CE 0425

EN: DENTAL IMPLANTS

PRODUCT IDENTIFICATION

Bone System dental implants are implantable devices designed to rehabilitate patients with total or partial edentulism. They are intended to be surgically inserted into the mandibular or maxillary bone.
The implants have a connection in the coronal part, intended to receive an implant abutment or abutment aimed at supporting a dental prosthesis (fixed or removable).
Dentures aim to restore aesthetic, phonetic, and masticatory function to patients.
In implant-prosthetic rehabilitation with Bone System implants, only original prosthetic components should be used. The use of compatible components limits the liability of Bone System Srl and voids the product warranty (see section "Defective Product Liability and Warranty Terms").
Appropriate surgical instruments, available individually or housed in Surgical Trays, must be used for surgical insertion of implants. It is recommended that original surgical accessories manufactured by Bone System Srl be used and that the directions in the Surgical Manual be followed. We are not responsible for the use of non-original surgical instrumentation or failure to follow the steps outlined in the surgical protocol.
Bone System implants can be placed in different locations in the oral cavity using various techniques and then connected to prostheses with different loading schedules. The implants come in both conical and cylindrical shapes, are screw-shaped, and have an external thread and an internal hex connection that serves to connect the prosthetic components ("abutments" or "abutments"). Depending on the surgical protocol, they can be implanted with a submerged (bone level) or transmucosal (tissue level) protocol; depending on the timing of use (functionalization) they can be rehabilitated with immediate or deferred loading. Bone System dental implants can be placed in already edentulous sites, in post-extraction sites either immediate (implant placement concurrent with tooth or root removal) or deferred (a period of about 3 weeks is normally allowed to elapse between extraction and implant placement).

INTENDED USE

Bone System dental implants are implantable-type medical devices intended for long-term use. All implants are offered for sale in single-use sterile packaging (single or within the All-in-One Kit that also contains the relevant prosthetic components).
The function of the implant is the replacement of missing tooth roots.
All implants are sold in a complete package with the respective cap screw (surgical screw); in the case of Paradigma line implants, the Healing Screw is also in the package.
Cap screws are also medical, implantable surgical-type devices intended to remain in the oral cavity for a duration of even more than 30 days.
Cap screws and Healing Screws are also available individually packaged; in that case the package is not sterile.
Bone System Srl declares itself to be the manufacturer of Bone System brand implants and identifies their risk class as shown in Table "CLASSIFICATION."
Dental implants intended for implantation in all individuals with the appropriate therapeutic indications should be used only by professional medical personnel with the necessary qualifications and licenses (Dentist).

IDENTIFICATION OF THE MANUFACTURER

Bone System Ltd.
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RAW MATERIAL USED

The materials used for the production of Bone System dental implants were selected based on the properties indicated for their intended use, in accordance with Regulation (EU) 2017/745.
They are manufactured from Titanium gr. 4 ASTM F67 that meets the harmonized standards, treated Double Acid Etching (DAE).
Titanium allergy is a very rare, but possible occurrence; therefore, it is still always necessary to check with patients beforehand that they have no such allergies or sensitization.
Dental implants manufactured by Bone System Ltd. contain no materials of human, animal or phthalate origin and are Nickel free.
Bone System Ltd. can provide material composition data sheets upon request.

DESCRIPTION

Bone System implants have a number of features designed to optimize the results of different clinical evidences and facilitate the surgical procedure in accordance with the latest implant protocols.
The morphology of the Bone System implants is characterized by the presence of coronal and apical loops whose functions are of considerable clinical importance both mechanically and biologically, related to the principles of alveolus remodeling and healing, as they create specific contact stimulation of the buccal cortical. The self-tapping design of the implants facilitate insertion into the post-extraction alveoli. The apical coils are intended to provide primary stability, and the coronal coils, placed in the position of the coronal third equidistant between the two corticals, promote stabilization. Sharp and penetrating but still totally tissue-friendly apical coils facilitate screwing and cause bone displacement in interspire chambers, given their ability to displace and compact bone trabeculae during insertion, according to the advanced principle of Dynamic Bone Regeneration (DBR). The apical coils are intended to provide primary stability, the coronal ones contact stimulation of the vestibule.

