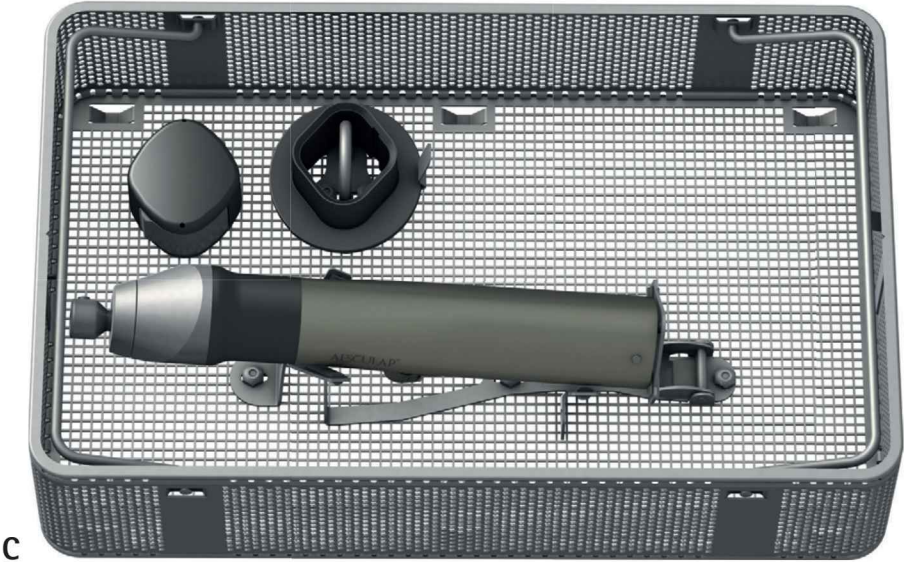
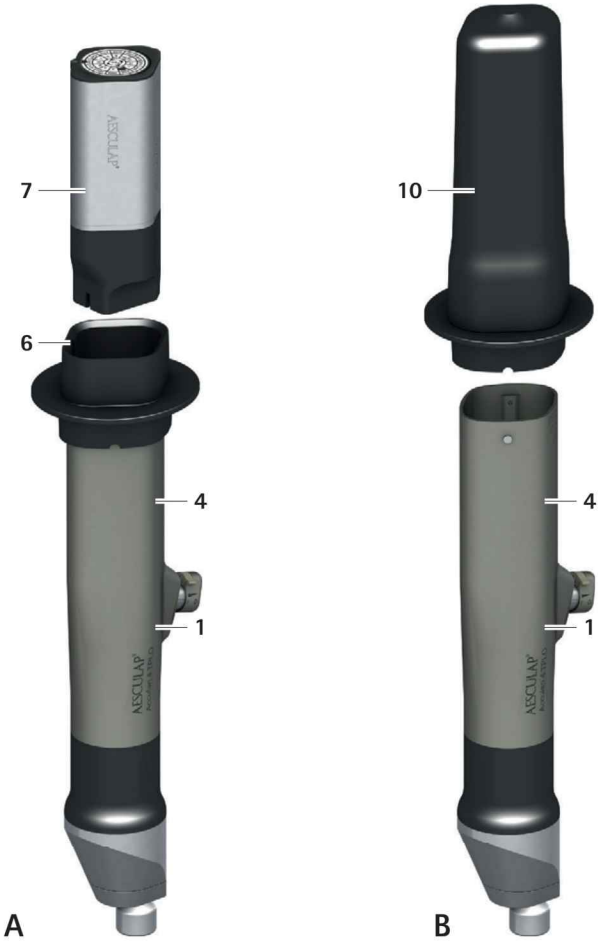


