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Product group: UB11_Monopolar

Products: U15-700-20 Coagulation Forceps Ulrich Pattern, 2.2 mm, 20 cm

Instruction manual UB11 - Class IIb 3.0 EN

This is a translation of the original in German

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Products

These instructions for use are valid for the Ulrich, Surgimed or Ulrich SilverLine medical devices listed below:

U15-700-20 Coagulation Forceps Ulrich Pattern, 2.2 mm, 20 cm of risk class IIb.

Intended use

The reusable monopolar forceps from Ulrich Swiss are used in all areas of open surgery. They are designed to grasp, manipulate and coagulate different tissues.

They must be connected to the monopolar output of an HF generator by means of a suitable electrical contact and may only be used with monopolar coagulation current.

Indication

These instruments have no 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 with this symbol carefully. Improper use of the products can lead to serious injury to the patient, the user or third parties.

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Intended purpose

<i1> The instrument may only be used for its intended purpose in medical specialties by appropriately trained and qualified personnel such as surgeons or doctors of similar specialties. The attending physician or the appropriately trained user is responsible for the selection of the instruments for specific applications or surgical use, the appropriate training and information and sufficient experience for handling the instruments.

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

Application environment

The reusable monopolar forceps are used in hospitals, clinics, outpatient clinics or similar healthcare facilities. The instruments are used manually and can be reprocessed in accordance with the reprocessing instructions. Moisture occurring during the sterilization process does not impair the function of the instruments.

Contraindication

<i2> The reusable monopolar forceps should not be used if the doctor decides that the risks for the patient outweigh the benefits of their use.

In the following cases, HF surgery should be avoided or limited:

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

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

Intended patient group

The reusable monopolar forceps can be used on all people, including adults, children, infants and pregnant women. However, precautions should be taken when using monopolar forceps on neonates and infants, as their skin is different from that of adults and therefore there is a higher risk of uncontrolled current spread. If possible, bipolar forceps should be preferred in such cases. Otherwise, there are no restrictions regarding the use of the surgical instrument on specific patient groups except for the restrictions mentioned in the contraindications.

Materials used

The instruments in product group UB11_Monopolar (monopolar forceps) consist of the following materials, which are in direct physical contact with the patient:

- Stainless steel
- Nylon

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Precautions and warnings

⚠ ATTENTION! <1>

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 checked for functionality.

Check the contact surfaces used for visible damage before use.

⚠ ATTENTION! <2>

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 for the HF device.

⚠ ATTENTION <3>

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

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

Match the HF output power to the procedure. Take clinical experience or references into account.

Keep contact surfaces of the product clean during the operation. 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 peak output voltage at which the product is operated in combination with a corresponding HF device, operating mode/setting (see IEC/DIN EN 60601-2-2).

⚠ ATTENTION! <4>

To avoid HF burns:

<4.1> Caution with disinfectants: The alcohol it contains can be ignited by electric arcs

<4.2> Patient should not touch any conductive objects

<4.3> Do not place instruments on or next to the patient

<4.4> We generally recommend removing jewelry (piercing, necklace, ring, etc.).

<4.5> Patient should be kept dry or drapes should be changed during surgery if necessary; place urinary catheter for longer procedures

<4.6> For patients with metal implants, care should be taken to ensure that the metal implant is not located between the monopolar forceps and the neutral electrode. The recommendations of the manufacturer of the metal implant must be observed.

<4.7> For patients with electronic implants, the recommendations of the manufacturer of the electronic implants must be observed.

<4.8> Before activating the HF device, ensure that the working end of the product does not touch any electrically conductive accessories.

<4.9> During HF activation, always keep the working end of the product within the user's field of vision.

<4.10> Visually inspect products before each use for: Damage and surface changes to the insulation.

We only recommend the simultaneous use of an HF device.

Follow the instructions for use of the HF device.

ATTENTION! <5>

If possible, bipolar rather than monopolar instruments should be used for newborns and infants, as they have a different skin composition than adults and are therefore exposed to a higher risk of uncontrolled spread of the electric current.

ATTENTION! <6>

The device must not be intended specifically for monitoring, diagnosing, controlling or correcting a defect in the heart or central circulatory system in direct contact with these parts of the body and therefore must not be used solely for such a purpose.

ATTENTION! <7>

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

ATTENTION! <8>

The instruments marked with the adjacent symbol are supplied non-sterile and must be thoroughly cleaned, disinfected and sterilized before they are used for the first time and before each subsequent use.

