
Instructions for Use

Warning
The following descriptions are insufficient to allow immediate use of the StarVent Dental Implant System. Knowledge of dental implantology and instruction in the handling of the StarVent Dental Implant System provided by a clinician with the relevant experience are always necessary.

Disclaimer of Liability
This product is part of the StarVent Dental Implant System and may only be used in conjunction with the corresponding original components and instruments according to Park Dental Research instructions and recommendations. Use of products and tools made by third parties detracts from the efficient functioning of the StarVent Dental Implant System and will void any warranty or other obligation, expressed or implied by Park Dental Research. Advice on the use of our products is provided verbally, in writing, by electronic media or in demonstrations. It does not relieve the user of Park Dental Research products of the responsibility of determining whether or not any product is suitable for the intended purpose, indications and procedures. Use of this product is not within the control of Park Dental Research. It is the responsibility of the user. All liability for loss or damage attributable to the use of this product is excluded. Within the framework of the Conditions at Sale and Delivery of Park Dental Research, we warrant the quality of the StarVent Dental Implant System.

Availability
Some items in the StarVent Implant System may not be available in all countries.

Description
Park Dental Research Corporation StarVent Internal Hex Screw Implant is a root form endosseous dental implant. It is fabricated from biocompatible titanium alloy, Grade 5 (Ti6Al4V). StarVent implants are available in lengths of 8, 10, 11.5, 13 and 16mm and diameters of 3.3, 3.75, 4.2 and 5.0mm. The surface is treated with resorbable blast media which is sandblasted, acid etched. StarVent implants are sold with a cover screw made of titanium alloy, Grade 5 (Ti6Al4V).

Figure 1

Indications
StarVent Internal Hex Screw Implant is intended for placement in the bone of the upper of lower jaw to support prosthetic devices such as artificial teeth, crowns, bridges or overdentures in edentulous or partially edentulous patients and to restore the patient's chewing function.

Contraindications
- serious internal medical problems
- bone metabolism disturbances
- uncontrolled bleeding disorders
- inadequate wound healing capacity
- poor oral hygiene
- maxillary and mandibular growth not completed
- poor general state of health
- uncooperative, unmotivated patient
- drug or alcohol abuse
- psychoses
- prolonged therapy-resistant functional disorders
- xerostomia
- weakened immune system
- illness requiring periodic use of steroids
- titanium allergy
- uncontrollable endocrine disorders
- inadequate bone to achieve desired outcome

Relative Contraindications
- Previously irradiated bone
- diabetes mellitus
- anticoagulation drugs
- hemorrhagic diatheses
- bruxism
- parafunctional habits
- unfavorable anatomic bone conditions
- tobacco abuse
- uncontrolled periodontitis
- temporomandibular joint disorders
- treatable pathologic diseases of the jaw and changes in the oral mucosa
- pregnancy
- inadequate oral hygiene

Local Contraindications
- inadequate bone volume and/or quality
- local root remnants
- in patients whom adequate sizes, numbers or desirable position of implants are not reachable to achieve safe support of functional or eventually parafunctional loads

Principles of Treatment Planning
The surgical part of implant treatment must be preceded by a comprehensive patient evaluation, preoperative diagnostics and therapy planning. Inadequate treatment planning may cause implant failure as well as case failure.

1. General Precautions
- 1.1. One hundred percent implant success can never be guaranteed.
- 1.2. With respect to pediatric patients, routine treatment is not recommended until the completion of jaw bone growth.
- 1.3. Pre-operative hard tissue or soft tissue deficits may yield a compromised esthetic result or unfavorable implant angulation.

2. Precautions Pre-surgery
- 2.1. A careful clinical and radiological examination of the patient has to be performed prior to surgery to determine the psychological and physical status of the patient.
- 2.2. Special attention has to be given to patients who have localized or systemic factors that could interfere with the healing process of either bone or soft tissues or the osseointegration process (e.g., cigarette smoking, uncontrolled diabetes, oro-facial radiotherapy, steroid therapy, infections in the neighboring bone and excessive alcohol consumption).
- 2.3. In general, implant placement and prosthetic design must accommodate individual patient conditions.
- 2.4. In case of bruxism or unfavorable jaw relationships reappraisal of the treatment option may be considered.

3. Precautions at Surgery
- 3.1. Particular caution should be used when placing narrow platform implants in the posterior region due to risk of prosthetic overload.
- 3.2. Lack of adequate bone quantity and/or quality of remaining bone, infection and generalized diseases may be potential causes for failure of osseointegration both immediately after surgery, or after osseointegration is initially achieved.
- 3.3. Besides routine precautions for any surgery, one must proceed with caution when drilling in the jaw bone and one must avoid damage to nerves and vessels by referring to anatomical knowledge, preoperative radiographs and CT scans.
  - 3.3.1. Failure to recognize actual lengths of step/twist drills relative to radiographic measurements or drilling beyond the depth intended can result in permanent injury to nerves or other vital structures, potentially resulting in permanent numbness to the lower lip and chin or leading to hemorrhage in the floor of the mouth.
  - 3.3.2. **Caution: A clinician should drill no closer than 1mm to any anatomical structure.**

