User Manual

alphatech® Implantate

Description of the Medical Product

The alphatech® Slim-Line® implant is a single-element, bicortically-anchored screw implant with a self-tapping thread. It is made of grade 5 (medical grade) titanium and has an HA-blasted, acid-etched surface (DUOTex®).

Safety Information

You must read this manual before using the alphatech® Slim-Line® Implant System. In addition, alphatech® Slim-Line® implants must only be inserted for the indications specified here and in observance of the general rules for dental/surgical procedures as well as in compliance with the work safety and accident prevention regulations.

Storage

Up until the time of insertion, the implants are to be stored in their closed, original packaging at room temperature in a dry location.

Brief Description of the alphatech® Slim-Line® Implant System

The alphatech® Slim-Line® Implant System contains surgical, prosthetic and lab components and instruments. The implants are available in the following lengths and diameters with spherical head or taper (four-edge posts):

Diameter	Length	Length	Length
∅ 2,5 mm	-	15 mm	20 mm
∅ 3,0 mm	-	15 mm	20 mm
∅ 3,6 mm	10 mm	15 mm	20 mm
∅ 4,2 mm	10 mm	15 mm	20 mm

The various components themselves or their packaging are color-coded to prevent mixing up components of different diameters.

Indications

The indications for alphatech® Slim-Line® implants encompass single tooth restorations of the mandibular incisors or mandibular bridges for the front teeth 2-2 (in the form of immediate or late implantation), the lateral maxillary incisors as well as interforaminal implants with ball head anchors in the case of edentulous mandibles for fixing the complete prosthesis or four interforaminal implants with post-supported superstructure for anchoring the prostheses.

Contraindications

The general contraindications for dental/surgical procedures must be observed. These contraindications include: weakened immune defense, steroid therapy, blood clotting disorders, uncontrolled endocrine disorders, rheumatic diseases, osseous system diseases, illnesses of the osseous system, osteomyelitis, radiotherapy in the head region, recurrent diseases of the oral mucosa, TMJ complaints, bruxism, parafunctions, missing or insufficient vertical/horizontal bone volume, jaw defects, poor oral hygiene, bisphosphonates.
Caution in the case of serious nicotine abuse. Implantation must not be performed in regions that are acutely inflammatory from surgery.

Precautionary Measures and Side Effects

There are currently no known side effects caused by titanium implants. Surgical procedures may be accompanied by temporary localized swelling, edema and hematomas. Temporarily impaired chewing function and reduced aesthesia may also occur. Strenuous physical activity must be avoided after the procedure. Despite the high level of success of dental implants, failures may occur in rare cases in the form of insufficient implant stability (insufficient osseointegration). This poor stability is generally the result of the technical procedure employed during the operation or the biological conditions and is not usually due to the product itself.

Operation Technique

The implant bed should be prepared with the utmost care. Thermal damage to the bone should always be prevented by ensuring optimum cooling and by observing the recommended drilling speeds. (speed: 400 to max. 1000 rpm with sufficient external cooling). The implant should be inserted with a **maximum** drilling speed of **20 rpm** in order to prevent thermal necrosis.
During insertion, screw each implant two rotations inwards and then once in the opposite direction backwards in order to minimize tensions in the bone tissue. To compensate for axial divergences with implants 15 mm or longer, the inserted implant can be given a maximum angulation of 10° in a direction one time.

Caution: The angulation must only be performed for implants 15 mm or longer and must only be performed once. The inserted implants must not undergo multiple, repeated angulations.

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Administration and Packaging

All implants are gamma-sterilized and intended for one-time use. The products are delivered in sterile form and must not be re-used (multiple times) as it would then no longer be possible to guarantee functionality and sterility. alphatech® Slim-Line® implants must not be re-sterilized. alphatech® Slim-Line® implants cannot be used if the packaging is missing or damaged or if the expiration date has passed. The manufacturer assumes no liability whatsoever for cases of non-compliance.

One package contains: 1 implant with instructions and 4 stickers for patient documentation.

Important: Before use on the patient, all parts that are used multiple times must be cleaned, disinfected and sterilized in compliance with validated procedures.

1. Preliminary Disinfection

Place components in a disinfectant solution immediately after use. Observe the specifications of the instrument/disinfectant maker.

2. Cleaning

Clean components with appropriate cleaning agents to remove residues from surgery.

3. Disinfection

Place components in disinfectant solution.

4. Sterilization

Perform sterilization with an appropriate program. Observe specifications of the device manufacturer.

Documentation

The manufacturer recommends seamless clinical, radiological, photographic and statistic documentation. Each implant can be traced with the LOT number. The patient stickers included with the implant are intended for documentation in the patient file.

Shelf Life

Unopened packages can be used until the expiration date printed on the packaging. The implants must not be inserted after the expiration date.

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