DESCRIPTION:

Insight Dental System (IDS) kits have instrumentation that is used for dental implant procedures such as site development, implant placement, and implant restorations within the specific indications of each implant system. The label on each kit contains important product information including whether the implant is bone or tissue level and the diameter size of the implant. Each kit will provide all the necessary instrumentation to surgically place the implant and place the healing screw, tissue healing abutment, or restorative abutment to support a treatment crown and final fixed crown. The IDS kit is supplied sterile for single-use only.

INDICATIONS FOR USE:

The Insight Dental Implant System is intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. The Insight Dental Implant System is intended for delayed loading.

CONTRAINDICATIONS:

IDS instruments should not be used with patients that have allergies to the specific materials used, including stainless steel and titanium alloy. IDS implants have not been evaluated for safety and compatibility in the MR environment.

DIRECTIONS FOR USE:

Proper surgical procedures and restorative techniques are the responsibility of the dental professional. Each clinician must evaluate the appropriateness of the procedure use based on personal dental surgical training, knowledge of bone type, and experience when applied to the patient case at hand. IDS strongly recommends completion of dental implant course(s) hands-on instruction and strict adherence to the instructions pertaining to IDS products. This kit is designed for Single Use only and re-use should not be attempted. This kit is sold sterile by gamma irradiation. Not recommended to re-sterilize.

Shelf Life:

IDS kits are considered sterile for 1 year from the date of initial sterilization. The product expiration date is labeled on Tyvek.

Drills and Taps:

IDS drills and taps are single use only. Each kit will have the precise drills to use and placed in order from left to right. Each drill and tap will contain the corresponding implant size.

Implant Insertion:

Use appropriate instrumentation to insert the implant. Thumb drivers, implant driver, torque wrench, and other various items are available for use.

One-Stage Surgical Procedure:

One-stage placement of implant and abutment at the time of surgery should not be attempted unless the implant-bone torque interface is at least 30 Newton-centimeters N*cm. If abutment and treatment crown are placed at the initial surgical appointment, it is recommended that all occlusal forces, both vertical and lateral, are eliminated from the treatment crown. It is also suggested that x-rays be taken

after abutment placement to make sure abutment is aligned properly.

Two-Stage Surgical Procedure:

After implant placement, a healing screw can be placed in the implant and surrounding tissue sutured over the implant. If a tissue abutment is going to be used in an attempt to eliminate a second surgical procedure, a tissue abutment can be placed in the implant with finger pressure and surrounding tissue sutured around the tissue abutment as close as possible to the abutment(s) and adjacent teeth.

Prosthetic Instruments:

Only use a torque wrench for final placement of prosthetic components requiring the specified installation torque. Finger-tightening of prosthetic components will result in insufficient torque and eventual loosening of the component. Abutment screws should be tightened to 30 Newton-centimeters N*cm with appropriate torque wrench. After waiting 10-15 minutes the screw should be retightened to 30 Newton-centimeters N*cm to allow for preload force dissipation and work hardening of screws, thus better abutment/implant surface adaptation.

WARNINGS AND PRECAUTIONS:

Clinician judgment, as related to individual patient presentations, must always supersede recommendations in any IDS Instructions for Use (IFU). Refer to OSHA standard 29CFR1910.1030 prior to cleaning and sterilization. Additional technical information is available upon request from IDS, or may be viewed and/or downloaded on website. Contact IDS Customer Care or your local representative with any questions you have regarding the IFU.

COMPLICATIONS AND ADVERSE EFFECTS:

The risks and complications with IDS instrumentation, prosthetic components, and implant(s)include, but are not limited to: (1) allergic reaction(s) to implant and/or abutment material; (2) implant and/or abutment breakage; (3) abutment screw and/or retaining screw loosening; (4) infection requiring revision of the dental implant; (5) nerve damage that could cause permanent weakness, numbness, or pain; (6) histologic responses possibly involving macrophages and/or fibroblasts; (7) formation of fat emboli; (8) implant loosening requiring revision surgery; (9) maxillary sinus perforation; (10) labial or lingual plate perforation; and (11) bone loss possibly resulting in revision or removal.

HANDLING AND STERILIZATION:

Always handle the IDS products with powder-free gloves and avoid contact with hard objects that may damage or contaminate the surface. If the product is supplied sterile, it should be considered sterile unless the package has been opened or damaged. Using accepted sterile technique, remove product from the package only after the correct size has been determined.

Attention! CAUTION: FEDERAL LAW (US) RESTRICTS THIS DEVICE TO THE SALE, DISTRIBUTION, AND USE BY OR ON THE ORDER OF A LICENSED MEDICAL/DENTAL PROFESSIONAL.

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