Instructions for use Bipolar forceps UB12 EN v2.4

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Products

These instructions for use are valid for the UlrichSwiss product group listed below:

Bipolar forceps of risk class IIb

Purpose

The Ulrich Swiss Bipolar Reusable Forceps are used in all areas of open surgery. They are designed to grasp and coagulate different tissues.

They must be connected to the bipolar output of an HF generator using a suitable bipolar cable and may only be used with bipolar coagulation current.

Indication

These instruments do not have a specific indication.

Important notes

Read these instructions for use carefully before each use and keep them easily accessible for the user or the relevant specialist personnel.

Read the warnings marked by this symbol carefully. Improper use of the products may result in serious injury to the patient, users or third parties.

Intended use

The instrument may only be used for its intended use in the medical specialities by appropriately trained and qualified personnel such as surgeons or doctors of similar specialities. The attending physician or the

appropriately trained user is responsible for the selection of the instrument for specific applications or surgical use, for appropriate training and information and for sufficient experience in handling the instrument.

The type of treatment must be determined in each individual case by the surgeon in cooperation with the internist and the anaesthetist.

Application environment

The application environment of the surgical instruments is hospitals, clinics, outpatient clinics or similar health care facilities. The instruments are used manually and can be reprocessed according to the reprocessing instructions. Moisture occurring during the sterilisation process does not affect the function of the instruments.

Contraindication

Bipolar forceps should not be used if the doctor decides that the risks to the patient outweigh the benefits of using them.

No or limited HF surgery should be performed in the following cases:

- Patients with electronic implants such as implantable cardiac pacemakers or deep brain stimulation devices
- In areas where flammable or explosive agents are present, e.g. in the gastrointestinal tract (fire and explosion hazard).
- Serious coagulation disorders
- Material intolerance (allergy; hypersensitivity)

The instrument must not be used if there are incompatibilities with the materials used.

Intended patient group

There are no restrictions on the use of the surgical instrument on specific patient groups except for the restrictions mentioned in the contraindications.

Materials used

The instruments of the product group UB12_Bipolar (bipolar forceps) are made of the following materials, which are in direct body contact with the patient:

- Stainless steel
- Nylon

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Precautions and warnings

ATTENTION!

Before each use, the instruments must be checked for wear and visible damage such as cracks or breaks. In addition, a functional test should be carried out to ensure safe use. In particular, the insulation should be checked for damage and the plug connection should be checked for functionality.

Check the contact surfaces used for visible damage before use.

ATTENTION!

Risk of injury due to ignition or explosion of flammable gases!

Sparks may occur when using the HF device as intended. Observe the safety instructions in the operating instructions of the HF device.

ATTENTION!

Thermal damage to the patient/user due to insufficiently insulated performance of active accessories!

Set the HF device so that the maximum output peak voltage is equal to or less than the rated accessory voltage specified for the product.

Match the RF output power to the procedure. Consider clinical experience or references.

Keep contact surfaces of the product clean during surgery. Wipe off dried tissue residues or body fluids with a moist swab.

The rated accessory voltage of the product is 600 Vp.

The rated accessory voltage must be greater than or equal to the maximum output peak voltage at which the product is operated in combination with a corresponding RF device, mode/setting (see IEC/DIN EN 60601-2-2).

ATTENTION!

To avoid HF burns:

During HF activation, always keep the working end of the product in the user's field of vision.

Patient should not touch conductive objects

Do not place instruments on or next to the patient

Basically, we recommend removing the jewellery (piercing, chain, ring, etc.).

For patients with metal implants, care should be taken that the metal implant is not between the 2 ends of the bipolar forceps. For this, the recommendations of the metal implant manufacturer should be followed.

For patients with electronic implants, follow the recommendations of the electronic implants.

Patient should be kept dry or drapes should be changed during surgery if necessary.

Place urinary catheters during longer procedures

Caution with disinfectants: The alcohol contained in them can be ignited by electric arcs.

Before activating the HF device, ensure that the working end of the product does not touch any electrically conductive accessories.

Visually inspect products before each use for: Damage and surface changes to the insulation, plug connection for functionality.

Follow the instructions for use of the HF device.

⚠ ATTENTION!

The instrument shall not be specifically intended for monitoring, diagnosis, control or correction of a defect of the heart or central circulatory system in direct contact with these parts of the body and therefore shall not be used solely for such determination.

