



en INSTRUCTIONS FOR USE

BIZZER Bipolar scissors

REF	Product Name
795-145	BIZZER, bipolar scissors, 145 mm, curved, pointed
795-180	BIZZER, bipolar scissors, 180 mm, curved, pointed
795-545	BIZZER, bipolar scissors, 145 mm, curved, pointed, COMFORT, cable, 4.5 m
795-580	BIZZER, bipolar scissors, 180 mm, curved, pointed, COMFORT, cable, 4.5 m
796-170	BIZZER, bipolar scissors, 170 mm, curved
796-570	BIZZER, bipolar scissors, 170 mm, curved, COMFORT, cable, 4.5 m
797-180	BIZZER, bipolar scissors, 180 mm, curved, slim
797-230	BIZZER, bipolar scissors, 230 mm, curved, slim
797-280	BIZZER, bipolar scissors, 280 mm, curved, slim
797-580	BIZZER, bipolar scissors, 180 mm, curved, slim, COMFORT, cable, 4.5 m
797-630	BIZZER, bipolar scissors, 230 mm, curved, slim, COMFORT, cable, 4.5 m
797-680	BIZZER, bipolar scissors, 280 mm, curved, slim, COMFORT, cable, 4.5 m
798-145	BIZZER, bipolar scissors, 145 mm, curved, fine
798-180	BIZZER, bipolar scissors, 180 mm, curved, fine
798-230	BIZZER, bipolar scissors, 230 mm, curved, fine
798-280	BIZZER, bipolar scissors, 280 mm, curved, fine
798-545	BIZZER, bipolar scissors, 145 mm, curved, fine, COMFORT, cable, 4.5 m
798-580	BIZZER, bipolar scissors, 180 mm, curved, fine, COMFORT, cable, 4.5 m
798-630	BIZZER, bipolar scissors, 230 mm, curved, fine, COMFORT, cable, 4.5 m
798-680	BIZZER, bipolar scissors, 280 mm, curved, fine, COMFORT, cable, 4.5 m

NOTICE

The BOWA COMFORT instruments with instrument identification Plug'n Cut COMFORT are compatible with the following software versions of your generator:

- ARC 400 starting from V 2.2.1
- ARC 350 starting from V 2.1.1

If you operate your generator with an older software version, a software update will be required in order to use the BOWA COMFORT instruments with Plug'n Cut COMFORT. Using it with software version 1.x.x is not possible as an update to a higher version is not supported.

European Medical Device Regulation
This product complies with Regulation 2017/745 on medical devices.



1 Intended Purpose

Electrosurgical equipment for tissue cutting and coagulation of tissue.

1.1 Indications

The bipolar scissors are intended to be used for the preparation, cutting and coagulation of tissue in various open surgery disciplines, such as general and abdominal surgery, urology, gynaecology and ENT.

The bipolar scissors may be used as conventional instruments (without electrical energy) or as electrosurgical instruments, in the latter case by connecting them to the bipolar output of a suitable HF generator by means of a bipolar cable.



Extensive coagulation



Coagulating before cutting



Coagulating during cutting



Punctate coagulation

1.2 Contra-indications

Do not use bipolar scissors in direct contact with the heart, central circulatory system or the central nervous system.

Do not use bipolar scissors where its surgical techniques are contraindicated.

Do not use bipolar scissors for the preparation of metallic implants, such as clips.

Do not use bipolar scissors for the contraceptive coagulation of the Fallopian tubes.

Do not use bipolar scissors if, in the opinion of an experienced physician or according to current professional literature, such use would cause endangerment of the patient, for example due to the general condition of the patient, or if other contraindications are present.

2 Physical principle of operation

When using high-frequency current with a frequency >300 kHz, the thermal effect occurs.

The electrolytic effect and the irritation effect are not detectable above a frequency of approx. 20 kHz. The coagulation of biological tissue is based on the thermal effect.

Cutting is done mechanically.