ATTENTION! <9>

If used incorrectly (i.e. incorrect positioning), the instrument may not or only partially fulfill its coagulation function. This can cause unnecessary delays during the operation. Particular care must therefore be taken when positioning the instrument.

ATTENTION! <10>

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 misuse can lead to premature wear of the surgical instruments.

ATTENTION! <11>

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

ATTENTION! <12>

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

⚠ ATTENTION! <13>

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

⚠ ATTENTION! <14>

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

⚠ ATTENTION! <15>

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

Risks and undesirable side effects

There are no other known risks or undesirable side effects.

General maintenance regulations, care and function control

<i3> The instruments must be checked for functionality and surface damage before and after each use. In the event of damage, the instruments must be disposed of or sent to the manufacturer for repair.

Check instruments visually for contamination or surface changes and for breakage. The coating in particular must be checked for cracks or detachment.

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

Pre-clean instruments interoperatively after use to remove chlorine or chloride-containing residues.

Allow the product to cool to room temperature.
Check the product after each cleaning, disinfection and drying:

- Dryness, cleanliness, function and damage, e.g. insulation, corroded, loose, bent, broken, cracked, worn and broken parts.
- Dry wet or damp product.
- Clean and disinfect unclean product again.
- Check product for function.
- Sort out damaged or non-functional products immediately and forward them to Ulrich AG.
- Check compatibility with the associated products.

Connection to generators:

The monopolar forceps must be operated with the following parameters:
Frequency range between 300 kHz and 4,000 kHz, max. operating voltage of the generator 2,000 Vp.

The necessary electrical tests of the IEC 60601 series were carried out with the worst-case instrument U15-700-30. This covered instrument lengths from 11 cm to 35 cm.

<i4> The monopolar forceps from Ulrich AG are approved for use with the following generators:

ERBE Elektromedizin GmbH

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

SUTTER Medizintechnik GmbH

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

KARL STORZ GmbH & Co KG

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

COVIDIA

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

BOWA-electronic GmbH & Co KG

Type	Article no.	max. mono. Cut/coag power
ARC 400	900-400	≤ 400 watts
ARC 350	900-351	≤ 400 watts
ARC 303	900-303	≤ 300 watts
ARC 250	900-250	≤ 250 watts
ARC 100	900-100	≤ 100 watts
ARC PLUS	900-000	≤ 90 watts

Olympus Surgical Technologies Europe

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

Söring GmbH

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

LAMIDEY NOURY MEDICAL

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

Integra LifeSciences Corporation

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

Gebrüder Martin GmbH & Co KG

Type	Article no.	max. mono. Cut/coag power
Mini cutter	80-008-03-04	≤ 80 watts
ME 102	80-010-02-04	≤ 100 watts
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 watts
ME MB 3, m version, 220-240 V	80-040-11-04	≤ 400 watts
ME MB 3, m version, 100-127 V	80-040-11-10	≤ 400 watts
ME MB 3, i-version, 100-127 V	80-040-12-04	≤ 400 watts

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

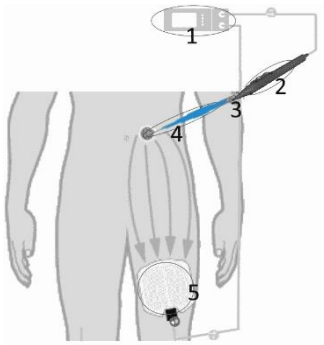
Aesculap AG / B. Braun Melsungen AG

Type	Article no.	max. mono. Cut/coag power
GN300	GN300	≤ 300 watts
GN640	GN640	≤ 300 watts

Suitable electrical contactors:

The monopolar forceps must be used with suitable electrical contactors and neutral electrodes. Before using the contactors and neutral electrodes, observe their operating instructions. The contact makers and neutral electrodes as well as their connections and controls are solely dependent on the HF generators used. They are freely selectable for use with the monopolar tweezers.

The cables of the contactors may only be connected to the monopolar output of electrosurgical units. Before using the monopolar forceps, observe the operating instructions of the generator as to how these cables are to be connected. Various hazards are associated with HF generators, such as incorrect operation, unintentional high-frequency burns, ignition of flammable liquids and gases (risk of explosion).



For example, a monopolar electrode handle (2) in combination with a measuring electrode (3) can be used as a contact transmitter. The cable of the electrode handle is connected to the HF generator (1). The knife electrode is inserted into the electrode handle. The measuring electrode is now connected to the HF generator and serves as the actual contactor. The electrode handle is used to switch the current flow on and off.

