IFU (GB)

"Reprocessing instructions for reusable surgical instruments"

This product fulfils the regulation MDD 93/42 EEC and 2017/745/EEC on medical devices.

You have decided in favour of a product from the company **Erbrich-Instrumente GmbH**, and we thank you for the trust that you have invested in us.

With the purchase of this instrument, you are receiving a high-quality product, the correct handling and use of which is represented in the following.

To keep hazards for patients and users as low as possible, we request you to carefully observe these instructions. The application, disinfection, cleaning and sterilisation of the instruments must only be performed by trained specialist personnel.

Intended use

These instruments are not connected to an active device and are to be used by trained and qualified medical personnel only.

Cutting: these instruments are for cutting, piercing, drilling, clipping, and performing similar functions on organic and non-
organic materials during surgery.

Scraping: These instruments are for scraping, scratching, and general surface removal of organic and non-organic materials during surgery.

Driving: These instruments are designed to direct, guide threads, wires, instruments, or other objects to facilitate the attachment or positioning of them onto organic and non-organic materials during surgery or are for applying non lateral force on and manipulating screws and bolts for surgical and clinical purposes

Impacting: These instruments are for applying impacting or crushing force onto organic and non-organic materials during surgery.

Holding: These instruments are for holding, guiding, bending, and basic manipulation of organic and non-organic materials during surgery.

Re-Distracting: These instruments are for retracting, distracting, compressing, or generally holding back organic and non-organic materials during surgery.

Diagnosing: These instruments are for qualitative diagnosing and examination of patients' anatomy and physiology for surgical and clinical purposes.

Indication:

These instruments are to be used by medical professionals only for the intended use of general surgery or clinical use.

Contraindications:

1. Local infection through poor soft tissue conditions in the area of the osteotomy.
2. Increased fibrous tissue around the operation site.
3. Early or late deep and/or surface infection.
4. Nerve damage is possible as consequence of a surgical intervention.
5. Failure of use through insufficient healing phase before the load.

Warnings:

These devices are not sold sterile. These devices must be cleaned, disinfected, sterilized, and inspected before use. Instruments made of different metals should be treated separately to prevent electrolytic reactions between metals. These devices must be disposed of if used on a patient with a prion disease, such as Creutzfeldt-Jakob Disease. As cutting instruments, the user must be careful when using these devices in order to avoid damaging crucial tissues.

The products of **Erbrich-Instrumente GmbH** may under no circumstances be combined with products and components of other manufacturers. Combinations with products from other manufacturers can have a negative impact on the result of the procedure and are not permitted because the components used may not be coordinated with each other. It is recommended to use only the instruments and accessories of **Erbrich-Instrumente GmbH** during use.

Intended Patient group

These devices are intended with all patient groups of all ages, as long as no contra-indications present themselves and the warnings are considered.

Medical conditions to be treated

Medical conditions to be treated by these devices will be determined by the medical professionals planning and performing the operations or clinical use, as these are general surgical instruments.

Materials

The used materials are stainless steels according to DIN EN ISO 7153-1

Control

Before and after every use, the instruments must be checked for their functionality.

Damages on the surface, such as scratches, cracks, notches, grooves, etc. as well as bent components indicate that they cannot be used. The products must then be repaired or are to be forwarded to the normal hospital disposal system. Do not undertake own repair attempts.

Instructions for automated reprocessing

Introduction

According to ISO 17664 [1], each manufacturer who distributes medical devices intended to be reprocessed, must provide a manual for the processing of the product. Information on processing given in the manual must be validated. The processing was started, validated by the "Clean-Controlling Medical" accredited laboratory.

Chemicals and Media

- Cleaning detergent: Neodisher Mediclean forte 0,5 % (v/v)
- Neutralization agent: Neodisher Z 0,1 % (v/v)

Devices

- Brushes: Interlock cleaning brush – double sided REF 09098 green
- Steam autoclave: Lautenschläger ZentraCert
- Washer-disinfector unit (RDG): Miele PG 8535

Reprocessing cycles

Due to the product design and the used materials no defined limit of the maximally performable reprocessing cycles can be specified. The end of the product life cycle is normally determined by the wear and tear and damage through the use.

Preparation on site

If possible, the instruments should be disinfected and cleaned immediately after use. Remove coarse contaminations from the instruments directly after the application. The contaminations should not dry on the objects, to not additionally impede the disinfection and the cleaning process. Do not use any fixing agents or hot water (> 40°C), as this leads to the fixing of residues and can influence the success of the cleaning. The instruments must under no circumstances be deposited in physiological saline solution, as longer contact leads to pitting corrosion and rust.

Pre-cleaning

- Soaking of the test items in cold tap water (<40°, according to drinking water ordinance) for 5 minutes
- Brushing the test items with a soft nylon brush under water until visibly clean

Recommended methods:

Step	Parameter	
Cleaning	Cleaning temperature	55°C
	Soaking time	300 s (worst case condition ERBRICH Instrumente GmbH) RKI recommendation 600 s
	Cleaning detergent	Neodisher Mediclean Forte
	Concentration	0,50 % (Lower quarter of usable conc. given by manufacturer) Standard (by Miele): 0,70 %
Neutralization	Rinsing temperature	Cold DI water < 15°C
	Soaking time	120 s
	Neutralization agent/	Neodisher Z
	Concentration	0,10%
Post-rinsing	Rinsing temperature/	Cold DI water < 15°C
	Soaking time	120 s
Thermal desinfection	Disinfection temperature	90°C ± 1°C (A0 3000)
	Soaking time	300 s
Drying	Adequate drying must be ensured by the system used	at 100°C ± 1°C for at least 30 min
Sterilisation/Autoclaving STERILISER; Steam autoclave Appropriate packaging for sterilisation according ISO 11607 and EN 868	Temperature	134°C ± 1°C
	Pressure:	2-3 bar (20 to 30 psi)
	Sterilization time	5 to 15 minutes

Instructions for manual cleaning and disinfection

Introduction

According to ISO 17664 [1], each manufacturer who distributes medical devices intended to be reprocessed, must provide a manual for the processing of the product. Information on processing given in the manual must be validated. The processing was started, validated by the "Clean-Controlling Medical" accredited laboratory.

