

Instructions for Use - Instruments

Use of Reciprocating Keel Blades for bone surgery

The instruments manufactured by Gomina AG are made from high-quality, corrosion-resistant materials. Only appropriate handling of these quality instruments will ensure the best results. Therefore, it is important to observe and comply with the following instructions for use and safe handling.

The surgical instruments have been developed especially for surgeons for the mechanical treatment of bones. These medical devices may only be sold to, or on behalf of, physicians. Before using the instruments, make sure that the surgical team and theatre staff have been adequately trained and made aware of the potential hazards.

Improper use may result in tissue damage, pre-mature wear and tear or destruction of the instruments and may present a risk to the safety of the user, patient or other parties.

Proper use

All instruments must only be used with the designated and properly fitting handpieces/drives in accordance with the handpiece/drive manufacturers' Instructions for Use (IFU).

Make sure that the instruments are only mounted in technically and hygienically well-maintained and cleaned handpieces/drives. To avoid damaging the instrument or causing injury to the patient/user, make sure that the instruments are always correctly inserted and tightened in accordance with the device manufacturer's instructions. The groove can be made using a template. The implant manufacturer ensures the template dimensions. The length and depth of the groove made in the bone are defined by the template.

Before sawing, the saw blade must be placed centrally in the groove of the template. The bone material along the template groove is then removed and the groove in the bone bed prepared by gradually milling along the entire length of the groove until there is flush contact with the template. Avoid tilting, levering or bending (risk of fracture) while using the instrument. Where templates are used (for example with knee endoprosthesis), only saw blades with a cut thickness that does not exceed the corresponding template thickness must be used. Prior to using the instrument on the patient, ensure the free and uninterrupted movement of the saw blade in the template. The saw blade must only be activated after its insertion into the template.

Strictly avoid tilting, levering or bending the saw blade (risk of fracture) during the sawing process with the aid of a template. Contact of the saw blade serrated edge with the template, a saw block or other metallic objects must be strictly avoided. Any contact with such objects will result in damage to the instrument, template or saw block. Damaged cutting teeth may also result in causing inadvertent injury to bones and surrounding tissue parts. Damaged accessories must be replaced immediately and must not be reused. Always keep appropriate saw blades in reserve in order to avoid any delays during an ongoing operation. Vulnerable patient areas must be adequately protected.

Risks/complications

Bleeding, damage to vessels or nerves, infections, heterotopic ossification, damage to soft tissue, mechanical and thermal tissue damage. In the case of severe osteoporosis, chipping at the cutting surfaces may occur. Pseudoarthrosis and reoperation, injury to the surgeon or theatre personnel, contamination through aerosol formation at the operating site, dispersion of metal particles around the operation site in the event of a fracture of the saw blade are potential risks which can be prevented by correct use of the devices.

Indications

GOMINA saw blades are designed for working on bones in orthopedics and surgery.

Contraindications

The general contraindications for orthopedic surgical interventions must be observed.

Pressure forces

Excessive pressure forces must be strictly avoided.

Such forces lead to thermal necrosis or undesirable rough surfaces due to chipped edges. In extreme cases, the device may fracture. Excessive pressure forces will shorten the lifespan of the devices.

Cooling

Ensure sufficient cooling with a commercially available isotonic saline solution NaCl to prevent the unwanted generation of heat.

Worn cutting teeth tend to be the cause of excessive generation of heat. This will result in insufficient removal of bone shavings which can become lodged in the saw edges thereby further diminishing the sawing performance. The increased generation of heat created in this way can lead to irreversible damage to bone tissue (thermal necrosis).

Single Use

The reciprocating keel blades are intended for single use only. This is indicated by the symbol ☉ and is displayed on the saw blade. Saw blades that have already been used or are damaged must not be used again. Multiple usage will lead to an increased risk for patients and to poor surgical results. The user is not able to check the sharpness adequately after use. In addition to the cutting performance and associated directional stability of the guide, it is not possible to ensure the precision of the groove. Multiple usage results in increased pressure forces and therefore increases the working temperature. This may result in thermal necrosis, fractured instruments and danger to the patient and user.

Storage, disinfection, cleaning, disposal

The instruments must be stored at room temperature in their original packaging and must be protected from dust and humidity until they are used for the first time. After use, the instruments must be cleaned and disinfected and properly disposed of.

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Safety and liability

The user is responsible for examining the product prior to use with regard to its suitability and fitness for purpose. Application of the instruments is the sole responsibility of the user. The user and operating staff must use appropriate eye protection when using the instruments.

Gomina AG shall not be liable for any damage caused by improper use of the instruments or failure to observe the instructions for use or warnings.

Symbols



┌ ┘ Indicates the date of manufacture of the medical device.



┌ ┘ Indicates the date after which the medical device must no longer be used.



┌ ┘ Indicates the manufacturer's batch ID so that the batch or lot can be identified.



┌ ┘ Indicates the manufacturer's order number so that the medical device can be identified.



┌ ┘ Indicates a medical device that has been sterilised by radiation.



┌ ┘ Indicates a medical device that has not undergone a sterilisation procedure.



┌ ┘ Indicates a medical device that is intended for single use only.



┌ ┘ Indicates the necessity for a user to refer to important safety-related details in the Instructions for Use such as warnings and precautionary measures which, for a variety of reasons, cannot be displayed on the medical device itself.

Procedure

1. The label on the sterile instruments is detachable and can be attached to the patient's file.
2. Ensure, as part of the preparations before use, that the instrument is compatible with the drive unit.
3. The packaging must be examined prior to opening. The content of the packaging is sterile/clean if the package does not show any signs of damage and the expiry date has not been exceeded. The content must not be used if the packaging is damaged.
4. Remove the instrument from the packaging and place in the sterile environment in accordance with the relevant instructions.
5. Examine the instrument with regard to its general condition and state. Do not use any instruments that show signs of damage.
6. Place/push the instrument into the drive unit and tighten sufficiently.
7. Proceed in accordance with the operation protocol.
8. Adequately protect the patient's tissue during the operation.
9. Ensure continuous flushing during the operation.

Manufacturer's contact details

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