Dental Implant and Abutment Instructions For Use

Indications Dental Implants

Intra-Lock® Implants have been designed to restore partially or fully edentulous patients. The implants have been designed to be used in either the mandible or the maxilla and to support removable or fixed prostheses, from single tooth replacement to full arch reconstruction. Intra-Lock® Implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore normal teeth functions.

Indications MILO™ Dental Implant Systems

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.

Indications Mini Drive-Lock™ Dental Implant System

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.

Indications Dental Implants Blossom

Intra-Lock® Implants have been designed to restore partially or fully edentulous patients. The implants have been designed to be used in either the mandible or the maxilla and to support removable or fixed prostheses, from single tooth replacement to full arch reconstruction. Intra-Lock® Implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore normal teeth functions.

Indications OP Dental Implants

For 3.0 mm - Intra-Lock® OP Dental Implants are indicated for long-term maxillary and mandibular tissue supported denture stabilization. They are also indicated for rehabilitation of single or maxillary lateral incisors and mandibular lateral and central incisors. Multiple iplants may be restored after a period of delayed loading or placed in immediate function when good primary stability is achieved with appropriate occlusal loading in order to restore normal teeth function.

For 3.75mm, 4.0mm & 4.75mm Intra-Lock OP Dental Implants

Intra-Lock® OP Dental Implants have been designed to restore partially or fully edentulous patients. The implants have been designed to be used in either the mandible or the maxilla and to support removable or fixed prostheses, from single tooth replacement to full arch reconstruction. Intra-Lock® Implants are intended for immediate function on single tooth

and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore normal teeth functions.

Indications Dental Abutments

Intra-Lock® abutments are intended for use with Intra-Lock® dental implants to support a prosthetic device in partially or fully edentulous patients. The abutments may be used in single and/or multiple tooth application in the mandible or maxilla.

Contraindications

Patients with alcohol addiction or psychiatric disorders, blood dyscrasias, uncontrolled diabetes, hyperthyroidism, oral infections, malignancies or patients who have had myocardial infarction within the last 12 months.

Patients with systemic diseases that compromise the immune system, such as AIDS, patients on medications that would compromise healing of an 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.

Tobacco usage increases the occurrence of complications and failures.

Material

Intra-Lock® implants and abutments are manufactured from Titanium 6AL-4V ELI Alloy, ASTM F136 or Commercially Pure Titanium, ASTM F-67. Intra-Lock® manufactures a temporary abutment from PEEK and Titanium 6AL-4V ELI.

How Supplied

Intra-Lock® dental implants are provided sterile (by gamma radiation) and are intended for single use only. Packaged implants are suspended on a titanium or polycarbonate support ring within a clear vial. This vial is placed into a Seal Pac™ plastic vial with a tamper evident seal, which provides an additional environmental barrier.

The label on the package provides the lot number, product name, 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.

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.

Prior to using Intra-Lock® dental implants, inspect the package and labeling for integrity. If the device is opened, damaged or contaminated in any way, DO NOT USE.

Intra-Lock® dental abutments are provided non-sterile and intended for single use only. Abutments should be sterilized prior to use by the instructions provided.

Prior to using Intra-Lock® dental abutments, inspect the package and labeling for integrity. If the device is opened, damaged or contaminated in any way, it must not be used.

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 and 5 minute drying time.

Preoperative Treatment Planning

Proper patient selection is important. 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 magnification is strongly encouraged as an adjunct to all 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 for the type and 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 on the implant body or it's prosthetic components if this aspect of planning is inadequate.

In overdenture cases four or more implants should be utilized for maxillary or mandibular tissue-supported denture stabilization.

When fixed prosthetics are utilized in single stage surgical procedures, 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.

Surgical Asepsis

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

Important Points to Remember

- The Conic Implants have a tapered thread body and are designed to fit the drilled depth.
- The final seating of the implant(s) should be achieved by the incremental turns of the Ratchet Wrench.
- Radiograph(s) should confirm proper depth, seating, orientation and placement of the implant(s).
- If a removable prosthesis is used near the implant site, in process of healing, it should be generously relieved and a soft tissue conditioner reline material placed.

Postoperative Care

Cold packs are recommended for the first 24 hours. Analgesics/Antibiotics may be prescribed at the discretion of the practitioner. The patient should be advised to favor the

opposite side of the mouth, maintain a soft diet and avoid hot liquids.

Warning

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.

Warnings

- 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.
- Care must be taken if performing electrosurgery around a dental implant. Electrosurgery generates heat, which can be conducted through a metallic implant and cause damage to surrounding tissue or 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.
- The external surface of Intra-Lock® Dental Implants should only come in contact with titanium surfaced instruments.
- Prior to the placement of all dental implants and dental abutments, appropriate and adequate training in all phases of implant and abutment procedures is strongly recommended.
- A comprehensive patient interview, medical/dental history and complete oral examination should be conducted.
- Diagnostic radiographs and mounted study models, if appropriate should also be obtained.

Warning

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

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