INSTRUCTIONS FOR USE

Product Description
IMPLANTIUM®, SuperLine® and Superline® II fixtures are Grade 4 titanium dental implants, Sandblasted with Large grit and Acid etched surface treatment designed to enhance osseointegration, a firm connection between the bone and the surface of the implant. The implant is packaged with a Cover Screw made of Titanium-6Aluminium-4Vanadium ELI Alloy.

Either a two-stage surgical procedure or a one-stage surgical procedure can be used. If a single surgical procedure is used, single or multiple fixtures may be inserted (type I, II or III bone) provided good initial stability (> 40 Ncm) is achieved and with appropriate occlusal loading. Single tooth cases on 7 mm length fixtures are not intended for immediate loading.

Indications for Use
IMPLANTIUM®, SuperLine® and Superline® II implants are indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. SuperLine® and Superline® II implants are indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Single tooth cases on 7 mm length fixtures are indicated for delayed loading.

Contraindications
IMPLANTIUM®, SuperLine® and Superline® II fixtures should not be used in patients whose medical conditions are not fit for general oral surgery such as uncontrolled general diseases including but not limited to; uncontrolled diabetes, cardiovascular disorders, bleeding disorder, or immune deficiency disorder. IMPLANTIUM®, SuperLine® and Superline® II fixtures should not be placed in patients with:
- Insufficient bone or poor quality bone or insufficient soft tissue coverage
- Poor patient motivation with an inability of the patient to manage proper oral hygiene
- Active inflammation such as periodontitis or acute pathology at implant surgery site
- Uncontrolled parafunctional habits such as bruxism or clenching
- Heavy smoking, tobacco abuse, alcohol and/or drug abuse
- Allergy to titanium or titanium alloys
- Unattainable prosthetic reconstruction

Breastfeeding or pregnant women are not candidates.

Dentium implants are not recommended for children under 18 years of age. Treatment of children (18 to 21 years of age) is not recommended until skeletal growth is complete and epiphyseal closure has occurred.

Warnings
- Implant surgery and restoration involve complex dental procedures which require specialized training. Training is mandatory prior to implant use. An improper treatment plan and technique and/or improper patient selection can result in irreversible damage to anatomical structures such as nerves and blood vessels, and could potentially lead to implant failure and/or loss of bone around the implant site.
- Small diameter implants and angled abutments are not recommended for use in the posterior region of the mouth.
- An abutment with minimum post height of 4 mm above the gingival collar is clinically recommended for single-unit loading applications.

MRI Safety Information
Dentium IMPLANTIUM®, SuperLine® and Superline® II implants have not been evaluated for safety in the MR environment. Dentium IMPLANTIUM®, SuperLine® and Superline® II implants have not been tested for heating or unwanted movement in the MR environment. The safety of Dentium IMPLANTIUM®, SuperLine® and Superline® II implants in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

Precautions
Thorough screening of implant candidates is critical to the success of the implant process. An appropriate radiographic examination should be utilized to determine patient candidacy for dental implant placement, including a review of the bone volume availability, periodontal status, and the location of important anatomical landmarks. Patient history such as periodontal
disease, radiation therapy on the implant surgery area, immune-suppressive status, Vitamin D deficiency, or bisphosphonate therapy, and long-term use of selective serotonin reuptake inhibitors or proton pump inhibitors can negatively affect the dental implant healing process and outcome. Post-operative radiographs are also required to assess the location and angulation of dental implants following implantation. 

The final prosthesis should be preliminarily designed prior to implant surgery as a part of the implant treatment plan and must be specific to individual patient conditions. Proper stress distribution must be considered when selecting appropriate sizes, numbers, and positioning of implants to support biomechanical loads and loading prosthesis. Inappropriate implant distribution or fixture size selection based on individual patient factors can result in improperly distributed occlusal forces resulting in early or late-stage osseointegration failure and potential loss of dental implants. All efforts must be made to minimize damage to the patient’s hard and soft tissue to avoid unwanted thermal and surgical trauma, contaminations, and infection. Because of the small size of dental implant components and/or instruments, care must be taken that these components and/or instruments are not swallowed or aspirated by the patient. Small components can cause suffocation or injury to patients. Exposure to magnetic resonance imaging, radiation, and chemotherapy agents may cause immune suppression which could impact the health of the patient and lead to compromised hard and soft tissue health around the dental implant. The risk of image distortion (MR, CT, etc.) should be taken under consideration prior to ordering a scan. These patients should be instructed to consult with their physicians prior to undergoing such treatment options. The use of electrosurgical instruments is not recommended around dental implant due to the risk of electrical shock and/or burns.

Instructions for Use (Surgical Procedure)

Caution: Refer to the Surgical / Prosthesis Manual for detailed instructions regarding the surgical procedure. IMPLANTIUM®, SuperLine® and Superline® II fixtures are only intended for use with Dentium Implant System Instruments, Abutments and Components.

IMPLANTIUM®, SuperLine® and Superline® II fixtures can be inserted using a one or two-stage procedure. One-stage implantation should only be considered for patients with good bone quality (Zarb-Lekolm classification I, II, III), proper oral hygiene, appropriate personal habits (non-smoker and no alcohol or drug abuse), and where an initial stability of the implant (> 40 Ncm) can be achieved.

Prior to implantation, a complete health evaluation, oral examination, and radiological assessment should be conducted for successful implant treatment.

All surgeries should be performed under aseptic conditions with sterile surgical instruments. All drills and instruments must be maintained in excellent condition and care must be taken not to damage dental implants including connection, threads, and surfaces.

