GB600880	Oil spray adapter for GA344/GA844
TA011944	Cleaning brush
GB482R	ECCOS fixation for GA344/GA844
TA014401	Instructions for use for ELAN 4 electro control unit GA800 (A4 for ring-binder)
TA014436	Instructions for use for ELAN 4 electro drill tool GA844 (A4 for ring-binder)
TA014437	Instructions for use of ELAN 4 electro drill GA844 (flyer)
TA014452	Instructions for use for attachments for the small drill tool GA344 and the drill tool GA844 (A4 for ring-binder)
TA014453	Instructions for use for attachments for the small drill tool GA344 and the drill tool GA844 (flyer)

12. Technical data

12.1 Classification acc. to Directive 93/42/EEC

Art. no.	Designation	Class
GA844	ELAN 4 electro drill	**IIa**

12.2 Performance data, information about standards

Max. power	approx. 200 W
Speed	0 rpm to max. 1,250 rpm ± 5 %
Rotational direction	Right and left rotation, oscillation
Cannulation	3.3 mm
Weight	0.8 kg ± 10 %
Cable length	4 m ± 10 %
Dimensions (L × W × H)	122 × 130 × 27 mm ± 5 %
Applied part	Type BF
EMC	IEC/DIN EN 60601-1-2
Conforming to standard	IEC/DIN EN 60601-1

After 350 preparatory cycles, the product was tested by the manufacturer and passed.

12.3 Short-time interval operation

Drilling (clockwise/counterclockwise rotation):

- 60 second application, 60 second pause
- 6 repetitions
- 30 min cooling time
- Max. Temperature 48 °C

Medullary reaming (clockwise/anti-clockwise rotation):

- 30 second application, 30 second pause
- 8 repetitions
- 30 min cooling time
- Max. Temperature 48 °C

Drilling (oscillation):

- 15 s application, 15 s pause
- 3 repetitions
- 30 min cooling time
- Max. Temperature 48 °C

Saw operation with GB891R:

- 30 second application, 60 second pause
- 4 repetitions
- 30 min cooling time
- Max. Temperature 48 °C

Saw operation with GB892R:

- 30 second application, 60 second pause
- 5 repetitions
- 30 min cooling time
- Max. Temperature 48 °C

Screws with GB896R and GB897R:

- 10 s machine application, 10 s manual application, 30 s pause
- 30 repetitions
- 30 min cooling time
- Max. temperature 48 °C

12.4 Environmental 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

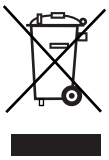
⚠ **WARNING**

Risk of infection from contaminated products!

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

Note

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



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

Effective

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