Instructions for Use with Implant (IFU)

ESi - Premium - Ultimate

Device Description

Dental implants (considered as an artificial tooth root) are biocompatible metal anchors made of grade 5 titanium (Ti 6Al-4V ELI) that come in 2 different surface coatings - SLA and RBM. They are surgically positioned in the jawbone underneath the gums to support an artificial crown where natural teeth are missing .

SpiralTech dental implants come in four product lines with four based on their thread designs. The ESi has sharp, square, and rounded threads. The Ultimate also has sharp threads. The Premium line features square and sharper threads in a more conventional design. The implants have diameters ranging from 3.0 mm to 6.0 mm, and the lengths from 6.5mm to 15 mm for USA and 8mm to 15mm for EC community. ESi, Ultimate, are intended to be used for immediate loading. The fourth implant type is the One Piece which comes with an abutment which cannot be used with low mechanical stability cases. See surgical guide for details on stability requirements and the exact sizes available. The implants are non-pyrogenic. Abutments are available in various types including straight, shoulder, angulated, ball attachments,multi-unit, temporary and healing. All abutments come in both hex and conical connections. Temporary abutments come in PEEK and zirconia. Healing abutments come in titanium alloy and zirconia. Permanent abutments come in titanium alloy the same as implant material and as a titanium base with zirconia abutment. Ball attachments and multi-units are titanium alloy. No SpiralTech abutments are intended to be modified. See the prosthetic guide for more information on abutment choices and sizes.

Intended Use

The Spiraltech Dental Implants are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patients chewing function.

Indications

Spiraltech implants are intended for single or multiple unit restorations on splinted or non-splinted applications. The implants ESi and Ultimate are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading. These implants [along with Premium and One Piece] can also be used for loading after a conventional healing period.

One Piece and 3.0mm/3.3mm diameter ESI/Ultimate Implants are intended to replace a lateral incisor in maxilla and/or a central/lateral incisor in Mandible. Mandibular central and lateral incisors must be splinted if using 2 or more 3.0mm/3.3mm implants.

This product is certified as a medical device in the European Union under the Medical Device Directive 93/42/EEC by SGS CE0120, exclusively for the above indications. Other non-medical uses ascribed to this device are not within the scope of CE certification, and users should be aware product performance and/or safety has not been evaluated by SGS for those purposes

*For more information on stability requirements, refer the SpiralTech Surgical Guide.

Short Implants

SpiralTech 6.5 mm length implants have a smaller surface area for bone anchorage and should thus be used only in conjunction with a longer implant to aid implant-borne reconstructions and as an auxiliary implant for bar constructions in a highly atrophied mandible supporting complete dentures.

Intended Patient and User Population

SpiralTech Implant System intended for prescription use only – by a dentist. Dental Implant systems are restricted to sale by or on the orders of a dentist or physician only. These devices are to be used by trained professionals. The patient population can be anyone including all genders, race and ethnicities with a missing tooth considering the contraindications and relative contraindications listed below.

Contraindications

Uncooperative or unmotivated patient, bone metabolism disturbances, inadequate bone volume and/or quality, psychoses, local root remnants, weakened immune system, serious internal medical problems, inadequate wound healing capacity, incomplete maxillary and/or mandibular growth, poor general state of health, drug or alcohol abuse, long therapy-resistant functional disorders, illnesses requiring periodic use of steroids, xerostomia, uncontrolled bleeding disorders, uncontrollable endocrine disorders. Allergies or hypersensitivity to chemical ingredients of materials used: grade 5 titanium.

Relative Contraindications

Unfavorable anatomic bone conditions, tobacco abuse, previously irradiated bone in head or neck region, untreated periodontal disease, pregnancy, acute infection of implant site, diabetes mellitus, anticoagulation drugs/hemorrhagic diatheses, parafunctional habits, treatable pathological diseases of the jaw and changes in the oral mucosa, inadequate oral hygiene, temporo-mandibular joint disorders.

Complications

Potential complications, advised precautions, and other necessary information regarding SpiralTech Implants should be made known to the patient through the informed consent process. Following the surgery, heavy physical exertion or strenuous activities should be avoided.

Temporary Symptoms

Gingival inflammation, pain, and/or swelling.

More Persistent Symptoms

Possible long-term sequelae of implant surgery include: loss of maxillary or mandibular ridge bone; permanent paresthesia/dysesthesia; localized or systemic infection; cessation of osseointegration specifically at the implant bone crestal area; oroantral or oronasal fistulae; irreversible damage to adjacent teeth; chronic pain in connection with the dental implant; fracture of the implant, jaw, bone, or prosthesis; hyperplasia; nerve damage; aesthetic problems; and/or exfoliation.

