Instruction for Use
Rib spreaders

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dimeda® SURGICAL INSTRUMENTS

GENERAL INFORMATION

Field of application

This instruction for use is valid for all rib spreaders and the corresponding blades with the following article numbers:

For adults: 56.210.xx, 56.220.04, 56.220.08, 56.220.09, 56.220.10, 56.220.60, 56.220.61, 56.220.62, 56.220.63, 56.220.64, 56.230.xx, 56.234.43, 56.234.44, 56.236.xx, 56.242.xx, 56.245.xx, 56.246.xx, 56.256.xx, 56.262.xx, 56.266.xx, 56.268.xx, 56.269.xx, 56.270.xx, 56.272.20, 56.273.15, 56.273.19, 56.273.30, 56.274.xx

➔ These rib spreaders may only used for to adults.

For children: 56.220.02, 56.220.03, 56.220.07, 56.220.11, 56.232.xx, 56.234.41, 56.234.42, 56.238.xx, 56.244.xx, 56.250.12, 56.251.xx, 56.258.xx, 56.260.xx, 56.264.xx, 56.265.15, 56.272.15, 56.273.16, 56.273.20

➔ These rib spreaders may only used children, possibly at the discretion of the surgeon as well for small adults.

For babies: 56.209.00, 56.212.12, 56.214.75, 56.220.01, 56.220.05, 56.220.06, 56.234.40, 56.234.75, 56.250.06, 56.250.07

➔ These rib spreaders may only used for babies, possibly at the discretion of the surgeon as well for small children.

The products are marketed by Dimeda Instrumente GmbH. To minimize risks for patients and users, please read the instructions carefully. The use of these products is only allowed for qualified personnel.

Basics

These instructions cannot replace training, carefulness and the user‘s knowledge of the state of the art. We therefore assume that the respective legal rules, standards and recommendations (e.g. those of “RKI” or also of “AKI”) are known.

ATTENTION: READ THESE INSTRUCTIONS VERY CAREFULLY BEFORE YOU PREPARE AND USE THE PRODUCT FOR THE FIRST TIME.

Intended use

Rib spreaders are used to stretch and to keep the tissue and bones open (in the area of the ribs and the sternum / general surgery). They provide surgical procedures for the surgeon by exposing the operating field trough self-retaining. It is recommended to use the rib spreader in the caudal region to reduce the complication of the rib fracture. The instruments have to be checked carefully of possible damages like sharp edges, cracks and missing or loose pieces before and after each use.

Indication for use the products

- Lung and thoracic surgery
- Surgical interventions at the sternum

Patient Population

There is no restriction concerning the patient population other than the ones provided in the section “Contraindications”. Devices intended to be used for specific population such as paediatric, are clearly identified on the label description.

Contraindication for use the products

- Contraindications are at the discretion of the doctor.
- No reuse the instruments after application on patients with Creutzfeldt-Jakob disease

Hazards

- Bleeding
- Anaesthetic risk
- Injury to nerves, blood vessels and organs
- Circulatory disorders (abdominal inflation due to the build-up of Carbon Dioxide, and in particular, patients with existing pulmonary disorders)
- Instrument breakage caused by the exertion of excessive force by the operator (extension of operating times)
- Infections caused by incorrectly reprocessed instruments
- Damage to surrounding tissue and nerves
- Fracture of the rib

Intended Users and Use Environment

Dimeda Instrumente GmbH rib spreaders must be used by physician that is familiar and sufficiently trained, Informed about current state of the art and having sufficient experience in the choice and use of rib spreaders. Physician is responsible for patient selection and surgical procedure to apply. Rib spreaders must be only used in hospital and/or appropriate centers in sterile state.

Reusability/ Life expectancy

The rib spreaders and the blades are reusable. The description of the cleaning, disinfection and sterilization included in chapter “processing”. 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 had no adverse effect on the functionality, biocompatibility and identification of the products.
After using the instruments, the user has to check and evaluate the instruments if a reapplication is possible. Damaged instruments must be rejected. Only qualified staff of the manufacturer may perform the repair of the instruments. The life expectancy can be extended if the storage conditions are observed.

