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IMPLANT INNOVATIONS

### 510(k) SUMMARY

**NEW INDICATION FOR USE: SINGLE STAGE SURGERY USING DEVICES  
ORIGINALLY INDICATED FOR A TWO-STAGE SURGICAL PROCEDURE.**

To the Requestor:

This information is taken directly from the original Pre-Market Notification [510(k)], submission, provided to the United States Food and Drug Administration. No information regarding safety or efficacy has been deleted from that submission, for this summary.

#### NEW INDICATION FOR USE:

**NON-RESORBABLE MEMBRANE FIXATION FOR ENDOSSEOUS DENTAL  
IMPLANT AND/OR GUIDED TISSUE REGENERATION PROCEDURES, USING  
OSSEOUS FIXATION (PLATE AND SCREW) SYSTEMS.**

#### 1. CLASSIFICATION NAME:

Bone Plate and/or Intraosseous Fixation Screw or Wire.

#### 2. COMMON/USUAL NAMES:

Bone Plates and Screws, Osseous Fixation Systems.

#### 3. PROPRIETARY NAME:

3i Osseous Fixation System(s).

Bone Fixation System, Stain Steel - K952811 (SE 08/30/95)  
Bone Fixation System, Co-Cr Alloy - K952812 (SE 08/30/95)  
Bone Fixation System, Titanium - K953386 (SE 09/15/95)

For the purpose of this submission, only Bone Fixation System (K952812), need be considered.

#### 4. CLASSIFICATION:

Bone Plates per 872.4760 have been classified as Class II devices. Bone plates per this section may also include the Screws necessary to secure the Plates. Intraosseous Fixation Screws or Wires per 872.4880, are also

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classified as Class II devices.

5. PERFORMANCE STANDARDS: Unknown

6. PRIOR INDICATIONS FOR USE:

The 3i Cobalt-Chrome Osseous Fixation System is designed as a temporary fixation device, used in oral and maxillofacial surgical procedures for rigid stabilization of fractured bone plates.

7. PROPOSED NEW INDICATIONS FOR USE:

In the past several years there has been extensive work published on the use of bone filling, grafting and augmentation materials and techniques. Many of these procedures, generally referred to as "Guide Bone Regeneration" (GBR), have been used in conjunction with dental restorative procedures using endosseous dental implants. It is not an uncommon practice for a clinician to develop a ridge of sufficient height and width (GBR), in those patients who otherwise may be contraindicated for dental implant treatment, due to a lack of adequate bone. GBR is also common treatment for repairing bony defects and to fill the sockets in and around implants placed in fresh extraction sites. In nearly all of these procedures, it is necessary to guide the bone regenerative process by providing an adequate, "regenerative space with a stable osseous base, free of connective tissue and epithelial cells and a blood supply emanating exclusively from the bony base" \*(1). This "regenerative space", is commonly constructed of components of one or more of the various bone plate and screw systems currently available, including the 3i Osseous Fixation System. Incorporated with the "regenerative space" framework is an firmly attached occlusive, biologically inert, non-resorbable membrane, used to protect the GBR site from soft (epithelial) tissue and bacteria invasion. With the use of unattached, unsecured membranes, micro-movement can cause scar tissue formation under the membrane, instead of bone. Also soft tissue (epithelial) and bacteria may invade the GBR site from around the margins of the unsecured membrane \*(1). Therefore, it has become standard practice to use bone plates/screws, tacks or other forms of fixation to attach and support membranes with framework over the GBR site. 007

Due to widespread, clinically accepted GBR procedures using lamellar bone, various bone grafting/augmentation

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\*(1) Meltzer AM, Edenbaum DR. Guided Bone Regeneration: Obtaining Predictable Results by Maximizing Membrane Adaptation and Stabilization.

materials and/or biologically inert, non-resorbable membranes, 3i is requesting marketing clearance for the new indication for use of its "Osseous Fixation System"; in GBR procedures to form and/or secure a GBR framework, and/or to secure Non-resorbable membranes to the bone, to minimize micro-movement, repress and prevent bacteria and soft tissue (epithelial) in-growth and to permit greater ease in removal of the membrane and framework.

**8. REFERENCES:**

Buser D, Dahlin C, Schenk RK. Guided Bone Regeneration in Implant Dentistry. Quintessence Publishing Company: 1994.

Meltzer AM, Edenbaum DR. Guided Bone Regeneration: Obtaining Predictable Results by Maximizing Membrane Adaptation and Stabilization.

Gore Regenerative Technologies. Flagstaff AZ. "The RegenTech Review, Vol 1, No. 4 June 1994.

Ultimatics, Inc. Springdale AZ. "Ultimatics Update", Vol #1 January 1992.

**9. CONTRAINDICATIONS:**

3i's Bone Screw and plate systems are contraindicated in cases of patient sensitivity to Cobalt, Chromium or Molybdenum; or when a patient is not indicated for GBR treatment as determined by the treating clinician.

