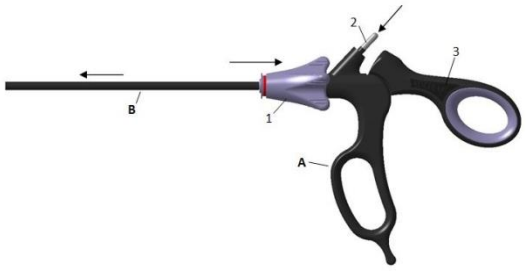
AESCULAP®

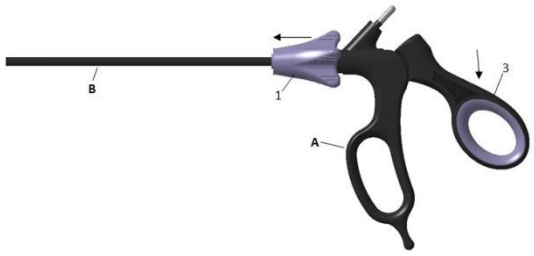
AESCULAP Surgical Instruments

USA Instructions for use/Technical description
Modular Monopolar Handle System

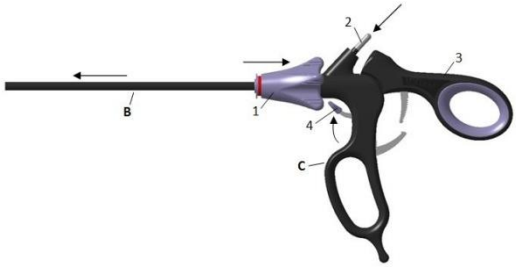
Removal of attachment – No ratchet (I)



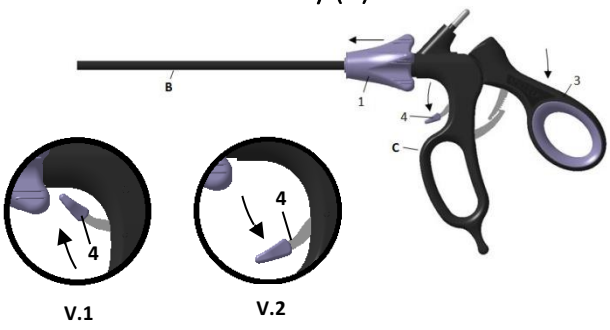
Insertion of attachment – No ratchet (II)



Removal of attachment – Ratchet (III)



Ratchet functionality (V)



Insertion of attachment – Ratchet (IV)

USA

Aesculap®

Modular Monopolar Handle System

Legend

A **Monopolar Handle without Ratchet**
1 Star wheel
2 HF pin
3 Proximal handle
4 Switch (lubrication point)
B **Monopolar Attachment**
C **Monopolar Handle with Ratchet**

Symbols on product and packages

Caution, general warning symbol
Caution, see documentation supplied with the product

Intended Use

Aesculap's modular endoscopic instruments are designed to cut, grasp, dissect and/or cauterize tissue during endoscopic surgical procedures. These instruments are intended to be introduced through a trocar cannula.

Safe Handling and Preparation

CAUTION

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

- Ensure that the product and its accessories are operated and used only by persons with the requisite training, knowledge, or experience from an accredited institution or hospital.
- Read, follow, and keep these instructions for use.
- Use the product only in accordance with its intended use, see Intended Use.
- Remove the transport packaging and thoroughly clean the new product manually prior to its initial sterilization.
- Store any new or unused products in a dry, clean, and secure storage place.
- Prior to each use, inspect the product for loose, bent, broken, cracked, worn, or fractured components.
- Do not use the product if it is damaged or defective. Set aside the product if it is damaged.
- To avoid damage to the working end: Carefully insert the product through the working channel (e.g. trocar).

