Instruction for Use

Cutting, Removing Instruments

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Dimeda Instrumente GmbH
Gänsäcker 54+58
78532 Tuttlingen
Tel:+49 (0) 7462 / 9461-0
Fax: +49 (0) 7462 / 9461-33
http://www.dimeda.de
info@dimeda.de

SRN DE-MF-000005584

1 Important Information

Read this Instruction for Use carefully before every application and keep it easily accessible for all users or the respective specialist staff.

Carefully read the warnings marked with this symbol. Improper use of the products may result in serious injuries to the patient, the users or third parties.

2 Scope

The instruments must be used according to their intended use in the medical fields and by respectively trained and qualified staff only. The treating physician and/or user is responsible for choosing the equipment for specific applications and/or operative use, for the appropriate training and information, and for the sufficient experience regarding the handling of the equipment.

3 Products / Intended use

The cutting instruments are intended for surgically invasive and partly also for non-surgically invasive treatments in various fields of medicine (of less than 60 min.). They correspond to risk class I/Ir.

Product family Scissors	
(Basic UDI-DI)	**Intended use**
General-purpose surgical scissor 404279638727BW	Instrument designed to cut a variety of tissues during open surgery
Nail scissors 404279638812BN	A hand-held device designed specifically for cutting the nails of a patient.
Nail clippers, reusable 404279612695AA	A device with an integral or exchangeable knife-like blade used to remove facial or body hair from a patient.
Bandage scissors 4042796134819U	A hand-held manual instrument intended to be used to cut bandages and cloth.
Intraocular scissors 404279613488AA	Ophthalmic surgical instrument intended to be used to cut intraocular tissue of the anterior segment (e.g., iris)
Ear scissors 404279633414A3	Instrument designed to cut tissue during ear surgery
Suture scissors 4042796135029B	A surgical instrument used during surgery to cut suture or ligature material
Tonsil scissors 404279616520A2	Surgical instrument used to cut tonsil tissue during ear/nose/throat (ENT) surgery.
Nasal scissors 404279613495A7	A surgical instrument used to cut tissue during ear/nose/throat (ENT) or plastic surgery in or on the nose and its associated structures.
Umbilical cord scissors 4042796326029X	Instrument designed specifically to cut the umbilical cord after birth
Cast cutting scissors 404279646314AW	Surgical instrument with specially strong, curved blades that is used to cut small plaster cast dressings and layers of thick material, e.g., bandages.
Rectal scissors	A surgical instrument
40427961350199	designed to cut tissue during rectal surgery.
Enucleation scissors 404279613487A8	An ophthalmic surgical instrument used to cut tissue during eye surgery involving enucleation of the eye and/or its related structures (i.e., the removal of the eyeball to, e.g., remove a malignant tumour or to relieve intolerable pain in a blind eye).
Rigid endoscopy scissors 404279646421AY	Rigid instrument used in endoscopic procedures for cutting tissue or suture material during an endoscopic procedure.
Product family Micro scissors	
(Basic UDI-DI)	**Intended use**
Micro scissors 404279644354AU	A hand-held, manual surgical instrument designed to cut a blood vessel (i.e., to cut over a blood vessel or cut longitudinally to split it open) during open vascular surgery
Product family Cutting Instruments	
(Basic UDI-DI)	**Intended use**
Scalpel handle 40427961223594	A device that is an interchangeable component of a scalpel and that functions as a handle designed to mount a compatible blade
Scalpel, reusable 404279635141A5	Instrument constructed as a one-piece handle and scalpel blade (not an exchangeable component) used by the operator to manually cut or dissect tissue.
Amputation knife 404279635131A2	Instrument which is used in surgery for the amputation of a limb
Periodontal knife 404279641544AE	Dental instrument used to excise the gums and other oral soft tissue during a periodontal intervention
Tonsil knife 4042796122559A	A surgical instrument intended for the removal of the tonsils during a surgical intervention
