

# Instructions for use

## Cutting instruments



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**SRN** DE-MF-000005584

### 1 Important note



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.

### 2 Area of application

The instruments may only be used for their intended purpose in the medical specialties by appropriately trained and qualified personnel. The attending physician or 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.

### 3 Products / Intended use

The cutting instruments are intended for surgically invasive and partly also for non-surgically invasive treatments in various medical specialties (less than 60 minutes). They correspond to risk class I/II.

Product family scissors	
(Basis UDI-DI)	Intended use
Surgical scissors 404279638727BW CE 0123	Instrument for cutting body tissue, suture material or other surgical material.
Nail scissors 404279638812BN CE	Instrument for shortening fingernails and toenails.
Nail cutter 404279612695AA CE	Instrument for cutting the nails of a patient or a person.
Bandage scissors 4042796134819U CE	Instrument for severing bandages.
Iris scissors 404279613488AA CE 0123	Instrument for cutting tissue during surgery on the iris of the eye.
Ear scissors 404279633414A3 CE 0123	Instrument for resecting tissue during ear surgery.
Thread scissors 4042796135029B CE 0123	Instrument for cutting suture or ligature material during a surgical procedure.
Tonsil scissors 404279616520A2 CE 0123	Instrument for resecting tonsil tissue in an ENT procedure.
Nose scissors 404279613495A7 CE 0123	Instrument for resecting tissue of the nose and associated structures in ENT or plastic surgery.
Umbilical cord scissors 4042796326029X CE 0123	Instrument for cutting the umbilical cord after birth.
Plaster shears 404279646314AW CE	Instrument for cutting plaster casts and several layers of thick material.
Rectal scissors 40427961350199 CE 0123	Instrument for resection of tissue in rectal surgery.

Enucleation shears 404279613487A8 CE 0123	Instrument for cutting through tissue during an operation involving enucleation of the eye and/or neighboring structures.
Rigid endoscopy scissors 404279644621AY CE 0123	Instrument for cutting tissue or suture material during an endoscopic procedure.
Product family Micro shears	
(Basis UDI-DI)	Intended use
Micro scissors 404279644354AU CE 0123	Instrument for separating fine tissue structures or vessels during surgical procedures.
Product family Cutting instruments	
(Basis UDI-DI)	Intended use
Scalpel handle 40427961223594 CE 0123	Interchangeable component of a scalpel that functions as a handle and on which a suitable blade is mounted.
Scalpel, reusable 404279635141A5 CE 0123	Instrument for cutting or dissecting tissue (non-replaceable blade).
Amputation knife 404279635131A2 CE 0123	Instrument for the surgical amputation of a limb.
Periodontal knife 404279641544AE CE 0123	Instrument for excision of gingival and other oral soft tissue during periodontal surgery.
Tonsil knife 4042796122559A CE 0123	Instrument for removing the tonsils in a surgical procedure.
Nose knife 404279638103AJ CE 0123	Instrument for resecting the internal structures of the nose.
Ear knife 40427961224597 CE 0123	Instrument for cutting and dissecting anatomical tissue of the ear during a surgical procedure.
Ophthalmic knife 404279632764AS CE 0123	Instrument for making precise incisions in eye tissue during surgical procedures on the eye and neighboring structures.
Cartilage knife 404279637840BL CE 0123	Instrument for cutting, scraping or contouring cartilage during a surgical procedure.
Razor 404279645078B2 CE 0123	Instrument for removing facial or body hair from a patient.
Plaster knife 404279635140A3 CE	Instrument for cutting or trimming hardened plaster casts.
Meniscus knife 404279635138AG CE 0123	Instrument for cutting the meniscus.
Laryngeal knife 404279638105AN CE 0123	Instrument for resecting the structures of the larynx during (ENT) surgery.
Myommeser 404279637835BT CE 0123	Instrument for removing fibroids.
Product family Cutting instruments Pin & Wire	
(Basis UDI-DI)	Intended use
Wire cutter 404279632885B7 CE	Instrument for cutting orthopaedic wires, cerclage and thin needles or pins.
Product family Chisels & Osteotomes	
(Basis UDI-DI)	Intended use
Orthopaedic chisel 404279632853AS CE 0123	Instrument with a single, single-beveled blade for cutting and contouring bones.

