

Instructions for Use - Instruments

Use of saw 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 and/or separation of bones. These medical devices may only be sold to or on behalf of physicians and are intended solely for use in operating theatres. 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. The sterile saw blade packaging must be inspected prior to opening. The contents of the packaging are sterile, if the packaging is undamaged, the expiry date has not been exceeded and storage conditions were not violated. If the packaging is damaged, its contents must not be used. Packaging that was opened unintentionally must also be discarded and may not be used.

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 instruments must be activated before making any contact with the bone. Avoid tilting, levering or bending (risk of fracture) while using the instrument.

Where resection 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 resection template.

Strictly avoid tilting, levering or bending the saw blade (risk of fracture) during the sawing process with the aid of a resection template.

Contact of the saw blade cutting edge with the resection 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 oral and maxillofacial 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).

Discarding of worn and damaged instruments

The use of saw blades with blunt, bent or chipped teeth must be discontinued. The use of such devices will lead to increased risks for patients and to poor surgical results. They induce increased pressure forces and therefore increase the working temperature. This may result in thermal necrosis, fractured instruments and danger to the patient and user.



Caution

Consult the Operating Instructions of the machine manufacturer.

Processing at the place of use (disinfection, cleaning, sterilization), storage/warehousing, transport and disposal

Saw blades supplied sterile

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. The saw blades are sterilized using gamma ray treatment. They are sterile packed in double packaging (primary packaging), the secondary packaging consists of a folding box. After use, the instruments must be cleaned and disinfected with appropriate disinfectant and cleaning agents.

If, after their first use, the saw blades are still in perfect condition, they may continue to be used at the user's risk after they have been treated in accordance with the GOMINA Instructions for Treatment (saw blades with blunt, bent or chipped teeth must be discontinued).

Saw blades supplied unsterile:

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. Prior to their first use, the instruments must be treated as described in the GOMINA Processing Instructions.

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Suitable disinfectants and cleaning agents with corrosion protection must be used for this.

The subsequent storage must be in hygienically maintained stands, trays or other suitable containers.



Caution

For sterilization: EN ISO 17665-1

Consult the GOMINA Processing Instructions.

Disposal

The instruments must be disposed of safely according to the applicable regulations (biologically contaminated material). Incorrect disposal may result in infections or microbiological hazards as the instruments may have been contaminated with infectious matter of human origin.

For sharp edged devices such as saw blades, the respective disposal areas must be protected. In this case, the infection, environmental and physical hazards must be considered during disposal.

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.

All serious incidents related to the product must be reported to the manufacturer and the responsible national authority.

Symbols



Consult the Instructions for Use or electronic Instructions for Use.

Indicates the need for the user to consult the Instructions for Use.



Date of Manufacture

Indicates the date, on which the medical device was manufactured.



Use-by date

Indicates the date, after which the medical device is not to be used



Batch code

Indicates the manufacturer's batch code, so that the batch or lot can be identified.



Catalogue number

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.



Double sterile barrier system

Indicates two sterile barrier systems.



Sterilized using irradiation

Indicates a medical device that has been sterilized using irradiation.



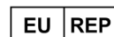
Caution

indicates that the Instructions for Use contain cautionary information such as important safety-related warnings and precautionary measures, which, for a variety of reasons, cannot be displayed on the medical device itself.



Manufacturer

Indicates the manufacturer of the medical device



Authorized representative

in the European Community

Indicates the authorized representative in the European Community



Do not use, if the packaging is damaged and consult the Instructions for Use.

Indicates a medical device that should not be used if the packaging has been damaged or opened and that the user should consult the Instructions for Use for additional information.



Medical device

Indicates that the product is a medical device.



0482 CE Conformity mark

Regulated by European legislation



Quantity

Indicates the quantity of the medical devices.

Procedure

1. The instruments must be inspected for mechanical defects such as tears, nicks or similar damage prior to use.
2. The label on the sterile instruments is detachable and can be attached to the patient's file.
3. Ensure, as part of the preparations before use, that the instrument is compatible with the drive unit.
4. 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

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5. has not been exceeded. The content must not be used if the packaging is damaged.
6. The instrument may be reused (see GOMINA Instructions for Treatment).
7. Remove the instrument from the packaging and place in the sterile environment in accordance with the relevant instructions.
8. Examine the instrument with regard to its general condition and state. Do not use any instruments that show signs of damage.
9. Place/push the instrument into the drive unit and tighten sufficiently.
10. Proceed in accordance with the operation protocol.
11. Adequately protect the patient's tissue during the operation.
12. Ensure continuous flushing during the operation.

Contact



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