⚠ ATTENTION!

The instrument shall not be specifically intended for direct contact with the heart, central circulatory system or central nervous system and therefore shall not be used solely for such purpose.

⚠ ATTENTION!

Instruments marked with the symbol opposite are supplied non-sterile and must be thoroughly cleaned, disinfected and sterilised before being used for the first time and before each subsequent use.

⚠ ATTENTION!

The instrument may not or only partially fulfil the coagulation function if used incorrectly (i.e. wrong positioning). This can cause unnecessary delays during the operation. Therefore, special care must be taken when positioning the instrument.

⚠ ATTENTION!

The surgical instruments have been designed for surgical use only and must not be used for any other purpose. Improper handling and care as well as improper use can lead to premature wear of the surgical instruments.

⚠ ATTENTION!

Improper or careless handling can injure or damage the surgeon or his protective clothing. The user is therefore urged to use the medical device with due care.

ATTENTION!

Improper or negligent handling (e.g. damage to the surface) and attacks of a chemical, electrochemical or physical nature can impair the corrosion resistance.

ATTENTION!

Surgical instruments corrode and their function is impaired when they come into contact with aggressive substances. For this reason, it is essential to follow the reprocessing and sterilisation instructions.

ATTENTION!

To ensure the safe operation of the surgical instruments, correct maintenance and care of the products is essential. For this reason, we refer to the relevant sections in these instructions for use.

ATTENTION!

All serious incidents occurring in connection with the product must be reported immediately to Ulrich AG and to the competent authority of the Member State in which the user is established.

Risks and undesirable side effects

There are no other known risks and undesirable side effects.

General maintenance regulations, care and function control

The instruments must be checked for functionality and surface damage before and after each use. In case of damage, the instruments must be disposed of or sent to the manufacturer for repair.

Visually inspect instruments for contamination or surface changes as well as for fractures. In particular, check the coating for cracks or detachment.

Damaged coatings cannot be safely restored. Tweezers with damaged coating must be disposed of.

After use, pre-clean instruments interoperatively to remove residues containing chlorine or chloride.

Allow the product to cool to room temperature.
Check product after each cleaning, disinfection and drying for: Dryness, cleanliness, function and damage, e.g. insulation, corroded, loose, bent, broken, cracked, worn and broken off parts.
Dry wet or damp product.
Clean and disinfect unclean product again.
Check product for function.
Immediately sort out damaged or non-functional products and forward them to Ulrich AG.
Check compatibility with the associated products.

Connection to generators:

The bipolar forceps are to be operated with the following parameters:
Frequency range between 300 kHz and 1,000 kHz, max. operating voltage of the generator 600 Vp.

Ulrich Swiss tweezers are approved for use with the following generators:

ERBE Elektromedizin GmbH

Type	Item no.	max. mono. Cut/coag power
VIO 300 D	10140-100	≤ 300 Watt
VIO 200 D	10140-200	≤ 200 Watt
VIO 300 S	10140-300	≤ 300 Watt
VIO 200 S	10140-400	≤ 200 Watt
VIO 100 C	10140-500	≤ 100 Watt
VIO 50 C	10140-550	≤ 50 Watt
ICC 350	ICC 350	≤ 300 Watt
ICC 300	ICC 300	≤ 300 Watt
ICC 200	ICC 200	≤ 200 Watt
ICC 80	ICC 80	≤ 80 Watt
ICC 50	ICC 50	≤ 50 Watt
ACC 451	ICC 451	≤ 300 Watt
ACC 450	ICC 450	≤ 400 Watt

SUTTER Medical Technology GmbH

Type	Item no.	max. mono. Cut/coag power
BM-780 II	360080-01	≤ 80 Watt

KARL STORZ GmbH & Co. KG

Type	Item no.	max. mono. Cut/coag power
AUTOCON® II 200	205322 20	≤ 220 Watt
AUTOCON® II 400	205352 20	≤ 300 Watt

COVIDIA

Type	Item no.	max. mono. Cut/coag power
Force FX™	Force FX™	≤ 300 Watt
ForceTriad™	ForceTriad™	≤ 300 Watt
Force EZ™	Force EZ™	≤ 300 Watt
SurgiStat™	SurgiStat™	≤ 120 Watt