Dental osteotome 404279644887C4 CE 0123	Instrument for shaping and compacting bone during a dental osteotomy.
Rongeur product family	
(Basis UDI-DI)	Intended use
Orthopedic surgeon 404279632853AS CE 0123	Instrument with cutting/nibbling action for removing bone in orthopaedic surgery.
Nasal rongeur 404279633442A8 CE 0123	Instrument for resection of hard or solid tissue (e.g. bone or cartilage) from the nasal passages by cutting/nibbling action.
Rib rongeur 404279635317AJ CE 0123	Instrument for cutting and shortening rib bones and for rounding the rib stumps.
Bone cutter 40427961045596 CE 0123	Instrument for severing a bone by cutting.
Product family Dermatome	
(Basis UDI-DI)	Intended use
Manual dermatome 404279638797CK CE 0123	Instrument for obtaining thin donor skin flaps for skin transplants or for excision of small skin lesions.
Urethrotome product family	
(Basis UDI-DI)	Intended use
Urethrotome 404279617633AP CE 0123	Instrument for opening strictures in the urethra.
Punching product family	
(Basis UDI-DI)	Intended use
Bone punch 40427961323193 CE 0123	Instrument with cutting/nibbling action for separating small bone sections.
Rubber dam punch 404279635553AY CE	Instrument for making holes in rubber dam cloths in order to be able to put them over the dental crowns.
Tonsil punch 404279632364A6 CE 0123	Instrument with cutting/nibbling action for removing the tonsils during a tonsillectomy.
Surgical biopsy forceps 404279611775A2 CE 0123	Instrument for taking biopsy samples from tumors or other tissue during a surgical procedure.
Product family snare instruments	
(Basis UDI-DI)	Intended use
Adenotome 40427961002589 CE 0123	Instrument for excising hypertrophic lymphatic tissue in the nasopharynx.
Lentil sling 4042796123199B CE 0123	Instrument for manual extraction of the crystalline lens and for gentle manipulation and/or irrigation of ocular tissue.
Nose loop 404279615676AT CE 0123	Instrument for resection of abnormal tissue in the nose during ENT surgery.
Ear loop 4042796310208U CE 0123	Instrument for resection of abnormal tissue in the ear during ENT surgery.
Tonsil loop 4042796136329R CE 0123	Instrument for removing the tonsils during ENT surgery.

### 4 Contraindications

The instruments may only be used for their intended purpose by appropriately trained and qualified personnel. The products are not intended for use on the heart or the central circulatory and nervous system.

The products are not intended for connection to active medical devices. There is a risk of injury to

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patients and users if HF, RF or laser devices are used at the same time.

### Product-specific contraindications

#### Manual dermatome:

- Bacterially contaminated wound bed
- Non-vascularized wound bed (tendons, bones, joint capsule)
- Heavy mechanical load at the receiver point
- Exposed vessels or nerves
- Exposed implants
- Aesthetic defects in the face
- Relative: Defects on the flexion side of joints (secondary shrinkage of the transplants)

#### Urethrotomes:

- Urinary tract infection
- Coagulation disorders

#### Snare instruments:

- Agranulocytosis
- Leukemia
- Coagulation disorders
- Cardiovascular insufficiency

### 5 Complications / side effects

#### **⚠ General:**

After contact with the instrument, hypersensitivity reactions may be triggered in a patient with material intolerance to stainless steel. In the event of such a reaction, the procedure must be stopped immediately and the necessary steps taken.

Further potential complications / side effects were identified in the course of market monitoring:

#### **⚠ Treatment-related complications / side effects / risks**

##### General:

- Injuries to surrounding vessels and tissue
- Nerve injury

#### Manual dermatomes:

- Removal of grafts that are too deep because the dermatome was not set correctly: In this case, the graft can either be refixed immediately at the donor site like a graft or this lifting site can be covered with another, correctly harvested graft.

