

Notes on use

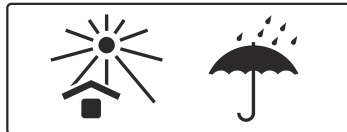
usa

Applicator with coagulation and suction

20150-236

Single use only! Sterility not guaranteed if package has been opened or damaged. Discard if package is damaged.

STERILE EO



ERBE

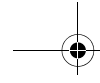
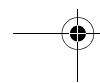
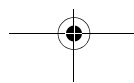
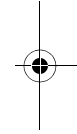
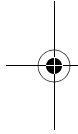


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IMPORTANT!

Please read all information carefully.

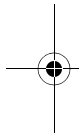
These notes on use do not replace the User Manuals of the Water Jet System and ElectroSurgical Unit (ESU) used! Read the User Manuals of the units and ask ERBE or your distributor in case of doubt!

Caution! Federal law (USA) restricts this device to sale by or on the order of a physician!



1 Intended Use

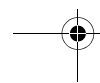
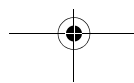
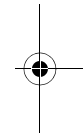
The Applicator is intended to cut and dissect soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME) as well as to provide suction and monopolar coagulation of the target tissue in open surgery.

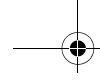


2 Normal Use

The Applicator is used with a designated Water Jet Unit, Suction Module, and ElectroSurgical Unit for the clinical applications per the intended use.

- ERBE electroSurgical units of series VIO with a monopolar 3-PIN receptacle.
- Water Jet Unit ERBEJET 2.
- External suction, e.g. the ERBE ESM 2. The suction pressure may be max. -11.6 psi (-800 mbar) independent of the unit used.





3 Maximum Electrical Capacity

The maximum electrical capacity of this product is:

- 2500 V_p



4 Safety Instructions

WARNING!

This product may only be used by medical personnel who have been trained per these instructions.

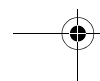
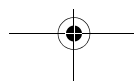
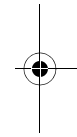
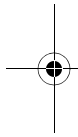
ERBE recommends that the product not be reprocessed after use. High temperatures in particular (e.g. in the autoclave) can affect material properties and product function making its Intended Use no longer possible.

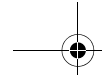
Materials and design of this product are intended for single use. Resterilization of the product can affect the performance of the product; adequate sterilization also cannot be ensured. Therefore, properly dispose of the product after use.

Before each use, check that the product is intact. Verify that there are no signs of physical damage.

If damaged, do not use this product!

When using and handling the product, the involved medical staff should wear personal protective equipment (e.g. gown, faceshield or eye protection, mask, gloves, etc.) to minimize the risk of exposure to infectious agents due to undesirable/unexpected spraying or splashing, mishandling of the contaminated accessory, etc.





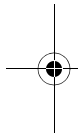
When using the HF current portion of the product, the cutting medium can act as a conductor. Therefore, do not use metal accessories such as connectors unless they are insulated. If in contact, any conductive item could inadvertently burn the patient or personnel.

Do not use in the presence of combustible or explosive materials!

Never lay this product on the patient or in his/her direct vicinity.

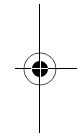
Protect this product from any form of mechanical damage! Do not throw! Do not use force! Do not kink or wrap the cable or tubing!

ERBE Elektromedizin expressly warns against modifying the product. Any modification exempts ERBE Elektromedizin from any and all liability.



5 Recommended Unit Settings

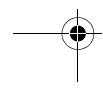
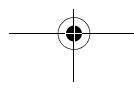
This chapter describes unit settings that may be used to operate the product without causing damage.

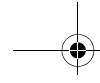


5.1 ERBEJET 2

All effect levels of the ERBEJET 2 may be used. Cutting/Dissecting with too high of a pressure can lead to tissue damage. Therefore use the lowest possible settings to achieve the desired surgical outcome.

Note: External suction, e.g. the ESM 2. The suction pressure may be max. -11.6 psi (-800 mbar) independent of the unit used.





5.2 ERBE VIO

For a monopolar COAG mode:

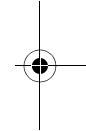
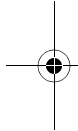
- Effect: Effect with an HF peak voltage (U HF) $\leq 2500 V_p^{1)}$
- Power: No restriction
- Use the lowest possible setting(s) to achieve the desired clinical outcome. However, power settings that are too low can be dangerous.

Note: ERBE electro-surgical units of series VIO with a monopolar 3-PIN receptacle are to be used.

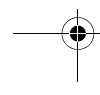
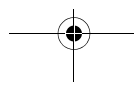


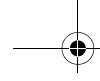
6 Information on electromagnetic compatibility (EMC) of the units

Notwithstanding the specifications in the ERBEJET 2, ESM 2 and VIO User Manuals, HF emissions are classified as Class A²⁾ according to CISPR 11 for common use of the product with the units. All other ECM specifications in the User Manuals for the respective units apply for their common uses.



