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Instructions For Use

Warning:

Implant Direct Sybron Manufacturing, LLC. Implants are to be placed only by dentists, doctors or operators trained in the use and placement of dental implants. Dental implants are to be used by prescription only.

Disclaimer of Liability:

The users of Implant Direct Sybron Manufacturing, LLC. products must determine whether or not a particular product is suitable for a particular application and circumstance. Implant Direct Sybron Manufacturing, LLC. disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages arising out of or in conjunction with any errors in professional judgment or practice in the use of Implant Direct Sybron Manufacturing, LLC. products. Users are advised and obliged to study the latest news and developments in implant dentistry, and to frequently review www.implantdirect.com for any updates to products and/or specifications. Implant Direct Sybron Manufacturing, LLC. has no control over the use of its products, which are the responsibility of the user. Implant Direct Sybron Manufacturing, LLC. assumes no liability whatsoever for damage arising thereof.

DENTAL IMPLANTS



Single Use
Rx Only



STERILE R




1: *Indications For Use, General:* Implant Direct Sybron Manufacturing, LLC.'s dental implant product line consists of one-piece and two-piece implants for one-stage or two-stage surgical procedures. These implants are intended for use in partially and fully edentulous upper and lower jaws in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework. *Implants can be placed in immediate function if adequate (35Ncm) initial stability can be established and in combination with other prosthodontic principals for this type of procedure.*

2: *Indications For Use, Specific:*

- **ScrewDirect Implants:** Indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. Is also indicated for multiple tooth replacements or denture stabilization. Wider diameter implants can be used in the upper and lower posterior. For cemented restorations only.
- **ScrewRedirect Implants:** Indicated for the support and retention of fixed single or multiple-tooth dental prosthesis. ScrewRedirect is indicated for immediate functional loading when four or more implants are splinted together in the edentulous upper or lower jaw.
- **ScrewIndirect Implants:** Indicated for the support and retention of bar overdentures or as a terminal or intermediary attachment for screw-retained fixed bridgework. Indicated for immediate functional loading when four or more implants are splinted together in the edentulous upper or lower jaw.
- **GoDirect Implant:** Indicated for the support and retention of overdentures or as an attachment for partially edentulous removable prosthesis retention. Indicated for immediate functional loading as outlined in item 1 of this section.

3: *Contraindications* include but are not limited to: vascular conditions, uncontrolled diabetes, clotting disorders, anticoagulant therapy, metabolic bone disease, chemotherapy or radiation therapy, chronic periodontal inflammation, insufficient soft tissue coverage, metabolic or systemic disorders associated with wound and/or bone healing, use of pharmaceuticals that inhibit or alter natural bone remodeling, any disorders which inhibit a patient's ability to maintain adequate daily oral hygiene.

4: *Oral contraindications* include but are not limited to: uncontrolled parafunctional habits (e.g. bruxing, clenching, gnawing), insufficient height and/or width of bone, insufficient interarch space, intraoral infection, poor or noncompliant patient oral hygiene.


5: *Single-Use Packaging:*  Single Use Rx Only This device is designed for Single Use Only. The effects of cleaning and sterilization or disinfection for the purpose of re-use are unknown, and it cannot be reasonably assured that the physical integrity and function of the device will remain present if used multiple times. The effects of multiple use have not been clinically or scientifically tested, and there is no data to support that the part will perform as designed after multiple use.

6: *Sterile Packaging:* **STERILE R** Implants and included materials are sold sterile by gamma irradiation. Implants may degrade if resterilization is attempted, which could lead to surgical rejection and/or post-operative infection.

Note: Implant Direct Sybron Manufacturing, LLC. takes no responsibility whatsoever for resterilized dental implants regardless of the individual performing the resterilization or the methods used for resterilization. If original packaging is compromised or vial seals broken, Implant Direct Sybron Manufacturing, LLC. will not accept the contents for return.

7: *Handling:* Implants must be stored in a dry place, at room temperature, in their original packaging. Dental implants are provided in sterile vials affixed to fixture-mounts. The fixture-mount is intended to

be used to transport the implant to the prepared surgical site. Do not handle implant surfaces directly. Users are advised to visually inspect vials to insure seals and contents are intact and in their original packaging prior to use.

8: *Shelf-Life*  : Dental implants are considered sterile for five years from the date of initial sterilization. Expiration dates are noted on the implant vial label.

9: *Surgical Techniques For Implant Placement*

9.1: *Pre-Operative Treatment Planning*: During the pre-operative stage, availability of bone-height and width must be determined. Appropriate radiography should be used to determine bone availability, optimal implant location and to avoid structures such as the mandibular canal, maxillary sinuses and adjacent teeth.

9.2: *Electrosurgery*: Due to the conductive nature of metallic implants, electrosurgery is contraindicated.

9.3: *Surgical Site Preparation*: Follow the corresponding drilling sequence for hard (H) or soft (S) bone preparation.