WARNING

Risk of injury from ignition or explosion of flammable gases! Sparks may occur when using the HF device as directed.
- **Observe the safety guidelines in the instructions for use of the HF device.**

WARNING

Thermal injuries to patients/users due to insufficient insulation of leads in active accessories!
- **Adjust the HF device to an appropriate setting to ensure that the peak output voltage matches or does not exceed the accessory voltage rating specified for the product.**

The manufacturer has tested the product and verified that its insulation can withstand 300 reprocessing cycles. In clinical practice, the service life will depend on the individual intraoperative usage and the hospital's specific reprocessing conditions.

- Adjust the HF power output (and argon flow rate) to the intervention to be carried out. Take into account clinical experience or reference values.
- Select the lowest possible HF power output.
- Keep the product's contact surfaces clean during surgery. Remove encrusted tissue residues or body fluids with a moistened swab.

The product is furnished with the following connection on the plug side: pin, 4mm, sprung.
Refer to our brochures to find a compatible cable.
The accessory voltage rating of the product is 2,500 Vp.
The accessory voltage rating must exceed or match the peak output voltage with which the product is operated in combination with a suitable HF device at an appropriate operating mode/setting (see IEC/DIN EN 60601-2-2).
To avoid HF burns:

- Always keep the working end of the product in the user's field of vision whenever the HF power is activated.
- Prior to activating the HF device, check that the working end of the product is not touching any electrically conductive accessories.
- Prior to each use, visually inspect the product for: damage or surface changes to the insulation.
- Never place the product on or next to the patient.
- When using accessories for endoscopy or laparoscopy, deactivate the automatic switch-on mode of the HF device.
- Follow the instructions for use of the HF device.

Safe Operation

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.**

- Open and close the distal end of the jaws: open and close the moveable part of the handle.

Handle without ratchet

WARNING

Risk of injury to user!
- **Power off and disconnect any HF power output before removing or inserting attachments.**

Removal of attachment

Note

For removal of attachment also see additional illustrations ***I.***

- While holding thumb on HF pin **2** slide the star wheel **1** proximally until it clicks into place. A red colored ring becomes visible.

- Detach the accessory **B** from handle **A**: Hold accessory **B** at its tip and extract it from handle **A**. Do not hold the moveable part of the handle (proximal handle **3**). The proximal handle **3** will move up.

Insertion of attachment

Note

*For insertion of attachment also see additional illustrations **II**.*

- Hold the accessory **B** at its tip with one hand.
- With the other hand, hold handle **A** behind the star wheel **1** at the fixed handle part. The proximal handle **3** must be freely moveable.
- Push the accessory **B** into handle **A**. The proximal handle **3** will move down. When the stop is reached, star wheel **1** automatically clicks into place at the distal end. The red colored ring will no longer be visible.
- Check to make sure that the instrument is working properly by opening and closing the jaws.

Handle with ratchet

WARNING

Risk of injury to user!

- **Power off and disconnect any HF power output before removing or inserting attachments.**

Removal of attachment

Note

*For removal of attachment also see additional illustrations **III.***

- Deactivate the ratchet mechanism on the handle by swinging switch **4** upward.
- While holding thumb on HF pin **2** slide the star wheel **1** proximally until it clicks into place. A red colored ring becomes visible.
- Detach the accessory **B** from handle **C**: Hold accessory **B** at its tip and extract it from handle **C**. Do not hold the moveable part of the handle (proximal handle **3**). The proximal handle **3** will move up.

Insertion of attachment

Note

*For insertion of attachment also see additional illustrations **IV.***

- Hold the accessory **B** at its tip with one hand.
- With the other hand, hold handle **C** behind the star wheel **1** at the fixed handle part. The proximal handle **3** must be freely moveable.
- Push the accessory **B** into handle **C**. The proximal handle **3** will move down. When the stop is reached, star wheel **1** automatically clicks into place at the distal end. The red colored ring will no longer be visible.
- Activate the ratchet mechanism on the handle by swinging switch **4** downward.
- Check to make sure that the instrument is working properly by opening and closing the jaws.

