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Product Group: UB04_retracting_exposing
Basic UDI-DI: 76300245UB04012YQ
Products: U40-574-03 Shoulder Retractor Darrach, 16.5 mm, 26 cm

Instructions for Use UB04 - Class Ir v3.4 EN

This is a translation of the original in German

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Products

These instructions for use apply to the product group listed below from the Ulrich, Surgimed, or Ulrich SilverLine brands:

U40-574-03 Shoulder Retractor Darrach, 16.5 mm, 26 cm in risk class Ir

Intended Purpose

Spreading and holding open natural or surgically created body orifices

The continuous duration of use 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 readily accessible to the user or the appropriate qualified personnel.

Carefully read the warnings marked with this symbol. Improper use of the products can result in serious injury to the patient, the user, or third parties.

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Intended Use

Retractable reusable surgical instruments in the UB04_retracting_exposing product group are used in all areas of open surgery. They are intended to retract and hold open natural or surgically created body orifices.

<i1> The instrument may be used exclusively for its intended purpose in medical specialties by appropriately trained and qualified personnel, such as surgeons or physicians in related specialties.

Intended Users

The intended users are healthcare professionals who are trained in performing the intended use of the product. This includes appropriately trained and qualified personnel, such as surgeons or physicians in a similar medical specialty. The treating physician or the appropriately trained user is responsible for selecting the instruments for specific applications or surgical procedures, ensuring adequate training and information, and having 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 anesthesiologist

Application Environment

The surgical instruments are intended for use in hospitals, clinics, outpatient centers, or similar healthcare facilities. The instruments are used manually and can be reprocessed in accordance with the reprocessing instructions. Moisture generated during the sterilization process does not impair the function of the instruments.

Contraindications

<i2> The instrument must not be used if there are any known incompatibilities with the materials used.

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

Intended Patient Population

There are no restrictions regarding the use of the surgical instrument on specific patient groups, except for the restrictions listed under “Contraindications.”

Materials Used

The medical device consists of the following materials, which come into direct contact with the patient’s body:

- magnetisierbarer Edelstahl

Precautions and Warnings

⚠ ATTENTION! <1>

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

WARNING! <2>

The device is not specifically intended 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.

CAUTION! <3>

Devices marked with the symbol shown here are supplied non-sterile and must be thoroughly cleaned, disinfected, and sterilized before first use and before each subsequent use.

CAUTION! <4>

"If used incorrectly (i.e., improperly positioned), the instrument may fail to perform its retraction function or perform it only partially. This can result in unnecessary delays during surgery. In addition, incorrect positioning may cause the instrument to exert excessive pressure on soft tissues, which can lead to hematoma formation. Therefore, special care must be taken when positioning the instrument. When positioning the instrument, ensure that the spreading surface of the instrument acts on the patient's tissue at as close to a right angle as possible, so that the pressure is distributed over the largest possible area."

"The instrument may injure patients or users if used in areas for which it is not intended. Therefore, special care must be taken when positioning the instrument during use."

CAUTION! <5>

Instruments may contain locks, locking mechanisms, sharp, cutting edges, or similar functional elements. If used improperly, the user may trap a body part or clothing in these elements. Therefore, special caution is required when handling these functional elements.

CAUTION! <6>

Before each use, the instruments must be inspected for wear and visible damage such as cracks or breaks. In addition, a functional test should be performed to ensure safe use.

CAUTION! <7>

The surgical instruments are designed exclusively for surgical use 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.

CAUTION! <8>

Visible changes in the material, such as discoloration, can result in material damage, such as cracks, breaks, or porous surfaces.

CAUTION! <9>

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

⚠ CAUTION! <10>

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

⚠ CAUTION! <11>

To ensure the safe operation of surgical instruments, proper maintenance and care of the products are essential. For this reason, please refer to the relevant sections in this user manual.

⚠ CAUTION! <12>

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

⚠ CAUTION! <13>

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

Risks and Adverse Effects

No other risks or adverse effects are known.

General Maintenance Guidelines and Functionality Checks

<i3> The instruments must be inspected before and after each use to ensure they are in working order and to check for surface damage. If damaged, the instruments must be disposed of or sent to the manufacturer for repair.

Visually inspect the instruments for contamination, surface changes, or fractures.

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

If grooves are present, they must not be worn down.

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

If there are through-pin or screw fasteners, check the fastener for stress cracks. Check for smooth operation. Check for the presence of fretting corrosion.

Care

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

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Assembly of Multi-Part Instruments

<i4> Instruments consisting of multiple parts must be assembled according to the markings on the instrument.

⚠ CAUTION! <14>

Please note that only the parts intended for this purpose may be assembled. No parts that do not belong to the instrument are permitted.