Combination with other products/instruments and accessories

The products are not intended and designed for combination with other products If instruments will be assembled after disassembling, the single components may not be exchanged with parts from other manufacturers, even if a part is exchangeable due to the product´s specific function (e.g. different inserts).
Replacement valves in various sizes and shapes are available as accessories for some products. The exchange valves are specified via article numbers and assigned to the corresponding products. The different diameters of the arms and the size of the holders also ensure that only permissible valves can be fitted. This rules out the use of oversized or undersized valves with rib spreaders that do not match.

Materials

The rib spreaders are made of stainless steel according to DIN EN ISO 7153-1 or aluminum alloy according to DIN EN 573-3. Following materials are used:

- 1.4021
- 1.4301
- 1.4305
- 1.4310
- AlMgSi1

Disposal; return consignment

Dimeda Instruments GmbH only accepts returns if the products are declared as „hygienically inoffensive” (i.e. they passed the whole reprocessing) and if they are marked as „decontaminated“(pink reparation note), and if they are safely packed. Defect or out-of-date instruments can be disposed of professionally or returned to a recycling system after cleaning and disinfection process.

Warranty

Security advice: The user is responsible for the appropriate cleaning, disinfection and sterilization of the instruments.
National rules, including restrictions, have to be observed as well. Dimeda Instruments GmbH excludes any warranty claims and assumes no liability for damages or subsequent damages resulting from:

- use for purposes other than intended
- inappropriate use, employment, or handling
- inappropriate treatment and sterilization
- inappropriate maintenance and reparations
- non-observance of these instruction guidelines

Reparations may only be made by companies or persons authorized by Dimeda Instruments GmbH. In case of nonobservance any warranty will be excluded.

PPROCESSING (cleaning, disinfection, and sterilization) of instruments

Fundamental points

All instruments are to be cleaned, disinfected, and sterilized prior to each application; this is required as well for the first use after delivery of the unsterile instruments (cleaning and disinfection after removal of the protective packaging, sterilization after packaging). An effective cleaning and disinfection is an indispensable requirement for an effective sterilization of the instruments.
You are responsible for the sterility of the instruments. Therefore, please ensure that only sufficiently device and product specifically validated procedures will be used for cleaning, disinfection, and sterilization, that the used devices (WD, sterilizer) will be maintained and checked regularly, as well as that the validated parameters will be applied for each cycle.
Additionally, please pay attention to the legal provisions valid for your country as well as to the hygienic instructions of the doctor´s practice or of the hospital. This applies particularly to the different guidelines regarding the inactivation of prions (not relevant for USA).
Attention: In case of some instruments additional or deviating procedure are required (see chapter “Specific aspects”).

Cleaning and disinfection

Basics

An automated procedure (WD (Washer-Disinfector)) should be used for cleaning and disinfection of the instruments. Before that, the pretreatment step should be performed.

Pre-treatment

Please remove coarse impurities of the instruments directly after application (within a maximum of 2 h).

Procedure:

1. Disassemble the instruments as possible without any tool (see chapter „Specific aspects“).
2. Rinse the instruments at least 1 min under running water (temperature < 35 °C/95 °F). Agitate movable parts at least three times during pre-rinsing.
3. Soak the disassembled instruments for the given soaking time in the pre-cleaning solution1 (ultrasonic bath, ultrasound not activated) so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments. Assist cleaning by careful brushing with a soft brush (at beginning of soaking). Agitate movable parts at least three times during pre-cleaning.
4. Activate ultrasound for an additional soaking time (but not less than 5 min).
5. Then, remove the instruments of the pre-cleaning solution and post-rinse them at least three times intensively (at least 1 min) with water. Agitate movable parts at least three times during post-rinsing.

Pay attention to following points during selection of the cleaning detergent[1]:

- fundamental suitability for the cleaning of instruments made of metallic material
- suitability of the cleaning detergent for ultrasonic cleaning (no foam development)
- compatibility of the cleaning detergent with the instruments (see chapter „material resistance”)

Pay attention to the instructions of the detergent manufacturer regarding concentration, temperature and soaking time as well as post-rinsing. Please use only freshly prepared solutions as well as only sterile or low contaminated water (max. 10 germs/ml) as well as low endotoxin contaminated water (max. 0.25 endotoxin units/ml), for example purified/highly purified water, and a soft, clean, and lint-free cloth and/or filtered air for drying, respectively.