#### Urethrotomes:

- Iatrogenic lesion of the urethra due to inadequate control of the incision.
- Bleeding from the urethra
- Penile or scrotal hematoma
- Urinary tract infection, urethritis, prostatitis, epididymitis
- Urethral perforation with formation of a via falsa
- Penile deviation

#### Snare instruments:

Risks associated with tonsillectomy

- Post-bleeding
- Revision surgery due to secondary bleeding
- Tooth damage
- Nerve damage
- Airway obstruction (edema)
- Emphysema
- Tasting disorders

#### **⚠ Product-related complications / side effects / risks**

Further potential complications / side effects were identified in the course of market monitoring:

##### Scissors:

- Breakage
- Possible unwanted perforation

##### Cutting instruments:

- Incorrect information in the GA regarding disassembly of the instrument
- Breakage of the blades
- Breakage of the working ends due to lever movements
- Ingestion of components after breakage

#### Cutting instruments, pins and wires:

- Breakage of the cutting edge, components
- Cutting defective

#### Chisels, osteotomes:

- Breakage of the cutting edge, components
- Cutting defective
- Rust on blade
- Blades not compatible with handle
- Incorrect labeling
- Residues (reprocessing)
- Blunt blades

#### Rongeurs

- Fracture of the jaws

### 6 Precautions and warnings

#### **⚠ Attention!**

The instruments are 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 instruments.

#### **⚠ Material incompatibility**

The medical devices should not be used under any circumstances if the user or specialist personnel become aware that the patient has material intolerances.

#### **⚠ Functional impairment**

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.

#### **⚠ Operating conditions**

Correct maintenance and care of the products is essential to ensure safe operation of the aforementioned products. Furthermore, a functional and visual inspection should be carried out before each use. For this reason, please refer to the relevant sections in these instructions for use.

#### **⚠ Combination with other products**

If instruments are reassembled after disassembly, individual parts must not be replaced with parts from other manufacturers! If parts are interchangeable due to the intended purpose of the product (e.g. different work inserts), parts from other manufacturers must not be used! We also recommend purchasing other accessories (e.g. care products) from Dimeda Instrumente GmbH.

#### **⚠ Storage**

There are no specific requirements for the storage of the products. However, we recommend storing the medical devices in a clean and dry environment.

#### **⚠ Creutzfeldt-Jakob disease**

With regard to the reprocessing of medical devices that have been used on patients suffering from Creutzfeldt-Jacob disease (CJD) or its variant (vCJD) or suspected cases of the disease, the requirements specified in the corresponding annex of the guideline for hospital hygiene and infection prevention and the requirements specified in publications in the Federal Health Gazette must be complied with. The medical devices that have been used on this patient group must be disposed of safely by incineration (European Waste Catalog EWC 18 01 03). Dry heat, ethanol, formaldehyde and glutaraldehyde have a fixing but not an inactivating effect on TSE pathogens. Of the available sterilization methods, only steam sterilization (in particular 134° C, 18 min) has been shown to have a limited effect.

#### **⚠ Pointed / sharp instruments**

Care should be taken when handling instruments with sharp points or sharp edges.

### 7 Combination products & accessories

The products are not used with other products except scalpels and are offered without accessories.

#### Scalpels with interchangeable blades

Scalpels can be combined with blades in accordance with DIN EN 27740. The scalpels are designed to be compatible with figures 3 and 4 in accordance with DIN 58849-2.

### 8 Liability and warranty

Dimeda Instrumente GmbH, as the manufacturer, is not liable for consequential damage caused by improper use or handling. This applies in particular to non-compliant use for the defined purpose or disregard of the reprocessing and sterilization instructions. This also applies to repairs or modifications to the product carried out by unauthorized personnel of the manufacturer. These exclusions of liability also apply to warranty services.

### 9 Sterility

#### **⚠ Delivery condition**

The medical devices are supplied in a non-sterile condition and must be prepared and sterilized by the user in accordance with the following instructions before the first and each subsequent use.

### 10 Preparation

#### **⚠ Warnings**

- Frequent reprocessing impairs the quality of the products.
- Urban water to be used must comply with Directive (EU) 2020/2184 on the quality of water intended for human consumption.
- The cleaning agents and disinfectants used for validation are specified in these reprocessing instructions. If an alternative cleaning agent and disinfectant (RK1 or VAH listed) is used, the responsibility lies with the reprocessor.
- Reassemble disassembled products before sterilization.
- Reprocessing may only be carried out by qualified medical personnel. Automated reprocessing must be qualified and validated by the user. The washer-disinfectors must fully comply with the requirements of DIN EN ISO 15883.
- Sterilization must be qualified and validated by the user. The autoclaves must fully comply with the requirements of DIN EN ISO 17665.

