Osteo-Ti Implant System – Notes for Dentists

Osteo-Ti Implant system
The Osteo-Ti system has been designed with the dentist in mind. It has been made to ensure the highest standard of aesthetics and function. The implant and abutments are made from medical grade titanium alloy that has been proven to be biocompatible. The surface of the implant has been acid etched and grit blasted to give maximum strength of osseointegration.

General information
The Osteo-Ti implant is designed to be a dental implant to support complete fixture prostheses, terminal or intermediate abutment for fixed bridgework or as a single tooth replacement. In the Osteo-Ti implant system there are a range of lengths, and diameters, which should be chosen on the merits of the individual’s clinical situation.

Packaging and labelling
All Osteo-Ti implants are packaged sterile and include a cover screw. The cover screw can be found under the black rubber cap on the white lid. The implant is held on the metal carrier by friction, which can be used as a driver tool for the initial stage of placement. Within the sterile pouch there is a self adhesive label with all the information on the implant for retention in the dentist’s notes including, the size of implant, lot number, and expiration date.

Handling procedures
The implant should never to touched with gloves, to transfer the implant from the carrier to extender the implant forceps should always be used. The inside of the pouch is sterile and should only be touched by those in the sterile environment of the surgery. To remove the implant from the packaging, pull off the white cap and dispose of the clear tube.

For mandible placement separate the white cap from the implant carrier by holding the body of the carrier with the implant forceps and pulling the white cap away from the head of the carrier.

For maxillary placement hold the white cap securely in one hand and with the implant forceps clasp the implant body. Free the implant with careful controlled motion and then load the implant onto an extender, ready for placement.

Ensure to keep all implant documentation for the patient’s notes.

Warranty
To achieve consistent and predictable results implants rely on good treatment planning and strict adherence to the systems surgical protocol. Patient selection must be taken with extreme caution, all implants must be placed and restored with the final result, patient’s anatomy and needs taken into account. Selection of individual or multiple implants of appropriate size and configuration for the existing anatomy is also crucial if success is to be expected.

Placing implants is a highly specialist activity and should only be carried out by dentists who have undertaken appropriate post graduate training. Osteo-Ti can give specialist system training and it is highly recommended that this is taken up if the best results are to be achieved.

Osteo-Ti should not and cannot control the factors under the scope of the dental practitioner, such as patient selection, surgical procedure, and restorative techniques, Osteo-Ti assumes not responsibility for the any failures that may have occurred due to any factor other than that directly relating to the design and manufacture of the Osteo-Ti implant.

All Osteo-Ti implants are made of titanium and are exceptionally resistant to loading, however, it is impossible to guarantee that any loading of the implant cannot and will not bend or fracture the implant

Osteo-Ti makes no warranties extending beyond the representation or beyond that description contained in any invoice. This warranty is in lieu of and excludes all other warranties, expressed or implied including merchantability and fitness for a particular purpose. Osteo-Ti and warrants to licensed dental practitioners who purchase implants, abutments and all other dental instrumentation for the specific purpose for which they are intended. Osteo-Ti makes no written warranty to any consumer, patient or end user and authorises no person to make any such written warranty on its behalf.

The remedies of any buyer from Osteo-Ti (and its liabilities) are solely and exclusively to replace or repair a defective Osteo-Ti implant, abutment or instrumentation when that product has been demonstrated to Osteo-Ti authorities within six (6) months of delivery to the buyer to have been defective at the time of shipment and is returned to Osteo-Ti for inspection, replacement or repair. Osteo-Ti is not liable to any person for any incidental, consequential or other damages of any kind whatsoever, whether the claim is based on the theories of contract, negligence, or tort.
Procedure

The procedure for placing an implant should only be undertaken by a dentist who has undergone specific training on the Osteo-Ti system. This specific training can be obtained on courses and seminars. System consultants with extensive clinical training are available to visit during surgery, which Osteo-Ti strongly recommends. Osteo-Ti implants should not be used in sites or situations other than those specifically indicated. All Osteo-Ti implants are to only be used with instrumentation and components supplied by Osteo-Ti.

Contraindications

Osteo-Ti implants should not be used in patients with contraindicated diseases such as blood dyscrasias, uncontrolled diabetes, hyperthyroidism, bruxism, oral infections and malignancies. Osteo-Ti must not be used in patients with contraindicated conditions such as myocardial infarction within the last year or in sufficient supportive bone to permit the use of an appropriately sized implant. Implants should not be placed if there is insufficient alveolar bone width and height to surround the bone.

Precautions

A Panoramic radiograph should be used to determine if adequate bone is present at the proposed implant site as well as to establish the correct position of critical local anatomical features. Additionally if only limited bone is available a CT scan or similar diagnostic imaging will be required to accurately determine the amount and position of the bone. Palpation and direct visual inspection of the prospective implant site are also required to determine the anatomy of the available bone.

