Directions for Use

Mini Drive-Lock™
Dental Implant System

Indications
Mini Drive-Lock™ Dental Implants, are intended for use as a self-tapping titanium screw for transitional or intra-bony long-term applications.
Mini Drive-Lock™ Dental Implants are also indicated for long-term maxillary and mandibular tissue-supported denture stabilization. Multiple implants should be used and may be restored after a period of time or placed in immediate function.

Contraindications
Patients with alcoholic addiction, 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(s), 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® Mini Drive-Lock™ dental implants are manufactured from Titanium 6A-4V ELI Alloy, ASTM F136.

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
Mini Drive-Lock™ Dental Implants are available in five lengths (10,11.5,13,15 and 18mm) and in two body diameters (2.0 and 2.5mm). The 2.0mm and 2.5mm diameter implants feature a 2mm gingival collar. The 2.5mm version is also available with a 4mm gingival collar.

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 tomographic radiographs. 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 and occlusal load. Fracture due to excessive load or metal fatigue can occur if this aspect of planning is inadequate.

Mini Drive-Lock Placement
1. Establish the correct number, angulations and placement positions for the Mini Drive-Lock Implant(s). The minimum distance between implants should be 3mm.
2. Administer local anesthetic. Crestal and buccal anesthesia are adequate. The anesthetic solution should be sufficient to anesthetize all the periosteal surfaces that will be encountered.
3. Mark the site(s) of initial penetration. Bleeding points or an indelible marker can be used.
4. Penetration of Gingiva and Cortical Bone The concept is to create a “pilot hole” into which the Mini-Implant can be inserted. Mini Drive-Lock Implant protocol calls for the use of a Pilot Twist Drill (1.2mm diameter) when penetrating the gingiva and cortical plate.

   DRILLING TECHNIQUE consists of a light, repeated, intermittent, vertical introduction of the Pilot Drill through the gingival tissue at the placement site. The procedure is performed at approximately 1200 rpm, with copious external irrigation with sterile saline, in order not to create excessive heat. Once the thickness of the gingival tissue and the periosteum has been breached, the drill will engage the cortical bone. Tactile sensation will indicate when the cortical plate is breached. This completes the drilling procedure. This technique calls for a pilot hole only. Careful care should be taken not to drill to the full length of the implant. The Mini Drive-Lock Implant must self-tap itself into the bone.
5. Removal of implants from Sterile Packaging: The sterile Mini Drive-Lock Implants are suspended on a titanium ring, in order to enable direct transfer to the surgical site. The Mini Drive-Lock Implant, Contra-angle Driver, (MDLCAD), snaps over the o-ball and engages the square driving feature. It permits the implant to be taken out

of the vial, carried to the site and placed into the pilot hole. Once in position, gently start the slow speed contra-angle. Recommended speed is 15 R.P.M. The Drive-Lock Driver and the implant will now begin to rotate and permit the self-tapping action of the Mini Drive-Lock Implant to take place. The use of an electric motor with a torque limiting feature is recommended. The torque limit should be set to 35 Ncm.

6. Threading the Mini Drive-Lock Implant The Initial Phase: The Mini Drive-Lock implant is self-tapping and once started, cuts its way through, threading and expanding the bone at the same time. Since no osteotomy site has been created, the Mini Drive-Lock Implant threads its way through untouched bone, thus expanding and taking advantage of the visco-elastic nature of the bone.
7. Threading the Mini Drive-Lock Implant Final Seating: The handpiece will stall when the torque limiting value of 35 Ncm is reached. Remove the contra-angle drive lock driver, (MDLCAD) from the head of the Mini Drive-Lock Implant by lifting and separating it. Insert the Mini Drive Lock Ratchet Driver, (MDLRD) into the Ratchet Wrench, (SRA).

   Utilization of the Ratchet Wrench: The MDLRD in the SRA wrench is then engaged over the head of the implant and snapped into place. Using small, incremental turns, continue seating. Pause between each quarter turn in order for the elasticity of the bone to allow the introduction of the Mini Drive-Lock Implant.

Note: The correct depth of the Mini Drive-Lock Implant is attained when the shoulder of the collar is flush with the height of the surrounding gingiva.

Prosthetic Techniques and Denture Retrofitting

1. Transfer the position of the O-Ball Abutments to the tissue-bearing surface of the denture. Tipping the heads of the O-Ball Abutments with a pencil or marking their impression with a soft wash, wax or triad can accomplish this.
2. Excavate a 5mm opening around the abutment impression markings with a round acrylic bur.
3. Inspect intra-orally to insure that the appliance is seated passively while in maximum intercuspation.
4. Place a Dental Rubber Dam, punched out to fit over the square of each abutment. Only the O-Ball head(s) should be protruding and exposed.
5. Lubricate the O-Ball heads to prevent any acrylic lock-on.
6. Snap the O-Ring encased in its' Metal Housing, over each O-Ball Abutment.
7. 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.
8. Have the patient close lightly in maximum intercuspation. Allow to polymerize.
9. Remove the denture. Trim flash and fill any minor voids or discrepancies. Polish denture.
10. Perform final occlusal equilibration. Patient should be instructed in denture placement, removal and general oral hygiene.

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 Mini Drive-Lock Implant System has not been evaluated for safety and compatibility in the MR environment. The Mini Drive-Lock Implant System has not been tested for heating or migration in the MR environment.

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