

Instructions for use

Spreading, holding away instruments

Valid from:	16.07.2025	Version:	05
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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 spreader, hold-away instruments are intended for surgically invasive and partly also for non-surgically invasive treatments in various medical specialties (of less than 60 minutes). They correspond to risk class I/II.

Mouth guard product family	
(Basis UDI-DI)	Intended use
Mouth guard, non-adjustable 404279616197AH CE	Product without adjustable parts that is placed between a patient's teeth to keep the oral cavity open
Mouth guard, adjustable 404279635085AL CE	Product with adjustable parts that is placed between a patient's teeth to keep the oral cavity open
Product family finger protection	
(Basis UDI-DI)	Intended use
Finger protection 4042796117199Q CE	Product to be worn on the examiner's finger to prevent contamination between patient and examiner
Specula product family	
(Basis UDI-DI)	Intended use
Vaginal speculum 404279635352AL CE	Instrument for dilating the vagina
Nasal speculum 404279635350AG CE	Instrument that is inserted into a nostril and spread manually
Rectal speculum 404279635351AJ CE	Instrument for spreading the rectal outlet/duct
Spreader/retractor product family	
(Basis UDI-DI)	Intended use
Wound retractor, semi-deep/deep 404279645918BV CE 0123	A surgical instrument for holding open/spreading the edges of total or subtotal dissections or ruptures
Dental retractor 4042796133809M CE 0123	Instrument for remote holding and protection of soft tissue, ensuring better visibility and accessibility of the surgical site during oral surgery

Self-retaining surgical retractor, reusable 404279645182AW CE 0123	Instrument for temporarily spreading tissue edges (e.g. keeping wound edges open) or other anatomical structures
Bone reduction hook 404279633542AD CE 0123	Instrument to grasp, hold and apply traction to the bone
Lid lock, reusable 404279635349AX CE	Instrument for retracting the eyelids or other eye tissue
Plaster spreader 4042796137089Z CE	Cutting and spreading hard plaster
Bone distraction forceps 404279644378BA CE 0123	Instrument with sturdy handles and spatula-like jaws used to distract two bone surfaces
Jaw bone separator 404279664306B7 CE 0123	Instrument for pushing apart or splitting bones in the face, mouth and/or jaw
Product family hooks (*excluded vessels: arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens up to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior and vena cava inferior)	
(Basis UDI-DI)	Intended use
Eye muscle hooks 404279632774AV CE 0123	Instrument used to atraumatically capture and restrain the outer eye muscles during an ophthalmic surgical procedure
Irish hook, reusable 4042796133819P CE 0123	Instrument for briefly spreading the edges of the iris
Fistula hook 404279642593B2 CE 0123	Instrument for hooking into or around a fistula
Rectal hook 404279635351AJ CE	Instrument for exerting traction on rectal tissue/fistulas
Tracheal hook 4042796351129W CE 0123	Instrument for holding the trachea in place when creating a tracheostoma and/or for spreading the edges of a tracheostoma
ENT middle ear hook 40427961303999 CE 0123	Instrument for manipulating structures of the middle ear, e.g. the stapes
Nerve/vascular hooks 404279646768C9 CE 0123	Instrument that is hooked around a nerve or blood vessel* during a surgical procedure to separate it from the surrounding tissue
Decapitation hook 4042796326019V CE 0123	Instrument for decapitation of a fetus

Spatula product family (*excluded vessels: arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens up to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior and vena cava inferior)	
(Basis UDI-DI)	Intended use
Surgical spatula, general 404279639610BF CE 0123	A surgical instrument for manipulating tissue during various types of surgical procedures
Vascular spatula 404279638127AY CE 0123	A surgical instrument for use within a blood vessel* to scrape, manipulate and remove tissue contained therein
Bone cement spatula 404279635344AM CE	Instrument for spreading orthopaedic bone cement on a surface
Lung spatula 404279635345AP CE 0123	Instrument for manipulating lung tissue/lung surfaces during a surgical procedure
Dilators product family (*excluded vessels: arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens up to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior and vena cava inferior)	
(Basis UDI-DI)	Intended use
Tracheal dilator 40427961126392 CE 0123	Instrument for tracheal surgery to create a tracheostoma and/or to hold open/spread the edges of a tracheostoma
Urethral dilator 40427961126596 CE	Thin, solid or hollow, flexible or semi-flexible surgical instrument for widening the urethra
Uterine dilators 4042796112679A CE	Rod-shaped solid surgical instrument for dilating the cervical canal after insertion through the cervix
Vascular dilator, reusable 4042796112689C CE 0123	Instrument for inserting into a blood vessel* to clear or dilate it during a surgical procedure or to measure the inner diameter of the vessel
Common bile duct dilator 40427961126595 CE 0123	Instrument for dilating the common bile duct
Depressor product family	
(Basis UDI-DI)	Intended use
Tongue depressor, 4042796140669K CE	Instrument for moving and fixing the tongue
Uterine depressor 404279642536AN CE	Instrument for displacing the uterus
Proctoscope product family	
(Basis UDI-DI)	Intended use
Proctoscope, reusable 404279635255AM CE	Endoscope with a rigid inserted part for visual examination and treatment of the rectum and anus

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

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

The products are contraindicated for all applications other than the techniques specified in the intended use / indication(s).

Product-specific contraindications

- No known contraindications.

5 Undesirable side effects / complications / Risks

⚠ 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.
- Breakage of the instruments
- Injury to vessels, tissue, nerves
- Infections
- Perforation of tissue, vessels and cavities
- Post-bleeding
- Necrosis
- Thromboses

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

⚠ Treatment-related complications / side effects / risks

Mouth guard

- Tooth injuries
- Soft tissue injuries

Specula

- Bleeding

Dilators:

- Perforation of vessels

Proctoscopes

- Bleeding

⚠ Product-related complications / side effects / risks

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

Mouth guard

- Breakage
- Soft tissue reaction
- Infection
- OP extension

Spreader/retractor

- Infections or
- Soft tissue reactions due to leaking fluids
- Breakage

Dilators

- Breakage
- Remaining fragments
- Deformation of components

Depressor

- Breakage
- Ingestion of components

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 and are offered without accessories.

8 Liability and warranty

Dimeda Instrumente GmbH, as the manufacturer, is not liable for consequential damage resulting from 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 (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)

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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 gone through 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
	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