BOWA-electronic GmbH & Co KG

Type	Item no.	max. mono. Cut/coag power
ARC 400	900-400	≤ 400 Watt
ARC 350	900-351	≤ 400 Watt
ARC 303	900-303	≤ 300 Watt
ARC 250	900-250	≤ 250 Watt
ARC 100	900-100	≤ 100 Watt

ARC PLUS	900-000	≤ 90 Watt

Olympus Surgical Technologies Europe

Type	Item no.	max. mono. Cut/coag power
ESG-100, 220-240 V	WB991036	≤ 120 Watt
ESG-100, 100-120 V	WB991046	≤ 120 Watt
ESG-400	WB91051W	≤ 320 watts

Söring GmbH

Type	Item no.	max. mono. Cut/coag power
MBC 600	MBC 600	≤ 350 watt
MBC 601	MBC 601	≤ 350 watt
MBC 601 UAM	MBC 601 UAM	≤ 350 watt
ARCO 3000	ARCO 3000	≤ 350 watt
MBC 200	MBC 200	≤ 200 Watt
BCC 140	BCC 140	≤ 350 watt

LAMIDEY NOURY MEDICAL

Type	Item no.	max. mono. Cut/coag power
Optima 4	Optima 4	≤ 370 watts
Optima 3	Optima 3	≤ 370 watts
Optima 2	Optima 2	≤ 200 Watt
MC 2	MC 2	≤ 200 Watt
MC 3	MC 3	≤ 400 Watt
MC 4	MC 4	≤ 400 Watt

Integra LifeSciences Corporation

Type	Item no.	max. mono. Cut/coag power
Electrotome® 621	Electrotome® 621	≤ 200 Watt
Electrotome® 630	Electrotome® 630	≤ 300 Watt

Gebrüder Martin GmbH & Co KG

Type	Item no.	max. mono. Cut/coag power
Minicutter	80-008-03-04	≤ 80 Watt
ME 102	80-010-02-04	≤ 100 Watt
maxium®, m version	80-042-00-04	≤ 360 watts
maxium®, i-version	80-042-02-04	≤ 360 watts
maxium®, e-version	80-042-04-04	≤ 360 Watt
ME MB 3, m version, 220-240 V	80-040-11-04	≤ 400 Watt

ME MB 3, m version, 100-127 V	80-040-11-10	≤ 400 Watt
ME MB 3, i-version, 100-127 V	80-040-12-04	≤ 400 Watt
ME MB 3, i-version, 100-127 V	80-040-12-10	≤ 400 Watt
ME 411	80-041-01	≤ 320 watts

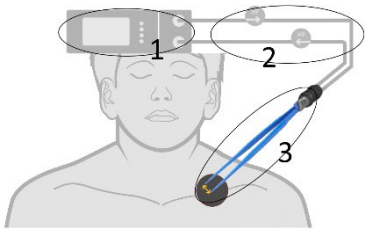
Aesculap AG / B. Braun Melsungen AG

Type	Item no.	max. mono. Cut/coag power
GN300	GN300	≤ 300 Watt
GN640	GN640	≤ 300 Watt

Suitable connection cables:

The bipolar forceps are approved for use with the following bipolar connection cables for the above generators:

Cable connection generator side
Ulrich AG
ERBE Elektromedizin GmbH, KARL STORZ GmbH & Co. KG
ERBE Elektromedizin GmbH - ICC Series, International
Aesculap AG / B. Braun Melsungen AG, Gebrüder Martin GmbH & Co. KG, Sutter Medizintechnik GmbH
COVIDIEN, LAMIDEY NOURY MEDICAL, BOWA-electronic GmbH & Co. KG, ERBE Elektromedizin GmbH - serie VIO, Olym-pus Surgical Technologies Europe, Söring GmbH
Cable connection on the tweezers side
European flat plug



These cables are only to be connected to the bipolar output of electrosurgical units. Before using the bipolar forceps, refer to the operating instructions of the generator on how to connect these cables. There are various dangers associated with HF generators, such as incorrect operation, unintentional high-frequency burns, ignition of flammable liquids and gases (risk of explosion).

One end of the cable (2) is connected to the HF generator (1). The other end is connected to the plug connection of the bipolar tweezers (3). The bipolar tweezers are now connected to the HF generator. The current is switched on at the HF unit. The current flows from one tip of the bipolar forceps (3) over the patient's body to the other tip of the bipolar forceps (3).

Storage and transport

Store instruments in a clean and dry place.

Protect instruments from mechanical damage.

