Instructions for Use

MILO™ Dental Implant System

Indications
MILO™ Dental Implants are indicated for long-term maxillary and mandibular tissue-supported denture stabilization. They are also indicated for the rehabilitation of single or maxillary lateral incisors and mandibular lateral and central incisors. Multiple implants may be restored after a period of time or placed in immediate function.

Contraindications
Patients with alcoholic addiction or psychiatric disorders, blood dyscrasias, uncontrolled diabetes, hyperthyroidism, AIDS, oral infections, malignancies or patients who have had myocardial infarction within the last 12 months. Patients on medications that would compromise healing of implant site, patients with a history of poor or non-compliance to oral hygiene procedures, or patients who cannot maintain oral hygiene procedures if implants are placed.

Material
Intra-Lock® implants are manufactured from Titanium 6A-4V ELI Alloy.

How Supplied 

Intra-Lock® implants are provided sterile (by gamma radiation) and are intended for single use only. Packaged implants are suspended on a titanium ring within a clear vial. This vial is within a Seal Pac™ plastic vial with a tamper evident label, which provides an additional environmental barrier. The label on the package provides the lot number, product description, catalog reference number and expiration date.

To ensure sterility, dental implants must be used before the end of the expiration date indicated on the outer package label.

Prior to use inspect the package and labeling for integrity. If the device is opened, damaged or contaminated in any way, it must not be used.

Never reuse, reclean or resterilize a dental implant. These activities can adversely affect implant materials and alter the surface characteristics, which may result in poor function and implant failure.

Configurations
MILO™ Dental Implants are available in four lengths (10,11.5,13 and 15mm) and in two thread profile configurations. Fine Pitch (FP) thread profile and Wide Pitch (WP) thread profile.

Preoperative Treatment Planning
Proper patient selection is a critical factor for success. A comprehensive patient interview and medical/dental history must be taken. A complete oral examination should then be conducted. Head and neck examination is followed by a thorough oral examination. The use of point source lighting and magnification is strongly encouraged as an adjunct to all intraoral examination procedures. Oral inspection includes palpation and the proper radiographic protocol(s). This may include periapicals, panorex and tomograms. Palpation of the ridges is also required and the use of intra-oral probes for tissue thickness is recommended. The diagnostic procedures will give the dentist an appreciation for the tissue quality and thickness, ridge morphology and position and the size of the implants that might be required. Measurements for implant size can be estimated utilizing radiographs, templates, calipers and millimeter rulers. Treatment planning should also take into consideration prosthetic biomechanics, occlusion in maximum intercuspation and eccentric movements, oral habits of compulsion, prosthetic design and occlusal loading. In overdenture cases four or more MILO™ implants should be utilized for maxillary or mandibular tissue-supported denture stabilization. When fixed prosthetics are utilized in single stage surgical procedures MILO™ Implants may be loaded immediately following insertion provided at least four implants are placed and are splinted with a bar. These implants should be placed principally in the anterior mandible, between the mental foramina, where good initial stability of the implants can most often be achieved. Fine Pitch MILO™ Implants, Wide Pitch MILO™ Implants as well as other implant designs and configurations can be used in conjunction in the same restoration. The implant body or prosthetic components can be compromised if proper planning in the abovementioned areas is inadequate.

Surgical Asepsis
As with all surgical procedures, the operating field should be maintained with sterile draping and coverings as much as possible (light handles, chair controls and attachments, bracket tray, all instruments and components). Barrier technology, sterile solutions and sprays, sterile coverings, proper autoclaving and handling techniques must be employed as indicated.

Sterilization of Abutments
Abutments may be sterilized using a full cycle pre-vacuum steam sterilization at a temperature of 132°C for an exposure time of 3 minutes.

Precautions
- Prosthetic components and drills may be autoclaved via standard procedures.
- Handling: The external surface of titanium dental implants should only come in contact with titanium surfaced instruments. All implants are provided suspended on titanium rings and are designed for use with the Drive-Lock™ drivers.
- This method will enable proper handling, transport and implantation procedures.

Soft Tissue Site Preparation
Once prepped (site isolation and local anesthesia achieved), the surgical procedure begins with identification of the implant site(s) via the creation of bleeding point(s). A flapless surgical protocol may be employed when there is certainty regarding the amount of available bone and the proximity of the mandibular foramen or other landmarks. The distance between implants and/or the natural dentition should be maintained within a range of 4-6mm.

Penetration of the Alveolar ridge
Copious internal and/or external irrigation must also be employed during this procedure It is of critical importance and mandatory that the final drill is CONDUCTED AT SLOW SPEED (60-120 RPM).