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Accessories

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

In general, accessories or replacement parts from third-party manufacturers must not be used with the instruments. Only accessories and replacement parts specified by Ulrich AG are approved for use.

Storage and Transport

The following environmental conditions must be observed:

Environmental Condition	
Ambient temperature:	+6°C to +32°C
Relative humidity:	30–60% non-condensing
Air pressure:	500–1,600 mbar

<i5> Store instruments in a clean, dry place.
Protect instruments from mechanical damage.
Store and transport instruments in secure, closed containers or packaging.
Handle instruments with great care; do not throw or drop them.
Instruments must be stored and transported to the reprocessing site in a sealed container to prevent damage to the instruments and contamination of the environment.

Service Life

The service life and number of reprocessing cycles depend on how carefully the product is handled and whether the product's reprocessing instructions are followed. The service life may be shortened in unspecified ways depending on the type of use.

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

To maintain the instrument's value, it is recommended that you send it to the manufacturer for repair or reprocessing after 100 uses.

Disposal

<i6> Disposal should be carried out in accordance with standard, proper, and professional procedures for surgical instruments, provided that the instruments have undergone the entire reprocessing process prior to disposal.

If the instruments are contaminated with infections, the applicable national regulations must be followed.

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Validated Reprocessing Procedure

General Information

<i7>

The reprocessing procedure has been validated such that the instruments should undergo pre-cleaning no later than 2 hours after being soiled with blood.

The specified chemicals were used for validation.

⚠ CAUTION! <15>

For patients with Creutzfeldt-Jakob disease (CJD), suspected CJD, or possible variants, as well as for patients with HIV infection, comply with the applicable national regulations regarding the reprocessing of the products. Otherwise, we accept no liability for reuse in these cases.

⚠ CAUTION! <16>

Please note that successful reprocessing of this medical device can only be ensured following prior validation of the reprocessing process. The operator/reprocessor bears responsibility for this.

⚠ ATTENTION! <17>

Comply with national legal regulations, national and international standards and guidelines, and your own hygiene regulations regarding reprocessing.

The cleaning and disinfection device must always have a verified efficacy (CE marking and validation in accordance with DIN EN ISO 15883).

The steam sterilizer using the fractionated vacuum method must have a verified efficacy (CE marking in accordance with DIN EN 285 and validated in accordance with DIN EN ISO 17665).

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 their final packaging.”

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

Country	Temperatur e	Holding Time
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 Before Use

Before first use, the surgical instrument must undergo thorough cleaning, disinfection, and sterilization.

Otherwise, no special initial treatment measures are required.

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Preparation at the Point of Use

Immediately after use (within a maximum of 2 hours), remove coarse dirt from the instruments. Special attention should be paid to the following design features of the instruments:

- Through-hole connection
- Screw-on closure
- Atraumatic grooving
- Nut & screw connection
- Leaf spring
- SGRIP (PPSU material)
- Ball thrust piece
- Spring
- Material: PEEK
- Cross-knurled
- Lumen

Do not use fixatives or hot water (>40°), as this can cause residues to set and may impair the cleaning process.

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

Pre-cleaning

The pre-cleaning processes described below—“manual pre-cleaning” and “ultrasonic cleaning”—are necessary to ensure a thorough cleaning result.

Soaking and Manual Pre-cleaning

After use, the instruments should be placed in a mildly alkaline disinfectant solution for 15 minutes (e.g., 2% Deconex 53 Plus, Borer Chemie; cold water must be used).

All visible contaminants should be removed with a sponge or a soft brush (e.g., B Instrument Brush, large).

Lumens should be cleaned through with a cleaning brush designed for the appropriate diameter (e.g., E Internal Brush 2 mm).

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

Pay special attention to cavities and hidden surfaces!

The following parameters have been validated:

Soaking with manual pre-cleaning	**Mildly alkaline disinfectant solution**
Disinfectant	deconex 53 Plus, Borer Chemie
Concentration	2% Disinfectant
Container	Container not specified
Temperature	Cold water
Treatment duration	15 minutes

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Other supplies	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., 3 ml per liter of Deconex Prozyme Active, Borer Chemie) in an ultrasonic bath.

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

Non-rigid components such as nuts, joints, or springs should be moved or manipulated in the ultrasonic bath for 30 seconds.

Pay special attention to cavities and hidden surfaces!