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- 1.) The HF peak voltage of an effect depends on the mode selected and the power setting (watts) used. More information about selecting an appropriate effect is available in the User Manual for the VIO HF electro-surgical unit.
 - 2.) The system is suited for use in environments other than domestic areas and in ones directly connected to a public power supply system that also supplies buildings being used for domestic purposes. The customer or the user of the system should ensure that it is used in such an environment.





7 How to Use



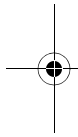
7.1 Sterile product for single use

ERBE recommends that the product not be reprocessed after use. High temperatures in particular (e.g. in the autoclave) can affect material properties and product function making its Intended Use no longer possible.

Materials and design of this product are intended for single use. Resterilization of the product can affect the performance of the product; adequate sterilization also cannot be ensured. Therefore, properly dispose of the product after use.

7.2 Check the expiration date

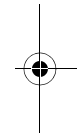
An expiration date is printed on the packaging of the product. Do not use any product beyond its expiration date!



7.3 Control and open packaging

Use this product only if the packaging has not been opened or damaged. If the packaging is open or damaged, the product is no longer sterile and must not be used. In this case, throw the product away!

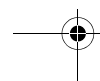
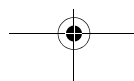
Use aseptic techniques when removing the product from the packaging!



7.4 Check the product

Before each use, check that the product is intact. Verify that there are no signs of physical damage.

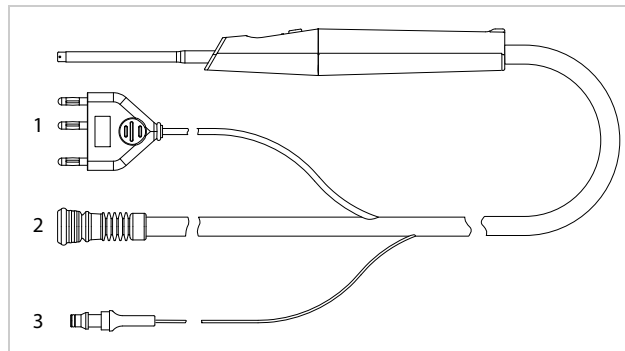
If damaged, do not use this product!



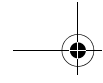
7.5 Obtain needed ERBEJET 2 accessory and cutting medium

- Pump cartridge (Art. No. 20150-300)
- Cutting medium: to select the suitable cutting medium please read the Notes on use for the pump cartridge

7.6 Connect up the product



1. Establish the water jet connection: On the sterile field, plug the extension tubing connector (3) into a pump cartridge by snapping it into place until it clicks. The attached pump cartridge is then inserted into the Water Jet System ERBEJET 2.
2. Connect the suction: Using aseptic technique, connect the suction hose (2) to the suction device.
If using the ESM 2, connect the Applicator's suction hose to the patient port of the suction bag or lid of the suction container (Note: Ensure that ERBEJET 2 and ESM 2 are connected via the ECB cable and the suction container is connected to the suction connection port of the ESM 2. To proceed follow the User Manual of the ESM 2).



3. Establish HF connection: Plug the HF connector (1) into the 3-pin monopolar receptacle of the ESU VIO Model. To operate the VIO ESU, please read its User Manual.

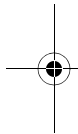


7.7 Using the product

The Water Jet is employed via the Footswitch of the ERBEJET 2 (Note: If using the ESM 2, see User Manual for employing suction.).

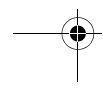
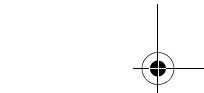
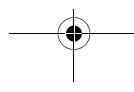
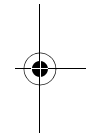
The HF current (COAG only) is delivered from the ESU by pressing the fingerswitch on the applicator or by pressing the blue pedal of the footswitch for the ESU.

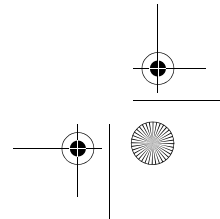
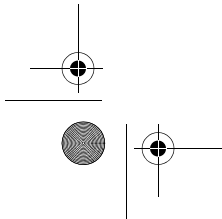
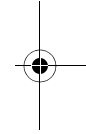
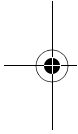
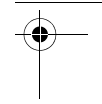
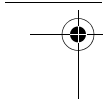
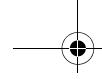
The modalities of the Water Jet and HF current are applied alternately.

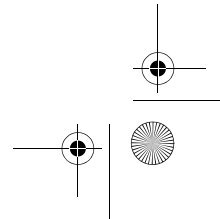
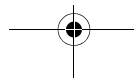
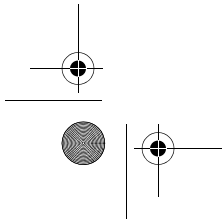
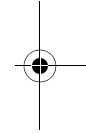
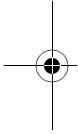
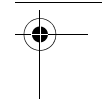
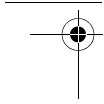
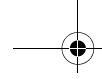


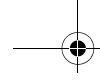
7.8 Use suction correctly

In order to prevent blockages of the aspirator tube or detect them early on, look out for adequate and constant suction during use.









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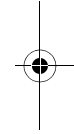
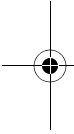
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