METHOD OF USE

Modern implantology, whether immediate load or deferred load, is a widely proven and reliable discipline that can solve almost any edentulous problem, whether functional or aesthetic.
The Bone System implant method involves two-stage surgical technique: in two stages, the first "submerged," i.e., with implant insertion, covering the connection well with cap screw, suturing and subsequent reopening of the mucosa after 2-6 months and insertion of the prosthesis.
Implants are placed in the bone following surgical protocols that must be designed according to the quantity and quality of the recipient bone, the type of implant, and the possible need for regenerative therapies. A site is created in the patient's bone through a series of calibrated progressive drills and with the use of suitable instruments such as the shoulder preparator (if necessary in case of compact bone).
Good primary stability is required for the implant to osseointegrate.
Generally, masticatory loading with fixed prostheses occurs later, after 2 to 3 months for the mandible, after 4 to 6 months for the upper jaw. In some, but not all, cases, immediate loading of implants is also possible; however, to be able to do this, certain basic criteria must be met:
- The presence of a certain amount of bone;
- Primary stability of the plant;
- Good periodontal (gingival) support;
- The absence of bruxism (teeth grinding) or severe malocclusion;
- The presence of good occlusal balance (correct masticatory occlusal plane).

There also needs to be a serious evaluation by the clinician who will have to assess with appropriate examinations and instruments the coexistence of all these factors, otherwise the choice will fall on a traditional technique, that is, with implants that require a longer, but safer, waiting time for masticatory loading.
Implants can replace a single tooth (crown on implant), a group of closely spaced teeth (bridge on implant), an entire dental arch, or can serve to stabilize an overdenture upper or lower total denture.
Bone System implants have been tested in a wide range of clinical situations:
- Standard operating procedures;
- Immediate load or post-extraction with immediate load;
- Contextual use with regenerative therapies (bone grafts).

The clinical indication for the choice of implant specification and size depends on the site for which the implant is intended, the recipient bone anatomy, the number of implants, and the choice of the most suitable protocol; the choice must be made exclusively by the clinician, who must have adequate preparation and properly plan prosthetic rehabilitations in advance. Implants with the largest possible diameter according to the thickness of the ridge should always be used whenever possible. The limitations of using the shortest implants should be taken into account.

Preoperative planning and preparation

The preparation phase of the intervention includes:
- Medical history, general medical examination, clinical (complete hematogram) and radiological examinations, CT scan, and if necessary consultation with the family physician.
- Informed consent (indications, contraindications, clinical picture, expectations, normal success and failure rates, alternative options, and need for periodic follow-ups).
- Hygiene plan, with possible periodontal interventions.
- Adoption of necessary drug prescriptions.
- Prosthetically guided surgical planning in collaboration with the dental technician.
- Risk assessment of inappropriate soft and hard tissue treatments.
- Choice of anesthetic and sedation techniques and monitoring to the extent necessary.
- Prosthetic planning in collaboration with the dental technician.

Operative intervention

Operative techniques for implants are learned in undergraduate dentistry undergraduates. However, the following factors should be kept in mind:
- Tissues, both hard and soft, should be treated with extreme care, taking all necessary precautions to achieve good implant integration.
- The biological principles of osseointegration known in the literature must be followed.
- Thermal trauma of tissues that would necrotize and compromise the possibility of implant osseointegration should be avoided by using surgical instrumentation with cutting edges in good condition while respecting the life cycle of the instruments, the rotational speeds of drills and in general of surgical instrumentation stipulated in the relevant instructions for use and manuals.
- comprehensive clinical, radiological, and radiographic records should be collected and archived.
- it is essential to respect the timing of soft and hard tissue biology recommended in implant surgery and to check periodically, including radiographic checks, the progressive state of osseointegration.

