

Instructions for Use and general guidelines for reprocessing, maintenance and care

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English

Caution
 Please read all information contained in this insert. Incorrect handling and care as well as misuse can lead to premature wear of surgical instruments.

1 Scope

These operating instructions are applicable for DEWIMED reusable surgical instruments of the risk class 1, as described in part 2 "Intended use" and part 5 "Normal use".

2 Intended use

Surgical instruments as standard instruments for surgical operation application in the human medical general surgery and in several surgical specialist disciplines. The instruments are intended for surgical interventions for grasping, holding, fixing, elevating, clamping, sweeping, spreading, dilating, cutting, punching, drilling, sawing, scratching, rasping, stapling, sewing, tacking or the like. The doctor in charge respectively the user is responsible for the selection of the instruments for specific applications.

3 Indication

For surgical operation application in general surgery and in several surgical specialist disciplines.

4 Contraindication

The instruments are not allowed to be used by direct contact with heart, central circulatory system or central nervous system.

5 Normal use

DEWIMED reusable surgical instruments of risk class I are not used in connection with an active medical device and used over a period of less than 60 minutes (added period of application) during surgical interventions. The instruments were delivered nonsterile and need to process before using according to part 9 "processing". The use of the instruments is only allowed by qualified personnel, which is familiar with the required surgical techniques of these medical devices. Further information for a secure use of the instruments are described in part 7 "Safety notice".

6 Liability / Warranty Claim

DEWIMED Medizintechnik GmbH as manufacturer and seller of these products assumes no liability for immediate or ensuing damages resulting from improper use or handling of the instruments, especially due to failure to use as directed or improper processing and service. If non-authorized persons undertake repairs, alterations of the products, or combination of DEWIMED products with the products of other manufacturer - the manufacturer cannot be held liable; furthermore all right of guarantee are forfeited. Parts having an effect of the safety of the products may be replaced by original parts only. Each repair service or alterations are written down in a protocol.

7 Safety notice

WARNINGS AND PRECAUTIONS!

The following safety aspects must be considered:
 During transportation, cleaning/sterilization and storage, surgical instruments are to be always treated with the greatest care – especially fine tips and other sensitive parts.
 Surgical instruments corrode when coming into contact with aggressive substances. This has negative effects on their function. Therefore, please follow the instructions of the cleaning agents.
 Proper care and service are necessary for the safe use of medical products. Therefore perform a thorough visual inspection of damages (especially porous and cracked rubber and plastic parts), sharp edges and rough surfaces and check also the completeness of the products.
 As a safety measure against potential injuries of patients and users, this check must always be performed after receipt of the instrumentation and before each use.
 The instruments must be kept in clean and dry surrounding. Please ensure sufficient protection of sharp and pointed instruments.
 Due to the way they are constructed, the instruments have only limited stability. Excessive use of force (for example by turning or by levering) can lead to damages and influences the function of the product.

NON STERILE
 The instrumentation is delivered non-sterile. Prior to the first time and subsequent times of use and before sending the products in for repair, the instrumentation has to be prepared according to a validated procedure (DIN EN ISO 17664) (In this regard see Section 9 "Processing"). A visual inspection must be performed before each use (see section 10 "visual inspection").

8 Life Cycle

The expected life cycle of the product up to 5 years, depends of the proper use and the number of cycles. Before each application of the product perform a visual inspection according section 10 "visual inspection".

9 Reprocessing

Proper cleaning, inspection and maintenance will help ensure correct function of the surgical instrument. Clean, inspect and test each instrument carefully. Clean, disinfect and sterilize all instruments before surgery. The instruments are to be taken from their packaging (for the first use). They must be placed in a designated for cleaning / sterilization container / device. If an instrument can be disassembled, it must be cleaned in the disassembled state. Keep all parts together and protected from being misplaced, do not intermix with other or similar devices of other manufacturer.

Warning !

Special attentions throughout the cleaning and sterilization process require the following problem areas in the product:
 - hidden cavities
 - slots
 - stops
 - ends
 - pipe properties
 These sites are particularly difficult to access. For this reason, they must be treated with special care.