4. Side-effects & Interactions, Complications
- 4.1. Immediately after insertion of dental implants, activities that demand considerable physical exertion should be avoided.
- 4.2. Possible complications following insertion of dental implants are:
  - **4.2.1. Temporary symptoms**
    - 4.2.1.1. pain
    - 4.2.1.2. swelling
    - 4.2.1.3. phonetic difficulties
    - 4.2.1.4. gingivitis
  - **4.2.2. More persistent symptoms**

4.2.2.1. chronic pain in connection with implant
4.2.2.2. permanent paresthesia
4.2.2.3. dysesthesia
4.2.2.4. loss of maxillary/mandibular ridge bone
4.2.2.5. localized or systemic infection
4.2.2.6. oroantral or oronasal fistulae
4.2.2.7. unfavorably affected adjacent teeth
4.2.2.8. irreversible damage to adjacent teeth
4.2.2.9. fractures of the implant, jaw, bone or prosthesis
4.2.2.10. esthetic problems
4.2.2.11. nerve damage
4.2.2.12. exfoliation
4.2.2.13. hyperplasia

4.2.3. Adverse events

4.2.3.1. Treatment by means of implants may lead to loss of bone, biologic or mechanical failures including fatigue fracture of implants.
4.2.3.2. **Necessary: Dental personnel should provide patient education regarding complications and adverse events as well as preventative maintenance such as abstinence from smoking, avoiding excessive alcohol and practicing good dental hygiene.**

5. Surgical Procedures

5.1. Implant length and diameter should be selected according to radiological examination prior to surgery.
5.2. Use a tissue punch to prepare site for drilling.
5.3. Use locator drill and twist drill to begin site preparation.
5.4. Bone quality needs to be considered when drilling.

5.4.1. Caution: Drilling must proceed with high speed, not to exceed 1000 rpm with internal and external irrigation using sterile saline.

5.5. Continue with the drilling sequence until the appropriate diameter and depth of osteotomy is achieved to insert selected implant.
5.6. Measure the implant site for final depth with the appropriate depth gauge. Depth gauges are measured at 8, 10,11,13,16 mm, accurate within 0.1 mm.
5.7. Using sterile gloves, firmly grasp the driver included with the implant prior to opening the pouch. Holding the implant driver secure, open the implant packaging and transfer the implant directly from the packaging into the osteotomy site using the implant driver.
5.8. Applying light pressure, turn the implant driver clockwise until the implant is securely seated in the osteotomy site. Fully seat the implant using the driver, torque wrench or handpiece.

5.8.1. Do not exceed **25 rpm** when using handpiece to place the implant.
5.8.2. For StarVent 3.3 implant, maximum installation torque is **45 Ncm.** Maximum torque for StarVent 3.75, 4.2 and 5.0 is **70 Ncm.**

5.8.3. Caution: One should avoid maximum torque when placing the implant as this increases the chance of necrosis of bone. Overtorqueing an implant may cause damage to the implant and fracture or necrosis of the bone site.

5.9. To ensure optimal prosthetic abutment orientation for internal conical connection implants, position one of the hexagon flat surfaces in the implant towards buccal/facial.
5.10. Depending upon surgical protocol of choice and/or treatment needs, place a cover screw or healing abutment on the implant.

Sterility & Packaging

StarVent dental implants are delivered sterile. The intact sterile packaging protects the gamma-sterilized implant from outside influences and, if stored correctly (see "Storage and Use" section), ensure sterility up the expiration date. The sterile packaging must not be opened until immediately prior to insertion of the implant.

Warning: Implants with damaged sterile packaging must not be used due to the risk of contamination. It is recommended to have a replacement on hand. Do not resterilize or reuse implants. Do not use implants after sterilization expiration date.

Storage & Use

- When removing the implant from the sterile packaging, the rules of asepsis must be observed.
- Store sterilized devices in a dry and dust-free environment.
- Sterilization can only be preserved if devices remain packaged, impermeable to microorganisms, following a validated process.
- Do not use implant after sterilization expiration date.
- Keep sterile and non-sterile products separate.
- This device should be observed for deterioration. In the event of a defect, return to Park Dental. Do not use.

Customer Information

No person is authorized to provide information which deviates from the information within this document.

Caution: U.S. Federal Law restricts this device to sale or use on the order of a dental professional.

Warranty

Park Dental Research Corporation warrants this product to be free of defects for a period of one (1) year from the purchase date. At its option, PDR will replace or refund the purchase price of this device, to the original purchaser, for returned items due to defects in material and workmanship. If a defect is found in a product, the product should not be used. This warranty covers only the cost of the product and not clinical and professional fee associated with the use of the product.

Limitation of Liability

Park Dental Research Corporation is not liable for any damages due to changes made to product by the user. It is the manufacturer's intention that the product be utilized in a manner that has been submitted to the appropriate governing regulatory bodies. The user is responsible for determining the suitability of the product for its intended application.

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