The current flows from the tip of the monopolar forceps (4) via the patient's body to the neutral electrode (5).

The following contact sensors and neutral electrodes and accessories are recommended

ERERBE Elektromedizin GmbH

Type	Article no.
Cable to neutral electrode	
Neutral electrode cable, VIO, ICC, ACC, T-series, standard, for neutral electrodes with contact tongue, 4 m	20194-077
Neutral electrode cable, VIO, ICC, ACC, T-series, standard, for neutral electrodes with contact tongue, 5 m	20194-078
Neutral electrode cable, VIO, ICC, ACC, third-party devices, international, for two-part neutral electrodes with contact tongue, 4m	20194-080

Neutral electrode cable, VIO, ICC, ACC, third-party devices, international, for two-part neutral electrodes with contact tongue, 5m	20194-087
Neutral electrode cable, VIO, ICC, ACC, third-party devices, international, for unsplit neutral electrodes with contact tongue, 4 m	20194-079
Neutral electrode cable, VIO, ICC, ACC, third-party devices, international, for unsplit neutral electrodes with contact tongue, 5 m	20194-086
Neutral electrode	
NESSY® RePlate 200, contact area 194 cm², reusable, can be monitored	20193-090
Monopolar electrode handles	
Slim-Line electrode handle with 2 buttons, VIO, ICC, ACC, Standard	20190-105
Slim-Line electrode handle with 2 buttons, VIO, ICC, ACC, third-party devices, International	20190-067
Slim-Line electrode handle with rocker, VIO, ICC, ACC, Standard	20190-104
Slim-Line electrode handle with rocker, VIO, ICC, ACC, third-party devices, International	20190-076
Monopolar electrodes	
Knife electrode, straight, 3.4 x 18 mm, length 40 mm	21191-172
Knife electrode, straight, 1.5 x 17 mm, length 40 mm	21191-101
Knife electrode, straight, 3.4 x 24 mm, length 45 mm	21191-100
Spade electrode, straight, 3 x 24 mm, length 45 mm	21191-102
Spade electrode, straight, 2.3 x 19 mm, length 45 mm	21191-159
Spade electrode, straight, insulated, 2.3 x 19 mm, length 45 mm	21191-161
Spade electrode, straight, flexible, 2 x 6 mm, length 45 mm	21191-107
Spade electrode, straight, flexible, 2 x 18 mm, length 45 mm	21191-106
Spade electrode, straight, flexible, 1.7 x 6 mm, length 50 mm	21191-105
Spade electrode, straight, flexible, 3 x 24 mm, length 60 mm	21191-103
Spade electrode, straight, flexible, 2 x 18 mm, length 80 mm	21191-104
Ball electrode, straight, ø 2 mm, length 40 mm	21191-123
Ball electrode, straight, ø 3 mm, length 40 mm	21191-163
Ball electrode, straight, ø 4 mm, length 40 mm	21191-124
Ball electrode, straight, ø 5 mm, length 40 mm	21191-164
Ball electrode, straight, ø 6 mm, length 40 mm	21191-125
Ball electrode, straight, ø 3 mm, length 110 mm	21191-165

Storage and transportation

The following ambient conditions must be observed:

Ambient condition	Storage	Transportation	Use
Ambient temperature:	+6°C - + 32°C	-20°C - + 45°C	+14°C - + 25°C
Relative humidity:	30 - 60% non-condensing	30 - 60% non-condensing	30 - 60% non-condensing
Air pressure:	500 - 1600 mbar	500 - 1600 mbar	500 - 1600 mbar

<i5> Store instruments in a clean and dry place.
Protect instruments from mechanical damage.

Store and transport instruments in secure containers / packaging.
Handle instruments with great care, do not throw or drop them.

Service life

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

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

Waste disposal

<i6> 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 prior to disposal.

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

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Validated preparation process

General information

<i7> The reprocessing procedure is validated in such a way that the instruments should be subjected to pre-cleaning no later than 2 hours after contamination with blood.

The specified chemistry was used for validation

⚠ ATTENTION! <16>

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

⚠ ATTENTION! <17>

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

⚠ ATTENTION! <18>

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

The washer-disinfector must always have a tested effect (CE marking and validation in accordance with DIN EN ISO 15883)

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

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

The following country-specific requirements for steam sterilization with fractionated vacuum apply, among others:

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 completely cleaned, disinfected and sterilized.