Instructions regarding handling and storage of the product

Implant procedures should be performed in appropriate environments with suitable asepsis. It is recommended to always cover surfaces with sterile drapes, cover the dental unit, micromotor with suitable coverings, isolate the surgical field by covering the patient with appropriate gowns, wear all PPE prescribed by regulations and procedures in place, and open instruments from sterile wrappings just before their use.
Bone System implants are packaged in a sterile double vial made of Polyethylene, which is in turn contained in a small cardboard box that is the outer wrapper. Inside the package are instructions for use and adhesive labels for the implant patent (patient card). The vial safeguards sterile conditions, is contoured and preformed in such a way as to limit the movement of the vial as much as possible, but allow easy access for its withdrawal. It is recommended that the vial containing the implant be opened only in a sterile environment immediately before insertion. A small label affixed to the outside of the vial identifies the size and lot no. of the contained implant.
Inside the vial, a Titanium gr. 4 ASTM F67 sleeve supports the implant, which is exposed only by the neck and its hexagon. The Titanium gr. 4 ASTM F67 cap screw is housed in the inner seat of the cap made of Polyethylene that closes the vial.
It is recommended that any contact between the implant surface and epithelial and connective tissue should be avoided, as it could affect the outcome of the surgery.
Upon completion of implant insertion, if the implant is submerged, the connection well should be sealed with the appropriate cap screw before closing the flaps. The cap screw can be withdrawn by friction with the appropriate driver and brought directly into the implant. At the end of the procedure, the flaps should be repositioned and sutured.
Each package bears the code, description of contents, lot number, "sterile" indication, and expiration date.
The package complies with the relevant European standards.
Implants should be stored in a cool, dry place, away from direct sunlight, water and heat sources.

STERILIZATION

The Bone System implants and associated Screw cap are sterilized by Gamma rays (25 kGy). The expiration date is marked on the package (shelf-life 5 years). The sterile blister pack should be opened only at the time of surgery. Before opening, check that the package is perfectly intact. Any damage could compromise the sterility of the implant and thus the success of the surgery. Previously used or non-sterile implants should never be reused.
The dental implant device is disposable; reuse of a dental implant is not permitted and can lead to implant loss and cross-infection.

CE 0425

CONTRAINDICATIONS
The placement of implants and implant prostheses is contraindicated in patients with poor general health, poor or insufficient oral hygiene, inability or poor ability to control their general condition, or who have previously undergone organ transplants. Psycholabile patients, or those who abuse alcohol or drugs, with poor motivation or insufficient cooperation should also be discarded. Patients with poor periodontal status should be preventively treated and recovered. If there is a lack of bone substance or poor quality of the recipient bone, such that the stability of the implant may be jeopardized, appropriate guided tissue regeneration should be performed in advance. The following also represent contraindications: allergy to Titanium, acute or chronic infectious diseases, chronic subacute jaw osteitis, systemic diseases, endocrine disorders, diseases resulting in microvascular disorders, pregnancy, lactation, previous radiation exposure, hemophilia, granulocytopenia, steroid use, diabetes mellitus, renal failure, fibrous dysplasia.
The normal contraindications common to all oral surgery should also be observed.
Patients on anticoagulant, anticonvulsant, immunosuppressive therapy, with active inflammatory-infectious processes of the oral cavity, in patients with creatinine and BUN values out of the normal range should not undergo surgery. Patients with cardiovascular disease, hypertension, thyroid or parathyroid disease, malignancies found in the 5 years prior to surgery, or nodular enlargements should be discarded.
Chemotherapies reduce or nullify the capacity for osseointegration, so patients undergoing such treatments should be carefully screened before intervening with implant-prosthetic rehabilitations. When bisphosphonates are administered, numerous cases of peri-implant osteonecrosis have been reported in the literature, more so in the mandible.

SPECIAL WARNINGS
As a precautionary measure after surgery, the patient should avoid activities that require physical exertion.
An implant tightening torque between a minimum of 35 Ncm and a maximum of 55 Ncm is recommended; use of excessive torque could lead to fracture of the coronal part of the implant especially in smaller diameters.
When tightening cap screws, abutment screws or prosthetic screws, it is recommended to follow the tightening torques recommended in the relevant instructions for use. Tightening torques that are too high can weaken the mechanical structure of the screws and compromise prosthetic stability, possibly resulting in damage that will extend to the implant connection.
Do not use toothpastes containing free fluoride as they may corrode the implant.

SIDE EFFECTS
The following can occur after dental implant surgeries: bone ridge loss, permanent paresthesia, dysesthesia, local or systemic infections, exfoliation, hyperplasia, oroantral and oronasal fistulas. Temporary complications such as pain, swelling, speech problems, gingivitis may occur.
Risks of implant surgery include: labial or lingual plate perforation, bone fractures, implant fractures, superstructure fractures, cosmetic problems, inadvertent sinus perforation, nerve injury, impairment of natural dentition. The following pathophysiological problems may increase risks: cardiovascular failure, coronary artery disease, arrhythmia, chronic pulmonary or respiratory disease, gastrointestinal disease, hepatitis, intestinal inflammation, chronic renal failure and urinary system disorders, endocrine disorders, diabetes, thyroid disease, hematological problems, anemia, leukemia, coagulation problems, osteoporosis or musculoskeletal arthritis, stroke, neurological disorders, mental retardation, paralysis.