Adverse reactions

The following reactions may occur following implant treatment but have not been proven to be because of the implant: delayed healing, parasthesia, edema, haematoma, infection, inflammation and general allergic reactions.

Healing collars and plugs

Used after second stage surgery for soft tissue manipulation. These are made of an inert radio-opaque biocompatible polymer. There are a variety of lengths and widths to ensure the correct soft tissue profile.

There are also soft tissue plugs which come in a variety of shapes that can be used in cases where a denture is to fit over the site of the implant, and at the same time soft tissue manipulation is required. The plugs do not have a hex on them and should not be used in any stage of the impression taking procedure.

<table>
<thead>
<tr>
<th>Bone type</th>
<th>D1</th>
<th>D2</th>
<th>D3</th>
<th>D4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant Diameter</td>
<td>Pilot to full working depth +USB to the 1st 5mm depth ring</td>
<td>Pilot to full working depth +USB to the 2nd 7mm depth ring</td>
<td>Pilot to full working depth +USB to the 1st 5mm depth ring</td>
<td>Pilot to full working depth +USB to the 2nd 7mm depth ring</td>
</tr>
<tr>
<td>3.25</td>
<td>3.75</td>
<td>4.5</td>
<td>5.5</td>
<td></td>
</tr>
<tr>
<td>Pilot +USB to full working depth</td>
<td>Pilot +USB to full working depth +USB to the 1st 5mm depth ring</td>
<td>Pilot +USB to full working depth +USB to the 1st 5mm depth ring</td>
<td>Pilot +USB to full working depth +USB to the 1st 5mm depth ring</td>
<td></td>
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</tbody>
</table>
| Mini Combi

Mini-Combi implants are designed only to be used where the local anatomy limits the use of the larger implants. All patients where Mini-Combi implants are fitted are to be closely monitored for any of the following conditions: Peri-implant bone loss, radiographic changes in bone to implant contact along the implant’s length.
Mini-burr

Mini-burrs have a stop at 7.5mm to enable the preservation of critical anatomy. A Mini burr has been designed for each of the Mini-Combi sizes. Working through the sizes of burrs until the correct size burr is used will ensure the correct site preparation. The Mini-burrs should only be used for site preparation of the Mini-Combi.

Mini-burr drilling protocol

Drilling Chart

<table>
<thead>
<tr>
<th>Implant Size</th>
<th>Protocol</th>
<th>3.75 x 7mm</th>
<th>4.5 x 7mm</th>
<th>5.5 x 7mm</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Pilot to 1st line +MB3 to full working depth</td>
<td>Pilot to 1st line +MB1 to full working depth + MB2 to full working depth</td>
<td>Pilot to 1st line +MB3 to full working depth</td>
</tr>
</tbody>
</table>

Abutments

All Osteo-Ti Ezee-Combi abutments fit all Ezee-Combi Implants. There are two types of abutments that can are chosen at the dentist discretion; Friction retained, and screw retained. Screw retained abutments should always be used in on implant retained bridges; Osteo-Ti does not accept any liability in cases where this is not followed.

Angled abutments

Abutments come in a range of sizes from 0-35 degrees in 5 degree increments. These should be chosen on a case by case basis, to enable the highest level of aesthetics and strength in the system.

Screw retained abutments

All abutments should be tightened up to 20 Nm. This is done buy the use of the Osteo-Ti Torque wrench. The Torque Wrench should be regularly tested to be 18Nm-22Nm, if it is not within this range it should be sent back to Osteo-Ti for calibration Osteo-Ti will not accept any liability for any failure because they have not been tightened to with the torque ranges stated above. Only genuine Osteo-Ti equipment should be used for any type of restoration.

Friction retained abutments

To ensure secure fit surface of the implant and the abutment should be made to be as clean and dry as possible. Friction retained abutments should be placed in the correct position and the Hex located. Once this is done a cotton wool roll should be placed over the implant and the patient told to bite together, this will cold weld the abutment and implant. If biting is not possible then a gentle tap with a mallet on the protected surface of the implant will secure the crown.

Cast on abutments

Cast-on abutments are to be used in cases where no pre fabricated abutments are suitable. It is also possible to fuse porcelain directly to the Cast-on to produce a custom made aesthetic abutment.

Indications for a castable abutment are:

- Over 3mm of soft tissue
- Over 30 degrees of angle of correction required
- Incorrectly aligned Hex

Failures

Osteo-Ti has a success rate of 98% when protocols and advise to the patient and dentist are adhered to. With this in mind Osteo-Ti will replace any failed implants providing a report and the failed implant are returned to Osteo-Ti and it is accepted by Osteo-Ti that the failure was out of the bounds of control of both the dentist and patient.