Ortho Medical GmbH
Hauptstraße 5
D-78589 Dürbheim
Germany
Phone 07424/9403-0
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www.orthomedical.de

Instructions for use

Reusable surgical instruments

This product fulfils the directive EU-2017/745 about medical devices.

You have decided in favour of a product from the company Ortho Medical 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 the instructions for use. The application, disinfection, cleaning and sterilisation of the instruments must only be performed by trained specialist personnel.

Tests

Before every use, the instruments must be checked for their functionality.
Damage on the surface, such as scratches, cracks, notches, grooves, etc. as well as bent components indicate that they must not be used. The products must then be repaired or are to be forwarded to the normal hospital disposal system. Do not use any damaged products!

Application area

We manufacture our instruments as standard instruments for surgical application in general surgery. The treating physician is however responsible for the selection of the instruments for certain applications, respectively the surgical application. The physician is also responsible for an appropriate training and sufficient information of the surgery personnel, and for sufficient experience in the handling of the instruments.

Handling

The instruments must not be overloaded through twisting or levering as this can lead to damage or to fracturing of instrument components.

Indication / Intended use:

The application of the product described below must only be performed through specialist personnel correspondingly trained and qualified to do this. These instructions for use cannot replace the training, care and the status of the technical understanding with the user. Instruments and accessories are intended for multiple usage. The instruments can be used individually for surgical application or be used as a component in a surgery set. Thereby attention must be given that the application purpose of the instrument of the company Ortho Medical is observed**.**

Wire cutting pliers	➡ To cut wires of different Ø
Bone holding forceps	➡ To hold bones (reposition forceps)
Rongeur	➡ To cut intervertebral discs, to expose the intended areas for the operation.
Raspatorium	➡ To push off the soft tissue from the bone and periosteum ("bone scraper")
Dilatator	➡ To dilate (bougienage) existing body openings (e.g. urethra, anus, oesophagus, vagina, cervix)
Rectum clamp	➡ To hold, clamp e.g. the large intestine
Pincettes	➡ To hold, grip or press tissue, organs, intestinal structures, etc. together
Retractor	➡ To hold tissue away, hold wounds open, or to expose internal tissue or organs
Osteotome	➡ To lift the periosteum
Container	➡ For storage of instruments in general, or to store instruments during sterilisation

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2. Contraindications:

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

Possibly occurring complications are in most cases not directly associated with the use of an instrument, but are more probably caused through the incorrect selection of the patient, through inadequate training, as well as through imprecise handling. With the exertion of too large forces unintended injuries of the tissue or the bones can lead to impairments, or even cause a fracture of the instruments. A cautious application of the instruments is therefore absolutely necessary.
To exclude a complication through damage of the instruments, the used material must always be checked before the application. The application of the instruments must only take place through trained personnel.

Combination with other products / instruments

The products from the company Ortho Medical GmbH must under no circumstances be combined with products and components from other manufacturers. Combinations with products from other manufacturers can negatively influence the result of the intervention and are not permitted as the used components may possibly not match each other. During application it is recommended to exclusively use the instruments and accessories from the company Ortho Medical GmbH.

Correct disposal of the instruments

Insofar as the instruments are no longer able to be used due to wear or damage, these are to be subject to correct disposal. This means that the instruments are to be disassembled (as far as possible) and the contaminations removed, and that the instruments are to be sterilised once again before the disposal. (See instructions on conditioning)

Materials

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

4. Application

Caution! The instruments must not be overloaded through twisting or levering as this can lead to damage or to fracturing of instrument components.

5. Control

Perform checks before and after every application. No longer use products that are damaged, incomplete or have loose components. Send damaged products with the loose components for repair. Do not undertake own repair attempts.

- Check products for damage, sharp edges, loose or missing components and rough surfaces.
- The opening and closing must move smoothly.

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Instructions for machine reconditioning

