BETA IMPLANTS

INSTRUCTIONS FOR USE

SHOE osteosynthesis plate

Read this instructions for use

Suitable for profesional use only

Non-reusable product

GENERALITIES

Intended use

Osteosynthesis implants are intended for the stabilisation and temporary fixation of properly reduced bone fragments until they achieve natural consolidation in the desired bone configuration.

Indications

This family of products is particularly indicated for stabilising the correct biomechanical alignment of the humerus using the SHO technique.

Target patient

Domestic dogs

Intended user

The use of these products is restricted solely to veterinary surgeons with specific training in traumatology and orthopaedics.

Materials

All implants are manufactured from titanium alloys authorised for medical use in accordance with ISO 5832-3.

Restricted substances

The implants do not contain any restricted substances.

Absolute contraindications:

- Existing or possible sensitivity to the material.
- Application in any bone other than the humerus.

Relative contraindications:

- Infections or inflammation (acute, chronic, local).
- Poor irrigation in the affected area.
- Insufficient stability for correct fixation of the implant.
- Patients with poor or no compliance with post-operative rehabilitation recommendations.
- Adiposis.
- Patients with epiphyseal plates still open.
- Insufficient soft tissue coverage.
- Contaminated open fractures with insufficient possibility of cleaning.

Required training

Only surgeons with relevant qualifications and experience in traumatology and orthopaedics, up to date with the latest veterinary science in this field, and who have the required practical training are permitted to implant this product.

HANDLING AND STORAGE

Identifiction

Product marking and labelling enable product identification. Batch numbers must be recorded on the operating theatre sheet and in the patient's medical records to ensure proper traceability.

Storage

The transport packaging of the implants is NOT suitable for sterilisation. It is only used for transport. It must be ensured that the implants do not suffer any alterations or damage due to storage. Storage conditions: in their original packaging, in a clean, dry place protected from sunlight.

PREPARATION

Preparation limitations

Implants with signs of corrosion, nicks, residues or contamination may not be prepared and must be discarded. Otherwise, the manufacturer declines all responsibility.

Cleaning and disinfection

The implants are delivered in a NON-STERILE state. The manufacturer's instructions for the cleaning and disinfection substances and equipment to be used must be strictly followed. It is advisable to pay special attention to critical areas, such as recesses and grooves. After cleaning and disinfection, rinse with purified water and dry immediately without exposing the parts to germs. Metal brushes must not be used under any circumstances.

Cleanliness check

Warning! Care must be taken to avoid recontamination of the medical device during the check.

1) Perform a visual check to detect any moisture residue. If necessary, finish drying with compressed medical air.
2) Visually check for debris, damage, deformation or corrosion.

Implants that are not in optimal condition must be replaced immediately.

Sterilisation

All NON-STERILE products can be sterilised in an autoclave using steam. Autoclaves must comply with ISO standards for validation, maintenance and control. The manufacturer's instructions regarding the loading and operation of the steriliser must be strictly followed.

Suggested procedure:

- Temperature: 134°C
- Exposure time: ≥ 5 min
- Drying period: ≥ 20 min

If the user applies other procedures, they must be validated in accordance with ISO 17665-1. The final responsibility for the validation of sterilisation techniques and equipment lies with the user.

Sterile transport

Products must always be handled with the necessary care. They must be transported under the following conditions:

- Separating contaminated items from sterile products to avoid cross-contamination.
- Taking the necessary measures to prevent damage, for example: avoiding knocks or friction between products.

Sterile storage

The storage area must have restricted access, temperature control, good ventilation, be dry and protected from dust, humidity, insects and parasites, and sunlight. Storage time depends on several factors, such as packaging, storage method, environmental conditions, and handling. The user must define the maximum storage period prior to use for sterile products.

Disposal

The disposal of products shall follow hospital management guidelines.

