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## AGGRESSIVE SLA / ACT IMPLANT

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### 1. Disclaimer of Liability

This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instruction's recommendation of BIOSTI Implant Systems. Non-recommended use of products made by third parties in conjunction with BIOSTI Implant Systems products will void any warranty or other obligation, express or implied, of BIOSTI Implant Systems.

The user of BIOSTI Implant Systems products have the duty to determine whether or not any product is suitable for the particular patient and circumstances.

BIOSTI Implant Systems disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of BIOSTI Implant Systems products. The user is also obliged to study the latest developments in regard to this BIOSTI Implant Systems product and its applications regularly. In cases of doubt, the user has to contact BIOSTI Implant Systems.

Since the utilization of this product is under the control of the user, it is his/her responsibility. BIOSTI Implant Systems does not assume any liability whatsoever for damage arising thereof.

### 2. Description of BIOSTI Implant System

BIOSTI Implant is a brand for implant materials for dental practices. The raw material of Aggressive Implant is Grade 4 Titanium. The abutment, prosthetic components for BIOSTI Implant System are compatible with BIOSTI Implant fixture only. Using this product in combination with products from other manufacturers may cause various problems including loosening and fracture due to incomplete locking and compatibility issues. Use BIOSTI Implants only with related concept products. Refer to manual or the catalogue or our website ([www.bioستي.ch](http://www.bioستي.ch)) for details. See the product label for the product code, specifications, manufacturing date, and expiration date.

### 3. Description

**Implant:** BIOSTI Implant is an endosseous threaded dental implant made of titanium with SLA or Active surface.

**Cover Screw:** A screw placed on the superior part of a dental implant immediately after it is placed in the bone, completely covering the top of the implant and sealing it off from the bone and other debris during the healing and integration period. The screw is removed at the beginning of the next phase of the implant process. The single use screw is for one patient for one treatment only and is delivered sterile with the implant package.





















**Healing Abutment:** Used to tissue opening for establish proper profile.

**Abutment vs Abutment Screw:** A dental implant abutment to be directly connected to an endosseous dental implant intended for use as an aid in prosthetic rehabilitation.

## 4. Surgical Procedure

1. During drilling procedures bone quality should be considered. (Please see Table 1)

Table 1. Recommended drill sequences based on bone quality

		Ø3.0 Fixture	Ø3.5 Fixture	Ø4.0 Fixture	Ø4.5 Fixture	Ø5.0 Fixture
						
<b>Table 1</b>						
Lance Drill		●	●	●	●	●
Ø2.3 AG Dental Drill		●	●	●	●	●
Ø3.0 AG Dental Drill		●	●	●	●	●
Ø3.5 AG Dental Drill			●	●	●	●
Ø4.0 AG Dental Drill				●	●	●
Ø4.5 AG Dental Drill					●	●
Ø5.0 AG Dental Drill						●
Ø3.0 AG Cortical Dental Drill		●				
Ø3.5 AG Cortical Dental Drill			●			
Ø4.0 AG Cortical Dental Drill				●		
Ø4.5 AG Cortical Dental Drill					●	
Ø5.0 AG Cortical Dental Drill						●
 Soft Bone		 Normal Bone		 Hard Bone		

Drilling must proceed at high speed (recommended 800 rpm - max. 1200 rpm) under constant and profuse external irrigation by sterile saline at room temperature.

**Depth measurement system:** The depth gauge has a true depth measurement system. All drills and components are marked to prepare the site to the correct depth and obtain a secure and predictable position with laser marking.

**Caution:**

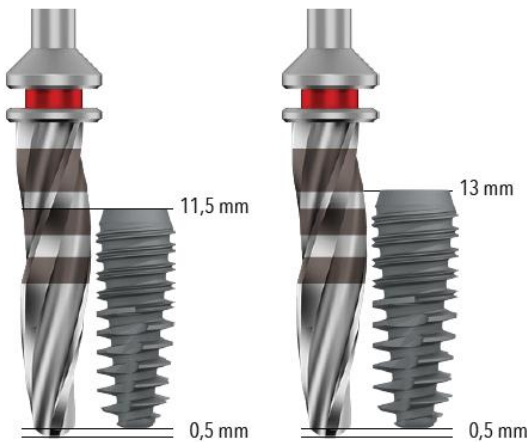
Drills are 0,5 mm longer than the implant when seated. Allow for this additional length when drilling near vital anatomical structures. (Please see Picture 1 for drill reference lines).

**Note:**

Final vertical positioning depends on several parameters, including esthetics, tissue thickness and available vertical space.

**Note:**

It may use drill extension in cases where adjacent natural teeth and the motorhead intersect to provide the drill to reach the desired depth.



Picture 1 shows  $\varnothing 4,0 \times 11,5$  dental drill and  $\varnothing 4,0 \times 13,0$  mm implant

2. Prepare implant site. When using a flapless approach add-on soft tissue height to drill depth.
3. Measure the final depth of implant site for applicable implant length using depth.
4. Remove the double sterile package of the implant from its outer packaging. Open the sterile packages and grasp the holding device of the implant and take it out of the inner box.

Remove the implant from the apparatus by attaching the Mount Driver or Mount Extension tool to the implant carrier part. BIOSTI implants are ideally installed with low speed, max 25 rpm, using drilling device or by hand using surgical driver.