The following parameters have been validated:

Ultrasonic Cleaning	**Neutral cleaning solution**
Disinfectant	deconex Prozyme Active, Borer Chemie
Concentration	3 ml per liter of cleaning solution
Container	Ultrasonic bath
Temperature	35°
Frequency	45 Hz
Duration of use	5 minutes
Manipulation duration	30 seconds
Other Tools	None

Machine cleaning

Loading

The instrument has a port for a hose to clean the lumens. The rinse hose provided by the cleaning device should be connected to this port on the instrument. This ensures that the rinse 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 agent

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

Intermediate rinse I

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

Intermediate rinse II

- With deionized water, 1 minute. Definition of deionized water quality: ≤ 10 CFU/100 ml, < 0.25 EU/ml endotoxin

Disinfection

Thermal disinfection:

- With deionized water, 90° Celsius, at least 5 minutes. Definition of deionized water quality: ≤ 10 CFU/100 ml, < 0.25 EU/ml endotoxin

Drying

Drying:

- 30 minutes at ≥ 60° Celsius

If residual moisture is still present, additional drying may be performed in a drying cabinet at ≥ 60° Celsius ± 5° Celsius

The following parameters have been validated:

Pre-rinse	with deionized water for 3 minutes
Cleaning with a mildly alkaline and an enzymatic cleaning agent	
Cleaning at 55° Celsius for 10 minutes	
Mildly alkaline cleaning agent	deconex Twin PH10
Dosage	From 30° Celsius: 4 ml per liter, until the cleaning cycle is complete
Enzymatic cleaning agent	deconex Twin Zyme
Dosage	40° Celsius and above: 2 ml per liter, until the cleaning cycle is complete
Intermediate rinse I	With warm tap water (42° Celsius), 1 minute
Intermediate rinse II	With deionized water, 1 minute Definition of deionized water quality: ≤ 10 CFU/100 ml, < 0.25 EU/ml endotoxin
Thermal Disinfection	With deionized water, 90° Celsius, 5 minutes Definition of deionized water quality: ≤ 10 CFU/100 ml, < 0.25 EU/ml endotoxin
Drying	30 minutes at 60° Celsius

Sterilization

All instruments must be sterilized before use.

Hold time of at least 5 minutes at 134° Celsius, followed by drying.

The following parameters have been validated:

Sterilization	**Steam sterilization with a fractional vacuum**
Temperature	134° Celsius
Holding time	5 minutes
Drying	10 minutes

When sterilizing, strictly follow the equipment manufacturer's instructions for the recommended use

Supplies

Recommended chemicals for washing and disinfecting

<i9>

Soaking and Pre-cleaning

Mildly alkaline disinfectant solution: 2%

- deconex 53 Plus, Borer Chemie

Ultrasonic cleaning

Neutral cleaning solution: 3 ml per liter

- deconex Prozyme Active, Borer Chemie

Cleaning

Mildly alkaline cleaning agent

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

Enzymatic cleaning component

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

Pre-cleaning aids

A Small instrument brush

B Large instrument brush

C Small cleaning clamp

D Large cleaning clamp

E Inner brush, 2 mm

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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. If damaged, the instruments must be disposed of or sent to the manufacturer for evaluation.



ATTENTION! <18>

Defective or non-compliant products must have undergone the entire reprocessing process before being returned for repair or service.



CAUTION! <19>

Permitted maintenance measures	It is permissible to remove silicate or water stains from the metal using a surface treatment. It must be ensured that the traceability information remains legible even after the treatment.
Prohibited maintenance measures	It is not permitted to alter the geometry of a medical device It is not permitted to bend a deformed medical device back into shape. It is not permitted to remove the traceability information visible on the medical device.

For repairs and reprocessing, please contact Ulrich AG. To maintain their conformity, the instruments may only be repaired or reprocessed by Ulrich AG or by partners authorized by them. This ensures that the comprehensive requirements for patient safety are met and documented even after a repair. If repairs are performed by companies not authorized by Ulrich AG to perform repairs, the repaired instruments may not be put back into service in accordance with Article 5, Section 1 of the MDR 2017/45. This also means that a CE marking on such instruments is not permitted.

Warranty

Ulrich AG delivers only tested and defect-free products to its customers. All of our products are designed and manufactured to meet the highest quality standards. Should defects nevertheless occur, please contact our customer service department. Liability is excluded for products that have been modified from the original, used for purposes other than intended, or handled or used improperly. The warranty is void if repairs are performed by companies not authorized by Ulrich AG to carry out repairs. Ulrich AG assumes no liability for incidental or consequential damages.

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Description of Symbols Used

	Caution! Follow the instructions
	Follow the instructions for use
REF	Item number
LOT	Lot
SN	Serial number
MD	Medical device
UDI	Unique Device Identification (UDI)
	Product is shipped non-sterile
EC REP	Authorized Representative in the European Union
	Manufacturer
 **May 26, 2020**	Date of Manufacture
	EU Importer
	Store in a dry place
CE 0123	CE Mark

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