10. **WARNINGS:** For safe and effective use of 3i implants and bone plate and screw systems in GBR procedures, it is strongly suggested that specialized training be undertaken since the surgical techniques required to create the "regenerative space" and membrane fixation and/or to surgically place dental implants are highly specialized and complex procedures. Improper patient selection and technique can cause fixture failure and/or loss of supporting bone.

11. **PRECAUTIONS:** Thorough screening of prospective surgical/implant candidates must be performed. Visual inspection as well as panoramic and periapical radiographs are essential to determine anatomical landmarks, occlusal conditions, periodontal status, and adequacy of bone. Lateral cephalometric radiographs, CT Scans, and tomograms may also be beneficial.

12. **ADVERSE EFFECTS:** Loss of the "regenerative framework" and/ or implant anchorage (failure to osseointegrate) and loss of the prosthesis are possible occurrences after surgery. Lack of quantity or quality of remaining bone, infection, poor patient oral hygiene or cooperation, and

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generalized diseases (diabetes, etc.) are some potential causes for loss of fixture anchorage.

13. **SURGICAL COMPLICATIONS:** The surgical procedure has risks, including localized swelling, dehiscence, tenderness of short duration, edema, hematoma, or bleeding. Numbness of the lower lip and chin region following lower jaw surgery, and of the tissue beside the nose following upper jaw surgery, is a possible side effect of the surgery. Though it would most probably be of a temporary nature, in very rare cases numbness has been permanent. Gingival/Mucosal (gum tissue) ulceration, tissue reaction, or infection may occur, but generally responds to local care.

14. **LABEL/LABELING MATERIALS:**

No direct product labeling changes are anticipated.

Any changes to Marketing materials will only include the indication for use with Non-Resorbable membranes in GBR procedures with and without endosseous dental implants.

15. **SUBSTANTIAL EQUIVALENCE:**

Straumann USA "Memfix" The Mini-Screw Membrane Fixation Kit" System K955369.

IMZ/Interpore Bone Tack System K952167.

Both IMZ and Straumann may have received a determination of Substantial Equivalence on their respective systems for use with Lamellar bone and (Straumann USA) membrane fixation in guided bone regeneration cases.

16. **510(k) CERTIFICATION AND SUMMARY FOR SUBMISSION:**

I certify that I have conducted a reasonable search of all information known or otherwise available to me about the types and causes of safety and/or effectiveness problems that have been reported for Endosseous Dental Implant systems.

Bone plate and screw:

Infection, caused by improper surgical technique, including mucosal damage during surgery and improper mucosal closure; Exposure or prominence of hardware, caused by the use of designs that are too thick for the soft tissue, particularly in the supraorbital, frontal and naso-orbital-ethmoid locations (prominence in these regions can be reduced by the use of micro-fixation devices); Possible alteration in the growth patterns of the craniomaxillofacial skeleton due to rigid fixation

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during skeletal development (preliminary evidence from animal studies; Breakage of screwdrivers during maxillofacial surgery, possibly resulting in retention of the screwdriver tip in the screw.

**Endosseous Dental Implants:**

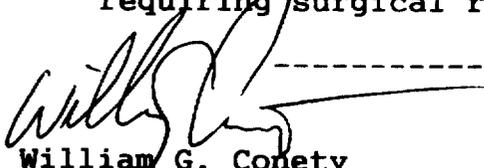
Failure of the implant to osseointegrate or loss of osseointegration can be caused by improper patient selection (patients with systemic diseases which affect bone physiology, patients with habits such as bruxing or clenching, patients who are physically or psychologically unable to carry out proper implant hygiene, heavy smoking or alcohol use), by improper surgical technique (overheating of bone) or improper case planning or restorative technique (over-loading of implants through improper placement, use of an insufficient number of implants or excessive cantilever). Improper implant processing by the manufacturer or improper handling by the customer, resulting in contamination, can also effect osseointegration.

Fracture of implants can occur, particularly in implants with apical cross-holes. Fracture occurs either on insertion of screw-type implants due to excessive torque (improper surgical technique such as an error in drill selection) or in service due to loss of bone.

Fracture of abutments and abutment screws occurs in implant systems and is usually attributed to factors within the control of the implant team, such as lack of passive fit of the restoration or excessive cantilever, or within the control of the patient, such as bruxing.

Other types of safety and efficacy problems which have been observed for endosseous dental implant systems are local soft tissue degeneration and bone resorption, paresthesia, perforation of the maxillary sinus, perforation of labial and lingual plates, local and systemic infection, prosthetic framework fracture, nerve injury, bone fracture, injury to adjacent teeth and their supporting bone, oroantral or oronasal fistula, gingival hyperplasia, soft tissue overgrowth, perforation of the gingiva by the healing screw, mucosal abscess, displacement of the implant into the mandibular canal, hemorrhage of the floor of the mouth due to transection of the sublingual artery and breakage of drill tip, requiring surgical removal.

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