

Product group: UBo4_retracting_exposing

Products: U36-114-00 Vaginal Speculum, CH Pattern, Fig. 0, 24x80 mm

Instructions for use UBo4 - 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:

UBo4_retracting_exposing of the risk class Ir

Intended use

Spreading reusable surgical instruments are designed to spread and hold open natural body orifices or those created by a surgical procedure. The instruments differ in shape and size depending on the application.

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 UBo4_retracting_exposing consist of the following materials, which are in direct physical contact with the patient:

- Magnetizable stainless steel

Precautions and warnings



ATTENTION! <i1>

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! <i2>

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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>

If used incorrectly (i.e. incorrect positioning), the instrument may not or only partially fulfill the function of spreading. This can cause unnecessary delays during the operation. In addition, the instrument can exert excessive pressure on the soft tissue due to incorrect positioning. This can cause hematomas to form. Particular care must therefore be taken when positioning the instrument. When positioning the instrument, care must be taken to ensure that the spreading surface of the instrument acts on the patient's tissue at as right an angle as possible so that the pressure exerted acts on as large an area as possible.



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.

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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.



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.

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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.

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.

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 ($>40^{\circ}$), as this will fix residues and may impair the cleaning success.

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!

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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

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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 $\geq 60^\circ$ Celsius

If there is still residual moisture, post-drying can be carried out in the drying cabinet at $\geq 60^\circ$ 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 |

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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

<ig>

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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