SpiralTech™
Superior Dental Implants

Instructions for Use with Implant (IFU)

Product Description
The SpiralTech implant system is a comprehensive product line that includes surgical parts, prosthetic instruments, corresponding abutments, and closure screws. SpiralTech dental implants are designed from biological materials that the human body recognizes for maximum bone anchorage. These are grade 5 titanium (Ti 6Al-4V ELI) implants that have undergone thorough large-grit sandblasting. To maintain implant integrity, the implant should be inserted within 15 minutes after removal from package.

Indications for Use
The SpiralTech system is intended for use in the upper or lower jaw by treatment of endosteal implantation. This allows for the esthetic and purposeful oral rehabilitation, specifically for partially dentate and edentulous patients, unless otherwise specified. Following loss or extraction of natural teeth, SpiralTech Implants may be used for immediate or early implantation. In order to restore chewing capabilities, implants may be placed for single or multiple tooth applications, through initial primary stability and satisfactory occlusal loading. SpiralTech prosthetic restorations are connected to the implants by their corresponding abutments. These restorations include: fixed and removable partial and complete dentures, as well as single crowns.

Indications
For details regarding minimum bone volume, implant spacing and spacing between teeth, see the SpiralTech Catalog.

One Piece Implant Use
Smaller diameter implants should not be used in cases with low mechanical stability. Specifically, 3.3 mm diameter implants should not be used in the molar region. A 3.3 mm diameter implant may potentially be indicated in the following sites: maxillary lateral incisors, mandibular incisors, and edentulous jaws that cannot accommodate larger diameter implants.

Short Implants
SpiralTech 6 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.

Contraindications
Consist of, but not limited to: 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, prolonged 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, temporomandibular 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
Consist of, but not limited to, 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. SpiralTech products have been properly sterilized. Repeat sterilization may compromise the integrity of the implant. SpiralTech Implants are specifically **ONE TIME USE ONLY.** Infection may result from re-use. 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.

Sterilization
SpiralTech implants are pre-packaged for immediate implantation. Implants that have been re-sterilized can be harmful to the patient, and as such, SpiralTech takes no responsibility for such implants. If they are cleaned by anyone but SpiralTech, any such warranty that SpiralTech was willing to provide will be revoked. The sterile condition of the SpiralTech implant is crucial to surgical success. If the initial packaging gets damaged then the pre-sterilized condition of the implant may become compromised. It is highly recommended to have a replacement implant on hand. SpiralTech cannot accept liability for implants that have had their initial packaging compromised.

Procedure
Please refer to the SpiralTech Surgical Technique F/7.5.1.1_54. 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 catalog 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 catalog 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	Rx Only	Federal law restricts this device to sale by or on the orders of a licensed dentist		

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

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