BHI implants Ltd.

INSTRUCTIONS FOR USE

CE 0483

Cyclone – Dynamic 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 BHI 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
- Fibrous dysplasia
- Ehler-Danios syndrome Prophylactic antibiotics
- Bone metabolism disorders
- Hypersensivity to implant components
- Abnormal values for BUN, serum calcium or creatinine
- Anticoagulation therapy
- Granulocyto penia
- Hemophilia
- Regional enteritis
- Thyroid or parathyroid disease

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. Use 30 Ncm to 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 abutment screw to 30 Ncm.

The standard abutments are symmetric in shape and may require modification by the dental technician in order to achieve proper fitting. The standard abutments are suitable for placement in the back teeth. The anatomic abutments allow for better achievement of individual aesthetics and adaption by the dental technician. The anatomic abutments are suitable for placement in the front teeth. 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

170/110 mm Hg
- Osteoradionecrosis
- Unexplained hypersensivity
- Patients receiving corticosteroids anticonvulsives or immunosuppressive therapy
- Organ transplantation

Inserting the Implant
Screw the lower part of the implant into the drill.
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.

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 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)

9. Properties of Products
The implants and abutments are constructed of a Titanium Alloy

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6. Surgical Tools and Abutments Cleaning and Sterilization
Prior to surgical use, the components shall be soaked in a mild, pH-neutral detergent for 2.5 minutes followed by water rinsing. In addition the drills lumen shall be flushed with hypodermic needle brushing the lumen (irrigation cannel) with a nylon brush for removing possible caught debris.

The components (drills, pins, abutments etc.) shall be sterilized by moist heat (134°C for 6 minutes followed by 30min drying cycle) using standard hospital/clinic steam autoclaves for medical devices sterilization. It is not recommended to use the surgical tools after 8 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:
1. 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 clinician based upon the length chosen for the implant.**

2. Insert the leading dowel into the drill. The dowel diameter is 2 mm and its length is 3 mm longer than the drilled hole. The dowel should be inserted to the end of the drill, so that they will project 3 mm above the bone.

The additional bits of 2.8, 3.6 and 4.2 mm diameter are of various shapes. Their use depends upon the implant type/size. Each is 8.5 mm in length. These bits are hollow and are attached over the dowels inside the drill to drill through the cortical bone to the maximum depth of 5.5 mm

Symbol	Description
STERILE R	Sterilized using gamma radiation
	Do not reuse
	Do not re-sterilize
	Caution, consult accompanying documents
	Use by date
	Do not use if package is damaged
LOT	Batch Code
REF	Catalog number
EC REP	EC representative
℞only	By Prescription Only