Printed in Germany

Subject to technical and design changes

Copyright by BOWA-electronic GmbH & Co. KG, Gomaringen | Germany

3 Safety instructions

3.1 Device-related

- Goods which are delivered non-sterile must be sterilised before use! Sterilisable up to max. 137°C.
- Make sure to correctly clean, disinfect and sterilise the product.
- Hot air sterilisation is prohibited.
- Check the instrument for damage prior to use. Bipolar scissors contain high-quality ceramic parts that must be handled with special care and protected against breakage. If damaged, the instrument must not be used.
- Do not apply loads that exceed the instrument's mechanical limits.
- Follow the instructions for use for the HF generator.
- Follow the instructions for use of the connection cable.
- Comply with the recommended power settings and maximum voltage. Always choose the lowest required power setting. The effectiveness of the settings must be assessed by the user.
- Repair / servicing not permitted!
- Caution! Risk of injury due to sharp edges.

3.2 Use-related

- The user must be trained in, and be familiar with, the basic principles, rules of application, and risks of HF surgery.
- Instruments must be used by trained medical staff only.
- The surgical field must be free of explosive gases or inflammable fluids and materials.
- The instrument must not contact other uninsulated instruments or objects.
- Route the cables, ensuring that no loops form and that they remain isolated from other cables and do not contact the patient.
- Do not touch scissor blades during activation as this may cause burns. The scissors may still be hot enough to cause burns immediately after HF power has been switched off.
- Avoid contact between activated bipolar and monopolar instruments. This may result in damage to the HF generator.
- To prevent personal injury in case of inadvertent HF activation, do not set down active HF instruments on the patient. When not in use, place the scissors in a container or in a clean, dry, non-conductive and clearly visible location away from the patient.
- Report any incidents or near accidents to your country's regulatory agency for medical devices. When doing so, follow your own facility's internal reporting system. Notify your local BOWA specialist retailer in such cases.
- For patients fitted with a pacemaker, consult the cardiologist before carrying out HF surgery.
- Caution: When the Autostart function is in use, HF application is activated by skin contact.
- Soiled scissor blades can result in inadequate coagulation.
- Before application, perform a functional test using a piece of gauze soaked in a saline solution.
- The "BF"/"CF" applied part of the employed HF unit is extended by the connected instrument.

3.3 EMC information

Medical electrical devices are subject to special EMC precautions, so please follow the instructions detailed below.

- The BOWA accessory is only intended to be connected to BOWA-specified HF equipment
- Using the accessories with medical devices from third-party manufacturers may result in higher emission levels or reduced interference immunity.

NOTICE

Combining medical devices is safe only if

- the relevant instructions for use permit the desired combination or
- the intended use and the interface specification of the products used in the combination are compatible.

The Instructions for use and interface specifications of medical devices used in combination must be strictly observed.

4 Description

4.1 Procedure during use

1. Products delivered in non-sterile condition must be sterilised before use.
2. Connect standard instruments with a suitable connection cable before use. After use, always disconnect the connection cable from the standard instrument.

4.2 Connection combinations

The standard instruments 795-145, 795-180, 796-170, 797-180, 797-230, 797-280, 798-145, 798-180, 798-230 and 798-280 additionally require the connection cable 378-045, 378-145 or 378-245.

The COMFORT items 795-545, 795-580, 796-570, 797-580, 797-630, 797-680, 798-545, 798-580, 798-630 and 798-680 have the 4.5 m connection cable permanently connected to the instrument. Generators with Plug'n Cut COMFORT recognise BOWA COMFORT instruments and automatically preselect the appropriate parameters.

4.3 Power recommendations

The instrument must always be used with a bipolar coagulation current.

In addition, the instrument may be used with BOWA ARC 400 (REF 900-400) and ARC 350 (REF 900-351) with the current form Bipolar cutting "Bipolar scissors".

The recommended power setting is 30 to 50W.

Do not exceed the maximum permissible voltage: 200V_p

4.4 Clinical benefit

During treatment with the BOWA HF-instruments, the patient benefits from established and safe state-of-the-art electrosurgical instruments used in cutting, coagulation and vessel ligation procedures in a variety of electrosurgical interventions within almost all surgical disciplines.

5 Reprocessing

5.1 General information

The preparation affects this product. Observe the safety instructions and instructions for checking the function of the product. In case of apparent damage or functional impairment of the product, it must no longer be used.