9.4: *Insertion Procedure*:

9.4.1: *Patient Information*: Peel off removable label from the outer vial and place the label in patient's chart.

9.4.2: *Open Outer Packaging*: Remove vial cap by turning counterclockwise until the tamper-resistant ring is detached. Pour inner vial which contains the implant onto a sterile tray.

9.4.3: *Remove From Inner Packaging*: All implants are packaged in a sterile plastic inner vial suspended from a fixture mount for ease of insertion.

9.4.3.1: *Titanium Fixture Mount*: Remove the implant assembly from the sterile inner vial and carry it to the implant osteotomy with an appropriate instrument or with powder-free sterile-gloved fingers. Avoid contact with the surface of the implant that will be in contact with bone.

9.4.3.2: *Plastic Carrier*: Remove the implant assembly from the sterile inner vial and carry it to the implant osteotomy with powder-free sterile-gloved fingers. Avoid contact with the surface of the implant that will be in contact with bone.

9.4.4: *Implant to Site*: Carry the implant to the prepared surgical site and begin threading the implant into place just enough to stabilize it.

9.4.5: *Implant Insertion*: Continue inserting the implant using appropriate instrumentation.

9.4.5.1: *Titanium Fixture-Mounts*: Rotate the fixture mount clockwise until the implant is fully seated into the osteotomy with the roughened surface level with the crest of the bone. For the two-piece titanium fixture mounts, use a 1.25mmD Hex Tool to unthread the retaining screw and remove the fixture mount. Continue inserting the implant using appropriate instrumentation.

9.4.5.2: *Plastic Carrier*: Rotate the implant by the plastic carrier clockwise until slight resistance frees the mount. Remove the carrier and finish seating the implant with the appropriate insertion tool and ratchet. For the ScrewIndirect and ScrewDirect, retrieve the comfort cap from the bottom and press fit onto the top of the implant. Suture the soft tissue around the implant.

9.4.6: *One and Two Stage Healing*:

9.4.6.1: *Cover Screw and Extender*: For two-piece implants, use the 1.25mmD Hex Tool and unthread the implant cover screw from the plastic mount located at the bottom of the inner vial and thread into the implant. The Legacy, SwishPlant, ScrewPlant and ScrewPlus implants are also provided with a 2mm extender for one-stage healing that is retained with a cover screw. Suture the soft tissue over the cover screw or around the 2mm extender.

9.4.6.2: *Fixture Mount / Abutment*: The titanium fixture mount provided with the Legacy3, SwishPlant, SwishPlus, ReActive, ScrewPlant, ScrewPlus and RePlus implants can be shortened to serve as a final abutment. Using a carborundum disc, separate the colored square from the tapered abutment portion of the fixture mount and attach the abutment to the implant using appropriate torque. Remove the snap-in mount (if included) at the bottom of the inner vial to retrieve the comfort cap and press fit onto the tapered abutment and suture the soft tissue around the comfort cap to maintain the tissue opening for one-stage healing.

9.4.7: *Post-Operative Care*: It is recommended that patients use a suitable mouth rinse and perform regular oral hygiene following surgery.

9.4.8: *Healing Time*: Usually implants are allowed to heal for a period of two to four months prior to being restored depending upon bone quality and type or any compromising medical condition.

9.4.9: *Instructions*  : Users are advised to consult packaged instructions for use and the technical support sections of our website (www.implantdirect.com) for assistance.

Prosthetic Components



Single Use
Rx Only



NON-STERILE 



1. *Training:* Implant restoration involves complex procedures and should be performed by dental professionals who have received implantology training in proper techniques. Inadequate training may result in failure of the restoration and further complications.

2. *Packaging:* All abutments and accessories are cleaned and packaged in a Class 10,000 clean room environment and are supplied non-sterile unless they are explicitly marked as sterile. Sterilization is required for all prosthetic components prior to being used interorally.

3. *Sterilization of non-sterile prosthetic components:* Steam autoclave titanium parts and plastic components for 80 minutes minimum at 121° C (250° F), 15-20 psig. Autoclave operation times vary from unit to unit. Multiple piece products should be disassembled to individual components prior to sterilization.

4. *Insertion Procedures For Abutments:*

4.1: Patient Information: Peel off removable label from the vial package containing and place the label in the patient's chart.

4.2: *Remove Abutments From Packaging:* All abutments are mounted on a plastic screw mount or carrier.

4.2.1: *Straight and Overdenture Abutments:* Remove the abutment assembly from the outer vial. A comfort cap and colored transfer component are located on the underside of the screw mount. Set these aside to be used later. Remove the abutment from the plastic screw mount by unscrewing the fixation screw with a 1.25mmD Hex Tool. When placing the plastic transfer component back onto the abutment for the impression phase, align the flat of the abutment to the flat and protruding feature found towards the top of the transfer. Press on the transfer until a distinct snap is felt and/or heard, which indicates the transfer is fully seated and ready for the impression phase.

