

Instruction for Use

Scraping, Dissolving Instruments

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Version:

04



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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 scraping, dissolving instruments are intended for surgically invasive and partly also for non-surgically invasive treatments in various specialties of medicine (of less than 60 min.). They correspond to risk class I/II.

| Product family Currettes, Spoons, Raspatories (Basic UDI-DI) | | Intended use |
|--|---|--------------|
| Bone curette 4042796313359Q CE 0123 | Instrument designed for cutting and excising bone tissue typically during an orthopaedic or a plastic surgery procedure. | |
| Intrauterine curette 404279623594AR CE 0123 | Instrument for removal of tissue during a gynaecological procedure, typically for the removal of an early or non-viable embryo/foetus. | |
| Endometrial biopsy curette 404279646871C3 CE 0123 | Instrument used to for the removal of small amounts of endometrial secretions and/or tissue from the uterus for biopsy purposes. | |
| Eye curette 404279646549BT CE | Instrument intended to be used to remove a foreign body/object embedded in or adhering to the surface of the eye globe. | |
| Endaural surgical curette 404279647522BE CE 0123 | Instrument designed for procedures during middle ear surgery. | |
| Paranasal sinus curette 404279647525BL CE 0123 | Instrument designed for scraping and/or excising tissue from one of the paranasal sinuses. | |
| Dental restoration carve 404279641861AV CE | A dental instrument intended to be used for producing and perfecting anatomical forms in dental composite. | |
| Dental restoration carver, amalgam 404279635793BN CE | Instrument intended to be used for producing and perfecting anatomical forms in dental amalgam restorations. | |
| Intrauterine scoop 404279646870BZ CE 0123 | Instrument with a spoon-like, used to access and scrape (gouge or scoop out) a particular area of the lining of the uterus for its removal during a gynaecological procedure. | |

| General-purpose curette 404279662558BN CE 0123 | Instrument designed for scraping and/or excising tissue from a wide variety of anatomical sites. |
|--|--|
| Gallstone scoop 4042796135099R CE 0123 | Instrument designed for the removal of gallstones. |
| Periodontal curette 404279641660AH CE 0123 | Instrument used with a pulling action to remove calculus of periodontal pockets and smooth root surfaces. |
| Periodontal hoe 404279631908AK CE | Instrument used with a pulling action to remove gross amounts of supragingival calculus. |
| Manual dental scaler 404279635320A7 CE | Instrument designed for removing calculus and other accretions from the surface and between the teeth during dental cleaning. |
| Ear excavator 404279635915BC CE 0123 | Instrument designed for cutting, scraping, scooping and removing tissue during a surgical procedure. |
| Dental excavator 404279635811AX CE | Instrument designed for cutting, scraping, and removing the carious dentine. |
| Product family Rasp (Basic UDI-DI) | |
| Intended use | |
| Nasal file/rasp 404279635296B3 CE 0123 | Instrument designed to remove and profile the cartilage/bone of the nose during ear/nose/throat (ENT) or plastic surgery. |
| Bone file/rasp, manual 404279635559BC CE 0123 | Instrument designed to scrape and smooth the surface of bone during a surgical procedure. |
| Periodontal file/rasp 4042796350139T CE 0123 | Instrument that has various forms of ridged cutting surfaces at its working end(s) designed to scrape and smooth during a periodontal procedure. |
| Manual endodontic file/rasp 404279631878B3 CE | Instrument designed to debride and enlarge the root canal and smooth its walls by a cutting or abrasive action when moved in a longitudinal direction. |
| Product family Dissector (Basic UDI-DI) | |
| Intended use | |
| Open-surgery dissector 40427961129095 CE 0123 | Instrument, used to separate a soft tissue or body structure from another. |
| Tonsil dissector 404279633452AB CE 0123 | Instrument, usually spoon-shaped or rounded at the working end, used during the dissection of the tonsils during 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.

The products are contraindicated for all other uses except for the techniques mentioned in the intended purpose / indication(s).

Product specific contraindications

Intrauterine curette

- The presence of acute or chronic cervical infection
- The presence of, or after recent Pelvic Inflammatory Disease (PID)

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.

- Breakage of the instruments
- Injury to vessels, tissue, nerves
- Infections
- Perforation of tissue, vessels, and cavities
- After bleeding
- Necroses
- Thromboses

Treatment-related complications / side effects / risks

General

- Injury to surrounding vessels and tissues
- Injury to nerves

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 Dimedada 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

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(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 and are offered without accessories.

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.
- 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 (RKI 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 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 A₀ value; e.g. A₀ 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

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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.

| | |
|---|---|
|  | Name and address of the manufacturer |
|  | Manufacturing date |
|  | Medical device |
|  | Unique Device Identification, code for identifying a product |
|  | Registration number of the manufacturer in the EUDAMED database |

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/demontageanleitungen/>

- Disassembly instructions for instruments

19 Description of symbols used

| | |
|---|---|
|  | Attention! |
|  | Observe the Instruction fo Use |
|  | Item number |
|  | Lot designation |
|  | CE labeling, if necessary m identification number of the notified body. |
|  | Indication of a non-sterile product |