ORTHOMEDICAL GmbH
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Instructions for use

Reusable surgical instruments

This device complies with Directive 93/42/EEC and Directive 2007/47/EC concerning medical devices.

Thank you for the confidence you have shown in us by deciding on a product from ORTHO-MEDICAL GmbH.
By purchasing this product you have acquired a high-quality instrument, the proper handling and use of which are explained in more detail below.

To minimise the risks to patients and users, please read and follow these instructions for use carefully. The instruments must only be used, disinfected, cleaned and sterilised by properly trained specialists.

Checks

The instruments must be checked to be in full working order before every use. If there is any damage to their surfaces, such as scratches, cracks, nicks and dents, etc., or any parts are bent, they must not be used further. The instruments must then be repaired or disposed of following the standard procedure in the hospital. Never use damaged instruments!

Field of application

We produce our instrument range as a standard instrument range for use in general surgery. However, the attending doctor is always responsible for selecting the instrument range to use for certain applications, e.g., the surgical intervention. The doctor is also responsible for the appropriate training of and provision of information to the surgical team and for having sufficient experience in the handling of the instruments.

Handling

The instruments must not be overloaded by twisting or levering, as this can damage or even break the instrument parts.

Risks

If the instruments are not handled carefully, the follow risks may arise:

- Injuries to nerves, vessels and tissue
- Haemorrhaging
- Infections

Period of use: Temporary (< 60 Min. under normal conditions) as per Directive 93/42/EEC).

1. Indications:

For operative use of different surgical disciplines by correspondingly trained and qualified personnel.

3. Contraindications:

- CJD – Creutzfeldt-Jakob disease
- Bovine spongiform encephalopathy (BSE); mad cow disease (e.g., Creutzfeldt-Jakob disease)
- TSE – Transmissible spongiform encephalopathy

The responsible doctor must decide based on the patient's general condition whether the foreseen application can be performed or not. Further information can be found in specialist literature.
If Creutzfeldt-Jakob disease is suspected or diagnosed, measures must be taken to prevent possible transmission to other patients, users and third parties. We reject all responsibility for reuse of instruments used on patients with Creutzfeldt-Jakob disease or an HIV infection.

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Combination with other products / instrument ranges

Products from ORTHO-MEDICAL GmbH must not be combined with products and components from other manufacturers under any circumstances. Combinations with products from other manufacturers can have a detrimental effect on the result of the intervention and are not permitted as the individual components may not be optimally matched.
We thus recommend exclusively using instruments and accessories from ORTHO-MEDICAL GmbH.

Disposal

If it is no longer possible to repair or prepare the instruments, they should be disposed of following the standard procedure in the hospital.

Shipping to repair at Ortho Medical GmbH

There are only instruments for repair or for service accepted if they have been cleaned, disinfected and sterilized according to the preparation instructions outlined above. An appropriate statement or proof must be enclosed with the returned item.

Materials

The materials used are stainless steels as per DIN EN ISO 7153-1.

4. Application

Caution! The instruments must not be overloaded by twisting or levering, as this can damage or even break them.

5. Inspections

Inspect the products before and after each use. Products which are damaged, incomplete or display loose parts must not be used. Damaged products with loose parts should be sent in for repair. Do not attempt to perform any repairs yourself.

- Check the products for damage, sharp edges, loose or missing parts and rough surfaces.
- The products should open and close smoothly.

Preparation instructions

Preparation cycles	Due to the product design and materials used, it is not possible to specify a defined maximum limit of preparation cycles which can be performed. The end of the product's life cycle is usually determined by wear and tear and damage caused by use.
Preparation at the site of use	Wherever possible, the instruments should be disinfected and cleaned immediately after use. Remove soiling from the instruments directly after application. Do not allow contaminants to dry onto objects, as this will make disinfection and cleaning more difficult. Do not use any fixing agents or hot water (>40°C), as this will fix the residues and affect the cleaning results. Under no circumstances should instruments be placed

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	in physiological saline solution, as prolonged contacted can result in pitting and rust.
Precleaning	Immerse the instruments in cold water for at least 5 minutes. Clean the instruments under cold water with a soft brush until no more residues are visible. Place the instruments in an ultrasound bath full of demineralised water at 40°C with 0.5% alkaline cleaner and clean with ultrasound for 15 minutes. Ultrasound frequency at least 35 kHz. Remove the instruments and rinse off with cold water.
Recommended cleaning methods:	Perform cleaning at 55°C ± 2°C for at least 5 minutes. For machine cleaning of thermostable and thermolabile instruments we recommend the alkaline cleaner neodisher® MediClean forte; 0.5% in the machine (measured pH value of approx. 10 in the liquid). If the water contains higher levels of chloride, pitting and stress crack corrosion may appear on the device. Using alkaline cleaners or demineralised water can minimise these types of corrosion. The results of the cleaning must be checked by means of a visual inspection. The instruments must be optically clean; repeat the procedure if necessary.
Intermediate rinsing (neutralisation)	Adding an acid-based neutraliser facilitates the rinsing off of the alkaline cleaner residue. We also recommend the use of a neutraliser when using neutral cleaners if the water quality is poor, e.g., has a high sodium content. We recommend performing the neutralisation with Neodisher® Z, in cold water, at 0.1%.
Thermal disinfection, final rinsing	Perform thermal disinfection at 90°C ± 2°C for at least 5 minutes (A0 value of >3000). For the disinfection we recommend, for example, disinfectants such as Braun Meliseptol Rapid. In any case, an RKI-listed agent should be used.
Drying	Sufficient drying must be guaranteed by the washer and disinfector or other suitable measures. Perform drying at 55-60°C for approx. 30 minutes. If there is any residual moisture, a second drying phase can be performed in a drying cabinet at 60°C. However, the drying period depends on the loading and the goods being rinsed.
Autoclaving	STERILISER: Steam autoclave: Temperature: 132° to 135°C, pressure: 2-3 bar (20 to 30 psi) with an exposure time of at least > 5 to 15 minutes.
	If the user deviates from the specified procedure, the selected procedure must be validated by the user. Disinfectant and cleaning solutions should be prepared fresh every day. Prolonged use could result in the following problems: Risk of corrosion due to contamination, risk of corrosion due to evaporation, reduction in disinfection effect due to contamination. The residue from the cleaning process must be reliably removed as otherwise patches and/or discolouration may appear on the instruments.

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For this reason, the manufacturer accepts no responsibility for the use of other different types of cleaning and disinfectant agents. The cleaning agent manufacturer's recommendations must be followed.

It is the responsibility of the person performing the preparation to ensure that the preparation actually performed with the equipment, materials and personnel employed in the preparation facility achieves the required results. This normally requires the validation and routine monitoring of the procedure.

Professional disposal of instruments

If the instruments can not be used through wear or damage to, these must be disposed of properly. This means that the instruments (if possible) disassembled, removed the impurities and the instruments must be sterilized prior to disposal again. (see instructions for preparation

Guarantee

The products are manufactured from high-quality materials and subjected to quality controls before delivery. Should errors nevertheless occur, please consult our Service department.
However, we are unable to offer any guarantee for whether the products are suitable for the respective intervention. The user must determine this on his/her own.
ORTHO-MEDICAL GmbH accepts no liability in cases where there is evidence that the instructions for use have not been followed.

Storage and transport

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

Meaning of the symbols

Product is **not** delivered in sterile condition

Attention Observe notes

Follow instructions for use