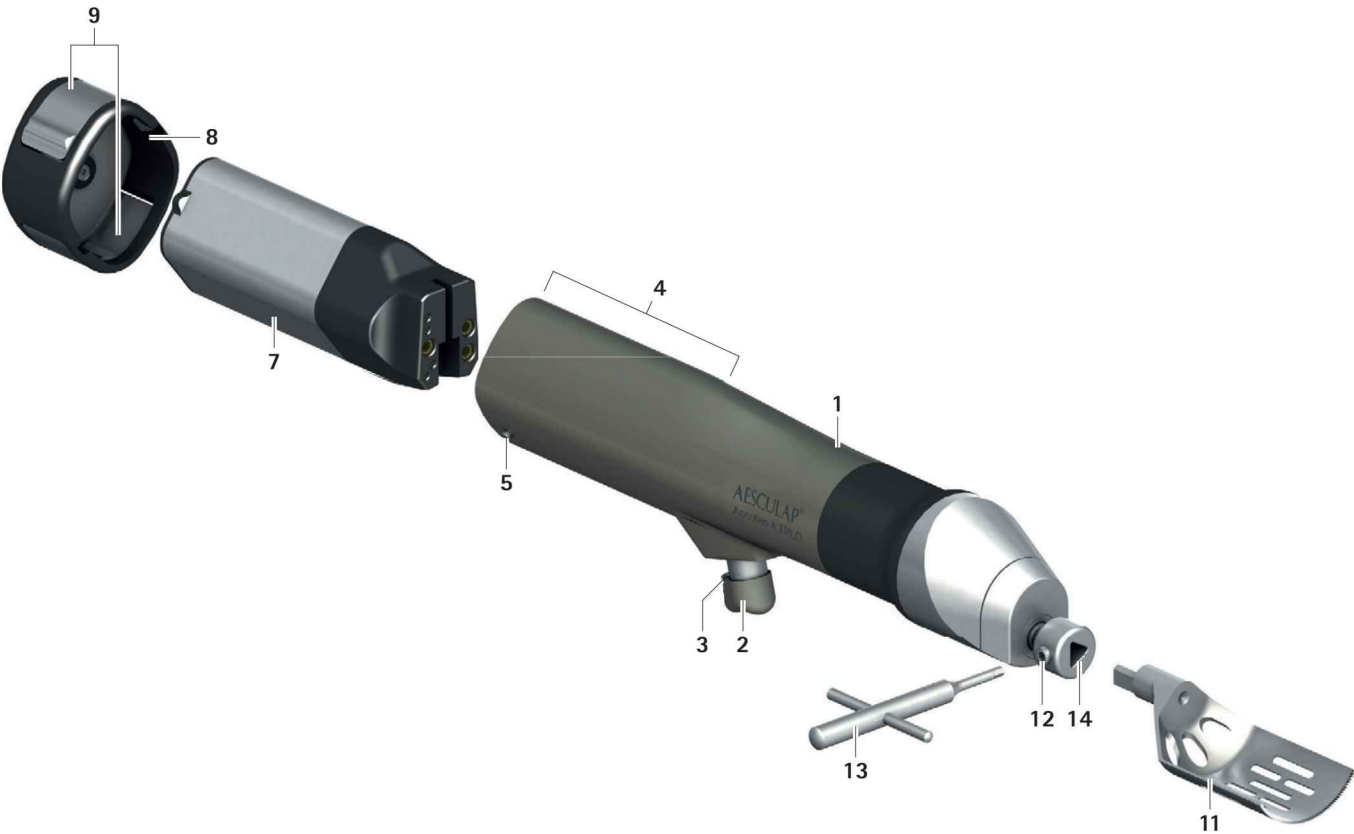
Aesculap® Acculan 4



- (GB)** Instructions for use/Technical description
- (USA)** TPLO saw GT666
- (D)** Gebrauchsanweisung/Technische Beschreibung
TPLO Säge GT666
- (F)** Mode d'emploi/Description technique
Scie TPLO GT666
- (E)** Instrucciones de manejo/Descripción técnica
Sierra TPLO GT666
- (I)** Istruzioni per l'uso/Descrizione tecnica
Sega TPLO GT666
- (P)** Instruções de utilização/Descrição técnica
Serra para TPLO GT666
- (NL)** Gebruiksaanwijzing/Technische beschrijving
TPLO-zaag GT666

- (S)** Bruksanvisning/Teknisk beskrivning
TPLO-såg GT666
- (RUS)** Инструкция по применению/Техническое описание
Пила TPLO GT666
- (CZ)** Návod k použití/Technický popis
Pila TPLO GT666
- (PL)** Instrukcja użytkowania/Opis techniczny
Piła TPLO GT666
- (SK)** Návod na použitie/Technický opis
Pila TPLO GT666
- (TR)** Kullanım Kılavuzu/Teknik açıklama
TPLO testere GT666
- (KR)** 사용 설명서 / 기술 설명
TPLO 톱 GT666







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TPLO saw GT666

Legend

- 1 Product (TPLO saw)
- 2 Trigger (for controlling the oscillation frequency)
- 3 Safety catch
- 4 Battery bay
- 5 Locking pin
- 6 Sterile funnel
- 7 Battery
- 8 Lid
- 9 Lid release element
- 10 Battery removal device
- 11 TPLO saw blade
- 12 Clamp screw (for saw blade release/fixing)
- 13 Hexagon wrench
- 14 Tool coupling

The depictions are schematic only.