5. Place and tighten the implant. For BIOSTI Implant Ø3.0 use maximum 45 Ncm installation torque and for BIOSTI Ø3.5, Ø4.0, Ø4.5 and Ø5.0 use maximum 70 Ncm installation torque.

6. Depending on surgical protocol of choice, place a cover screw or healing abutment or abutment and suture.

## **5. Intended Use**

BIOSTI Implants are dental implants intended to be used in the upper or lower jaw bone anchoring or supporting tooth replacements to restore chewing function.

## **6. Indications**

BIOSTI Implant Systems are designed for use in dental implant surgery. It replaces the natural tooth root surgically inserted into the upper or lower alveolar bone. The Implant can restore the injured tooth by connecting abutment after osseointegration with the alveolar bone.

## **7. Contraindications**

BIOSTI Implants should not be placed in patients discovered to be medically unfit for the intended treatment. Prior to clinical intervention, prospective patients must be thoroughly evaluated for all known risk factors and conditions related to oral surgical procedures and subsequent healing.

Contraindications include but are not limited to:

- Patient not prepared to undergo total oral rehabilitation
- Vascular conditions
- Uncontrolled diabetes
- Clotting disorders
- Anticoagulant therapy
- Metabolic bone disease
- Chemotherapy or radiation therapy
- Chronic periodontal inflammation
- Insufficient soft tissue coverage
- Metabolic or systemic disorders associated with wound and/or bone healing
- Use of pharmaceuticals that inhibit or alter natural bone remodelling
- Any disorders which inhibit a patient's ability to maintain adequate daily oral hygiene e.g. bruxism
- Uncontrolled parafunctional habits
- Insufficient height and/or width of bone
- Insufficient interarch space
- Treatment of children is not recommended until growth is finished and epiphyseal closure has occurred.
- Patients who are allergic or hypersensitive to titanium.

## 8. Warnings

The following instructions are not sufficient to allow inexperienced clinicians to administer professional prosthetic dentistry. BIOSI Implants, surgical instruments, and prosthetic components must only be used by dentists and surgeons with training/experience with oral surgery, prosthetic and biomechanical requirements, as well as diagnosis and preoperative planning.

The implant site should be inspected for adequate bone by radiographs, palpations and visual examination. Determine the location of nerves and other vital structures and their proximity to the implant site before any drilling to avoid potential injury, such as permanent numbness to the lower lip and chin. Absolute success cannot be guaranteed. Factors such as infection, disease, and inadequate bone quality and/or quantity can result in osseointegration failures following surgery or initial osseointegration.

Dental implants must not be altered in any way. Implant mobility, bone loss or chronic infection may indicate implant failure. Do not reuse the implants. The reuse of such device on another patient is not recommended due to the risks of cross-contamination or infection. Implant cannot be re-sterilized.

BIOSI Implants have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of BIOSI Implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

## 9. Cautions

Procedural Precautions, Surgery: All efforts must be made to minimize damage to the host tissue, paying special attention to thermal and surgical trauma and to the elimination of contaminants and sources of infection. The surgical procedure requires a high degree of precision and care, and the limits for acceptable tissue handling are much narrower than in general oral surgery. Any divergence from the principle of least possible trauma at implant installation increases the risk of failure to establish osseointegration.

All drilling procedures should be performed at approximately 800~1200 rpm. All drilling and pretapping procedures require the use of dedicated, sharp instruments under constant and profuse irrigation for cooling. Implants are ideally installed in a stable manner. All instruments used in surgery must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components. Because of the small size of implant components and instruments, care must be taken that they are not swallowed or aspirated by the patient. After the implant installation, the surgeon's evaluation of bone quality and initial stability will determine when implants may be loaded.

Procedural Precautions, Prosthetics: Especially important is proper stress distribution: passive adaptation and fitting of the bridge to the implant abutments; adjusting occlusion to the opposing jaw; avoiding excessive transverse loading forces, particularly in immediate loading cases. Because of the small size of prosthetic components, care must be taken that they are not swallowed or aspirated by the patient.

Caution for Patient: To keep completely the oral hygiene. Do not apply bite force until final prosthetic placement.

## 10. Cleaning and Sterilization Instructions

BIOSTI Implants are delivered sterile for single use only prior to the labelled expiration date.



### **Caution**

- Implants are single use product and must not be reprocessed. Reprocessing could cause loss of mechanical, chemical and/or biological characteristics. Reuse could cause cross contamination.

All Drills are delivered non-sterile and intended for re-use. Prior to re-use, clean, disinfect and seal the product in a pouch and steam sterilize using the recommended parameters.

### **Warning:**

- Do not use device if the packaging has been damaged or previously opened.

### **Warning:**

















- Use of non-sterile device may lead to infection of tissues or infectious diseases.
- Steam sterilize at 121°C for 20 minutes.

## 11. Storage and Handling

The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics leading to failure.

## 12. Disposal

Products that have come into contact with the patient should be treated as medical waste. Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.

	Manufacturer		Do not use if package is damaged
	Production date		Sterilized using gamma radiation
	Use by date		Keep away from sunlight
	Batch code		Keep dry
	Catalog number		Caution, consult accompanying documents
	Medical device		Do not reuse
	By prescription only		Double sterile barrier system
	European authorized representative		Consult electronic instructions for use



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