

INSTRUCTION FOR USE DENTAL IMPLANT SYSTEM

Manufacturer **BIOSTI Swiss Technology of Implantology And Biomaterials GmbH**
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	Manufacturer
	Production Date
	Use by Date
	Batch Code
	Catalog Number
	By Prescription Only
	Do not reuse
	Do not use if package is damaged
	Sterilized using gamma radiation
	Keep away from sunlight
	Keep dry
	Caution, Consult accompanying documents

Description of BIOSTI Implant System

BIOSTI Swiss Technology of Implantology And Biomaterials GmbH is a brand for implant materials for dental practices, and the fixtures and the abutments are made Grade 5 titanium. The abutment, prosthetic components for BIOSTI Swiss Technology of Implantology And Biomaterials GmbH 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. Refer to manual or the catalogue or our website (www.biosti.ch) for details. See the product label for the product code, specifications, manufacturing date, and expiration date.

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 Swiss Technology of Implantology And Biomaterials GmbH. Non-recommended use of products made by third parties in conjunction with BIOSTI Swiss Technology of Implantology And Biomaterials GmbH products will void any warranty or other obligation, express or implied, of BIOSTI Swiss Technology of Implantology And Biomaterials GmbH.

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Description

Implant: BIOSTI Implant is an endosseous threaded dental implant made of titanium with SLA or STI 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 and Abutment Screw: A dental implant abutment to be directly connected to an endosseous dental implant intended for use as an aid in prosthetic rehabilitation.

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.

Indications

BIOSTI Implants 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.

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 remodeling
- 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.

Warnings

The following instructions are not sufficient to allow inexperienced clinicians to administer professional prosthetic dentistry. BIOSTI 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. BIOSTI Implant 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 BIOSTI Implant in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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 must 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.

Surgical Procedure:

- During drilling procedures bone quality should be considered (please see Table 1)

Recommended drill sequences based on bone quality: Table 1

Bone Type	Final Drill				
	Ø 3,0 Fixture	Ø 3,5 Fixture	Ø 4,0 Fixture	Ø 4,5 Fixture	Ø 5,0 Fixture
Soft	Ø 3,0 Twist Drill	Ø 3,0 Twist Drill	Ø 3,5 Taper Drill	Ø 4,0 Taper Drill	Ø 4,5 Taper Drill
Normal	Ø 3,0 Twist Drill	Ø 3,5 Taper Drill	Ø 4,0 Taper Drill	Ø 4,5 Taper Drill	Ø 5,0 Taper Drill
Hard	Ø 3,0 Twist Drill	Ø 3,5 Cortical Drill	Ø 4,0 Cortical Drill	Ø 4,5 Cortical Drill	Ø 5,0 Cortical Drill

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

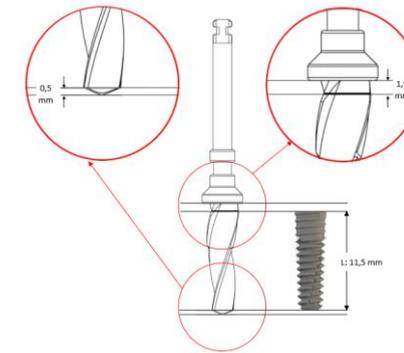
Depth measurement system: the depth gauge has a true depth measurement system. All drills and components are marked to prepare the site to the correct depth and obtain a secure and predictable position with laser marking.

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 lists).

Caution: Drills extend up to 1,5 mm longer than the laser marking. Allow for this additional length when drilling near vital anatomical structures

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 Ø 4.0 x 11.5 Taper Drill and Ø 4.0 x 11.5 mm implant

- Prepare implant site. When using a flapless approach add-on soft tissue height to drill depth.
- Measure the final depth of implant site for applicable implant length using depth.
- Open the implant package and pick up the implant from inner casing by applying light pressure on the implant driver and carefully turn the implant sleeve counter clockwise until implant driver is fully seated. BIOSTI Implants are ideally installed with low speed, max 25 rpm, using drilling device or by hand using surgical driver.
- Place and tighten the implant. For BIOSTI Implant 3.0 use maximum 45 Ncm installation torque and for DTI 3.5, 4.0, 4.5 and 5.0 use maximum 70 Ncm installation torque.
- Depending on surgical protocol of choice, place a cover screw or healing abutment or abutment and suture.

Cleaning and sterilization instructions

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

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

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: Use of non-sterile device may lead to infection of tissues or infectious diseases.

Steam sterilize at 121°C for 20 minutes.

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.

Disposal

Disposal of the device shall follow local regulations and environmental requirements, taking different contamination levels into account.