

## Instruction manual Coagulation Forceps UB11

v2.4 EN

This is a translation of the original in German



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#### **Products**

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

UB11\_Monopolar (Monopolar forceps) of risk class IIb

### **Purpose**

Ulrich Swiss monopolar forceps 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 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

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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

Monopolar 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 product group UB11\_Monopolar (monopolar 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.

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

We generally recommend removing jewellery (piercing, necklace, ring, etc.).

For patients with metal implants, care should be taken to ensure that the metal implant is not between the monopolar forceps and the neutral electrode. For this, the recommendations of the metal implant manufacturer should be followed.

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.

We recommend only simultaneous use of an HF device.

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Follow the instructions for use of the HF device.



#### ATTENTION!

The instrument shall not be specifically intended for monitoring, diagnosing, controlling or correcting 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.

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#### 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.



#### ATTENTION!

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

#### 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 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 monopolar forceps are to be operated with the following parameters:

Frequency range between 300 kHz and 4'000 kHz, max. operating voltage of the generator 2'000 Vp.

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The Ulrich Swiss monopolar forceps are approved for use with the following generators:

#### ERBE Elektromedizin GmbH

Тур	Artikel-Nr.	max. monop. Coagulation performance
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 Medizintechnik GmbH

Тур	Artikel-Nr.	max. monop. Coagulation performance
BM-780 II	360080-01	≤ 80 Watt

#### KARL STORZ GmbH & Co. KG

Тур	Artikel-Nr.	max. monop. Coagulation performance
AUTOCON® II 200	205322 20	≤ 220 Watt
AUTOCON® II 400	205352 20	≤ 300 Watt

#### **COVIDIEN**

Тур	Artikel-Nr.	max. monop. Coagulation performance
Force FX <sup>TM</sup>	Force FX™	≤ 300 Watt
ForceTriad™	ForceTriad™	≤ 300 Watt
Force EZ <sup>TM</sup>	Force EZ™	≤ 300 Watt
SurgiStat™	SurgiStat™	≤ 120 Watt

#### BOWA-electronic GmbH & Co. KG

Тур	Artikel-Nr.	max. monop. Coagulation performance
ARC 400	900-400	≤ 400 Watt
ARC 350	900-351	≤ 400 Watt
ARC 303	900-303	≤ 300 Watt

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ARC 250	900-250	≤ 250 Watt
ARC 100	900-100	≤ 100 Watt
ARC PLUS	900-000	≤ 90 Watt

## Olympus Surgical Technologies Europe

Туре	Artikel-Nr.	max. monop. Coagulation performance
ESG-100, 220-240 V	WB991036	≤ 120 Watt
ESG-100, 100-120 V	WB991046	≤ 120 Watt
ESG-400	WB91051W	≤ 320 Watt

## Söring GmbH

Тур	Artikel-Nr.	max. monop. Coagulation performance
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

Тур	Artikel-Nr.	max. monop. Coagulation performance
Optima 4	Optima 4	≤ 370 Watt
Optima 3	Optima 3	≤ 370 Watt
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

Тур	Artikel-Nr.	max. monop. Coagulation performance
Elektrotom® 621	Elektrotom® 621	≤ 200 Watt
Elektrotom® 630	Elektrotom® 630	≤ 300 Watt

### Gebrüder Martin GmbH & Co. KG

Тур	Artikel-Nr.	max. monop. Coagulation performance
Minicutter	80-008-03-04	≤ 80 Watt
ME 102	80-010-02-04	≤ 100 Watt
maxium®, m-Version	80-042-00-04	≤ 360 Watt
maxium®, i-Version	80-042-02-04	≤ 360 Watt
maxium®, e-Version	80-042-04-04	≤ 360 Watt

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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 Watt

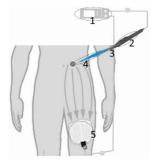
#### Aesculap AG / B. Braun Melsungen AG

Тур	Artikel-Nr.	max. monop. Coagulation performance
GN300	GN300	≤ 300 Watt
GN640	GN640	≤ 300 Watt

#### Suitable electrical contactors:

The monopolar forceps must be used with suitable electrical contactors and neutral electrodes. Before using the contactors and the neutral electrodes, their operating instructions must be observed. The contactors and the neutral electrodes as well as their connections and control depend solely on the HF generators used. They can be freely selected for use with the monopolar forceps.

The cables of the contact generators are only to be connected to the monopolar output of electrosurgical units. Before using the monopolar 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).



For example, a monopolar electrode handle (2) in combination with a measuring electrode (3) can be used as a contactor. The cable of the electrode handle is connected to the HF generator (1). The knife electrode is inserted into the electrode handle. The knife 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) over the patient's body to the neutral electrode (5).

The following contactors and neutral electrodes as well as accessories are recommended

#### ERERBE Elektromedizin GmbH

Туре	Item 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

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Neutral electrode cable, VIO, ICC, ACC, foreign devices, International, for two-part neutral electrodes with contact tongue, 4m	20194-080
Neutral electrode cable, VIO, ICC, ACC, foreign devices, International, for two-part neutral electrodes with contact tongue, 5m	20194-087
Neutral electrode cable, VIO, ICC, ACC, foreign devices, International, for unsplit neutral electrodes with contact tongue, 4 m	20194-079
Neutral electrode cable, VIO, ICC, ACC, foreign devices, International, for unsplit neutral electrodes with contact tongue, 5 m	20194-086
Neutral electrode	l
NESSY® RePlate 200, contact surface 194 cm², reusable, monitorable	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, foreign 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 Equipment, 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
Spatula electrode, straight, 3 x 24 mm, length 45 mm	21191-102
Spatula electrode, straight, 2.3 x 19 mm, length 45 mm	21191-159
Spatula electrode, straight, insulated, 2.3 x 19 mm, length 45 mm	21191-161
Spatula electrode, straight, flexible, 2 x 6 mm, length 45 mm	21191-107
Spatula electrode, straight, flexible, 2 x 18 mm, length 45 mm	21191-106
Spatula electrode, straight, flexible, 1.7 x 6 mm, length 50 mm	21191-105
Spatula electrode, straight, flexible, 3 x 24 mm, length 60 mm	21191-103
Spatula 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 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.

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## 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 applicable national regulations regarding 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.

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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	Alnstrument 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.

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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 of 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:

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Pre-flush 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

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Enzymatic cleaning component

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

### Aids for pre-cleaning

Alnstrument 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. We accept no liability for products that have been modified from the original, misused or improperly handled or used. The warranty does not apply to repairs carried out by companies which are not authorised by Ulrich AG to carry out repairs. Ulrich AG shall not accept any liability for accidental or resulting damage.

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# Description of symbols used

$\triangle$	Attention! Observe notes
Ţi	Follow the instructions for use
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 including production date
<del>*</del>	Store dry
CE	CE mark

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