Store and transport instruments in safe containers / packaging.

Handle instruments with great care, do not throw or drop them.

Lifetime

The service life and number of reprocessing cycles depend on how carefully the product is handled and whether the reprocessing instructions for the product are followed. The service life may be shortened unspecifically depending on the type of application.

The instrument is approved for a maximum of 100 reprocessing cycles.

It is recommended to send the instrument to the manufacturer for repair/ reconditioning after 100 uses in order to maintain its value.

Disposal is carried out as part of the normal proper and professional disposal of surgical instruments, provided that the instruments have undergone the entire reprocessing process before disposal.

If the instruments are contaminated by infections, the applicable national regulations must be observed.

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Validated reprocessing procedure

General notes

The reprocessing procedure is validated so that instruments should be subjected to pre-cleaning no later than 2 hours after contamination with blood.

The specified chemistry was used for validation

⚠ ATTENTION!

In the case of patients with Creutzfeldt-Jakob disease (CJD), suspected CJD or possible variants as well as in the case of patients with an HIV infection, comply with the respective applicable national regulations with regard to the reprocessing of the products. Otherwise, we decline any responsibility for reuse in these cases.

⚠ ATTENTION!

It should be noted that successful reprocessing of this medical device can only be ensured after prior validation in the reprocessing process. The responsibility for this lies with the operator/reprocessor.

⚠ ATTENTION!

Comply with national legal regulations, national and international standards and directives and own hygiene regulations for reprocessing.

The washer-disinfector must always have a tested effect (CE marking and validation according to DIN EN ISO 15883).

The steam steriliser in the fractionated vacuum process should have a tested effect (CE DIN EN 285 and validated according to DIN EN ISO 17665).

The validation of the sterilisation was carried out for soft packaging (sterilisation pouches from Steriking/ Wipak). Please observe the relevant requirements of the standard "DIN EN ISO 11607 Packaging for medical devices to be sterilised in the final packaging".

Among others, the following country-specific requirements for steam sterilisation with fractionated vacuum apply:

Country	Temperature	Holding period
Switzerland	134° C	18 min
France	134° C	18 min
Austria	134°C	5 min
Germany	134°C	5 min
Italy	134°C	7 min

Initial treatment at the point of use

Before first use, the surgical instrument must be subjected to complete cleaning, disinfection and sterilisation.

Otherwise, no special measures are required for initial treatment.

Preparation before cleaning

Remove coarse dirt from the instruments immediately after use. Special attention should be paid to the following design features of the instruments:

-atraumatic groove

Do not use fixing agents or hot water (>40°) as this will fix residues and may affect the cleaning success.

Storage and transport of instruments to the reprocessing site must be in a closed container to avoid damage to the instruments and contamination of the environment.

Pre-cleaning

The pre-cleaning processes "manual pre-cleaning" and "ultrasonic cleaning" below are necessary for a perfect cleaning result.

Soaking and manual pre-cleaning

After use, the instruments should be soaked in a mildly alkaline disinfectant solution for 15 minutes (e.g. 2% deconex 53 Plus, Borer Chemie. Cold water should be used).

All visible contamination should be removed with a sponge or a soft brush (e.g. B instrument brush large).

Lumen should be pierced with a cleaning brush for the appropriate diameter (e.g. E inner brush 2mm).

Non-rigid components such as screw nuts, joints or springs should be moved or manipulated during cleaning.

Pay special attention to cavities and hidden surfaces!

The following parameters were validated:

Soaking with manual pre-cleaning	**Mildly alkaline disinfectant solution**
Disinfectant	deconex 53 Plus, Borer Chemistry
Concentration	2% Disinfectant
Container	Unspecified container
Temperature	Cold water
Duration of application	15 minutes
Other aids	AInstrument brush small

Ultrasonic cleaning

After pre-cleaning, the instrument should be treated for 5 minutes in a neutral cleaning solution (e.g. 3ml / litre deconex Prozyme Active, Borer Chemie) in an ultrasonic bath.

The ultrasonic bath should be set at 35° Celsius and with 45Hz ultrasound.

Non-rigid components such as screw nuts, joints or springs are to be moved or manipulated in the ultrasound for 30 seconds.

