SpiralTech™
Superior Dental Implants

Instructions for Use (IFU) with Abutments

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

NOTE: Care & maintenance of reusable instruments are crucial for a successful treatment and are essential for the successful outcome of the total treatment.

Product Description
SpiralTech Abutments are used in conjunction with SpiralTech's dental implants of different types, diameters, lengths and connections. All these products are delivered non-sterile and **must be sterilized** prior to use. **Aseptic handling and packaging after sterilization procedure is essential.**

Materials
Titanium Alloy—Ti-6Al-4VELI
Zirconia Oxide
PEEK—Refer to warning before use.

Non-Sterile Components
NON STERILE

SpiralTech Abutments are delivered non-sterile and have a "Non-Sterile" marking on the label. Opened packages of Abutments that have never entered the oral cavity of a patient must be cleaned and sterilized autoclaved. It is essential to sterilize components prior to placing them into an oral cavity.

Procedure
Refer to SpiralTech Surgical Guide (control number F 7.5.1.1_54) or SpiralTech Prosthetic Guide (control number F 7.5.1.1_45) for detailed product instructions on clinical and/or use of steroids, xerostomia, uncontrolled bleeding disorders, uncontrollable endocrine disorders and allergies and/or hypersensitivity to chemical ingredients of materials used.

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.

Warning
Using contaminated components may lead to infection. Because of device size, extreme care must be exercised so abutment is not swallowed or aspirated by the patient. It is strongly recommended that clinicians, new or experienced implant users, always go through special training before undertaking a new treatment method.

PEEK abutment material is made for temporary usage only and must be extracted withing a 6-month period from initial time of use.

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

Potential Adverse Reactions
Consists of, but not limited to, gingival inflammation, pain, and/or swelling. 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.

Sterilization
1. PEEK and Titanium
   a. Sterilize the instruments by applying a fractionated pre-vacuum process (according to ISO13060/ISO17665) under consideration of the respective country requirements. Note parameters for the pre-vacuum cycle: 3 pre-vaccum phases with at least 60 mill bar.
   b. Autoclave (pre-vacuum), at a temperature of 132°C (270°F).
   c. Minimum Holding time: 4 min.
   d. Drying time: minimum 20 min.

2. Zirconia
   a. Dry heat (140°C / 320°F for 4 hours).
   b. Liquid Chemical Sterilization / High Level Disinfection is recommended.
   c. This material should not be sterilized in a steam autoclave, the process of steam can affect the mechanical properties of Zirconia.

Storage and Handling
Store the sterilized in a dry, clean and dust free environment in the original packaging abutment at modest temperatures (5°C to 40°C / 41°F to 104°F). Incorrect storage may influence device characteristics leading to failure.

	Use by		Caution, consult accompanying documents
LOT	Batch code / Number		Manufacturer
Rx Only	Federal law restricts this device to sale by or on the orders of a licensed dentist.	NON STERILE	Non-Sterile
		REF	Catalog Number

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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