WARNINGS, PREVENTIVE MEASURES AND POSSIBLE SIDE EFFECTS

Before the procedure, the surgeon must accurately understand and explain the following warnings, preventive measures and side effects to the patient. These warnings do not include all general side effects applicable to surgical procedures; they are important considerations specific to osteosynthesis implant systems.

Warnings

1) Training: A lack of knowledge or experience with the products may lead to complications. The content of these instructions for use and the surgical instructions are not sufficient on their own to perform the surgery. Detailed information on application can be obtained from the relevant medical manuals, specific operating instructions or training documentation. To prevent possible complications, even surgeons experienced in orthopaedics and traumatology should learn the necessary techniques from a surgeon familiar with the system or through specific training with models. The surgeon, as well as the clinical staff, must be fully familiar with the medical and surgical aspects of BETA products and know the mechanical limitations as well as the combinability and correct handling of the implants and instruments. BETA has training resources available and organises training courses on a regular basis.
2) Planning: Choosing the correct size of implant is of paramount importance. The choice of implant must take into account, among other factors, the patient's body weight, level of activity and bone condition. Likewise, the position of the implant in relation to the bone fragments, together with their size and shape, affects the shape and stability of the implants. Proper planning is essential to improve the desired clinical outcome and minimise risks. BETA offers a specialised planning service.
3) Regardless of the aetiology for which the implantation of these systems was decided, bone consolidation is expected and required. Implant systems cannot be expected to provide support indefinitely without solid biological support. Implant systems can fail in various ways, including failure of the metal-bone contact surface, implant fracture, or bone failure. Due to anatomical limitations, and despite modern surgical materials, metal implants cannot guarantee their function indefinitely.
4) Compatibility: BETA system components cannot be used in combination with components from other manufacturers, unless specifically indicated
5) The implantation method shall be chosen in accordance with the current state of science in this field.

6) Exposure to excessive load can fracture the implant as a result of delayed or absent consolidation. Implant systems allow load distribution to ensure correct alignment until complete restoration. The implant may fracture due to material fatigue if restoration is delayed or does not occur. The degree of stabilisation, weight load and intensity of activity, among other factors, are decisive for the durability of the implant. Notches, scratches and deformations of the implant caused during surgery can also accelerate failure. Patients should be given detailed information about the risks of implant failure.

7) Patient selection: When determining which patients are eligible for the implant system, the following factors may be decisive for the future success of the treatment:

- Overweight: An obese or overweight patient may overload the implant to such an extent that failure is likely and the success of the surgery is compromised.
- Patient activity: If the patient's natural activity includes muscular exertion, body twists, jumping, running or pulling, these activities should be avoided until complete bone restoration. Even after full recovery, the patient may not be able to successfully resume these activities.
- Certain degenerative diseases: In some cases, a degenerative disease may be so advanced at the time of implantation that the expected duration of implant function is significantly reduced and, in the case of osteoporosis, the necessary fixation may not be achieved. In these cases, orthopaedic devices can only delay degeneration or temporarily halt its progression.
- Sensitivity to foreign bodies: It should be noted that no preoperative test can completely rule out a possible sensitivity or allergic reaction. The patient may develop a sensitivity or allergy even if the implant has been in their body for some time.

8) Postoperative follow-up: Adequate postoperative review is extremely important to assess the stabilisation of the bone fragments and the condition of the implant components.

PRECAUTIONS

1) Do not reuse! Osteosynthesis implants are NOT reusable. A recovered metal implant cannot be reused. Even if the implant appears undamaged, it may have minor defects and have suffered invisible stress that could cause premature wear. The same applies to implants that had to be replaced during surgery for any reason. In the event of non-compliance, the manufacturer declines all responsibility. The consequences of reuse (the following is a list of consequences by way of example, which is not intended to be exhaustive)

- Implant failure
- Contamination
- Imprecise fit

2) Correct handling of the implant is of great importance. Osteosynthesis implants should only be shaped with the instruments provided for this purpose. When shaping the implant, the surgeon must avoid nicks, scratches or repeatedly bending the product back and forth, as this compromises the mechanical strength in a significant way and can therefore lead to implant failure. The use of custom-made implants is recommended in cases where the implant needs to be shaped.