[1] In case of application of a cleaning and disinfection detergent for this (e.g. in consequence of personnel´s safety) please consider, that this should be aldehyde-free (otherwise fixation of blood impurities), possess a fundamentally approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking), be suitable for the disinfection of instruments made of metallic material, and be compatible with the instruments (see chapter „material resistance„). Please consider, that a disinfectant used in the pre-treatment step serves only the personnel`s safety, but cannot replace the disinfection step later to be performed after cleaning.

Automated cleaning/disinfection (WD (Washer-Disinfector))

Pay attention to following points during selection of the WD:

- fundamentally approved efficiency of the WD (for example CE marking according to EN ISO 15883 or DGHM or FDA approval/clearance/registration)
- possibility for an approved program for thermal disinfection (A0 value ≥ 3000 or – in case of older devices - at least 5 min at 90 °C/194 °F; in case of chemical disinfection danger of remnants of the disinfectant on the instruments)
- fundamental suitability of the program for instruments as well as sufficient rinsing steps in the program
- post-rinsing only with sterile or low contaminated water (max. 10 germs/ml, max. 0.25 endotoxin units/ml), for example purified/highly purified water
- only use of filtered air (oil-free, low contamination with microorganisms and particles) for drying
- regularly maintenance and check/calibration of the WD

Pay attention to following points during selection of the cleaning detergent:

- fundamental suitability for the cleaning of instruments made of metallic material
- additional application - in case of non-application of a thermal disinfection - of a suitable disinfectant with approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) compatible to the used cleaning detergent
- compatibility of the used detergents with the instruments (see chapter „material resistance")

Pay attention to the instructions of the detergent manufacturers regarding concentration, temperature and soaking time as well as post-rinsing.

Procedure:

1. Disassemble the instruments as possible without any tool (see chapter „Specific aspects").
2. Transfer the disassembled instruments in the WD (pay attention that the instruments have no contact).
3. Start the program.
4. Remove the instruments of the WD after end of the program.
5. Check and pack the instruments immediately after the removal (see chapters „check", „maintenance", and "packaging", if necessary after additional post-drying at a clean place).

The fundamental suitability of the instruments for an effective automated cleaning and disinfection was demonstrated by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory by application of the WD G 7836 CD, Miele & Cie. GmbH & Co., Gütersloh, (thermal disinfection) and the cleaning detergent Neodisher medizym (Dr. Weigert GmbH & Co. KG, Hamburg) considering to the specified procedure.

Check

Check all instruments after cleaning or cleaning/disinfection, respectively, on corrosion, damaged surfaces, and impurities. Do not further use damaged instruments (for limitation of the numbers of re-use cycles see chapter „reusability„). Still dirty instruments are to be cleaned and disinfected again.

Maintenance

Assemble disassembled instruments again.
Use only instrument oils (white oil) admitted to steam sterilization considering the maximum possible sterilization temperature and with approved biocompatibility. Apply only a small amount to the joints (no complete spraying, grease must not be applied).

Packaging

Pack cleaned and disinfected instruments in single-use sterilization packagings (single or double packaging) and/or sterilization containers, which fulfill the following requirements (material/process):

- EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)
- suitable for steam sterilization (temperature resistance up to at least 142 °C (288 °F), sufficient steam permeability)
- sufficient protection of the instruments as well as of the sterilization packagings to mechanical damage
- regular maintenance according to the instructions of the manufacturer (sterilization container)

Sterilization

Please use for sterilization only the listed sterilization procedures; other sterilization procedures must not be applied.

Steam sterilization

- fractionated vacuum/dynamic air removal procedure[2, 3] (with sufficient product drying[4])
- steam sterilizer according to EN 13060/EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- validated according to EN ISO 17665 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ))
- maximum sterilization temperature 138 °C (280 °F; plus tolerance according to EN ISO 17665)
- sterilization time (exposure time at the sterilization temperature):

Area	fractionated vacuum/dynamic air removal	gravity displacement
USA	at least 4 min at 132 °C (270 °F), drying time at least 20 min[4]	not recommended
Germany	at least 5 min[5] at 134 °C (273 °F)	not recommended
other countries	at least 4 min[5] at 134 °C (273 °F)	not recommended

[2] at least three vacuum steps

[3] The less effective gravity displacement procedure must not be used in case of availability of the fractionated vacuum procedure and requires device, procedure, parameter, and product specific validation under sole responsibility of the user.