Ratchet functionality

Note

*For ratchet functionality also see additional illustrations **V.***

- Press switch **4** to release the ratchet mechanism.
- To activate the ratchet mechanism, release switch **4**. Switch **4** can be placed in the upward position to deactivate the ratchet mechanism.
- To deactivate the ratchet mechanism on the handle: position switch **4** upward as shown in **V.1**. The switch slides into the upward position.
- To activate the ratchet mechanism on the handle: position switch **4** downward as shown in **V.2**. The switch slides into the downward position.

Validated Reprocessing Procedure

General Safety Instructions

Note

Adhere to state and national standards and directives as well as the local, clinical hygiene instructions for sterile processing.

Note

For patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants of CJD, observe the relevant national regulations concerning the reprocessing of products.

Note

Successful processing of this medical device can only be ensured if the processing method is first validated. The operator/sterile processing technician is responsible for this.

Note

If there is no final sterilization, then a virucidal disinfectant must be used.

Note

For the latest information on reprocessing and material compatibility see www.aesculapusa.com

The validated steam sterilization procedure was carried out in an Aesculap sterile container system cleared by the FDA.

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 hours; also, neither fixating pre-cleaning temperatures >113 °F nor fixating disinfecting agents (active ingredient: aldehydes/alcohols) should be used. Excessive measures of neutralizing agents or basic cleaners may result in a chemical attack and/or fading to the laser marking. Residues containing chlorine or chlorides (e.g. in surgical residues, medicines, saline solutions and in the service water used for cleaning, disinfection and sterilization) will cause corrosion damage (pitting, stress corrosion) and result in the destruction of stainless steel products. These must be removed by rinsing thoroughly with demineralized water and then drying. Only process chemicals that have been tested and approved (e.g. VAH or FDA approval) and which are compatible with the product's materials according to the chemical manufacturer's recommendations. All chemical manufacturers' 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 surfaces and could cause corrosion.

Disassembling the product before carrying out the reprocessing procedure

- Disassemble the product immediately after use as described in these Instructions for Use.
- Open up instruments with hinges.

Preparation at the place of use

- If applicable, rinse non-visible surfaces, preferably with deionized water, with a disposable syringe or similar method.
- Remove any visible surgical residues to the extent possible with a damp, lint-free cloth.
- Transport the dry product in a sealed waste container for cleaning and disinfection within 6 hours.

Preparation before cleaning

- Disassemble the product prior to cleaning, see appropriate Removal of Attachment section in these Instruction for Use.

Cleaning/disinfection

Product-specific safety notes on 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 use, for example on plastic materials and high-grade stainless steel**
  - **do not attack softeners (e.g. in silicone).**
- **Observe specifications regarding concentration, temperature and exposure time.**
- **Do not exceed the maximum permitted cleaning temperature of 200 °F.**

Immersion treatment in a 3% H_2O_2 solution for approx. 5 minutes is a particularly effective and gentle method to dissolve encrustations from HF instruments. Subsequently, the debris can be removed by hand, with a medium-hard brush and/or in an ultrasonic bath. This is followed by the conventional reprocessing steps.

- Use suitable cleaning/disinfecting agents if the product is put away in a wet condition. To prevent foam formation and reduced effectiveness of the process chemicals: Prior to mechanical cleaning and disinfection, rinse the product thoroughly with running water.
- Carry out ultrasound cleaning:
  - as an effective mechanical supplement to manual cleaning/disinfection.

Validated cleaning and disinfection procedure

Validated procedure	Specific Requirements	Reference
Manual cleaning with ultrasound and immersion disinfection	▪ Cleaning brush, e.g. PM995R or GK469R ▪ 20 ml disposable syringe ▪ Drying phase: Use lint-free cloth or medical compressed air	Chapter Manual cleaning/disinfection and sub-chapter: ▪ Chapter Manual cleaning with ultrasound and immersion disinfection

Manual cleaning/disinfection

- Prior to manual disinfecting, allow water to drip off for a sufficient length of time to prevent dilution of the disinfecting solution.
- After manual cleaning/disinfection, check visible surfaces visually for residues.
- Repeat the cleaning/disinfection process if necessary.