Nasal knife 404279638103AJ	Instrument designed to cut and dissect internal nasal tissue, including the nasal septum, during ear/nose/throat (ENT) surgery
Ear knife 40427961224597	Instrument intended to cut and dissect tissues of the ear during a surgical intervention
Ophthalmic knife 404279632764AS	Ophthalmic surgical instrument designed to make precise incisions in the eye and surrounding tissues during ophthalmic surgery.
Cartilage knife 404279637840BL	Instrument designed for cutting, shaving or shaping cartilage during a surgical intervention.
Razor 404279645078B2	A device with an integral or exchangeable knife-like blade used to remove facial or body hair from a patient.
Cast/plaster knife 404279635140A3	Instrument which is used to cut or trim the plaster of a cast.
Meniscus knife 404279635138AG	A surgical instrument designed to apply pressure to and/or cut the crescent-shaped disk of fibrocartilage that borders and partly covers the articulating surfaces of the tibia and femur at the knee (meniscus).
Laryngeal knife 404279638105AN	Instrument is designed to cut and dissect laryngeal tissue, including the vocal cords, during ear/nose/throat (ENT) surgery.
Myomatome 404279637835BT	A surgical instrument designed for the removal of a myoma.
Product family Cutting Instrument, pin & wire	
(Basic UDI-DI)	**Intended use**
Wire cutter 404279632885B7	Instrument to cut orthopaedic wires, cerclages, and small diameter pins or bolts.
Product family Chisel & Osteotome	
(Basic UDI-DI)	**Intended Use**
Orthopaedic chisel 4042796108259H	Instrument, designed to cut and shape bone during orthopaedic surgery
Dental osteotome 404279644887C4	Instrument used typically when performing a dental implant surgical procedure
Product family Rongeure	
(Basic UDI-DI)	**Intended Use**
Orthopaedic rongeur 404279632853AS	Instrument designed to remove bone during an orthopaedic intervention of the limbs/joints
Craniofacial rongeur 404279633442A8	Instrument designed for cutting tough tissues (cartilage, sinew) or bone, through a cutting/biting action, during surgery
Rib rongeur 404279635317AJ	Instrument designed to cut and shorten rib bones, and round the rib stumps, during a surgical intervention.
Bone cutter 40427961045596	Instrument designed to separate a bone into two parts through a cutting action.
Product family Dermatome	
(Basic UDI-DI)	**Intended use**
Dermatome handle 404279638797CK	Instrument designed to cut from the body (harvest) thin donor slices of skin for skin grafting, or to excise small skin lesions
Product family Urethrotome	
(Basic UDI-DI)	**Intended use**
Urethrotome 404279617633AP	instrument with small knife at the distal end which is used for incising strictures in the urethra
Product family Punches	
(Basic UDI-DI)	**Intended use**
Bone punch 40427961323193	instrument with a cutting/biting action used to cut small cross-sectional pieces of bone
Rubber dam punch 404279635553AY	Instrument used to place holes in rubber dam material to permit the passage of the dam over the crowns of the teeth
Tonsil punch forceps 404279632364A6	Instrument with a cutting/biting action intended to be used for the removal of the tonsils during a tonsillectomy
Open-surgery biopsy forcep 404279611775A2	Instrument designed to obtain soft-tissue biopsy specimens from an open surgical wound or from within/near a large natural orifice
Product family Snare Instrument	
(Basic UDI-DI)	**Intended use**
Adenotome 40427961002589	Instrument designed to excise hypertrophic

	lymphoid tissue in the nasopharynx
Lens loop 4042796123199B	Instrument designed for eye lens extraction and gentle manipulation and/or irrigation of eye tissues during an ophthalmic surgical procedure.
Nasal snare 404279615676AT	Instrument intended to be inserted into the naris for the removal of tissue, typically polyps, tumours, and other abnormal tissue from the nasal cavity during ear/nose/throat (ENT) surgery
Ear snare 4042796310208U	Instrument for incision in the ear to remove tissue, typically tumorous or damaged tissue, from the ear during ear/nose/throat (ENT) surgery
Tonsil snare 4042796136329R	Instrument inserted into the oral cavity to remove the tonsils during ear/nose/throat (ENT) surgery

4 Contraindication

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 and the central circulatory and nervous system.