REPROCESSING INSTRUCTIONS

Preparation at the Point of Use

Remove gross soiling by submerge the instrument into cold water (<40°C) immediately after use. Don't use a fixating detergent or hot water (>40°C) as this can cause the fixation of residua which may influence the result of the reprocessing process.

Transportation

Safe storage and transportation in a closed container to the reprocessing area to avoid any damage and contamination to the environment.

Preparation for Decontamination

The devices must be reprocessed in an opened or disassembled state.

AUTOMATED CLEANING PROCESS

Pre-Cleaning:

- Brushing

Brush the instrument under cold water with a soft brush until all visible contamination is removed. If possible, dismantle the instrument and brush it with a soft brush under cold water until all visible contamination is removed.

- Rinsing

Rinse instruments with lumen (such as laparoscopic instruments) and Luer-Lock rinse port or adapter for cleaning with Luer Lock connector with the water jet pistol (static pressure above 4 bar) for a minimum time of 10 seconds. Use the water jet pistol to rinse holes, hinges, gaps and cavities. Use the water jet pistol to rinse tubes of flexible instruments.

- Ultrasonic (necessary for instruments with hidden and riveted surface, for example Locking Pliers): Immerse the instrument in cold water for 5 minutes. Then fill in the detergent (0,5 % Neodisher FA, Dr. Weigert) and clean it in an ultrasonic bath (frequency 35 kHz) for at least 10 minutes at 45°C. Avoid sonic Parameters:

- 45°C
- 10 min.
- 0,5 % Cleaning Solution (Neodisher FA, Dr. Weigert)
- 35 kHz

The instrument is taken out of the bath and flushed with a water jet pistol for minimum 20 seconds. Then rinse the instrument with cold tap water again.

Automated Cleaning

Washer/ Disinfector: Miele G 7735 CD (Miele)
 Instrument Rack: E 327-06, E439 (Miele)
 Key Hole Surgery Rack E 450/1 (Miele)
 Detergent: Neodisher FA, Dr. Weigert
 Validation Report: SMP 10109011407

Put the Standard-instruments opened and or, if possible, in a disassembled state on an instrument tray. Put the tray on an instrument rack in the washer disinfector and start the cycle.
 (Put the MIS-instruments opened and or, if possible, in a disassembled state on a special key hole surgery rack. Not suitable instruments are placed on an instrument tray below and start the cycle.)

Step	Time (min)	Process step	Reagents	Temp (°C)
1	1	Pre-cleaning	Tap water	cold
2		Drain		
3	3	Pre-cleaning	Tap water	cold
4		Drain		
5	5	Cleaning	Tap water with 0,5% alkaline detergent (Neodisher FA, Dr. Weigert)	55
6		Drain		
7	3	Cleaning and Neutralization	Tap water	cold
8		Drain		
9	2	Final rinsing	Tap water	cold
10		Drain		

Automated Disinfection

Automated Thermal Disinfection in washer/disinfector under consideration of national requirements in regards to A0-Value (see ISO 15883).

Drying

Drying of outside of instrument through drying cycle of washer/disinfector. Insufflate cavities of instruments by using sterile compressed air.

Visual inspection

Perform visual inspection for cleanliness; if required, perform an assembly and visual inspection according chapter 10. If necessary, repeat the reprocessing process until the instrument is optically clean.

Maintenance

After cleaning and before sterilization, treat all instruments with an oil which is considered as being physiologically safe (paraffin oil according to DAB 8 of Ph. Eur. of USP XX), especially their blades, ends, stops, snaps and all moveable parts. Distribute the lubricant uniformly in the joint by opening and closing the instrument several times. Use only instrument oils, which are approved for sterilization and taking into account the maximum sterilization temperature applied.

Packaging (in case of packaging before sterilization):

Packaging has to comply with ISO 11607 and EN 868 standards for packaging for sterilized instruments.