Warning:

Avoid implant aspiration, as this may lead to infection or injury. Use extreme caution during implant bed preparation near the mandibular nerve channel. Remain at least 1 mm from the mandibular nerve channel during implant bed preparation and insertion.

Caution

Using contaminated components may lead to infection. SpiralTech products have been designed to have specific properties and design characteristics. Putting SpiralTech implants in a location that is not dry, protected from sunlight, and at room temperature, may compromise the integrity of the product and lead to adverse patient outcomes. Reverse rotation with intent to correct the vertical position of the implant will detract from primary stability.

MR Safety Information

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

Compatibility Information

SpiralTech has different implant lines. Each line has corresponding connections and parts. Pair corresponding parts accordingly. The smallest diameter conical versions for the ESi, Ultimate, Dynamic and Premium implants are only compatible with the 0° and 15° titanium conical abutment models. The smallest diameter hex versions for the ESi, Ultimate, Dynamic and Premium implants are only compatible with the 0°, 15° and 25° titanium hex abutment models

Sterilization

SpiralTech implants are delivered sterile and should not be re-sterilized.

Drills are to be steam sterilized (gravity) at a temperature of 134°C (273°F) for a full cycle time of 4 min, and a dry time minimum of 10 min.

Procedure

Please refer to the SpiralTech Prosthetic Guide for restoration choices and instructions. Also available at www.SpiralTech.com for download.

Prior to Operation

Each patient is different. Therefore the specific SpiralTech implants should be selected accurately. These decisions affect the diameter, type, number, and position of the implants. Radiographic imaging will aid in deciding crucial surgical details, such as deciding which size implant and its placement location. Please refer to the surgical guide for surgical technique.

Implant Bed Preparation

Osteotomy preparation without proper irrigation and technique can lead to excess heat generation and damage to the patient's bone cells. This excessive heat can prevent or delay the healing process. Precautions such as drill speed limitations, cooling techniques, and frequent pauses are some of the steps that must be taken to prevent this occurrence. For more information see the surgical guide for surgical technique.

Insertion

There are two recommended ways of placing the SpiralTech implants. Manual insertion may be carried out with a ratchet. Alternatively, handpiece placement may be used, with a recommended maximum speed of 15 rpm.

Post Insertion

A cover screw or healing abutment is screwed on to the implant prior to wound closure.

Healing Phase

SpiralTech implants are specifically designed to facilitate swift patient recovery. Other key factors to a timely recovery are the initial implant loading and amount of primary stability. Healing phase varies within the scope of indication. For immediate loading of single or multiple units for edentulous or partially edentulous patient one must consider good primary stability and good occlusal loading. Single-tooth immediate loading is preferred in the anterior region when possible. For the posterior area it must be light or completely out of occlusion. For the partially edentulous patient, a multiple-tooth implant must be splinted. For completely edentulous implant, a minimum of 4 implants must be splinted. Primary closure is preferred for non-immediate loading. When the healing phase is completed, and prior to placement of the final prosthesis, a radiograph is advised for comparing peri-implant bone levels to their levels at initial placement.

Further Information

SpiralTech is here to help. Please feel free to request more detailed information from SpiralTech regarding implants and various components.

Take Care

Dental implants constitute an advanced form of dental treatment and care, and their use requires proper training. All treatment should be carried out with caution, with adherence to the manufacturer instructions. The licensed practitioner assumes responsibility to discern the proper procedures, with the proper implants, at the proper time. Any misuse of judgment by the practitioner revokes all SpiralTech liability.

	Use by		Single Use ONLY DO NOT REUSE		DO NOT Resterilize
	Date of Manufacture		Manufacturer		DO NOT USE if package damaged
STERILE R	Sterilized using irradiation	LOT	Batch Code / Number		CAUTION, consult accompanying documents
REF	Catalog Number		Non-Pyrogenic	Rx Only	

Caution: Federal and EU law restricts this device to sale by or on the orders of a dentist or physicians. These devices are only to be used by trained professionals.

NOTE: For further details please refer to SpiralTech Dental Implants at www.spiraltech.com or use the contact information below.

SpiralTech Superior Dental Implants, Inc.
875 N. Michigan Avenue, Suite 3106 Chicago, Illinois 60611 USA
Toll Free: 800 988 8996 Tel: +1 312 440 7777
info@spiraltech.com www.SpiralTech.com