The service life may vary depending on the demands placed on the product.

Manual reprocessing methods are not recommended due to their significantly lower effectiveness.



Follow the chemical manufacturers' statements on concentrations and exposure times. The medical device manufacturer shall not be liable if other types of cleaning agents and disinfectants are used.

5.2 Product-specific information

Insulated parts must not come into contact with hard, sharp or heavy devices, as this could damage the electrical insulation.

Do not use wire brushes, abrasives or other products which could damage the surface.

BOWA has verified a service life of 25 cycles under the condition of proper and professional use and preparation; the actual service life may be higher or lower depending on the demands placed on the product.	
Reprocessing step	Description
Manual pre-cleaning	
1.A Soaking ¹	Soak the product at room temperature (<25°C) for at least 5 minutes immediately, but no later than 2 hours, after use. Only use enzymatic, aldehyde-free disinfectants suitable for disinfecting medical devices (e.g., DGHM or FDA approval or CE marking). Remove all visible soiling with a soft plastic brush. BOWA recommends the use of Gigasept® Instru AF (Schülke & Mayr GmbH).
1.B Ultrasound ²	Place the product in the ultrasonic bath for at least 5 minutes. BOWA recommends the use of Gigasept® Instru AF (Schülke & Mayr GmbH).
2 Rinsing	Rinse the product thoroughly for at least 1 minute at room temperature (<25°C) under running tap water (at least drinking water quality). Allow residual water to drip off sufficiently.
Machine cleaning, thermal disinfection and drying	
3 Machine cleaning ³	Store the product in its open state for machine cleaning and thermal disinfection. Use a washer-disinfector (WD) with tested effectiveness (in accordance with ISO 15883) and a neutral to alkaline (max. pH 11.5) enzymatic cleaning agent. Depending on the concentration, agents including alcohol- and/or aldehyde-containing ingredients may be used. BOWA recommends the use of neodisher® MediClean forte (Chemische Fabrik Dr. Weigert) at 55°C for 10 minutes. The intermediate rinsing must include at least two rinsing steps with fully demineralised water (deionised water) (at least 1 minute at >10°C each).
4 Thermal disinfection ⁴	An A ₀ value of >3000 must be attained. BOWA recommends a temperature of 90°C for at least 5 minutes and the use of demineralised water.
5 Drying	Drying is carried out according to the WD programme and depends on the total load. The maximum temperature is 100°C for 25 minutes. If necessary, dry with filtered compressed air at max. 3 bar.
Inspection	After machine cleaning and disinfection, carry out a visual inspection to check for residues. Repeat the reprocessing, if necessary.
Steam sterilisation	
6 Steam sterilisation ⁵	BOWA recommends steam sterilisation using the fractionated vacuum method with a sterilisation time of 3–20 minutes and a temperature of 134–137°C in a suitable sterilisation packaging.

BOWA has validated:

¹ Soaking for 5 minutes with Gigasept® Instru AF (Schülke & Mayr GmbH), 3% v/v, brushing

² Ultrasound for 5 minutes with Gigasept® Instru AF (Schülke & Mayr GmbH), 3% v/v

³ Neodisher® MediClean forte (Chemische Fabrik Dr. Weigert), 0.5% v/v

⁴ Thermal disinfection at 90°C for 5 minutes

⁵ Half-cycle with 3 pre-vacuum phases at 132°C for 1.5 minutes, packaging: double-packaged in paper/film sterilisation pouch

9 Ambient conditions

9.1 Transport and storage

BOWA recommends storing the products in their original packaging until their first use.

Store the products in a location where they are protected against direct sunlight.

Transport or store the instrument in a dry environment.

9.2 Operation

Use the product at room temperature, protected from mechanical force such as pulling or kinking.

10 Disposal

Dispose of the medical devices, packaging material and accessories in accordance with the respective applicable country-specific regulations and laws.

11 Symbols to note

Symbol	Definition	Symbol	Definition
	Follow the instructions for use		Medical device
	Catalogue number		Quantity
	Batch code		CE mark and identification number of notified body
	Keep away from direct sunlight		Manufacturer
	Keep dry		Caution: Federal (US) law, restricts this device to sale by or on the order of a physician