Instructions For Use
(Spectra-System, ScrewPlant, ScrewPlus, ScrewIndirect, ScrewDirect, ScrewRedirect, GoDirect, Legacy, RePlant, RePlus, ReActive, SwishTapered, SwishPlus, SwishActive and InterActive Systems)

Caution: Federal law restricts this device to sale by or on the order of a dentist.

Small diameter implants and angled abutments are not recommended for the posterior region of the mouth.

For short implants, clinicians should closely monitor patients for any of the following conditions: peri-implant bone loss, changes to implant’s response to percussion, or radiographic changes in bone to implant contact along the implant’s length. If the implant shows mobility or greater than 50% bone loss, the implant should be evaluated for possible removal. If the clinicians choose a short implant, then clinicians should consider a two-stage surgical approach, splinting a short implant to an additional implant, and placement of the widest possible fixture. Allow longer periods of osseointegration and avoid immediate loading.

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. Please note that some products detailed in this instruction for use may not be regulatory cleared, released or licensed for sale in all markets.

DENTAL IMPLANTS

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 indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.

- **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.
- Narrow Diameter (3.0, 3.2, 3.3mm) Implants: Indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. Also indicated for multiple tooth replacements or denture stabilization.

Page 1 of 12
2: **Compatibility:**

- **ScrewPlant, ScrewPlus, ScrewIndirect, ScrewDirect, ScrewRedirect & GoDirect Systems:** Surgically compatible with **Zimmer Dental Tapered Screw-Vent** drills.
- **Legacy System:** Legacy implants are surgically compatible with **Zimmer Dental Tapered Screw-Vent** system drills. Prosthetically compatible with **Zimmer Dental Tapered Screw-Vent** system 3.5mm platform implants (3.7mmD, 4.1mmD, 8mm-16mm Length), 4.5mm platform implants (4.7mmD, 8mm-16mm Length), and 5.7mm platform implants (6.0mmD, 8mm-16mm Length). Also prosthetically compatible with **BioHorizons** (3.5mm, 4.5mm, & 5.7mm internal hex platform) implants and **MIS** (Standard & Wide internal hex platform) implants.
- **RePlant System:** Surgically compatible with **Nobel Biocare NobelReplace Tapered** tri-lobe system drills. Prosthetically compatible with NP, RP, WP, and 6.0mm Platform tri-lobe system implants.
- **RePlus & ReActive Systems:** Prosthetically compatible with **Nobel Biocare NobelReplace** tri-lobe system NP, RP, and WP implants.
- **SwishTapered System:** Surgically compatible with **Straumann** twist drills for soft bone protocols. Surgically compatible with **Straumann** twist drills and **Implant Direct** final drills for dense bone protocols (**Bone Level Tapered** implant surgical instruments are not compatible with any product). Prosthetically compatible with **Straumann Standard, Standard Plus,** and **Tapered Effect** tissue-level RN platform implants (3.3mmD-4.8mmD, 6mm-16mm Length) and WN platform implants (4.8mmD, 6mm-14mm Length).
- **SwishPlus System:** Surgically compatible with **Straumann Standard** and **Standard Plus** 4.1mm and 4.8mm implant diameter systems. **Bone Level Tapered** implant surgical instruments are not compatible with any product. Prosthetically compatible with **Straumann Standard, Standard Plus** and **Tapered Effect** tissue-level system RN platform implants (3.3mmD-4.8mmD, 6mm-16mm Length) and WN platform implants (4.8mmD, 6mm-14mm Length).
- **SwishActive Implants:** Surgically compatible with **Straumann** twist drills and **Implant Direct** final drills for dense bone protocols (**Bone Level Tapered** implant surgical instruments are not compatible with any product). **SwishActive** implants are prosthetically compatible with **InterActive** 3.0 and 3.4mm abutments and **Nobel Biocare** conical connection **NobelActive™** NP (Narrow Platform – 3.0mm diameter) and **NobelActive™** RP (Regular Platform – 3.4mm diameter) titanium abutments. **InterActive** 3.0 and 3.4mm abutments are prosthetically compatible with **Nobel Biocare** conical connection **NobelActive™** NP (Narrow Platform – 3.0mm diameter) and **NobelActive™** RP (Regular Platform – 3.4mm diameter) (3.5-5.0mmD, 8.5-18mm Length).
- **InterActive System:** **InterActive** 4.3mmD and 5.0mmD implants are Surgically compatible with **Nobel Biocare NobelReplace Tapered** drills (only 4.3 & 5.0mmD implant drills) and InterActive implants are surgically compatible with **Zimmer Dental Tapered Screw-Vent** drills. **InterActive** implants are prosthetically compatible with **InterActive** 3.0 and 3.4mm abutments and **Nobel Biocare** conical connection **NobelActive™** NP (Narrow Platform – 3.0mm diameter) and **NobelActive™** RP (Regular Platform – 3.4mm diameter) titanium abutments. **InterActive** 3.0 and 3.4mm abutments are prosthetically compatible with **Nobel Biocare** conical connection **NobelActive™** NP (Narrow Platform – 3.0mm diameter) and **NobelActive™** RP (Regular Platform – 3.4mm diameter) (3.5-5.0mmD, 8.5-18mm Length) implants.

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. **Implant Direct Dental Implants** have not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of **Implant Direct Dental Implants** in the MR environment is unknown. Scanning a patient who has this device may result in patient injury. **Implant Direct Dental Implants** are not represented to be “non-pyrogenic.”

4: Surfaces: Implant Direct implants are made of titanium alloy (6Al-4V ELI). The SBM surface is created using irregularly-shaped hydroxyapatite particles to create a medium-rough texture. The HA coating surfaces are achieved via a plasma spray process using hydroxypatite particles.

