Instructions for Use: Chisels with Accessories
Use of chisels, templates and handle 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 risks.
Improper use may result in tissue damage, premature wear and tear or destruction of the instruments and could present a risk to the safety of the user, patient or third parties.

Proper use and Precautions for Use
In the preparation for use, it is important to ensure that the chisels are compatible with the handle used. Each chisel may only be used in the matching handle specifically designed for it by Gomina AG. A safe and proper use of the chisels cannot be guaranteed, if they are used in handles made by other suppliers.
Please ensure that the chisels are only used in technically and hygienically impeccable handles that have been checked and cleaned. The chisel 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 chisel, handle or causing injury to the patient/user or third parties, make sure that the chisels are always correctly inserted in the handle and have been tightened using the tension lever.
Before using, ensure that the chisel is correctly mounted in the required position in the handle. For this, the chisel is inserted between the opened tension lever and the retainer and positioned centrally between the curvilinear contours with the labeled side of the chisel facing upwards towards the user. Then check that the chisel sits correctly in the curvilinear contours. The chisel must lie flat between the contours and may not rest on the contours under any circumstances. This would result in damage to the chisel and handle. The tension lever is now lowered to the end position, thereby clamping the chisel in the handle. The position number (1, 2 or 3) must be visible through the closed tension lever. Before using, check once again that the chisel is fitted correctly and is at the required position in the handle. Make sure that the chisel can no longer be moved.
The bone tissue is prepared freehand following the pre-operative plan of the responsible physician. The handle is held with one hand. It is important to ensure that the tension lever remains pressed up to the end position throughout the procedure. A sudden loosening of the tension lever can result in damage to the chisel, the handle or cause injury to the patient/user or third parties.

The chisel is gradually introduced into the tissue by striking the designated area of the handle with a suitable tool (e.g. hammer). Avoid tilting, levering or bending the instrument during use (risk of breakage). Also, the handle must under no circumstances come into contact with metallic objects such as implants. This will damage the handle or even cause it to break.
If the handle with chisel is used for loosening an implant, the chisel must be extended by resetting it when the handle comes close to the implant or a longer chisel must be used to prevent the handle from coming into contact with the implant. The chisel should always be mounted as far back as possible in the handle or as far forwards as necessary, in order to counteract the spring action of the chisel when hammering. This prevents unnecessary bending of the chisel during use and ensures greater stability.
Either the extraction bolt or the semicircular extraction plate can be used to extract the chisel. The extraction plate is already attached at the front of the handle; the extraction bolt can be mounted on whichever side of the handle the physician prefers. If the extraction bolt is used, it must be fully screwed into the corresponding thread to prevent damage to the handle or the extraction bolt (risk of breakage).
When using templates, only use chisels whose cutting depth (blade thickness) does not exceed the corresponding thickness of the template guide slot. Also, only use chisels that are explicitly designed for the size of template used (starter chisels). Before using the instrument on the patient, ensure that the chisel can move freely and unhindered in the template. The tissue around the implant must be sufficiently exposed to ensure the correct fit for positioning and fixing the template. The chisel must first be inserted through the guiding slots of the template before it may be used for the preparation.
During preparations carried out with the aid of a template, avoid tilting, levering or bending the chisel (risk of breakage). Before starting the preparation, it is imperative to check that the template fits correctly and to verify that the template and chisel sizes match. An incorrect pairing of template and chisel size may result in an uncontrolled preparation and injuries to the bone or surrounding tissue. Contact of the chisel's cutting edge with the template or other metallic objects must be strictly avoided. Any such contact will result in damage to the instrument, template or accessories. Damaged cutting edges may also result in inadvertent injury to bones and surrounding tissue. Damaged accessories must be replaced immediately and must not be reused. Always have the appropriate spare instruments ready, in order to avoid any delays during an ongoing operation. The patient's vulnerable areas must be adequately protected.

Caution
- The handle must under no circumstances come into contact with metallic objects such as implants. This will damage the handle or even cause it to break.

Instructions for Use: Chisels with Accessories
Use of chisels, templates and handle for bone surgery

- Contact of the chisel's cutting edge with the template or other metallic objects must be strictly avoided. This will result in damage to the instrument, the template or to the accessories.

Risks/complications
Bleeding, damage to vessels or nerves, infections, heterotopic ossifications, damage to soft tissue, mechanical and thermal tissue damage, in the case of severe osteoporosis, chipping may occur at the cut surfaces. 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 breakage of the chisel are potential risks that can be prevented by correct use of the device.

Indications
GOMINA chisels are designed for working on bones in orthopedics and oral and maxillofacial surgery and for loosening implants.