4.2.2: *Angled, Cast-To Gold, and Straight Contoured Abutments and Plastic Temporary Abutments:* Remove the abutment assembly from the outer vial. Remove the abutment from the plastic screw mount by unscrewing the fixation screw with a 1.25mmD Hex Tool.

NOTE: The Plastic Temporary Abutments are intended for use with unloaded conditions for a period of less than 28 days.


4.3: *Placement of Fixed Prosthetic Comfort Caps:* Line up the flat on the comfort cap to the corresponding flat on the straight abutment, or modified fixture mount, and snap into place. For added retention, rotate the cap until a tight fit has been achieved. To remove, rotate cap to realign the flats and pull up. **NOTE:** The use of Comfort Caps should not exceed 28 days.

4.3.1: *Placement of Ball, GPS and Screw-Receiving Abutment Comfort Caps:* Press fit comfort cap into place. No specific orientation of the cap is necessary with these components.

4.4: Proceed with disinfection and sterilization instructions as detailed in item #3 above.

4.5: *Insertion of Abutments:* Abutments are initially seated using a 1.25mmD Hex Tool in conjunction with either a fixation screw (straight, scalloped, gold and angled abutments) or by accessing the hex portion of the abutment top (overdenture and ball abutments). Abutments should then be torqued to 30Ncm to ensure fixation between mating components.

5: *Post-Restorative Care:* It is recommended that patients use a suitable mouth rinse for the first 7 to 10 days following implant restoration. Subsequently, patients should perform regular oral hygiene and maintain regular dental prophylaxis.

6: *Instructions*  : Users are advised to consult packaged instructions for use and the technical support sections of our website (www.implantdirect.com) for assistance.

Surgical Instruments



Surgical Instruments – Drills



1: Surgical instruments (drills, hex tools, insertion instruments) and Surgical Trays.

2: *Packaging*: Surgical instruments are packaged non-sterile. Surgical instruments should be cleaned and sterilized prior to each use.

3: *Cleaning and Disinfection*: Prevent body fluids, hard and soft tissues from drying on the instruments by cleaning as soon as possible after use.

3.1: *Preparation*: Automated cleaning may not be effective. Thorough manual cleaning process is recommended. When applicable, disassemble trays and instruments prior to cleaning.

3.2: *Cleaning and Disinfection*

3.2.1: *Agents*: Cleaning agents containing hydrogen peroxide, chlorine or chloride must not be used as the active agents are corrosive to stainless steel.

3.2.2: *Preliminary Manual Cleaning*: For heavily soiled instruments, or for instruments that have accumulated organic debris, a preliminary manual cleaning is advised. Use a soft brush (no metal bristles) so as to completely remove residue.

3.2.2.1: *Wipe instruments using a soft, disposable non-shedding wipe.*

3.2.2.2: *Soak in lukewarm enzymatic solution for 20 minutes.*

3.2.2.3: *Universal precautions for the handling of contaminated or biohazardous materials should be observed.*

3.3: *Routine Cleaning*

3.3.1: *Wash the instruments using a broad spectrum cleaning solution. Rinse in water and dry thoroughly.*

3.3.2: *Prepare a neutral pH enzyme cleaning detergent solution per manufacturer's instructions and place in a sonication unit.*

3.3.3: *Completely submerge instrument in cleaning solution and sonicate for 10 minutes, preferably at 45-50kHz.*

3.3.4: *Rinse instrument in purified (de-ionized) water thoroughly for at least 3 minutes.*


3.3.5: Repeat above two steps with freshly prepared cleansing solution.

3.3.6: Dry the instrument with a clean, disposable, absorbent non-shedding wipe.

4: *Packaging For Sterilization*: Enclose the product to be sterilized in a standard polyethylene / Tyvek (or equivalent) sterilization pouch. Sets of instruments may be loaded into dedicated instrument trays or general purpose trays for sterilization.

5: *Sterilization*: Steam sterilize using a gravity cycle for 20 minutes at a minimum temperature of 132°C (270°F). To avoid deformation, surgical tray should not touch walls of steam sterilizer. When sterilizing multiple instruments in one steam sterilization cycle, ensure that the sterilizer manufacturer's maximum load requirements are followed. Drying times will vary according to load size.

6: *Storage*: Keep instruments in sterilization packaging and in a dry and clean environment. Maintain packaging integrity. Check before usage.

7: *Instructions*:  Users are advised to consult packaged instructions for use and the technical support sections of our website (www.implantdirect.com) for assistance.

Note: Cleaning and sterilization instructions validated by Implant Direct Sybron Manufacturing, LLC. to obtain:

***Cleaning*: An average 99.9980% reduction in viable counts of bioburden. ENZOL Enzymatic Detergent and Renu-Klenz neutral pH detergent were used to validate this per the manufacturer's dilution instructions.**

Sterilization: 10-6SAL



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