Manual cleaning with ultrasound and immersion disinfection

Phase	Step	T [°F]	t [min]	Conc. [%]	Water quality	Chemical
I	Ultrasonic cleaning	RT (cold)	>15	2	D-W	Prolystica® 2X Concentrate Enzymatic Cleaner
II	Intermediate rinse	RT (cold)	1	-	D-W	-
III	Disinfection	RT (cold)	15	2	D-W	Prolystica® 2X Concentrate Enzymatic Cleaner
IV	Final rinse	RT (cold)	1	-	FD-W	-
V	Drying	RT	-	-	-	-

D-W: Drinking water
FD-W: Fully desalinated water (demineralized, low microbiological contamination: drinking water quality at least)
RT: Room temperature

- Note the information on the appropriate cleaning brushes and disposable syringes; see validated cleaning and disinfection procedure.

Phase I

- Clean the product in an ultrasonic cleaning bath (frequency 35 kHz) for at least 15 min. Ensure that all accessible surfaces are immersed and acoustic shadows are avoided.
- Clean the product with a suitable cleaning brush in the solution until all discernible residues have been removed from the surface.
- If applicable, brush through non-visible surfaces with an appropriate cleaning brush for at least 1 min.
- Mobilize non-rigid components, such as hinges, triggers, etc. during cleaning.
- Thoroughly rinse these components with the cleaning disinfectant solution (at least five times), using a disposable syringe.

Phase II

- Rinse/flush the product thoroughly (all accessible surfaces) under running water.

- Mobilize non-rigid components, such as hinges, triggers, etc. during rinsing.
- Drain any remaining water fully.

Phase III
- Fully immerse the product in the disinfectant solution.
- Mobilize non-rigid components, such as hinges, triggers, etc. during rinsing.
- Rinse lumens at least five times at the beginning of the exposure time with an appropriate disposable syringe. Ensure that all accessible surfaces are moistened.

Phase IV
- Rinse/flush the product thoroughly (all accessible surfaces) under running water.
- Mobilize non-rigid components, such as hinges, triggers, etc. during final rinse.
- Rinse lumens with an appropriate disposable syringe at least five times.
- Drain any remaining water fully.

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

Inspection, maintenance, and checks

CAUTION

Damage (metal seizure/friction corrosion) to the product caused by insufficient lubrication!
- **Prior to function checks, lubricate moving parts (e.g. joints) at the marked lubrication points, using maintenance oil suitable for the respective sterilization process (e.g. for steam sterilization: Aesculap STERILIT® I oil spray JG600 or STERILIT® I drip lubricator JG598).**

- Allow the product to cool down to room temperature.
- After each complete cleaning, disinfecting and drying cycle, check that the instrument is dry, clean, operational, and free of damage (e.g. broken insulation or corroded, loose, bent, broken, cracked, worn, or fractured components).
- Dry the product if it is wet or damp.
- Repeat cleaning and disinfection of products that still show impurities or contamination.
- Check that the product functions correctly.
- Immediately put aside damaged or inoperative products and send them to Aesculap Technical Service, see Technical Service.
- Assemble products as described in these Instructions for Use.
- Check for compatibility with associated products.

Packaging
- Appropriately protect products with fine working tips.
- Store products with ratchet locks fully opened or locked no further than in the first notch.
- Place the product in its holder or in a suitable tray.
- Pack trays appropriately for the intended sterilization process (e.g. in sterile Aesculap containers).
- Ensure that the packaging provides sufficient protection against recontamination of the product during storage.

Steam Sterilization

Note

To avoid breakage due to stress crack corrosion, sterilize the handle with the lock fully open or locked no further than the first ratchet tooth.