#### **⚠ Place of use**

The first steps of proper reprocessing begin in the operating room. If possible, coarse soiling and residues should be removed before the instruments are put away. To do this, the instruments should be rinsed under cold tap water (< 40°C). If this procedure is not sufficient to remove the obvious soiling, a soft plastic brush can be used to remove soiling. Wherever possible, dry disposal is preferable, as prolonged immersion of medical devices in solutions can lead to material damage (e.g. corrosion). Drying of residues must be avoided! Long waiting times before reprocessing, e.g. overnight or over the weekend, should be avoided with both types of disposal (<60 minutes).

#### **⚠ Transportation**

If possible, the products must be disposed of dry immediately (<60 min) after use. This means that the products must be transported in a closed container from the place of application to the processing facility so that the products do not dry out.

#### Preparation for decontamination

If possible, the products must be disassembled before the subsequent reprocessing steps or fed to the subsequent reprocessing steps in an open

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state. Avoid rinsing shadows. The products must be processed in suitable sieve baskets or rinsing trays (select size according to product). The products should be placed at a minimum distance from each other in the cleaning basket. Avoid overlapping in order to prevent damage to the products during the cleaning process.

### Pre-cleaning

1. pre-clean products completely under cold water (city water drinking water quality <40°C) using a soft brush.
2. rinse cavities and hard-to-reach areas, gaps and slits on the instrument with cold water (city water drinking water quality <40°C) for 60 seconds using a water pressure gun.
3. soak the products in an alkaline cleaner (0.5 % Neodisher Mediclean forte) in an ultrasonic bath at 35 kHz for 5 min.
4. rinse products under cold water (city water drinking water quality <40°C) for 15 sec.
5. rinse cavities and hard-to-reach areas, gaps and slits on the instrument with cold water (city water drinking water quality <40°C) for 30 seconds using a water pressure gun.

### Preparation

#### Automatic preparation

(Miele Disinfector G7835 CD according to ISO 15883):

- 1 minute pre-cleaning
- Water drainage
- 4 minutes pre-cleaning
- Water drainage
- 6 minutes cleaning with an alkaline cleaner (0.5 % Neodisher Mediclean) at 58°C +/- 1°C
- Water drainage
- 3 minutes neutralization (0.1 % NeodisherZ) with cold water
- Water drainage
- 2 minutes cleaning with cold water low in germs and endotoxins (max. 10 germs/ml and max. 0.25 endotoxin units/ml)

#### Automatic disinfection

Automatic thermal disinfection in washer-disinfector, taking into account the national requirements for the A<sub>0</sub> value; e.g. A<sub>0</sub> value >3000: With 5 minutes at >92°C

#### Automatic drying

Automatic drying according to the automatic drying process of the washer-disinfector for 30 minutes at 92°C +/- 2°C.

### 11 Sterilization

(Type B autoclave from Tuttnauer in accordance with DIN EN 13060)

Sterilization of the products using the fractionated pre-vacuum process (in accordance with DIN EN ISO 17665-1/ DIN EN 285), taking into account the respective national requirements. The products must be sterilized in suitable sterilization packaging in accordance with DIN EN ISO 11607-1 and EN 868.

#### Please observe chapter 12 before packing!

Sterilization must be carried out using a fractionated pre-vacuum process with the following parameters:

- 134°C,
- At least 5 minutes holding time
- 3 pre-vacuum cycles
- Drying in a vacuum for at least 20 minutes

The autoclave manufacturer's instructions for use and the recommended guidelines for the maximum load of sterilization items must be observed. The autoclave must be installed, maintained, validated and calibrated in accordance with the regulations.

#### Additional information

The reprocessor is responsible for ensuring that the reprocessing actually carried out with the equipment, materials and personnel used in the

reprocessing facility achieves the desired results. This generally requires validation and routine monitoring of the process and the equipment used.

### 12 Maintenance-inspection-testing

Cool the instruments down to room temperature!