Otherwise, no special measures are required for initial treatment.

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Preparation before cleaning

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

-atraumatic scoring

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

<i8> Instruments must be stored and transported to the reprocessing site in a closed container to prevent damage to the instruments and contamination of the environment.

Pre-cleaning

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

Soaking and manual pre-cleaning

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

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

Lumens should be pierced with a cleaning brush for the corresponding 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 particular 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 Chemie
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 / liter deconex Prozyme Active, Borer Chemie) in an ultrasonic bath.

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

Non-rigid components such as screw nuts, joints or springs should be moved or manipulated ultrasonically for 30 seconds.

The following parameters were validated:

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

Machine cleaning

Loading

There is a connection for a hose on the instrument for cleaning the lumen. The rinsing hose provided by the cleaning device for this purpose should be connected to this connection on the instrument. This ensures that the rinsing fluid flows through the instrument.

Pre-rinsing

- with deionized water for 3 minutes

Cleaning with a mildly alkaline and an enzymatic cleaning component

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

Intermediate rinse I

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

Intermediate rinsing II

- With demineralized water, 1 minute. Definition of the water quality of the demineralized water: ≤ 10 CFU/100 ml

Disinfection

Thermal disinfection:

- With demineralized water, 90° Celsius, for at least 5 minutes. Definition of the water quality of the demineralized water: ≤ 10 CFU/100 ml

Drying

Drying:

- 30 minutes at ≥ 60° Celsius

If there is still residual moisture, post-drying can be carried out in the drying cabinet at ≥ 60° Celsius +/- 5° Celsius

The following parameters were validated:

Pre-rinsing	with deionized 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 / liter until the cleaning step is finished
enzymatic cleaning component	deconex Twin Zyme
Dosage	from 40° Celsius: 2ml / liter until the cleaning step is complete
Intermediate rinse I	With warm city water (42° Celsius), 1 minute
Intermediate rinsing II	With deionized water, 1 minute Definition of the water quality of the demineralized water: ≤ 10 CFU/100 ml
Thermal disinfection	With deionized water, 90° Celsius, 5 minutes Definition of the water quality of the demineralized water: ≤ 10 CFU/100 ml
Drying	30 minutes at 60° Celsius

Sterilization

All instruments should be sterilized before use.

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

The following parameters were validated:

Sterilization	**Steam sterilization with fractionated vacuum**
Temperature	134° Celsius
Holding period	5 minutes
Drying	10 minutes

During sterilization, the instructions for use of the device manufacturer for the recommended use must be strictly observed

Aids

Recommended chemicals for washing & disinfecting

<i9>

Soaking and pre-cleaning

Mildly alkaline disinfectant solution: 2%

- deconex 53 Plus, Borer Chemie

Ultrasonic cleaning

Neutral cleaning solution: 3ml / liter

- deconex Prozyme Active, Borer Chemie

Cleaning

Mildly alkaline cleaning component

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

Enzymatic cleaning component

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

Aids for pre-cleaning

AInstrument brush small

Technical service/ preventive and regular maintenance measures

To minimize application-related health and safety risks, only limited maintenance measures are permitted. In the event of damage, the instruments must be disposed of or sent to the manufacturer for clarification.

⚠ ATTENTION! <19>

Permitted maintenance measures	It is permissible to remove silicate or water stains on the metal by means of a surface treatment. It must be ensured that the traceability information is still legible after the treatment.
Non-permissible maintenance measures	It is not permitted to recoat the electrosurgical forceps. It is not permitted to work on the surface of the coating of the electrosurgical forceps. It is not permitted to bend back a deformed medical device. It is not permitted to remove the traceability information visible on the medical device.

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

⚠ ATTENTION! <20>

Defective or non-compliant products must have gone through the entire reconditioning 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. However, should faults occur, please contact our

customer service department. We accept no liability for products that have been modified, misused or improperly handled or used compared to the original. Repairs carried out by companies not authorized by Ulrich AG are not covered by the warranty. Ulrich AG accepts no liability for accidental or consequential damage.

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Description of symbols used

	Attention! Observe notes
	Follow the instructions for use
	Item number
	Batch
	Serial number
	Medical device
	Product is delivered non-sterile
	Authorized representative in the European Union
	Manufacturer
 **2020-05-26**	Date of manufacture
	Store in a dry place
	CE mark

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