The products are not intended for connection to active medical devices. There is a risk of injury to patients and users when using RF, RF or laser devices simultaneously.

Product specific contraindications

Manual dermatome:

- Bacterially contaminated wound bed
- Non-perfused wound bed (tendons, bones, joint capsule)
- Heavy mechanical stress at the recipient site
- Exposed vessels or nerves
- Exposed implants
- Aesthetic defects on the face
- Relative: defects on the flexion side of joints (secondary shrinkage of grafts)

Urethrotome:

- Urinary tract infection
- Coagulation disorders

Snare Instruments:

- Agranulocytosis
- Leukemia
- Coagulation disorders
- Cardiovascular insufficiency

5 Complications / Side effect

⚠ General:

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

In the course of market monitoring, further potential complications / side effects were identified:

⚠ Treatment-related complications / side effects / risks

General:

- Injury to surrounding vessels and tissues
- Injury to nerves

Manual Dermatome:

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

Urethrotome:

- 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

- Rebleeding
- Revision surgery due to secondary bleeding
- tooth damage
- nerve damage
- Airway obstruction (edema)
- Emphysema
- Tasting disorders

⚠ Product-related complications / side effects / risks

In the course of market monitoring, further potential complications / side effects could be identified:

Scissors:

- Fracture
- Possible unwanted perforation
- **Cutting instruments:**
- Incorrect information in the IFU regarding disassembly of the instrument.
- Breakage of the blades
- Breakage of working ends due to lever movements
- Swallowing of components after breakage

Cutting instruments, pins & wires:

- Breakage of the cutting edge, components
- Cutting edges defect

Chisels, Osteotomes:

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

Rongeure

- Breakage of 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 improper use can lead to premature wear of the instruments.

⚠ Material intolerance

Under no circumstances must the instruments be used if the user or specialist staff become aware of the patient being intolerant to the material.

⚠ Functional Impairment

Surgical instruments corrode and become impaired in their functionality if they come into contact with aggressive substances. It is therefore necessary to observe the storage and Sterilization instructions.

⚠ Operating Conditions

The aforementioned products require correct maintenance and care in order to guarantee that the products operate safely. In addition to this, functionality testing and a visual check should be performed prior to each application. For this reason, please pay attention to the respective chapters in this Instruction for Use.

⚠ Combination with other products

Should the products be reassembled after disassembly, individual parts must not be replaced with parts from other manufacturers! If the intended purpose of the product entails certain parts being exchanged (e.g. different attachments), no parts from different manufacturers must be used! We recommend to also purchase other accessories (e.g. detergents) at Dimeda Instrumente GmbH.

⚠ Storage

There are no specific storage requirements concerning the products. Nevertheless, we recommend storing medical products in a clean and dry environment.

⚠ Creutzfeldt Jakob Disease

With regard to the reprocessing of medical devices that have been used on patients or suspected patients suffering from or suspected of suffering from Creutzfeldt-Jacob disease (CJD) or its variant (vCJD), the requirements specified in the corresponding appendix of the guidelines for hospital hygiene and infection prevention and the requirements specified by publications in the Federal Health Gazette must be adhered to. The medical devices that were used on this group of patients must be disposed of by incineration (European Waste Catalogue EAK 18 01 03) without risk. Dry heat, ethanol, formaldehyde and glutaraldehyde have a fixing but no inactivating effect on TSE pathogens. Of the sterilization methods available, only steam sterilization (especially 134°C, 18 minutes) has been shown to have a limited effect.

⚠ Pointed / sharp instruments

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

7 Combination products & accessories

The products are not applied with other products except scalpels and offered without accessories. Scalpels with interchangeable blades Scalpels can be combined with blades according to DIN EN 27740. The scalpels are designed to be compatible with figures 3, 4 according to DIN 58849-2.

8 Liability and Warranty

As a manufacturer, Dimeda Instrumente GmbH is not liable for consequential damage resulting from improper use or handling. This particularly applies to use which is not compliant with the defined intended use, or non-compliance with the instructions on preparation and Sterilization. This also applies to repairs or changes to the product which are not carried out by authorized staff of the manufacturer. These disclaimers also apply to warranty services.

