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Product group: UB02_grasping_holding

Products: U14-310-14 Tissue Forceps, 1 mm, 14.5 cm

Instructions for use UB02 - Class Ir v3.0 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 product group listed below:

UB02_grasping_holding of the risk class Ir

Intended use

Gripping and holding reusable surgical instruments are designed to grip or hold different materials. Possible materials include tissue, skin and bone. Depending on the application, the instruments differ in shape and size.

The uninterrupted application time per procedure is less than one hour.

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 use

<i1> The instrument may only be used for its intended purpose in medical specialties by appropriately trained and qualified personnel such as surgeons or physicians 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 in 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 surgical instruments 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 instrument must not be used if there are any incompatibilities with the materials used.

There are no other known contraindications to the instrument. The use of the instrument is contraindicated if, in the opinion of the responsible physician, such use would endanger the patient, for example due to the patient's general condition or if the surgical technique itself would be contraindicated.

Intended patient group

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

Materials used

The instruments in product group UB04_retracting_exposing consist of the following materials, which are in direct physical contact with the patient:

- Magnetizable stainless steel

Precautions and warnings

⚠ ATTENTION! <1>

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! <2>

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 <3>

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! <4>

The instrument can injure patients or users if used in places not intended for this purpose. Special care must therefore be taken when positioning the instrument during use.

ATTENTION! <5>

Instruments may contain catches, locking mechanisms, sharp, cutting edges or similar functional elements. If used incorrectly, the user may pinch a part of the body or clothing. Special care must therefore be taken when handling the corresponding functional elements.

ATTENTION! <6>

Before each use, the instruments must be checked for wear and visible damage such as cracks or breaks. A functional test should also be carried out to ensure safe use.

ATTENTION! <7>

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! <8>

Visual material changes such as discoloration of the material can result in material damage such as cracks, fractures or porous surfaces.

ATTENTION! <9>

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! <10>

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! <11>

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.

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⚠ ATTENTION! <12>

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.

⚠ ATTENTION! <13>

The instrument is made of magnetizable stainless steel. Therefore, it must not be used in an MRI or magnetic resonance imaging (MRI) environment.

Risks and undesirable side effects

There are no other known risks or undesirable side effects.

General maintenance regulations and functional checks

<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.

Check the instrument for traces of corrosion (e.g. pitting corrosion).

If grooves are present, they must not be worn.

If atraumatic grooves are present, check for burrs or sharp edges.

If there are through or screw connections, check for stress cracks in the final part. Check for even running. Check for the presence of fretting corrosion.

Care

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

Assembly for multi-part instruments

<i4> Instruments consisting of several parts are assembled according to the marking on the instrument.

⚠ ATTENTION! <14>

It must be ensured that only the parts intended for this purpose are assembled. No parts that do not belong to the instrument are permitted.Accessories

The instruments can be used with different accessories depending on individual requirements.

In general, no accessories or spare parts from other manufacturers may be used for the instruments. Only accessories and spare parts as specified by Ulrich AG are permitted for operation.

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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	6°C - + 32°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 and closed 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.

We recommend sending the instrument to the manufacturer for repair/reconditioning after 100 uses in order to preserve its value.

<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

<i7>

General information

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! <15>

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

⚠ ATTENTION! <16>

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! <17>

National

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

The cleaning and disinfection device 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

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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.

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:

- push-through connection
-Applied screw lock
-atraumatic scoring
-Screw nut & screw connection
-Leaf spring
-SGRIP (material PPSU)
-Ball pressure piece
-Spring
-PEEK material
-Cross knurl
-Lumen

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	B Large instrument brush
	D Large cleaning clamp

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.

Pay particular attention to cavities and hidden surfaces!

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

Disinfection

Thermal disinfection:

- With deionized water, 90° Celsius, 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

A Instrument brush small

B Instrument brush large

C Rleaning clamp small

D Cleaning clamp large

E Internal brush 2mm

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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 change the geometry of a medical device 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.

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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