Drilling Technique and Sequence
The slow-speed, highly irrigated drilling procedure is conducted while angling the drill such that the direction of the drill bisects the ridge. The drill should also be held vertically, avoiding a mesial or distal cant. Depth gauge/alignment components can be the diameter and length of the 1.5mm MILO Twist Drill (D15) that prepares the crestal bone to accept the geometry and is periodically inserted into the osteotomy site to monitor the angle of penetration. The 2.5mm Finishing Drill (D25) technique is performed with a precise, up and down pumping action. The drill angle is maintained in order to preserve the concentricity of the hole, while the pumping action allows for incremental depth penetration and periodic cleansing of the flutes. It is recommended to use the fine pitch MILO (FP) and MILO wide pitch (WP) in conjunction with the ø2.5mm final drill (D25).

Completion of Site Preparation
A paralleling pin (PP)/depth gauge (DG) indicator should be utilized when multiple implant sites are prepared. As each site is completed, a paralleling pin can be inserted into the osteotomy site and used as a guide for the preparation of the next site.

Handling
The surface of titanium dental implants should only come in contact with titanium-surfaced instruments. All MILO™ Implants are suspended within a sterile vial on two titanium rings. The implants are designed for use with Drive Lock™ attachment drivers. These instruments will facilitate proper handling, transport and implantation protocols.

Drive-Lock Direct Transfer
The MILO™ Drive Lock carrier/ placement driver is used to pick up the implant directly from the sterile vial, carry it to the osteotomy site and thread it into place. This driver is available in versions that are compatible with both contra-angle and ratchet drives. A Surgical Ratchet Wrench (SRA) with a MILO™ Ratchet Driver (MLRD) or a MILO™ Round Hand Driver (MLMW) can be used to provide greater initial Torque and enhance tactile sensation for final seating. Threading should proceed at a rate no greater than 10 RPM. The implant is fully seated when the tip of Drive-Lock carrier is flush with the surrounding tissue.

Radiographic Verification

Appropriate radiograph(s) should be taken to confirm proper depth, seating, orientation and placement of the implant(s).

Postoperative Care

Cold packs are recommended for the first 24 hours. Analgesics/Antibiotics may be prescribed at the discretion of the practitioner. The patient is advised to favor the opposite side of the mouth, maintain a soft diet and avoid hot liquids. Sutures, if utilized, may be removed after 5-7 days.

Warning

- Dental implant surgery is a complex dental procedure.
- Appropriate and adequate training in all phases of implant procedures and proper technique is strongly recommended prior to implant use.
- Improper patient selection, diagnosis, treatment planning or technique can result in implant failure and/or loss of supportive bone.
- The use of small diameter implants and angled abutments in the posterior region of the mouth is not recommended due to possible failure of the implant.

Note: The Intra-Lock® Dental Implant System has not been evaluated for safety and compatibility in the MR environment. The Intra-Lock® Dental Implant System has not been tested for heating or migration in the MR environment.

Prosthetic Protocol For Denture Retrofitting

Chairside Pick-up

1. Transfer the position of the O-Ball Abutments to the tissue-bearing surface of the denture by tipping the heads of the O-Ball Abutments with a dense lead pencil or marking their impression with the use of soft silicone, wax or triad.
2. Evacuate approximately a 5mm opening around the abutment impressions or markings with a resin bur.
3. Try the denture in the patient's mouth and check intra-orally that the appliance is seated passively while in maximum intercuspation [With no interference on the O-Balls].
4. Snap the O-Ring, encased in Metal Housing, over each O-Ball Abutment.
5. Try the denture in the patient's mouth again and check intra-orally to ensure that the appliance is seated passively while in maximum intercuspidation.
6. Remove the O-Rings, encased in Metal Housings. Lubricate O-Ball heads to prevent any acrylic lock-on. To further protect against acrylic lock-on a Dental Rubber Dam may be placed over the square of the abutment leaving only the O-Ball protruding and exposed.
7. Snap the O-Ring, encased in Metal Housing, over each O-Ball Abutment in preparation for final seating.
8. Clean and wash the denture. Fill the abutment recesses with Cold-cure acrylic. As soon as the acrylic becomes resistant to flow seat the denture.
9. Have the patient close lightly in maximum intercuspidation. Allow acrylic to fully polymerize.

10. If utilized, remove Dental Rubber Dam material. Trim flash and fill any minor voids or discrepancies and polish denture.
11. Perform final occlusal equilibration. Patient should be instructed in denture placement, removal and general oral hygiene.

Prosthetic Protocol for Fixed Restorations

1. Slide MILO Impression Coping(s) (MTL) over each MILO O-ball assembly.
2. Pick-up the MILO Impression Coping(s) in an impression tray using the impression material of your choice.
3. After the impression material has set remove the impression tray from the mouth and place Milo Analog(s) (MLA) into the Impression Coping(s).
4. Pour working model.
5. Prepare the MILO abutments and fabricate the final restoration as per your usual prosthetic protocol.
6. Cement MILO abutment(s) over each MILO O-ball assembly with resin cement.
7. Finish the prosthesis by verifying final occlusion in centric position and eccentric excursions.

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