Reconditioning cycles	Due to the product design and the used materials no defined limit of the maximally performable reconditioning 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, so as 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	Deposit instruments in cold water for at least 5 minutes. Clean instruments under cold water with a soft brush until residues are no longer visible. Deposit instruments for 15 min in an ultrasonic bath in demineralised water at 40°C with 0.5% alkaline cleaning agent and start the ultrasonic treatment. Ultrasonic frequency at least 35 kHz. Remove instruments and rinse with cold water.
Recommending cleaning method:	Perform the cleaning at 55°C ± 2°C for at least 5 minutes. For machine cleaning of both thermally stable and thermally labile instruments we recommend the alkaline cleaning agent neodisher ® MediClean forte; 0.5% in the machine (pH of approximately 10 measured in the rinsing liquid). If elevated chloride concentrations are present in the water, then pitting corrosion and stress corrosion cracking can occur in the instruments. Through the use of alkaline cleaners or the application of completely demineralised water this type of corrosion can be minimised. The cleaning result is to be verified through a visual control. The instruments must be visually clean, if applicable, the procedure must be repeated.
Intermediate rinsing (neutralisation)	Through the addition of a neutralisation agent on acid basis the rinsing of alkaline cleaning agent residues is facilitated. With the application of neutral cleaning agents with unfavourable water quality, e.g. with high mineral content, the application of a neutralising agent is also recommended to prevent the formation of deposits. It is recommended to perform the neutralisation with Neodisher ® Z, in cold water 0.1%.
Thermal disinfection Final rinsing	Perform the thermal disinfection at 90°C ± 2°C for a least 5 min (A0-value of >3000). For the disinfection we recommend e.g. the disinfection agent BBraun Meliseptol Rapid. Under all circumstances a RKI-listed agent should be used
Drying	A sufficient drying is to be ensured through the cleaning and disinfection device or through other suitable measures. Perform the drying at 55-60°C for approximately 30 min. Should there still be any residual moisture present then a subsequent drying can be performed in the drying cabinet at 60°C. However, the drying time depends on the loading, as well as the items for rinsing.
Autoclaving	STERILISER Steam autoclave: Temperature: 132° to 135° centigrade, pressure: 2-3 bar (20 to 30 psi) with a reaction time of at least > 5 to 15 minutes.

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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. With longer term use the following problems can arise: Hazard of corrosion through contamination, hazard of corrosion with increased concentration through evaporation, reduction of the disinfection effect through contamination. The residues from the cleaning process must be reliably removed, as otherwise stains and/or discolorations occur on the instruments.

Instructions for manual cleaning and disinfection

In the selection of the applied cleaning and disinfection agents attention is to be given

- that these are principally suitable for the cleaning, respectively disinfection of instruments made of metals and plastics,
- that the cleaning agent – if applicable – is suitable for the ultrasonic cleaning (no foam development), we recommend the cleaning agent BONDERITE C-NE 20
- for the manual pre-cleaning of medical instruments, we recommend the disinfection agent ECOLAB Sekusept® MultiEnzyme P
- that the applied chemicals are compatible with the instruments (see chapter "Material durability“).

If possible combined cleaning/disinfection agents should not be used. Only in cases with very low degree contamination (no visible contaminations) can combined cleaning/disinfection agents be applied. The concentrations and exposure times of the cleaning and disinfection agents specified by the manufacturer must be specifically observed.

Procedure cleaning

(1) Disassemble the instruments as far as possible (if intended for this by the manufacturer); respectively open the joints, jaw components as far as possible.

(2) Products must be rinsed under flowing city water (>50°C) until all visible contaminations have been removed. If necessary a soft brush should be used to remove visible contaminations.

(3) Place the instruments in the cleaning bath for the specified exposure time (recommendation of the manufacturer) so that the instruments are sufficiently covered. If possible an ultrasound supported cleaning is preferable (1 x precleaning / 1.5 minutes, 1 x fine cleaning / 1.5 minutes, respectively with 45 kHz). Thereby make sure that the instruments do not touch each other.

(4) Subsequently remove the application forceps from the disinfection bath and rinse these thoroughly for at least 1 min under flowing demineralised water, or in a basin filled with demineralised water > 40°C.

(5) Check the application forceps (see tests).

Procedure disinfection

(1) Place the cleaned and tested instruments in the disinfection bath for the specified exposure time so that the instruments are sufficiently covered. Thereby make sure that the instruments do not touch each other. Move movable parts backwards and forwards at least five times at the beginning and at the end of the exposure time.

(2) Subsequently remove the instruments from the disinfection bath and rinse these thoroughly for at least 1 min under flowing demineralised water, or in a basin filled with demineralised water > 40°C.

(3) Dry the instruments through blowdown/blowout with filtered compressed air.

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Other information

The certification of the fundamental suitability of the instruments for an effective manual as well as machine reconditioning procedure has been substantiated through the accredited testing laboratory Clean Controlling. Hereby the above-described procedure has 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 manufacturer are to be observed.

The reconditioning party carries the responsibility that the actually performed reconditioning (manual or machine) with the applied equipment, materials and personnel at the reconditioning facility achieves the desired results. For this usually validation procedures and routine monitoring of the procedure are necessary.

Service shipping for repair at Ortho Medical GmbH

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

Use as intended / 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 reconditioning, 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.
Ortho Medical GmbH does not undertake any liability if these instructions for use have not been observed.

Storage and transport

- Temperature: -20°C - +50°C;
- Relative air humidity: 0 - 75%, non-condensing;
- Air pressure: 500 - 1600 hPa.

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Meaning of the symbols

	Product is delivered non-sterile		**Article number**
	Attention! Observe notes		**Lot. No. / Batch No.**
	Observe instructions for use		**CE label.**
	Manufacturer		