Chemicals and Media

- Cleaning detergent: Neodisher Mediclean forte 0,5 % (v/v)
- Neutralization agent: Neodisher Z 0,1 % (v/v)

Devices

- Brushes: Interlock cleaning brush – double sided REF 09098 green
- Steam autoclave: Lautenschläger ZentraCert
- Washer-disinfector unit (RDG): Miele PG 8535

Recommended methods:

Step	Parameter	
Manuell Cleaning	Disassembly of the test items as far as possible, opened position of joints and jaw parts.	
	Soaking of the test items in cold tap water.	<40°, according to drinking water ordinance for 5 minutes
	Brushing the test items with a soft nylon brush under water until visibly clean	
	Ultrasonic treatment of the test items.	For 20 minutes in cleaning solution (0,5% neodisher MediZym in DI water)
	Brushing the test items with a soft nylon brush until visibly clean.	
	Soaking of the test items in cold DI water.	For 2 minutes
	Rinsing of the test items with cold DI water	For 1 minute
Then check the instruments visually for cleanliness		
Manual disinfection	Soaking of the test items in disinfection solution	(1% Bomix® plus solution) for 15 minutes, moving of movable parts 5 times each at beginning and end of the disinfection
	Rinsing the test items DI water	For 1 minute
Drying	Drying of the test items using filtered air pressure	
Sterilisation/Autoclaving STERILISER; Steam autoclave Appropriate packaging for sterilisation according ISO 11607 and EN 868	Temperature	134°C ± 1°C
	Pressure	2-3 bar (20 to 30 psi)
	Sterilization time	5 to 15 minutes

Other information

The certification of the fundamental suitability of the instruments for an effective manual as well as automated reprocessing procedure has been substantiated and validated through the accredited testing laboratory Clean Controlling, hereby the above-described procedures have been taken into account.

The application of other different type cleaning and disinfection agents takes place outside of the responsibility of the manufacturer. The recommendations of the cleaning agent manufacturers have to be observed.

The reprocessing party carries the responsibility that the performed reprocessing (manual or automated) with the applied equipment, materials and personnel at the reprocessing facility achieves the desired results. Should the user deviate from the specified procedure, then the selected procedure must be validated by the user.
Disinfection and cleaning solutions are to be used that are freshly prepared daily. The residues from the cleaning process must be reliably removed, as otherwise stains and/or discolorations occur on the instruments.

Reprocessing validation study information
The following testing test devices, materials & machines have been used in the validation studies;

Manual Cleaning:

Detergent:	Neodisher Medizym 0,5 % (v/v)
Ultrasonic bath	ELMA Elmasonic S300H

Manual Disinfection:

Disinfectant:	Bomix® plus, BODE Chemie 1 % (v/v)

Automated Cleaning:

Ultrasonic bath	ELMA Elmasonic S300H
Detergent:	Neodisher Mediclean Forte
Neutralisation:	Neodisher Z
Washer / Disinfector:	Miele PG 8535

Sterilisation:

Autoklave:	Systec DX-45
Steril packaging	hospital common sterilization packaging (paper/film packaging) according to ISO 11607 and EN 868

Service shipping for repair at Erbrich-Instrumente GmbH

Instruments for repair, respectively for servicing will only be accepted if these have been cleaned, disinfected and sterilised according to the reprocessing instructions described above. A corresponding statement, respectively certification is to be enclosed with the return shipment.

Misuse

The instruments must be exclusively used as intended in the specialist medical areas through correspondingly trained and qualified personnel.
The treating physician, respectively the user is responsible for the selection of the instruments for certain applications, respectively the surgical application, the appropriate training and information and the sufficient experience in the handling of the instruments.
Misuse, deficient care and reprocessing, incorrect handling, misappropriation and modifications to the instrument can severely impair its usability, cause damage and be the reason for serious injuries of the patient and user.

Guarantee

The products are manufactured from high-quality materials and are subject to a quality control before the delivery. If defects should nevertheless occur, then contact our service department.
We are however not able to undertake any guarantee that the products are suitable for the respective intervention. This must be ascertained by the user.
Erbrich-Instrumente GmbH does not undertake any liability if these instructions have not been observed.

Storage and transport

Storage and transport of sterilized instruments in a dry, clean and dust free environment at modest temperatures.

meaning of the symbols on the Label

LOT	Indicates the manufacturer's Batch/ Lot code so that the batch or lot can be identified		Indicates the medical device manufacturer
REF	Indicates the manufacturer's catalogue number so that the medical device can be identified		
NON STERILE	Indicates a medical device that has not been subjected to a sterilization process		
CE	CE Label		
	Indicates the medical device manufacturer		
Vor Sonne schützen	Protect from the sun		
	Store dry		

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