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).
	Date of manufacture
	Follow the instructions for use
	Labeling of electrical and electronic devices pursuant to directive 2002/96/EG (WEEE)

	Classification Type BF
	Oscillation frequency control
	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
	Operating mode

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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. General information

2.1 Intended use

Task/Function

The TPLO saw GT666, combined with the relevant tool, is used for processing hard tissue, cartilage and the like, as well as for bone replacement materials.

Application Environment

The product fulfills the requirements for type BF pursuant to IEC/DIN EN 60601-1 and is used in operating rooms in sterile environments of explosion risk areas (such as areas with pure oxygen or anaesthesia gases).



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2.2 Main functions and design characteristics

Oscillation frequency	min. 0 min ⁻¹ to max. 15 000 min ⁻¹
Operating mode	Operation with non-periodic load and speed changes (type S9 pursuant to IEC EN 60034-1) ■ 30 second application, 30 second pause ■ 10 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 the 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 Indications

The TPLO saw, combined with the relevant tool, is used for a Tibia Plateau Leveling Osteotomy (TPLO) in veterinary medicine.

2.4 Absolute contraindications

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

2.5 Relative contraindications

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.
 - Follow TA022450 "Notes on electromagnetic compatibility (EMC) for Acculan components", see Aesculap Extranet at <https://extranet.bbraun.com>
 - 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 fixation system, adhere to the appropriate instructions for use for TA009721, see Aesculap Extranet at <https://extranet.bbraun.com>

4. Product description

4.1 Scope of supply

Art. no.	Designation
GT666	TPLO saw
GA678	Sterile funnel
GB020R	Hexagon wrench
TA004103	Fixing screw (spare)
TA014554	Instructions for use for TPLO saw GT666 (flyer)

4.2 Components required for operation

- Li-Ion battery short GA346 (charged)
- Sterile funnel GA678
- Lid GA675
- TPLO saw blade

4.3 Operating principle

The product **1** contains an electric motor, which is powered by a replaceable battery **7**.

The charged non-sterile battery **7** is inserted into the product **1** via the sterile funnel **6** and sealed with the lid **8** so that it is sterile.

The oscillation frequency is controlled electronically and can be continuously regulated with the trigger **2**.

The product **1** has a coupling, which allows for the attachment of various saw blades **11**.

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 pursuant 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 guide.



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6.1 System set-up

6.1.1 Connecting the accessories



DANGER

Risk of injury due to unapproved configuration using additional components!

- Ensure that the classification of all components used is consistent with the classification of the product (such as type BF or type CF).

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 fulfill the fundamental standard IEC/DIN EN 60601-1. The person connecting the devices with each other is responsible for the configuration and must ensure that the fundamental standard IEC/DIN EN 60601-1 or relevant national standards.

- 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 Inserting the rechargeable battery

- Product 1 with the battery shaft 4 must be turned upwards and the sterile funnel 6 (sterile) attached, see Fig. A.
- Battery 7 (non-sterile) is inserted into the battery shaft 4 by a second (non-sterile) person, see Fig. A.

Note

After the battery has been inserted, multiple signals will sound, which indicate that the product is ready to use.

- After insertion of the battery, have the sterile funnel 6 (non-sterile) removed by a second person.
- Attach the lid 8 (sterile) in such a manner that it clicks into place with both release catches 9.

Note

The sterility of the product is only guaranteed with a correctly placed cap.

6.1.3 Intraoperative battery change



WARNING

Risk of injury from hot battery!

Battery may be hot after use in the machine.

- Remove the battery with the battery removal device and let it cool.

The battery removal device is used for intraoperative battery changes ensuring that sterile conditions are safely maintained.

