

Sterile Implant Components

Instructions For Use



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Order online at www.sterngold.com

Description:

The Sterngold ImplaMed Implant System consists of various screw implants and coated cylinder implants along with required components to provide an osseointegrated prosthesis for oral reconstruction. A series of abutment products are also available to satisfy a variety of restorative options.

Indications:

The Sterngold ImplaMed Implant System can be used in dental implant applications for oral rehabilitation of edentulous and partially dentate patients in the maxilla and mandible. Implant retained restorations may consist of single crowns or bridges as well as complete or partial dentures.

Contraindications:

The following conditions would obviate the use of dental implants: inadequate bone substance or quality, intractable poor oral hygiene, acute or chronic infection, abuse of drugs or alcohol, allergies to titanium, smoking, systemic conditions that would impair healing, excessive occlusal parafunction, history of radiation or patient otherwise not suitable for long or complicated surgery, or the inability to construct a functional prosthesis.

Warnings:

It is possible that an implant may fail to integrate to the surrounding bone which would lead to loss of the implant and restoration supported by the implant. Potential causes for failure include: lack of bone quantity or quality, inadequate surgical technique, infection, and poor patient oral hygiene. Temporary or permanent numbness (anesthesia), paresthesia, or dysesthesia are possible complications of implant surgery. Loosening or fracture of implant and restoration components may occur over time.

Precautions - Implants:

Implant surgery is a highly specialized and complex procedure and special training is required. Practitioners should attend courses designed to teach proper techniques. Improper technique can result in implant failure and substantial loss of surrounding bone. Radiographs or other diagnostic reviews should be performed to determine position and topography of the maxillary sinus, nasal cavities, inferior alveolar nerve, mental foramen, natural tooth positions and other anatomical features that may affect implant placement or prognosis. Consultation between the surgeon,

restorative dentist, and dental laboratory is essential for success.

During implant surgery, pay special attention to thermal and surgical trauma to minimize tissue damage, infection and excessive post-operative bleeding. Thermal trauma severely impedes implant integration to bone. Reduced drill speeds of 1000-1500 r.p.m., the use of sharp drills, sufficient irrigation, and use of pilot drills in successively increasing sizes are essential. Recommended healing period is 4-6 months for mandible and 6-8 months for maxilla prior to healing abutment placement. Healing abutment should be left in place for approximately 4 weeks prior to prosthetic placement and loading. Where applicable, relin the denture after implant placement to avoid premature loading.

Refer to Sterngold ImplaMed Dental Implant Surgical Technique sheet for detailed procedural instructions.

Precautions - Prosthetics:

During prosthetic placement procedures, care should be taken to minimize tissue damage and infection. Radiographs and other diagnostic reviews are needed during prosthetic reconstruction to ensure proper fit to implants and abutments. Prosthodontic procedures must consider: proper stress distribution, passive adaptation and fitting of prosthesis to fixture abutments, adjusting of occlusion to opposite jaw, and avoiding excessive transverse load.

Refer to appropriate Sterngold ImplaMed prosthetic technique sheet for detailed procedural instructions.

How Supplied:

Sterngold ImplaMed implants are supplied sterile and should be handled with sterile titanium instruments. Implants are intended for single use only and should not be resterilized if contaminated. Refer to instructions for implant packaging provided on this insert.

Where the label indicates, disinfect products supplied non-sterile prior to use.

Caution:

Federal (USA) law restricts this device to sale by or on the order of a dentist (or other licensed practitioner).

Labeling Symbols: Symbols are used for products sold internationally for ease in identification.

	Refers to product "Catalog Number"
	Symbol for product "Lot Number"
	Symbol for "Refer to Instructions"
	Symbol for "Sterilized using Irradiation"
	Symbol for "Use by Date"
	Symbol for "Do Not Reuse"
	0197 Symbol for CE Mark

Sterngold ImplaMed products are manufactured in the United States:

Sterngold ImplaMed
23 Frank Mossberg Drive
Attleboro, MA 02703



European Representative:
SQP
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INSTRUCTIONS FOR IMPLANT PACKAGING

Remove sealed blisters from outer box. Patient labels are provided for placement in patient chart. To open the blister hold the bottom of the outer blister and peel away the top lid by pulling at the PEEL HERE tab. Non Sterile Assistant to drop inner blister package into sterile field.

Sterile Assistant to peel away inner blister lid by holding bottom of blister and pulling at the PEEL HERE tab. Rotate the tube and implant assembly to the upright position and press the tube down into the round cavity at its base to lock into position as shown in the following figures.

Screw Implants provided without a mount require assembly of a preferred implant mount onto external hex of implant. Be sure to completely seat the assembly onto the implant. Lift the implant assembly from the tube, place in prepared implant site and install using standard methods. See figure 1.

Direct Delivery Screw Implants are supplied with a mount and mount screw attached to a disposable plastic holder, and a separate cover screw. Grip the holder and lift screw implant assembly from tube and place in prepared implant site. Partially or completely install the implant with holder in place. Remove holder with an upward motion. Place cover screw on implant. See figure 2.

Hex Cylinder Implants are supplied with a pre-assembled cover screw attached to a disposable plastic holder. Grip the holder and lift cylinder assembly from tube and place in prepared implant site. Holder may remain on the implant until installation is complete. Cylinder seating tool may be used with holder in place. Remove holder with a sideways motion. See figure 3.

Figure 1

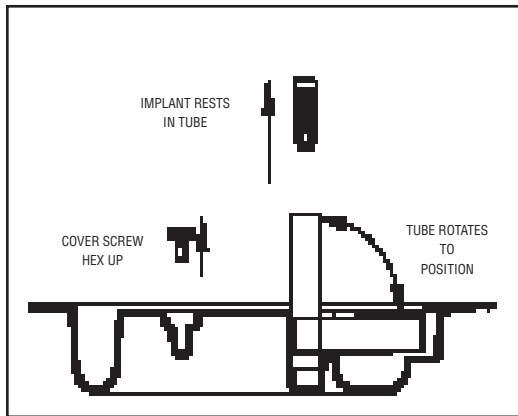


Figure 2

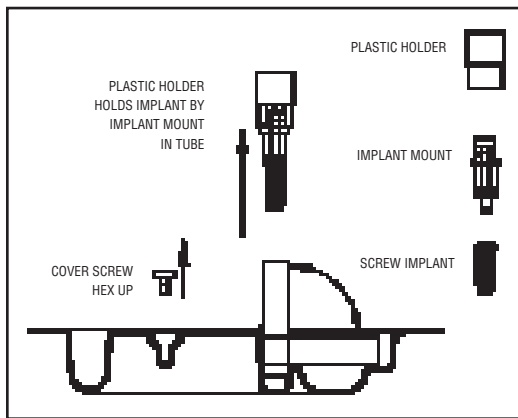


Figure 3

