BETA IMPLANTS

INSTRUCTIONS FOR USE

Drill Guide GLE

Read this instructions for use

Suitable for profesional use only

GENERALITIES

Intended use

Las guías de taladrado permiten dirigir la broca en la orientación indicada en orificios bloqueados.

Indications

This product is intended for use with BETA implants from the Elite range.

Target patient

Domestic dogs and cats.

Intended user

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

Materials

Las guías de taladrado se fabrican en aleaciones de titanio autorizado para uso médico de acuerdo con la norma ISO 5832-3.

Restricted substances

The drill guide do not contain any restricted substances.

Absolute contraindications:

- Any use other than the intended use
- Use with BETA implants that are not Elite range
- Use with implants from other manufacturers

Relative contraindications:

- The drill guide has no relative contraindications.

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 use this product.

HANDLING AND STORAGE

Identification

Product marking and labelling enable product identification to ensure proper traceability.

Storage

The transport packaging of the instruments is NOT suitable for sterilisation. It is only used for transport. Ensure that the drill guides are not altered or damaged during storage. Storage conditions: in their original packaging, in a clean, dry place protected from sunlight.

PREPARATION

Preparation limitations

Antes de cada uso, debe comprobarse que el roscado de la guía no está dañado.

No podrán prepararse y deberán descartarse las guías que presenten daños. En caso contrario, el fabricante declina cualquier responsabilidad.

Cleaning and disinfection

The drill guides 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.

Control de limpieza

Cleanliness check

Attention! Avoid recontamination of the medical device during inspection; extreme caution must be exercised.

1) Perform a visual check to detect any residual moisture. If necessary, finish drying with compressed medical air.
2) Visually check for the presence of residues, deterioration, deformations or corrosion.

Drill guides 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 the following warnings, precautions, and side effects. These warnings do not include all applicable general side effects; they are important considerations regarding drill guides.

Advertencias

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 instruments. BETA has training resources available and organises training courses on a regular basis.
2) Compatibility: BETA Elite system components cannot be used in combination with components from other manufacturers or non-Elite BETA systems, unless specifically indicated.
3) Improper use may result in breakage or premature wear of the product.
4) Correctly locking the guide is essential to prevent damage to the implant, people, or the patient.
5) Repairs carried out by companies or individuals not authorised by BETA Implants will void the product warranty and may result in the modified product being charged for if it belongs to a rental service.
6) The user must report any problems related to BETA Implants products.
7) In the event of serious incidents involving the products, the user must report this to BETA Implants as the manufacturer and to the competent authority of the Member State in which the user resides.
8) Meter components may become deformed, broken or loose due to improper use. Damaged meters can cause harm to the people working with them and even to patients, so they must be replaced.

Preventive measures

1) If any damage is detected in the gauges, they must be inspected and repaired if necessary, or replaced.
   - Never attempt to repair them yourself. Maintenace and repairs should only be carried out by BETA Implants.
2) Pre-use inspection. Before each cleaning, disinfection and sterilisation process, the items must be inspected for defects, cracks or other damage. Defective products must be discarded. Before surgery, it must be checked that all the necessary equipment is available.
3) To avoid damage to the guide, do not activate the motor until the drill bit is fully inserted into the guide.
4) Check the lock and direction before activating the motor

Possible side effects

There are no known side effects associated with this product.

Interaction with diagnostic imaging techniques.

- This product is not designed for interaction with diagnostic imaging techniques.

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: 1 **Updated:** 22/11/2024

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)