The following parameters were validated:

Ultrasonic cleaning	**Neutral cleaning solution**
Disinfectant	deconex Prozyme Active, Borer Chemie
Concentration	3ml / litre cleaning solution
Container	Ultrasonic bath
Temperature	35°
Frequency	45Hz
Duration of application	5 minutes
Manipulation time	30 seconds
Other aids	none

Machine cleaning

Loading

For cleaning the lumens, there is a connection for a hose on the instrument. The irrigation hose provided by the cleaning device for this purpose should be connected to this connection on the instrument. This ensures that the irrigation fluid flows through the instrument.

Pre-flush

- with deionised water for 3 minutes

Cleaning with a mildly alkaline and an enzymatic cleaning component

- with deionised water
- Clean at 55° Celsius for 10 minutes
- Dosing the mildly alkaline cleaning component (e.g. deconex Twin PH10 at 30° Celsius: 4ml / litre).
- Dosing of the enzymatic cleaning component (e.g. deconex Twin Zyme at 40° Celsius: 2ml / litre).

Intermediate rinsing I

- With warm city water (42° Celsius), 1 minute

Intermediate rinsing II

- With deionised water, 1 minute

Disinfection

Thermal disinfection:

- With deionised water, 90° Celsius, at least 5 minutes

Drying

Drying:

- 30 minutes at ≥ 60° Celsius

If there is still residual moisture, it can be dried in a drying cabinet at ≥ 60° Celsius +/- 5° Celsius.

The following parameters were validated:

Pre-flush	with deionised water for 3 minutes
Cleaning with a mildly alkaline and an enzymatic cleaning component	
Clean at 55° Celsius for 10 minutes	
Mildly alkaline cleaning component	deconex Twin PH10
Dosage	from 30° Celsius: 4ml / litre, until cleaning step is finished
enzymatic cleaning component	deconex Twin Zyme
Dosage	from 40° Celsius: 2ml / litre, until cleaning step is finished
Intermediate rinsing I	With warm city water (42° Celsius), 1 minute
Intermediate rinsing II	With deionised water, 1 minute
Thermal disinfection	With deionised water, 90° Celsius, 5 minutes
Drying	30 minutes at 60° Celsius

Sterilisation

All instruments should be sterilised before use.

Holding time at least 5 minutes at 134° Celsius and subsequent drying.

The following parameters were validated:

Sterilisation	**Steam sterilisation with fractionated vacuum**
Temperature	134° Celsius
Holding period	5 minutes
Drying	10 minutes

During sterilisation, the instructions for use of the appliance manufacturer for the recommended use must be followed exactly

Resources

Recommended chemistry for washing & disinfecting

Soaking and pre-cleaning

Mild alkaline disinfectant solution: 2%

- deconex 53 Plus, Borer Chemistry

Ultrasonic cleaning

neutral cleaning solution: 3ml / litre

- deconex Prozyme Active, Borer Chemie

Cleaning

Mildly alkaline cleaning component

- deconex Twin PH10, Borer Chemie, at 30° Celsius: 4ml / litre

Enzymatic cleaning component

- deconex Twin Zyme, Borer Chemie, at 40° Celsius: 2ml / litre

Aids for pre-cleaning

AInstrument brush small

Technical service

For repair and reconditioning, contact Ulrich AG. In order not to lose their conformity, the instruments may only be repaired at Ulrich AG or at partners authorised by them. This ensures that the extensive patient safety requirements are met and documented even after a repair. If repairs are carried out by companies that are not authorised by Ulrich AG to carry out repairs, the repaired instruments may not be put back into service in accordance with Article 5, point 1 of MDR 2017/45. This also means that CE marking of such instruments is not permitted.

⚠ ATTENTION!

Defective or non-conforming products must have gone through the entire remanufacturing process before being returned for repair/service.

Warranty

Ulrich AG only delivers tested and faultless products to its customers. All our products are designed and manufactured to meet the highest quality standards. Should faults nevertheless occur, please contact our customer service. Liability is excluded for products that have been modified from the original, misused or improperly handled or used. Repairs carried out by companies which are not authorised by Ulrich AG to carry out repairs shall invalidate the warranty. Ulrich AG shall not accept any liability for accidental or resulting damage.

Description of symbols used

	Attention! Observe notes
	Follow the instructions for use

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ULRICH

REF	Article number
LOT	Charge
SN	Serial number
MD	Medical device
NON STERILE	Product is supplied non-sterile
EC REP	Plenipotentiary in the European Union
2020-05	Manufacturer with date of manufacture
	Store dry
CE	CE mark

CE 0123