- Turn the product 1 with the battery shaft 4 upwards.
- Press both safety catches 9 on the lid 8 at the same time and remove the lid 8.
- Attach the sterile battery removal device 10, see Fig. B.
- Shake the product 1 with the attached battery removal device 10 with battery shaft 4 slightly downwards.
The battery 7 will slide easily into the battery removal device 10.
- Give the battery removal device 10 including dead battery 7 to the non-sterile person.
- Insert a charged battery 7, see Inserting the rechargeable battery.

6.1.4 Removing the rechargeable battery



WARNING

Risk of injury from hot battery!

Battery may be hot after use in the machine.

- Let the battery cool in the machine and then remove.
– or –
- Remove the battery with the battery removal device and let it cool.



CAUTION

Damage to the battery caused by knocking it against hard objects!

- Only remove battery by tapping the product on the palm of the hand.



CAUTION

Damage to, or destruction of the batteries due to processing!

- Do not sterilize batteries.

Rechargeable battery must be removed after each surgical procedure and prior to processing of the device.

Note

The battery removal device can be used for easier battery removal, see Fig. B.

- ▶ Turn the product **1** with the battery shaft **4** upwards.
- ▶ Press both safety catches **9** on the lid **8** at the same time and remove the lid **8**.
- ▶ Tightly grasp the battery shaft **4** at the lower end.
- ▶ Tap the battery shaft **4** on the palm of the hand until the battery **7** slides out of the battery shaft **4** and can be removed.

6.1.5 Protection against inadvertent activation

To prevent inadvertent activation of the product during tool change, the trigger can be locked.

To lock trigger:

- ▶ Twist the safety catch **3** to position OFF.
The trigger **2** is blocked and the product **1** cannot be operated.

To unlock trigger:

- ▶ Twist the safety catch **3** to position ON.
The trigger **2** is unlocked and the product **1** can be operated.

6.1.6 Attaching and detaching the saw blade



WARNING

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

- ▶ Only attach/remove tools in the OFF position.

Coupling the saw blade

- ▶ Secure product **1** against inadvertent activation with the safety catch **3**.
- ▶ Insert the TPLO saw blade **11** all the way into the tool holder **14** with the connection side in the desired position,
- ▶ Secure the TPLO saw blade **11** with the clamp screw **12** using the pin spanner **13**.

Uncoupling the saw blade

- ▶ Secure product **1** against inadvertent activation with the safety catch **3**.
- ▶ Loosen the clamp screw **12** with the pin spanner **13**.
- ▶ Pull out TPLO saw blade **1** from the tool holder **14**.

6.2 Function checks

The function checks must be carried out prior to each use and after each intraoperative battery change.

- ▶ Make certain there is a battery **7** inserted.
- ▶ Ensure that the lid **9** has completely clicked into place.
- ▶ Pull on the TPLO saw blade **11** to check that the TPLO saw blade **11** is securely coupled.
- ▶ Check that the cutting edges of the TPLO saw blade **11** do not exhibit any mechanical damage.
- ▶ Release product **1** for use (ON position).
- ▶ Briefly operate product **1** at maximum oscillation frequency.
- ▶ Do not use the product **1** if it is damaged or defective.
- ▶ Set aside the product **1** if it is damaged.

6.3 Safe operation



WARNING

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

- ▶ 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 or injury through aerosol formation or particles ejected from the tool!

- ▶ Use suitable protection (such as waterproof protective clothing, face mask, safety glasses, 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 tool may get caught in drapes (such as textiles).

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



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WARNING

Risk of burns to skin and tissue due to blunt saw blades/lack of product maintenance!

- ▶ Only use perfectly sharp saw blades.
- ▶ Replace blunt saw blades.
- ▶ Maintain the product properly, see maintenance guide.

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 Operating the product

Note

The slight whistling noise when the product is starting up is due to the construction.

- ▶ Activate trigger 2.
The oscillation frequency of the product 1 is continuously variable.
- ▶ Start the sawing procedure at a moderate oscillation frequency, which is then slowly increased.

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 chemistry 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.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 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.

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 Preparations at the place of use

- ▶ Remove all attached components from the product (tool and 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.

7.4 Preparation before cleaning

- ▶ Prior to the first mechanical cleaning/disinfection process, mount the ECCOS fixations in a suitable tray (e.g. GB243800).
- ▶ Insert the products in the correct position into the ECCOS fixations, see Fig. C.

7.5 Cleaning/disinfection

7.5.1 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 the maximum temperature of 96 °C during thermal disinfection with FD water.
- ▶ Dry the product for at least 10 minutes at a maximum of 120 °C.



