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 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 reciprocating keel 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 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 risks 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.

⚠ **Caution**
Consult the Operating Instructions of the machine manufacturer.

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

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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 reciprocating keel 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.

 Double sterile barrier system
Indicates two sterile barrier systems.

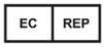
Sterilized using irradiation
Indicates a medical device that has been sterilized by irradiation.

 Do not reuse
Indicates a medical device that is intended for one single use only.

 Do not resterilize
Indicates a medical device that is not to be resterilized.

 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.

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

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