STERILIZATION

Sterilization of instruments by applying a fractionated pre-vacuum process (according. ISO 13060 / ISO17665) under consideration of the respective country requirements. Parameters for the pre-vacuum cycle:

1. 3 prevacuum phases with at least 60 milli bar
2. Heat up to a minimum sterilization temperature of 132°C; maximum temperature 137°C
3. Minimum Holding time: 3 min (full cycle)
4. Drying time: minimum 1min

Validation: SMP-Report-No.: 28012

Packaging (in case of packaging after sterilization):

Packaging has to comply with standards for packaging for sterilized instruments.

Storage

Sterilized instruments have to be stored in a dry, clean and dust-free area at moderate temperatures from 5°C to 40°C.

MANUAL REPROCESSING

Validation Report No.: 15812

Pre-Cleaning

Immerse the instrument into cold tap water for at least 10 minutes. Activate all movable parts several times up to the stop. Brush the instrument with a soft brush until all visible impurities are removed. Flush the Instrument with a water jet pistol for minimum 20 seconds.

Ultrasonic

Immerse the instrument completely into an ultrasonic bath with enzymatic detergent (0,8%) and treat with ultrasonic (frequency 35 kHz) for at least 10 minutes at 45°C. Avoid sonic shadow.

- Parameters
- 45°C
 - 10 min.
 - 0,8 % Cleaning solution
 - 35 kHz

The instrument is taken out of the bath and flushed with a water jet pistol for minimum 20 seconds. Then rinse the instrument with cold tap water again.

Ultrasonic bath: Bandelin Sonorex RK 1028 H
 Detergent: Cidezyme/Enzol of company ASP (enzymatic)
 Validation: SMP-Report-No.: 15812

Manual Chemical Disinfection

Validation: SMP-Report-No.: 26913

Immerse the instrument completely into a 4%-Mucocit-T solution (Company Merz Hygiene GmbH) at room temperature as specified by the manufacturer.

Drying

Manual drying is carried out using sterile compressed air - in particular take care for drying cavities and channels.

Continuation of the process: Visual inspection, Maintenance, Packaging, STERILIZATION and Storage as described in the above section "AUTOMATED CLEANING PROCESS".

If the chemicals and machines described before are not available, the user is obliged to validate the process used.

10 Visual Inspection

It is very important to carefully examine each instrument for breaks, cracks or malfunctions before use. It is especially essential to check areas such as blades, points, ends, stops and snaps as well as all moveable parts. Check insulation, cables and connectors for cuts, voids, cracks, tears, abrasions, etc. Do not use damaged instruments. Do not use damaged instruments. It is not permissible to use instruments exhibiting damage or pressure points.

11 Repair and modification

Never attempt to perform repairs yourself. Service and repair work may only be performed by persons qualified and trained accordingly. Defective Surgical instruments may be sent to DEWIMED Medizintechnik GmbH for repair. Unauthorized modifications and repairs are strictly prohibited and will entail invalidation of the manufacturer's warranty.

Attention: Defect products must pass the complete reprocessing process and be signed as "hygienically safe" before being returned for repair.

12 Packaging, Storage, Transportation and Handling

Surgical instruments must be stored in a clean and dry environment. They must be individually stored in a protective container with individual compartments or heat-sealed in film. The instruments must always be handled with the utmost care during transportation, cleaning, upkeep, sterilization and storage. This applies in particular for fine tips and other sensitive areas.

13 Returns











Returns will be accepted only if they have passed the complete reprocessing process and are marked appropriately. Returns must be securely packaged for shipping.

14 Disposal

Surgical instruments, the packaging material and the accessories must be disposed of in accordance with the regulations and laws specific to the country in which they are used.

15 About these Instructions of use

Throughout the period of use of surgical instruments, the instructions for Use must be kept freely accessible for every user.

	Note accompanying documents Warning: Failure to comply could result in death or injury		Protect from moisture
	Follow instructions for use		Keep away from sunlight
	Article number		Batch code
	Non-sterile		Manufacturer
	CE-Mark Class I		Do not dispose of residual waste