[4] The effectively required drying time depends directly on parameters in sole responsibility of the user (load configuration and density, sterilizer conditions...) and by this is to be determined by the user. Nevertheless, drying times less than 20 min must not be applied.

[5] respectively 18 min (inactivation of prions, not relevant for USA)

The fundamental suitability of the instruments for an effective steam sterilization was demonstrated by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory by application of the steam sterilizer HST 6x6x6 (Zirbus technology GmbH, Bad Grund) and the fractionated vacuum/dynamic air removal procedure. For this, typical conditions in clinic and doctor´s practice as well as the specified procedure were considered.
The flash/immediate use sterilization procedure must not be used.

Do not use dry heat sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization, as well as plasma sterilization.

Storage

Please store the instruments in the sterilization packaging at a dry and dust-free place after sterilization.

Material resistance

Attention: The cleaning or disinfection detergent may not contain the following substances listed below:

- organic, mineral, and oxidizing acids (minimum admitted pH-value 5.5)
- lyes (maximum admitted pH-value 8.5 (aluminium instruments, neutral/enzymatic cleaner recommended)) /
  strong lyes (maximum admitted pH value 11 (pure stainless steel instruments, neutral/enzymatic or alkaline cleaner recommended))
- oxidizing agents (for example: peroxide)
- halogens (chlorine, iodine, bromine)

Please consider during selection of the detergents in addition, that corrosion inhibitors, neutralizing agents, and/or rinse aids may cause potential critical remnants on the instruments.
Acid neutralizing agents or rinse aids must not be applied.
Please do not clean any instruments and sterilization containers by use of metal brushes or steel wool.
Please do not expose any instruments and sterilization containers to temperatures higher than 142 °C (288 °F)!

Marking label symbols


Manufacturer


Date of manufacturing

Medical device

Item or order number

Batch number

Inscription for non-sterile products

European approval symbol


Follow the instructions for use


Protect against sunlight


Keep dry


Attention

All serious incidents occurring in connection with the product must be reported immediately to the manufacturer and to the responsible authority of the Member State in which the user and/or the patient is located.


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Specific aspects

Art. no	Article specification	Specific/additional procedure in case of			Packaging	Sterilization	Recommended classification according to KRINKO/RKI/BfArM guidance (only Germany, with respect to intended use)
		Pretreatment	Automated cleaning/ disinfection	Maintenance			
56.210.xx 56.214.xx 56.220.xx 56.236.xx 56.238.xx 56.245.xx 56.246.xx 56.256.xx 56.258.xx 56.260.xx 56.262.xx 56.264.xx 56.265.xx 56.266.xx 56.268.xx 56.269.xx 56.270.xx 56.272.xx 56.274.xx	other rib spreaders / rib contractors (stainless steel)	standard	openings downwards	Lubrication only in the joints!	mounted	mounted	The rating / risk assessment has to be adjusted by the Operator on the basis of the effective field of application.
56.212.xx 56.220.xx 56.230.xx 56.232.xx 56.234.xx 56.242.xx 56.244.xx 56.250.xx 56.251.xx 56.273.xx	other rib spreaders / rib contractors (aluminium, marked)	only neutral-enzymatic cleaning detergents admitted	only neutral-enzymatic cleaning detergents admitted, openings downwards	Lubrication only in the joints!	mounted	mounted	The rating / risk assessment has to be adjusted by the Operator on the basis of the effective field of application.
56.220.xx 56.238.xx 56.245.xx 56.256.xx 56.258.xx 56.266.xx 56.268.xx 56.269.xx 56.270.xx 56.274.xx	single valves (stainless steel) (stainless steel)	standard	openings downwards	Lubrication not admitted!	standard	standard	The rating / risk assessment has to be adjusted by the Operator on the basis of the effective field of application.
56.242.xx 56.244.xx	single valves (aluminium, marked)	only neutral-enzymatic cleaning detergents admitted	only neutral-enzymatic cleaning detergents admitted, openings downwards	Lubrication not admitted!	standard	standard	The rating / risk assessment has to be adjusted by the Operator on the basis of the effective field of application.