CAUTION

Damage or destruction of the batteries due to processing!

- ▶ Protect battery from moisture.

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.



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7.6 Manual cleaning with wipe disinfection

Phase	Step	T [°C/°F]	t [min]	Conc. [%]	Water quality	Chemicals
I	Pre-cleaning	RT (cold)	≥ 2	-	DW	Until visually clean
II	Cleaning with enzyme solution	RT (cold)	≥ 2	0.8	D-W	pH-neutral*
III	Intermediate rinse	RT	≥ 5	-	DW	-
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	-	-	-	-

D-W: Drinking water

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

RT: Room temperature

* Validated with enzyme cleaner "Cidezyme Johnson & Johnson"

- ▶ 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

- ▶ Mobilize non-rigid components during cleaning.
- ▶ Clean the product under running water, using a suitable cleaning brush until all visible residues have been removed from the surfaces.
- ▶ Brush difficult to access surfaces with a suitable plastic cleaning brush for at least 1 min.

Note

For details on difficult to access surfaces, see Acculan pre-cleaning and care information TA016000 (available in Aesculap Extranet at <https://extranet.bbraun.com>).

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

- ▶ Mobilize non-rigid components 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.
- ▶ Contamination should be removed with a lint-free cloth or soft brush moistened with enzyme cleaner.
- ▶ Flexible components and cannulations should be rinsed 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).

7.7 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.

7.7.1 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

- ▶ Mobilize non-rigid components during cleaning.
- ▶ Thoroughly clean the product under running water.

Phase II

- ▶ Mobilize non-rigid components during cleaning.
- ▶ Brush difficult to access surfaces with a suitable plastic cleaning brush for at least 1 min.
- ▶ After manual preparation, check visible surfaces for residue and repeat the pre-cleaning process as needed.

Note

For details on difficult to access surfaces, see Acculan pre-cleaning and care information TA016000 (available in Aesculap Extranet at <https://extranet.bbraun.com>).



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7.7.2 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	-	-	-	mind. 10 min at max. 120 °C

DW: Drinking water

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

*Recommended: BBraun Helimatic Cleaner alkaline

- ▶ Insert the product in its proper position in the ECCOS fixation.
- ▶ After automatic cleaning/disinfection, check visible surfaces for residues and repeat the cleaning/disinfection process as needed.

7.8 Inspection, maintenance and checks

Note

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

- ▶ 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.
- ▶ Check the product for any damage, abnormal running noise, overheating or excessive vibration.
- ▶ Inspect the tools/saw blades for broken, damaged or blunt cutting edges.
- ▶ Set aside the product if it is damaged.

7.9 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).
- ▶ Insert product 1 in the correct position in the ECCOS fixations, see Fig. C.
- ▶ Pack trays appropriately for the sterilization process (e.g. in Aesculap sterile containers).
- ▶ Ensure that the packaging will prevent a recontamination of the product.

7.10 Steam sterilization



CAUTION

Damage or destruction of the batteries due to processing!

► **Do not sterilize the rechargeable battery.**

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

- Check to ensure that the sterilizing agent will come into contact with all external and internal surfaces (e.g. by opening any valves and faucets).
- 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.

7.11 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.

7.12 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.



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



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9. Troubleshooting list

► Have defective products repaired by Aesculap Technical Service, see Technical Service.

Issue	Cause	Detection	Remedy
Product not running	No battery	No battery in the battery shaft	Insert battery.
	Battery not charged	No signal tone when inserting the battery	Charge battery in charger.
	Battery defective	No signal tone when inserting the battery	Have the manufacturer repair the battery.
	Product in locked OFF position	Safety catch is in OFF position	Turn the safety catch into the ON position.
	Product defective	Product not running	Have the manufacturer repair the product.
Product becomes too hot	Excessive use	Product heating	Follow operating instructions (operating mode).
	Reprocessing/maintenance carried out incorrectly	Product heating	Follow operating instructions (preparation, care). Preventative: lubricate product before every sterilization.
	Fall damage, product defective	Product heating	Have the manufacturer repair the product.
	Blunt tool	Heating of tool and product	Change tool.
Insufficient power	Product defective	Insufficient product performance	Follow operating instructions (preparation, care). Preventative: lubricate product before every sterilization. Have the manufacturer repair the product.
		Large amount of heat generated after a short time	Follow operating instructions (operating mode). Have the manufacturer repair the product
	Blunt tool	Tool blades worn out	Change tool.
Loud running noise	Defective product drive/ball bearings	Loud, perceptible noise during operation	Follow operating instructions (preparation, care). Preventative: lubricate product before every sterilization. Have the manufacturer repair the product
Lid cannot be attached/removed	Lid not compatible	Lid does not click into place	Use the compatible lid for GT666.
	Lid deformed/defective	Lid is difficult or cannot be mounted/removed	Have the manufacturer repair the lid.
	Connection to product deformed/defective	Lid is difficult or cannot be mounted/removed	Have the manufacturer repair the product.