Note

The product can be sterilized either in the disassembled or assembled state.

- 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 the FDA in K792558 or K112671. 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.

WARNING

If this device is/was used in a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross contamination.

Storage
- Store sterile products in sterile barrier packaging, protected from dust, in a dry, dark, room temperature-controlled area.

Technical Service

WARNING

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

- For service and repairs, please contact your local/Aesculap agency. Modifications carried out on medical technical equipment may result in loss of guarantee/warranty rights and forfeiture of applicable licenses.

Service Address
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

Accessories/Spare parts

For accessories and spare parts, please contact Aesculap Customer Service 800-282-9000.

Disposal

- Adhere to national and/or local, hospital regulations when disposing of or recycling the product, its components, and its packaging!

Manufactured for:

Note
Contact your local Aesculap representative for product information and complaints

Aesculap Inc.
3773 Corporate Parkway
Center Valley PA, 18034

+1 (800) 258-1946
www.aesculapusa.com

SOP-AIC-5001686 Rev. 3 0722

CHANGE HISTORY

DEPARTMENT *(The department that is accountable for the document)*	Danielle Fletcher
VERSION AUTHOR *(Employee updating current version)*	Matthew Santoianni, Associate Design Engineer

B.DoCS and TRAINING REQUIREMENTS				
☐ **New**	☐ **Revision**	☐ **Admin**	☐ **Obsolete**	☒ **Form**
Minimum read/ understand. **Submit SOP-AIC-5001026**, ISOTrain Change Request Form.	Minimum read/ understand. **Submit SOP-AIC-5001026**, ISOtrain Change Request Form for significant change(s), change(s) to the responsibility section and new sections.	No training required.	No training required. **Submit SOP-AIC-5001026** to notify Training Department about obsolescence.	No training required (ex. PSPECs, Lists, Set Lists, SIP's, IFU's, etc.).

CHANGE SUMMARY		
Change Control Number:	**CC-025-22**	
Section	**Description of Change**	**Rationale/Justification**
Page 1	Correction to Illustration "Ratchet functionality (V)".	Adjusted placement of arrows in illustrations **V.1** and **V.2** to clarify the movement direcction of switch **4**.
Page 4	Changed chemical cleaner from "Aldehyde-free, phenol-free, and QUAT-free concentrate, pH ~9*" to "Prolystica® 2X Concentrate Enzymatic Cleaner".	Instruct US customers to use a pH neutral cleaner to standardize current US market reprocessing needs.
Page 4	Removed line "*Recommended BBraun Stabimed".	Recommendation was removed due to the removal of the associated chemical cleaner.
Page 5	Changed "Rev. 2 0218" to "Rev. 3 0722".	New document revision.
All pages	Adjusted formatting and spacing of document.	Alignment of document columns was adjusted to improve paragraph readability.

Note: Add a new row for each change

ADD / DELETE KEYWORDS FOR THIS DOCUMENT	Indicate if keywords are to be added or deleted.
ADD:	*N/A*
DELETE:	*N/A*

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APPROVERS: Maximum number of approvers for a document is 10. Please follow **SOP-AIC-5002064** Minimum Required Document Approvers. **This section is required**.		
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Melissa Bevan	Manager II, Design Assurance – Medical Device	☐N/A Row
Danielle Fletcher	Product Manager	☐N/A Row
Tim Stoudt	Associate Director - Regulatory Affairs	☐N/A Row
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Title: Manager II, Design Assurance – Medical Device
Date: Thursday, 21 July 2022, 14:13 W. Europe Daylight Time
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Title: Project Engineer
Date: Thursday, 21 July 2022, 21:50 W. Europe Daylight Time
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UserName: Fletcher, Danielle (fletdnus)
Title:
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UserName: Oyedele, Motolani (oyedmous)
Title:
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Title: INSTRUCTIONS FOR THE MODULAR MONOPOLAR HANDLE SYSTEM Initiator: Matthew ? Santoianni

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