First Stage Implant Surgery

1) Incision and flap resection

2) Drilling Sequence (Refer to Surgical and Prosthetic Manual for specific instructions)

<table>
<thead>
<tr>
<th>Platform Diameter</th>
<th>Drilling Sequence</th>
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<tbody>
<tr>
<td>3.6</td>
<td>LG→LF→F3.6→CS3.6</td>
</tr>
<tr>
<td>4.0</td>
<td>LG→LF→F3.6→F4.0→CS4.0</td>
</tr>
<tr>
<td>4.5</td>
<td>LG→LF→F3.6→F4.0→F4.5→CS4.5</td>
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<td>5.0</td>
<td>LG→LF→F3.6→F4.0→F4.5→F5.0→CS5.0</td>
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<tr>
<td>6.0</td>
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</tr>
<tr>
<td>7.0</td>
<td>LG→LF→F3.6→F4.0→F4.5→F5.0→CS6.0→CS7.0</td>
</tr>
</tbody>
</table>


Caution: If immediate placement into an extraction socket is being performed, limited drilling may be required depending on extraction socket size. If bone density is Type I or Type II, it may be recommended to use the countersink to avoid damage to the bone.

Warning: Irrigate during drilling to avoid overheating the bone. Overheating can cause bone damage resulting in osseointegration failure and loss of the fixture as well as other biological complications.
3) Fixture installation

**Caution:** When opening the holder cap, hold the fixture container upright, engage the Hand-piece Adapter into the fixture and connect firmly together.

Remove the fixture from the packaging, attaching the fixture to the Hand-piece Adapter. Insert the fixture into the bone, turning clockwise at 20rpm/30-45N.cm using the Hand-piece Adapter.

It is recommended that the top level of the fixture be located 0.5mm sub-crestal. Refer to the Dentium Surgical / Prosthesis Manual.

Place label identifying the LOT number and REF number of the fixture in the patient’s chart to ensure traceability to the implant used.

**Warning:** Applying excessive torque (more than 45N.cm) may result in damage or fracture of the fixture and/or damage to the bone.

4) Cover Screw or Healing Abutment

Thoroughly clean any blood or fluid from the internal aspect of the fixture prior to attaching the cover screw or healing abutment according to the treatment plan. Failure to properly clean the fixture can cause difficulty in removing the cover screw or healing abutment at a later stage.

For two-stage procedures, apply the cover screw using a hex driver with 5-10 N.cm of torque. For one-stage procedures, apply the healing abutment or other restoration part appropriately according to the treatment plan.

5) Soft tissue suturing

If a tissue flap was raised, close the tissue flap with sutures of a suitable material and diameter according to the surgical plan and clinical situation. Ensure minimal flap movement after suturing.

The healing period after the first stage surgery is dependent on the patient’s pre-surgical condition including bone quantity and quality. Radiographs are required prior to the implantation surgery to evaluate the bone condition as well as after the second stage surgery prior to loading the fixture.

**Second Stage Surgery (following application of the cover screw)**

1) Create an incision through the soft tissue for removal of the cover screw (Unscrew in a counterclockwise direction)
2) Insert the healing or final abutment using the hex driver according to the treatment plan
3) Close the tissue flap with sutures

**Impression and Restoration Fabrication**

**Warning:** Evidence of osseointegration should be confirmed radiographically or by other means prior to loading a fixture.

**Postoperative Follow-up**

Comprehensive regular follow-up care by a trained dental professional is advised for a treatment outcome with a good prognosis.

**Adverse Effects**

The implant surgery has known risks, including failure of osseointegration, loss of osseointegration, perforation of nasal and maxillary sinus, perforation into soft tissue, local or systemic infection, nerve injury, bleeding, and technical problems including fixture and/or restoration part fracture. Refer to the applicable dental literature regarding these issues. Other surgical complications include but are not limited to separation of the tissue flaps in the sutured area, temporary swelling, hematoma, numbness or paresthesia, and ulceration.

Patients should be instructed to seek trained dental professional care if there are any signs of a problem with the implant, such as looseness, infection, exudates around the implant, pain, swelling or other symptoms.

Loss of the implant can be possible. Reasons for this can include, but are not to limited to insufficient quality or quantity of the supporting bone, poor placement of the implant, improper alignment of the fixture and/or improper loading prior to adequate osseointegration. The patient’s oral hygiene habits should be optimal prior to and after dental implant placement to prevent the inflammation of the soft tissues and compromised osseointegration. As with all implant systems, there is the risk of peri-implantitis or bone loss around the implant over time which can result in loss or removal of the implant.
Cautions

Federal law restricts this device to sale by or on the order of a dentist or physician.

The product is gamma sterilized and will remain sterile as long as the blister packaging is unopened and undamaged.

Do not use the product if the packaging is damaged or opened. Do not use beyond the stated expiration date. The product is designed for single use only and is not to be re-sterilized. An opened, unused product may not be returned to the company.

Delivery, Storage and Handling

Outer Box: NON-Sterile
Blister Packaging: NON-Sterile
Outer Vial: Sterile-R
Inner Vial: Sterile-R
Fixture: Sterile-R
Cover Screw: Sterile-R

The products should be stored at room temperature in the original package. The products should be opened using aseptic techniques to avoid contamination after the correct size has been determined prior to implantation. Handle the fixture carefully to avoid damaging the fixture’s surface and area for connection with the restoration component. Avoid touching the rough outer surface prior to implantation.

Additional product labels containing the product LOT number and REF number are provided with the fixture. These labels are to be placed in the patient’s chart and medical records to ensure complete traceability of the implant for future reference or questions.

To obtain additional information on IMPLANTIUM®, SuperLine® and Superline® II implants, please contact:

Dentium USA
6761 Katella Ave. Cypress, CA 90630 U.S.A
Tel: 1-877-304-6752
www.dentiumusa.com

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