Contraindications
The general contraindications for orthopedic surgical interventions must be taken into account.

Pressure force
Excessive pressure forces must be strictly avoided.
These can result in deformation of the chisel, damage to the handle or undesirable rough surfaces caused by chipped edges. A breakage of the instrument cannot be ruled out in extreme cases. Excessive pressure forces will shorten the service life of the instruments.

Cooling
No special cooling is required, as the use of chisels does not produce increased heat.

Discarding of worn and damaged instruments
Chisels with blunt, bent or chipped cutting edges must not be reused. Besides the cutting performance and associated directional stability of the guide, a precise preparation is therefore not guaranteed. Damaged chisels cause increased pressure forces and therefore increase the risk of a breakage or bending of the chisel. Handles with insufficient clamping force due to wear or incorrect chisel clamping must not be reused. Templates that can no longer be guaranteed to fit on the relevant shank system due to wear or whose guide slot can no longer be guaranteed to guide the chisel as required due to wear must not be reused. This can pose a risk to patient/user or third parties.
The use of such instruments will lead to increased risks to patients and to poor surgical results.

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

Instruments (chisels) 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 chisels are sterilized using gamma ray treatment. They are sterile packed in double packaging (primary packaging), the secondary packaging consists of a folding box. The chisels are intended for single use only. This is indicated by the symbol ⊗ which can be found on the chisels. Chisels that have been used or are damaged must not be used again. Using more than once will lead to increased risks for the patient and to poor surgical results. The user is not able to check the sharpness adequately after use. Besides the cutting performance and associated directional stability of the guide, a precise preparation is therefore not guaranteed. Using more than once results in increased pressure forces. This can lead to broken instruments and pose a risk to patient/user or third parties.

Instruments (handles, templates) 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. Suitable disinfectants and cleaning agents with corrosion protection must be used for this purpose.
The subsequent storage must be in hygienically maintained stands, trays or other suitable containers.
The handle and template are intended for 50 reprocessing cycles.

⚠ **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 chisels, the respective disposal areas must be protected. In this case, the infection, environmental and physical hazards must be considered during disposal.

Safety and liability
Prior to use, the user is obligated to examine the product on his own responsibility for its suitability and possibilities for its use for the intended purpose. The application of the instrument is the sole responsibility of the user. The user and oper

ating staff must use appropriate eye protection when using the instrument.

Gomina AG does not accept any responsibility for damage caused by improper use of the instrument 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.

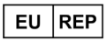
Sterilized using irradiation
Indicates a medical device that has been sterilized using irradiation.

 Do not reuse
Indicates a medical device that is for intended for one single use only or for use on a single patient during a single procedure.

 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

Instructions for Use: Chisels with Accessories
Use of chisels, templates and handle for bone surgery

Indicates the quantity of the medical devices.

Procedure for handle and template

1. The instruments must be inspected for mechanical defects such as tears, nicks, or similar damage prior to use.
2. Chisels are supplied sterile and are intended for single use. Before being used for the first time, handles and templates must be sterilized following the GOMINA Processing Instructions.
3. Remove the instrument from the packaging and place in the sterile environment in accordance with the relevant requirements.
4. Examine the instrument with regard to its general condition and state. Damaged instruments must not be used.
5. Place/push, position the instrument in the handle and secure using the tension lever.
6. Proceed in accordance with the operation protocol.
7. Adequately protect the patient's tissue during the operation.
8. The instrument may be reused (see GOMINA Processing Instructions).

Procedure for chisels

1. The label on the sterile instruments is detachable and can be attached to the patient's file.
2. As part of the preparations before use, it must be ensured that the instrument is compatible with the handle used.
3. The packaging must be examined prior to opening. The contents of the packaging are sterile/clean, if the package does not show any signs of damage and the expiry date has not been exceeded. If the packaging is damaged, the contents must not be used.
4. Remove the instrument from the packaging and place in the sterile environment in accordance with the relevant requirements.
5. Examine the instrument with regard to its general condition and state. Damaged instruments must not be used.
6. Place/push the instrument into the handle and secure.
7. Proceed in accordance with the operation protocol.
8. Adequately protect the patient's tissue during the operation.

Contact

Gomina AG, Raiftstrasse 4, 3989 Niederwald, Switzerland
Telephone: +41 (0)27 970 12 70
Telefax: +41 (0)27 970 12 75
www.gomina.ch
info@gomina.ch

CE 0482

EU REP

GOMINA Deutschland GmbH, Ludwig-Vierling-Strasse 7,
89233 Neu-Ulm, Germany
info@gomina.de

Version 2025-09
Last revised on: 22.09.2025