9 Sterility

⚠ State upon Delivery

Medical products are delivered in a non-sterile condition and need to be prepared and sterilised by the user prior to the first application and any subsequent application according to the following instructions.

10 Reprocessing

⚠ Warnings

- Frequent reprocessing impairs the quality of the products.
- City water to be used must comply with COUNCIL DIRECTIVE 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.
- This treatment instruction specifies the detergents and disinfectants used for validation. If an alternative detergent and disinfectant (RKI or VAH listed) is used, the responsibility rests with the reprocessor.
- Reassemble disassembled products before sterilization.
- Reprocessing may only be performed by qualified medical personnel. Machine reprocessing must be qualified and validated by the user. The washer-disinfectors must fully comply with the requirements of DIN EN ISO 15883.

⚠ Use Site

The first steps of a proper reprocessing take place in the operating theatre. Coarse contaminations must be removed prior to storing the instruments if possible. For this purpose, 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.

Whenever possible, dry removal (moistened, closed system) should be the method of choice. A drying of any residues should be avoided! Wherever possible, dry disposal is to be preferred, since with wet disposal the prolonged lying of the medical devices in solutions can lead to material damage (e.g. corrosion). Long periods of waiting until the reprocessing, for instance overnight or over the weekend, must be avoided with both types of removal (<60 minutes).

⚠ Transport

The products must be disposed of in a dry state immediately (<60 min) after use, if possible. This means that the products have to be transported in a closed container from the place of application to the purification, so that the products do not dry up.

Preparing the Decontamination

The products must be disassembled prior to the following reprocessing steps and/or must be exposed to the following reprocessing steps in an open condition, where possible. Rinse residue must be avoided. The products must be reprocessed in appropriate screen baskets or rinsing shields (choose size according to product). The products must be positioned in the cleaning basket at a minimum clearance from one another. Avoid overlapping so that the damaging of the products during the cleaning process can be excluded.

Pre-cleaning

1. Pre-clean products completely under cold water (city water drinking water quality <40°C) with a soft brush.
2. Flush cavities and hard-to-reach areas, gaps and slots on the instrument with cold water (city water drinking water quality <40°C) for 60 sec using a water pressure gun.
3. Soak 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. Flush cavities and hard-to-reach areas, gaps and slots on the instrument with cold water (city water drinking water quality <40°C) for 30 sec using a water pressure gun.

Cleaning/disinfection

Automated cleaning and/or disinfection process

(Miele Disinfector G7835 CD as per ISO 15883):

- 1 Pre-clean for 1 minute
- Drain water
- Pre-clean for 4 minutes
- Drain water
- Clean for 6 minutes at 58°C +/- 1°C using 0.5 % alkaline detergent (0,5 % Neodisher Mediclean forte)
- Drain water
- Neutralize for 3 minutes (0.1% 0,1 % NeodisherZ) with cold tap water suitable for use as drinking water <40°C
- Drain water
- Clean for 2 minutes with FD water <40°C

Automated Disinfection

Automated thermal disinfection in a cleaning and disinfection device taking into consideration the national requirements for the A0 value; for instance, A0 value 3000:

>5 minutes at >95°C.

Automated Drying

Automated drying in accordance with the drying operation of the cleaning and disinfection device for at least 30 minutes at 92°C +/- 2°C.

11 Sterilization

(Typ B Autoclave by Tuttmauer as per DIN EN 13060)

Sterilization of products with a fractionated pre-vacuum method (according to DIN EN ISO 17665-1) taking into consideration the respective national requirements. The Sterilization of the products must be conducted in suitable Sterilization packaging according to DIN EN ISO 11607-1 and EN 868

The Sterilization must be completed using a fractionated pre-vacuum method with the following parameters:

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

The Instruction for Use of the manufacturer of the autoclave and the recommended directions for maximum loading with goods to be sterilised must be observed. The autoclave must be installed, maintained, validated and calibrated in accordance with requirements.

⚠ Additional Information

The reprocessor is responsible for ensuring that the actual reprocessing, including the used equipment, materials and the staff involved in the reprocessing facility, achieves the desired results. This typically requires the validation and routine monitoring of the method and the equipment used.