MAINTENANCE
Complications related to implant prostheses are well known in the literature. Such complications can lead to loss of osseointegration and implant failure. Proper maintenance by the patient, regular home hygiene, and periodic checkups related to professional hygiene sessions extend the useful life of the device.
Complications such as unscrewing the screws tightening the prosthesis to the implants, or bone resorption causing loss of mucosal support in removable prostheses can be easily prevented by periodic follow-up visits. If prosthetic screws need to be tightened, such operations should be performed by the clinician using appropriate devices equipped with torque control. Periodic verification of the calibration of such devices is appropriate.
If the patient is aware of the occurrence of such eventualities, he or she should seek medical attention as soon as possible for restoration of proper prosthetic function.
A delay in seeking medical attention can lead to fracture of the clamping screw, the prosthesis, in the former case, and loss of the implant in the latter, with impairment of the rehabilitative outcome.
It is necessary for the physician to educate the patient to comply with the specific directions received.
Complications can be biological (loss of integration) or mechanical (fracture of a component due to excessive loading). If complications do not occur, the durability of the devices and entire prosthetic apparatus depends on the mechanical strength as a function of the accumulated fatigue of the device.
Bone System Srl subjected the dental implants to mechanical strength tests according to appropriate standards and further evaluated by finite element calculation.

EXPIRATION DATE
It is recommended not to use the implants beyond the indicated expiration date.

REGULATORY REFERENCES
The design and manufacture of Bone System dental implants is carried out in accordance with the most up-to-date directives and harmonized standards for materials used, manufacturing processes, sterilization, information provided, and packaging.

DISPOSAL PROCEDURES
Dental implants removed from the oral cavity due to biological or mechanical failure should be treated as biological waste for disposal according to local regulations.
Should the same be sent to Bone System Srl for verification these must have been previously sterilized and bagged.

DEFECTIVE PRODUCT LIABILITY AND WARRANTY TERMS
Optimal patient care and attention to the patient's needs are necessary conditions for implantological success, and it is therefore necessary to carefully select the patient, inform him or her of the inherent risks and duties associated with treatment, and encourage him or her to cooperate with the dentist for the successful outcome of treatment. It is therefore necessary for the patient to maintain good hygiene, confirmed during follow-up visits, it must always be ensured and documented as, moreover, pre- and post-operative indications and prescriptions must be observed and documented.
The instructions provided by Bone System Ltd. are available at the time of treatment and accepted by dental practice; they must be observed and applied at all stages of care, from patient history to postoperative check-ups.
The warranty covers only ascertained manufacturing defects after sending the part identified by part number and lot number.

DATE AND VALIDITY OF THESE OPERATING INSTRUCTIONS
These operating instructions are valid and effective from 09/01/2023.

The **Summary of Safety and Clinical Performance (SSCP)** can be accessed at EUDAMED (https://ec.europa.eu/Tools/eudamed), identifying it through the basic UDI-DI codes, and until that platform is fully operational it can be requested by sending an email to: vendite@bonesystem.it

It is necessary to report any serious incident occurring in relation to the medical device we supply to the Manufacturer, the Notified Body and the Competent Authority of the Member State where you are located.

CLASSIFICATION

Device	Package	Classification	Classification rule	Risk class
Dental implants	Disposable and sterile package, implant complete with screw cap	Implantable devices intended for long-term use (greater than 30 days)	8	IIb
Surgical screws and Healing screws	Placed for sale as a complete package with the respective implant (sterile) or individually (non-sterile)	Implantable devices intended for long-term use (greater than 30 days)	8	IIb

SIMBOLISM

	Caution! See instructions for use.
	Lot number
	Code
	Manufacturer
	Country of production
	UDI code, Unique Device Identifier
	Medical Device
	Consult the instructions for use.
	CE conformity marking Where applicable: the identification number of the notified body must follow this symbol
	Do not reuse, single-use product
	Do not use if the packaging is damaged.
	Non-sterile product

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