#### Visual inspection (before assembly):

Check the surface of the instruments or individual components before assembly. Particular attention must be paid to checking joints (end piece), profiles, grooves and other structures that are difficult to access:

- Is there any residual dirt or residue? If yes, manual post-cleaning and complete mechanical cleaning and disinfection again.
- Are traces of corrosion (rust, pitting) visible?
- Is the surface damaged by cracks (including hairline cracks) or other signs of wear?
- Is the labeling on the instrument no longer legible?

If so, the instrument in question must be labeled and immediately discarded and replaced.

#### Assembly and maintenance

- Assemble the disassembled instruments in a functional manner.
- Manually treat moving parts such as joints, threads and sliding surfaces with suitable, medically approved instrument oil (steam-sterilizable care product based on paraffin/white oil, biocompatible according to EU standard). EU standard) manually.
- Distribute the oil in the joint by opening and closing it several times, remove excess care product with a clean, lint-free cloth

Do not use mineral oil or silicone lubricant! Do not immerse instruments completely in the care product!

#### Function test

During the functional test, pay particular attention to the following aspects and possible malfunctions:

- No damage, such as broken tips, bent or loose parts (screws)
- Flawless closure of jaws
- Correct and safe function of detents and locks
- Easy and smooth movement of handles, gait with as little play as possible
- Flawless cutting function for scissors
- Holding and spring pressure in order (punches, gouge cutters, etc.)
- Patency of lumen
- No other signs of wear, e.g. on seals, insulation or coatings

If defects are found during the functional test, the instruments must be labeled and absolutely excluded from further use.

### 13 Service life of the products

The useful life of the products depends on their function, careful reprocessing in accordance with these instructions and careful handling of the instruments. It is therefore not possible to set a general limit on the number of reprocessing cycles. The user can recognize the end of the service life with regard to the functionality or identity of the products by the possible faults and limiting properties of the products specified under maintenance, inspection and testing, and biocompatibility can only be guaranteed up to 350 reprocessing cycles. After that, the products should be disposed of.

### 14 Service and repair

#### Service and repair

Do not carry out any repairs or modifications to the product yourself. Only authorized personnel of the manufacturer are responsible and intended for this. If you have any complaints, claims or comments regarding our products, please contact us.

#### Return transportation

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

### 15 Packaging, storage and disposal

Store sterile products in a dry, clean and dust-free environment, protected from damage, at moderate temperatures.

The manufacturer's medical devices should be stored and kept in individual packaging, boxes or protective containers. Please handle the instruments with the utmost care during transportation, storage and reprocessing. The maintenance of the sterile condition after the sterilization process must be ensured by the user or the specialist personnel designated for this purpose.

The disposal of the products, packaging material and accessories must be carried out in accordance with the applicable national regulations and laws. The manufacturer does not provide specific instructions for this.

### 16 Reporting obligations

Product defects that have occurred during proper use of our products should be reported directly to us as the manufacturer or to your specialist dealer. Defects in which patients, users or third parties have been harmed by the products (so-called reportable incidents) must be reported immediately to the manufacturer and, if applicable, to your competent authority. Incidents must be reported immediately after they occur so that important reporting deadlines can be met.

The affected products must be discarded, reconditioned and sent to the manufacturer for examination. Your specialist dealer will be happy to help you with this.

After receiving your notification, we will inform you within a reasonable period of time about the further measures required.

### 17 Additional information

Further information on the reprocessing of medical devices:







- Internet: <http://www.rki.de>
- Internet: <http://www.a-k-i.org>
- Hygiene requirements for the reprocessing of medical devices Recommendation of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene requirements for the reprocessing of medical devices"
- DIN 96298-4 Functional check in the preparation process

### 18 Applicable documents

You can find instructions on how to properly dismantle the listed products on our homepage: <https://www.dimedada.de/demontageanleitung/>

- Disassembly instructions for instruments

### 19 Description of symbols used

	Attention!
	Follow the instructions for use
	Item number
	Batch designation
	CE mark, if applicable with identification number of the notified body.
	Indication for non-sterile product






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	Name and address of the manufacturer
	Date of manufacture
	Medical device
	Unique Device Identification, code for identifying a product
	Registration number of the manufacturer in the EUDAMED database