12 Maintenance-Control-Inspection

Cool down the instruments to room temperature!

Visual inspection (before assembly):

Check the surface of the instruments or the individual components before assembly. Pay particular attention to checking joints (final part), profiles, grooves and other structures that are difficult to access:

- Is there any residual soiling or residue?

If so, manual re-cleaning and renewed complete mechanical cleaning and disinfection.

- Are traces of corrosion (rust, pitting) visible?
- Is the surface damaged by cracks (including hairline cracks) or other signs of wear?
- Is the instrument labeling no longer legible?

If so, the instrument in question must be marked and immediately sorted out and replaced.

Assembly and maintenance

- Assemble the disassembled instruments in a functionally correct manner.
- Treat moving parts, such as joints, threads and sliding surfaces, manually with suitable, medically approved instrument oil (steam-sterilizable care product based on paraffin/white oil, biocompatible according to EU standard). EU standard).
- Distribute the oil in the joint by opening and closing 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 check, pay particular attention to the following aspects and possible malfunctions:

- No damage, such as broken tips, bent or loose parts (screws)
- Proper closure of jaws
- Correct and safe function of detents and locks
- Easy and even movement of handles, as backlash-free as possible
- Proper cutting function of shears
- Re- and spring pressure in order (punches, gouge pliers etc.)
- Continuity of lumens
- No other signs of wear, e.g. on seals, insulation or coatings

If defects are found during the functional test, the instruments must be marked and excluded from further use without fail.

13 Lifespan of the Products

The service life of the products results from their function, gentle reprocessing in accordance with these instructions and careful handling when handling the instruments. Therefore, a limit to the number of reprocessing cycles cannot be set across the board. Nevertheless, 100 reprocessing cycles were simulated, which showed no impairment of functionality, biocompatibility and identification of the products. The user recognizes the end of the usage cycle by the possible defects and limiting properties of the products indicated under maintenance, inspection and testing.

14 Service and Repair

⚠ Service and Repair

Do not carry out any repairs or changes to the product yourself. Authorized staff of the manufacturer are solely responsible for such work. Should you wish to make complaints or queries, or offer us any advice regarding our products, please feel free to contact us.

⚠ Returns

Defective or non-compliant products must go through the entire reprocessing process before being sent back for repairs/service.

15 Packaging, Storage and Disposal

Standard packaging of the products for Sterilization according to ISO 11607 and EN 868.

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

The medical products of the manufacturer should be stored and kept in single packaging, boxes or protective containers. Please handle the instruments with care during transportation, storage and reprocessing. The user and/or specialist staff intended for this is responsible for ensuring that the sterile state is maintained after the Sterilization.

The disposal of the products, packaging as well as the accessories must be performed in accordance with current rules and laws. No specific instruction regarding this matter is provided by the manufacturer.

16 Reporting obligations

Product defects which have occurred during proper use of our products should be reported directly to us as the manufacturer or to your supervising 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 necessary, to your competent, responsible authority. This reporting of incidents must take place immediately after they occur so that important reporting deadlines can be met.
The affected products must be discarded, reprocessed and sent to the manufacturer for examination. Your servicing dealer will be pleased to help you with this.
After receipt of your notification, we will inform you within a reasonable time frame about the further measures required.

17 Additional information

If the chemicals and machines described here are not available, and if the reprocessing process cannot be carried out as described, it is the user's responsibility to validate his process accordingly.

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 control in the reprocessing process

18 Other applicable documents

Instructions for the proper disassembly of the listed products can be found on our homepage:
www.dimeda.de/ifu

- Disassembly instructions for instruments

19 Description of Symbols Used

	Attention!
	Observe the Instruction fo Use
REF	Item number
LOT	Lot designation
CE xxxx	CE labeling, if necessary m identification number of the notified body.
	Indication of a non-sterile product
	Name and address of the manufacturer
	Manufacturing date
MD	Medical device
UDI	Unique Device Identification, code for identifying a product
SRN	Registration number of the manufacturer in the EUDAMED database