

BHI implants Ltd.

INSTRUCTIONS FOR USE

Cyclone, Shark, SIXt – Dynamic and Conical Dental Implants



WARNING:

BHI implants products are intended for use by adequately certified dentists with specific implant training. The Implantation procedure shall be performed by using BHI implants prosthetics and surgical tools only

1. Indications

The BHI implants Implant system is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw, to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient chewing function. The drill implants Implant System is also indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

2. Caution

Federal law (US) restricts this device for sale by, or on the order of, a physician.

Note

Before use, it is necessary to ascertain if the patient has sufficient alveolar bone width to support the implant. In addition, careful evaluation of the nerves, vital blood vessels, maxillary sinus, and soft tissue spaces relative to the proposed implant site, should be performed before implantation.

3. Contraindications

- Pregnancy
- Renal failure
- Steroid use
- Hypertension above 170/110 mm Hg
- Osteoradionecrosis
- Unexplained hypersensitivity
- Patients receiving corticosteroids anticonvulsives or immunosuppressive therapy
- Organ transplantation
- Fibrous dysplasia
- Ehler-Danlos syndrome
- Prophylactic antibiotics
- Bone metabolism disorders
- Hypersensitivity to implant components
- Abnormal values for BUN, serum calcium or creatinine
- Anticoagulation therapy
- Granulocytopenia
- Hemophilia
- Regional enteritis
- Thyroid or parathyroid disease

Inserting the Implant

Screw the lower part of the implant into the drill osteotomy. After the initial 5.5 mm, the implant continues by threading, via cutting and compressing the bone.

Immediate Loading

The BHI implants Implant System is also indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Recommended insertion torque - minimum 35Ncm.

One Stage Procedure

When stabilization is adequate and a one stage protocol is desired, a BHI implants healing cap should be placed using the hexagonal 1.25mm driver. Manually close the healing cap screw. The healing cap is left in place for the desired healing period (maximum 180 days).

Two Stage Procedure

After a post-operative integration period of approximately 12 weeks in the mandible and 24 weeks in maxilla, the implants may be exposed. Osseointegration is evaluated clinically in conjunction with radiographs

Restoration

The final restoration is provided according to the treatment plan, taking into account occlusal and aesthetic requirements. The appropriate abutment - standard or anatomic - is selected in relation to the tooth position for the proposed implant. The hexagonal 1.25mm driver is used to tighten the final abutment screw to 30 Ncm.

The standard abutments may require modification by the dental technician in order to achieve proper fitting. The anatomic abutments allow for better achievement of individual aesthetics and adaption by the dental technician. If the treatment plan includes using anatomically-shaped abutments, such as the angled or straight abutments, the rotational position of the implant can be adjusted at the time of placement to ensure optimal positioning of the final abutment.

4. Risks

Short-term risks associated with the use of these products include anesthetic and surgical risks, psychological and psychiatric risks, pain, gingivitis, speech problems.

Long-term risks include nerve damage, bone loss, local or systemic bacterial infections, infectious endocarditis.

The following table lists the organ systems that may be affected together with the associated risks.

Organ System	Effect
Cardiovascular	Arrhythmias, coronary heart disease, cardiovascular failure
Respiratory	Chronic obstructive pulmonary disease
Gastrointestinal	Hepatitis, malabsorption, inflammatory bowel disease
Genitourinary	Chronic renal failure
Musculoskeletal	Arthritis, osteoporosis
Hematological	Anemia, leukemia, blood clotting disorders
Endocrine	Diabetes, thyroid diseases, pituitary and adrenal disorders

5. Packaging & Sterility

BHI implants are delivered sterile. The intact sterile packaging protects the gamma-sterilized implant from outside influences and, if stored correctly, ensures sterility up to the expiration date. When removing the implant from the sterile packaging, the rules of asepsis must be observed. The sterile packaging must not be opened until immediately prior to insertion of the implant. Implants with damaged sterile packaging must not be used due to risk of contamination. It is recommended to have a replacement implant on hand.

The implant is for single use only and is not to be re-sterilized. Reuse of the device may cause contamination and/or cross-contamination to the patient as well as care givers involved (Dentist, Nurse, Technician).

The implant system parts should be stored in their package in a clean, dry and stress-free place, at room temperature out of direct sunlight.

6. Surgical Tools and Abutments Cleaning and Sterilization

Prior to surgical use, the components shall be cleaned and sterile according to the instruction for use of the specific product.

The components (drills, drivers, abutments etc.) shall be sterilized by moist heat (124°C for 6 minutes followed by 30min drying cycle) using steam autoclave suitable for medical devices sterilization. It is not recommended to use the surgical tools after 15 sterilization cycles. In any case, all components must be checked before use.

7. Changes in Performance

It is the clinician's responsibility to inform the patient about the precautions, side effects, and contradictions should the performance of the implant be in question. It is the responsibility of the patient to seek medical care if any of the side effects occur.

8. Surgical Procedure Drilling

Irrigate the area with surgical saline to avoid trauma to adjacent structures such as sinuses, mental foramina, and mandibular canals, perform a radiographic exam of the proposed implant area. Inspect the drill for damage or wear before each use.

The drilling procedure is performed in two steps:

Use marking drill to mark the drilling point. and Perform the initial drilling with 2 mm diameter bit, which is appropriate for implant lengths of 10 or 13 mm. **The depth is determined by the dentist according to the implant length and the drill protocol.**

Continue to drill with successive size drills according to the drill protocol as shown in product catalog.

The depth and diameter of the drilling is determined by the dentist according to implant size and the drill protocol.

9. Properties of Products

The implants and abutments are constructed of a Titanium Alloy Ti-6Al-4V ELI.

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Symbol	Description
	Sterilized using gamma radiation
	Do Not Reuse / Single Use Only
	Do not re-sterilize
	Caution, consult accompanying documents
	Use by date
	Do not use if package is damaged
	Batch Code
	Catalog number
	Authorized Representative in the European Community
	Prescription Only. U.S. Federal Law Restricts This Device to Sale by or on the Order of a Physician or Properly Licensed Practitioner