ENGLISH

INSTRUCTIONS FOR USE

SATURNO™ NARROW DIAMETER IMPLANT SYSTEM

Includes: Implants with a straight o-ring ball attachment, implants with a 20 degree angled o-ring ball attachment and surgical, restorative and dental laboratory components and tools.

IMPORTANT: This document contains the most current Instructions for Use. Please read and retain.

DESCRIPTION:

The SATURNO™ Narrow Diameter Implant System is comprised of 2.0mm, 2.4mm or 2.9mm diameter endosseous dental implants (available in 10, 12 and 14mm lengths). A straight or 20 degree angled o-ring ball attachment is available on each implant size. The implant cuff heights are available in 2mm or 4mm.

INDICATIONS

The SATURNO™ Narrow Diameter Implant System is designed to retain overdentures or partial dentures in the mandible or maxilla. The SATURNO™ Implant is used to restore masticatory function for the patient and may be suitable for immediate function if sufficient primary stability of the implant is achieved at the time of placement.

CONTRAINDICATIONS

Not appropriate where a totally rigid connection is required. Use of a single implant with a straight o-ring ball attachment with divergence of greater than 15 degrees from the path of insertion is not recommended. Use of a single implant with a 20 degree angled o-ring ball attachment with divergence of greater than 35 degrees from the path of insertion is not recommended. Dental implants should not be used in patients with serious medical problems or in a poor general state of health. Patients with medical problems such as; uncontrolled bleeding disorders, drug or alcohol abuse, weakened immune system, or uncontrollable endocrine disorders should be carefully evaluated prior to treatment.

Not for use with o-rings other than the SATURNO™ Micro O-Ring (3.5mm outside diameter, 1.8mm Ball).

CAUTION

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

WARNINGS, PRECAUTIONS & DIRECTIONS FOR USE

The SATURNO™ Narrow Diameter Implant System has not been evaluated for safety and compatibility in the MR environment. The SATURNO™ Narrow Diameter Implant System has not been tested for heating or migration in the MR environment.

For specific warnings, precautions and directions for use, refer to the corresponding SATURNO™ Narrow Diameter Implant System Technique Manual.

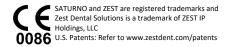
SINGLE-USE DEVICES

The SATURNO™ Narrow Diameter Implant System is a single-use device. Please refer to the corresponding SATURNO™ Narrow Diameter Implant System Technique Manual for consequences of inadvertent re-use of single use devices.

If reused, ZEST Anchors cannot guarantee the functionality or the safety of the product. ZEST Anchors, LLC accepts no responsibility







for components re-sterilized by the user.

STERILIZATION

The SATURNO™ Narrow Diameter Implant is packaged and supplied *STERILE* (subjected to radiation (gamma) as a means of sterilization).

All other restorative components, instruments, and replacement o-rings (sold separately) are supplied NON-STERILE.

Please refer to the corresponding SATURNO™ Narrow Diameter Implant System Technique Manual for sterilization & cleaning instructions for re- usable components/tools.

SURGICAL and PROSTHETIC PROCEDURES

Please refer to the SATURNO™ Narrow Diameter Implant System Technique Manual.

TECHNIQUE MANUAL

The SATURNO™ Narrow Diameter Implant System Technique Manual is available from the manufacturer or your distributor. It is also available online at www.zestanchors.com.