Issue	Cause	Detection	Remedy
Battery cannot be inserted/removed	Battery not compatible	Battery cannot be completely inserted into the battery shaft	Use the compatible battery for GT666.
	Battery deformed/defective	Battery is difficult or cannot be mounted/removed	Have the manufacturer repair the battery.
	Battery shaft to product deformed/defective	Battery is difficult or cannot be mounted/removed	Have the manufacturer repair the product
Sterile funnel or battery removal device not attachable	Sterile funnel or battery removal device not compatible	Sterile funnel or battery removal device not attachable to the battery shaft	Use compatible sterile funnel or battery removal device for GT666.
	Sterile funnel or battery removal device deformed/defective	Sterile funnel or battery removal device difficult or not attachable	Change sterile funnel or battery device.
	Battery shaft to product deformed/defective	Sterile funnel or battery removal device difficult or not attachable	Have the manufacturer repair the product.
Speed control knob not working	Product in locked OFF position	Safety catch is in OFF position	Turn the safety catch into the ON position.
	Speed control knob sticks/is defective	Speed control knob not working	Have the manufacturer repair the product.
Saw blade not moving	Loud running noise from motor	Defective gearings	Have repaired by manufacturer
Insufficient cutting performance of the saw blade	Saw blade teeth worn	Blunt saw blade	Replace saw blade
	Battery too weak	Insufficient motor power/speed	Charge battery
	Battery worn/defective		Replace battery
	Saw blade overheated	Inadequate chip removal	Move the saw back and forth during sawing and ensure sufficient irrigation of the saw blade
Saw blade cannot be inserted	Dirt on the saw blade and/or in the tool holder	Debris	Clean saw blade and/or tool holder
	Distorted tool holder	Deformation	Have repaired by manufacturer
	Distorted saw blade		Replace saw blade
	Distorted clamp screw		Replace clamp screw
	–	Incompatible saw blade	Insert a compatible Aesculap saw blade, see Accessories/Spare parts
Saw blade cannot be removed	Distorted tool holder	Deformation	Have repaired by manufacturer
	Distorted saw blade saddle shaft		Replace saw blade
	Distorted clamp screw		Replace clamp screw



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10. Technical Service



WARNING

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 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
GA675	Lid
GA346	Li-Ion battery short
GA678	Sterile funnel
GA679	Battery removal device
GB020R	Hexagon wrench
GB600	STERILIT Power Systems oil spray
GB498R	ECCOS fixation for straight machine
GB487R	ECCOS fixation for lid
GB488R	ECCOS fixation for sterile funnel
GB489R	ECCOS fixation for battery removal device
e.g. GC538R GC539R GC544R - GC548R	TPLO saw blades
TA004103	Fixing screw
TA014554	Instructions for use for TPLO saw GT666 (A4 for ring binder)

12. Technical data

12.1 Classification acc. to Directive 93/42/EEC

Art. no.	Designation	Class
GT666	TPLO saw	Ila

12.2 Performance data, information about standards

Max. power	approx. 250 W
Max. oscillation frequency	15 000 min ⁻¹
Weight (operational)	1,44 kg ±10 %
Dimensions (L x W x H, ready for operation)	280 mm x 55 mm x 84 mm ±5 %
Applied part	Type BF
EMC	IEC/DIN EN 60601-1-2
Conforming to standard	IEC/DIN EN 60601-1

The product was subject to 500 preparation cycles as a test by the manufacturer and has passed.

12.3 Operating mode

Operating mode	Operation with non-periodic load and speed changes (type S9 pursuant to IEC EN 60034-1)
	■ 30 second application, 30 second pause ■ 10 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

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