Instruction for Use

Spreading, Holding away Instruments

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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 spreading, holding away 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/Ir.

Product family Mouth gag	
(Basic UDI-DI)	**Intended use**
Mouth gag, non-adjustable 4049216161978B	A device without adjustable parts placed between the teeth of the upper and lower jaws of a patient to maintain an open oral cavity, typically during emergent placement of an artificial airway or for an oral surgical intervention
Mouth gag, adjustable 4049216350858E	A device with adjustable parts intended placed between the teeth of the upper and lower jaws of a patient to maintain an open oral cavity, typically during emergent placement of an artificial airway or for an oral/dental surgical intervention
Product family Finger-stall	
(Basic UDI-DI)	**Intended use**
Finger-stall 40492161171197J	A device intended to be worn on an examiner's finger to prevent contamination between patient and examiner
Product family Speculum	
(Basic UDI-DI)	**Intended use**
Vaginal speculum 4049216353528E	Instrument intended to dilate the vagina after insertion
Nasal speculum 4049216353508A	Instrument inserted into a nostril and manually expanded to maximally open the nostril by stretching the tissue around the nasal
Rectal speculum 4049216353518C	Instrument intended to be used to expand or stretch the rectal orifice/canal after it is inserted
Product family Spreader / Retractor	
(Basic UDI-DI)	**Intended use**
Hand-held surgical retractor 4049216459189P	Instrument intended to be used to separate/draw aside the margins of a wound/incision to allow access to tissues/organs during open surgery
Hand-held dental retractor 4049216133807F	Instrument to displace soft tissues of the oral cavity to improve their visualization and access, and to afford them protection during oral surgical procedures.
Self-retaining surgical retractor 4049216451828Q	Instrument intended to be used to separate/draw aside the margins of a wound/incision to allow access to tissues/organs during open surgery
Bone hook 40492163354287	Instrument used for hooking around or into bone, typically to grasp, hold, and apply traction to the bone during a surgical intervention
Eyelid speculum 4049216353498R	Instrument intended to be used to retract the eyelids during an opthalmologic examination or procedure
Self-retaining surgical retractor 4049216L0399GD	Instrument, used for separating the edges or drawing aside the margins of a surgical incision to permit excision
Cast spreader 4049216137087T	Instrument with specially designed blades used to separate and spread hardened plaster
Bone distraction forceps 40492164437894	Instrument with sturdy handles and blade-like jaws designed to distract (force apart) two bone surfaces to enable a surgical procedure, e.g., two vertebrae during a spinal surgical intervention
Maxillofacial bone separator 4049216643068Z	A surgical instrument intended to split/force apart bones in the face, mouth and/or jaws during maxillofacial surgery
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 und vena cava inferior)	
(Basic UDI-DI)	**Intended use**
Eye muscle clamp 4049216327748P	Instrument designed to atraumatically grasp and hold the extraocular muscles (EOM) during an ophthalmic surgical intervention
Eyeball tissue retractor 4049216133817H	Instrument intended to be used explicitly for the temporary mechanical retraction/dilatation of tissues of the eyeball during ophthalmic surgery
Fistula hook 4049216425938U	Instrument used for hooking into or around a fistula
Rectal hook 4049216156738F	Instrument designed to apply traction to rectal tissue/fistulae
Tracheal hook 4049216351127Q	Instrument designed to hold the trachea steady during the creation of a tracheostoma and/or for separating/drawing aside
Middle ear pick 40492161303973	Instrument intended to be used to manipulate the structures of the middle ear
Nerve/vessel retractor 404921646768A3	Instrument intended to be used for retracting a nerve, tendon, or blood vessel to separate it from the surrounding tissue
Obstetrical decapitation hook 40492163260017P	Instrument which is designed to decapitate a foetus
Product family Spatula (*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 und vena cava inferior)	
(Basic UDI-DI)	**Intended use**
General-purpose surgical spatula 40492163961099	Instrument designed to manipulate tissue during various types of surgical interventions
Vascular spatula 4049216381278S	Instrument designed to be used within the vasculature (a blood vessel) to scrape, manipulate, and remove tissue therein
Orthopaedic cement spatula 4049216353448F	Instrument designed to spread orthopaedic bone cement material onto a surface.
Lung spatula 4049216353458H	Instrument designed to manipulate the pulmonary tissue/surfaces of the lungs during a surgical intervention in the thorax
Product family Dilators (*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 und vena cava inferior)	
(Basic UDI-DI)	**Intended use**
Tracheal surgery dilator 4049216112636U	Instrument intended to be used during surgical intervention of the trachea to dilate tracheal
Urethral dilator 4049216112656Y	Instrument designed to dilate the urethra, mainly to treat strictures of the urethra
Uterine dilator 40492161126774	Rod-shaped solid surgical instrument for dilatation of the cervical canal after insertion through the cervix
Vascular dilator 40492161126876	Instrument designed for insertion into a blood vessel (the vasculature) to unblock
Common bile duct dilator 4049216112566X	Instrument designed to dilate the common bile duct
Product family Depressor	
(Basic UDI-DI)	**Intended use**
Tongue depressor 4049216140667D	Instrument designed to displace and maintain the tongue in a fixed position
Uterine depressor 4049216425368G	Instrument used to displace (depress - to press down or aside) the uterus to facilitate examination
Product family Proctoscope	
(Basic UDI-DI)	**Intended use**
Proctoscope 4049216352558F	An endoscope with a rigid inserted portion intended for the visual examination and treatment of the rectum and anus

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

- No contraindications known

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

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

⚠ Treatment-related complications / side effects / risks

Mouth Gag

- Tooth injuries
- Soft tissue injusries

Speculum

- Bleeding

Dilators

- Perforation of vessels

Proctoscopes

- Bleeding

⚠ Product-related complications / side effects / risks

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

Mouth Gag

- Fracture
- Soft tissue reaction
- Infection
- Op extension

Spreader / Retractor

- Infection
- Soft tissue reaction due to leaking fluids
- Rupture

Dilators

- Fracture
- Remaining fragments
- Deformation of components

Depressor

- Fracture
- Ingestioni 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 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 CM 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 and are offered without accessories.

8 Liability and Warranty

As a manufacturer, CM 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
- 3 minutes Neutralization (0.1 % NeodisherZ) with cold water
- 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 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 lum
- 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.cm-instrumente.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