3) Implant removal. If the system is not removed after completion of its intended function, the following complications may occur, either individually or in combination: (1) corrosion with pain or local tissue reactions; (2) changes in implant position with associated injuries; (3) risk of additional injury due to post-operative trauma; (4) deformation, loosening and/or fracture, making removal difficult or impossible; (5) pain, discomfort or abnormal sensation due to the presence of the product; (6) a possibly increased risk of infection; and (7) loss of bone substance due to disuse. The surgeon needs to carefully weigh the risks and benefits before rescuing an implant. After implant removal, adequate postoperative follow-up should be performed to prevent re-fracture.

4) Correct implant placement. When placing implants, special attention must be paid to the possibility of severe or fatal bleeding, as well as neurological injury, due to the proximity of vascular and neurological structures to the implantation area of this product. Serious or fatal bleeding may occur if large vessels are eroded, if they are injured during implantation or due to fracture or migration of the implant after implantation, or if they suffer pulsatile erosion due to close apposition.

5) Pre-use inspection. Before implantation, the implant should be inspected for defects, cracks, or other damage. Defective implants should be discarded. Before implantation, check that all necessary instruments are available.

6) Postoperative clinical supervision and the patient's ability to follow instructions are the most important aspects for effective bone recovery. The patient must be aware of the limitations of the implant and obtain instructions on how to avoid or reduce physical activity. The patient must assume that a metal implant does not have the same strength as normal, healthy bone.

7) Deformation, fracture or loosening of the implant components may occur due to overload or persistent limitations (especially in cases of incomplete consolidation), even if the recommendations received regarding rehabilitation are followed. Therefore, the patient should be informed of this possibility and the associated risks. Displaced or damaged implants may migrate and damage nerves or blood vessels, so their removal should be considered.

Possible side effects

Caution! This list may not be exhaustive. (1)Deformation or fracture of the implant (implant failure), (2)Loosening of the implant and possible loss of stability, (3)Sensitivity to metal or allergy to foreign bodies, (4)Early or late infection, (5) Poor or delayed fracture healing, (6) Loss of bone density due to disuse, due to the support provided by the implant, (7) Pain, discomfort or abnormal sensations due to the presence of the implant, (8) Nerve damage due to surgical trauma or the presence of the implant, (9) Bursitis, (10) Paralysis or limited mobility, (11) Vascular injury due to surgical trauma or internal fixator. Vascular injuries can lead to dangerous or life-threatening bleeding. Implants placed incorrectly, close to large vessels, can erode these vessels and cause potentially fatal bleeding in the late postoperative phase, (12) Injury to lymphatic vessels and/or lymphatic exudate, (13) Bone fracture, (14) Tendinitis or tendon rupture, (15) Loss of reduction, (16) Osteoarthritis or pseudoarthrosis, (17) Intra-articular screws, (18) Inflammation, (19) Dysesthesia, (20) Death.

Interaction with diagnostic imaging techniques.

- Magnetic resonance imaging (MRI): Limit its use.

INCIDENT REPORTING

Any serious incident involving a BETA Implants product must be reported to the manufacturer (info@betaimplants.com) for product monitoring purposes..

LIMITED WARRANTY AND DISCLAIMER

BETA products are subject to a limited warranty against defects in material and workmanship upon delivery to the original purchaser; any other implied or express warranty, such as the warranty of merchantability and fitness for a particular purpose, is hereby excluded.

Legal manufacturer: Grupo tecnológico ARBINOVA S.L (Polígono Industrial Veigadaña, Calle Anel do perral 47, 36416 Mos, Pontevedra España.)

DOCUMENT CONTROL

Document version: 0 **Updated:** 09/12/2025

Digital document availability: www.betaimplants.com

If more than two (2) years have passed between the date of delivery/review and the date of consultation, please request updated product information from BETA Implants (info@betaimplants.com)