5: **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.

6: Single-Use Packaging:  Single Use Only devices are not permitted to be re-used. The effects of multiple-use have not been clinically or scientifically tested, and there is no data to support that the device will perform as designed after multiple uses. Reprocessing and resterilization of Single Use Only devices is not allowed. There is a high risk of infection, unacceptable performance, or device failure if they are not processed and used as specified.

7: Sterile Packaging: Implants and included materials are sold sterile by gamma irradiation. Do not re-sterilize.

8: Handling: Do not use if packaging is damaged. Implants must be stored in a dry place, at room temperature, in their original packaging. Dental implants are provided in sterile vials mounted to fixture-monts, carriers, or provided mount-free. The fixture-mount or carrier are intended to be used to transport the implant to the prepared surgical site. Appropriate sterilized insertion tools, with retention, are used to transport and place the mount-free implants. 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.

9: Shelf-Life YYYY-MM-DD: Dental implants are considered sterile for five years from the date of initial sterilization. The product expiration date is indicated by the hourglass symbol on the product label, followed by the year and month of expiration.

10: Surgical Techniques for Implant Placement

10.1: 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.

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

10.3: Surgical Site Preparation: Follow the corresponding drilling sequence for hard (H) or soft (S) bone preparation. Reference current catalogs online at www.implantdirect.com for more information on implant specific drill protocols.
<table>
<thead>
<tr>
<th>Implant Diameter</th>
<th>3.0/3.2</th>
<th>3.3 (Note 1)</th>
<th>3.5</th>
<th>3.7</th>
<th>4.1 (Note 1)</th>
<th>4.2/4.3</th>
<th>4.3 (Note 2)</th>
<th>4.7</th>
<th>4.8</th>
<th>4.8/6.5 (Note 1)</th>
<th>5</th>
<th>5.0 (Note 2)</th>
<th>5.2</th>
<th>5.7 (Note 1)</th>
<th>5.7</th>
<th>6.0 (Note 2)</th>
<th>7.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>LDRILL</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
</tr>
<tr>
<td>2.3</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
</tr>
<tr>
<td>2.8</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.4</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
</tr>
<tr>
<td>3.5</td>
<td>S</td>
<td>H</td>
<td></td>
<td></td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
</tr>
<tr>
<td>3.8</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.2</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
</tr>
<tr>
<td>4.4</td>
<td>H</td>
<td></td>
<td></td>
<td></td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
<td>S</td>
<td>H</td>
</tr>
<tr>
<td>4.8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.8/6.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.7/6.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.8/5.4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note 1: Use Swish Drills. When placing SwishTapered and SwishPlus implants so that the shoulder is at bone level, the drill depth must be 2mm more than the implant length (Example: The preparation depth for the 10mm SwishTapered implant, inserted to shoulder level, must have a 12mm depth).

Note 2: Use RePlant Drills
10.4: Insertion Procedure:

10.4.1: Patient Information: Catalog numbers are specified on labels. Peel off removable label from the outer vial and place the label in patient’s chart.

10.4.2: 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.

10.4.3: Remove From Inner Packaging: All implants are packaged in a sterile plastic inner vial. The fixture mount or carrier is used to remove the mounted implant from the inner vial. For mount-free implants, remove the titanium disc color-coded to the implant prosthetic platform, then utilize the appropriate sterilized insertion tool to remove the mount-free implant from the inner vial.

10.4.3.1: 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.

10.4.3.2: 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.

10.4.3.3: Mount-free: Remove the implant from the sterile inner vial and carry it to the implant osteotomy with the appropriate sterilized retentive tool using powder-free sterile-gloved finger. Ensure tool is fully engaged with implant before removing. Avoid contact with the surface of the implant that will be in contact with bone.

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

10.4.5: Implant Insertion: Continue inserting the implant using appropriate instrumentation.

10.4.5.1: 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. Use the appropriate instrumentation to unthread the retaining screw and remove the fixture mount.

10.4.5.2: 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.

10.4.6: One and Two Stage Healing:

10.4.6.1: Cover Screw and Extender: For two-piece implants, use the appropriate instrumentation and unthread the implant cover screw from the plastic mount located at the bottom of the inner vial and thread into the implant. Some 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.

10.4.6.2: Fixture Mount /Abutment: The titanium fixture mount provided with some implants can be shortened to serve as either a titanium temporary or final abutment, reference 4.2.2 below for recommended modification parameters. 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. For implants packaged with a two-piece fixture-mount, remove the colored square by hand and shorten the fixture mount at the groove for a functional final abutment to attach 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.
10.4.7: *Post-Operative Care*: It is recommended that patients use a suitable mouth rinse and perform regular oral hygiene following surgery.

10.4.8: *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.

10.4.9: *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**

In addition to the implant systems previously identified, this section also applies to prosthetic components for the Pitt-Easy and Endopore systems as well as Attachments International.

*Prosthetics Indications for Use, General*: Implant Direct abutments are designed to be used in support of a dental implant(s) to provide support for prosthetic restorations in a partially or completely edentulous patient. Abutments are intended for use in the mandible or maxilla in support of single or multiple-unit restorations and terminal or intermediate support for fixed bridgework. Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.

*Indications for Use, Abutments for snap-on retained restorations*: Abutments for snap-on retained restorations are designed to be used in support of a dental implant(s) to provide support for prosthetic restorations in a partially or completely edentulous patient. These abutments are designed to only receive a fabricated multi-unit bridge or overdenture. Abutments are intended for use in the mandible or maxilla. Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.

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 cleanroom environment with the exception of prosthetic components for the Pitt-Easy and Endopore systems and Attachments International which are packaged in a non-cleanroom environment. All abutments and accessories are supplied non-sterile unless they are explicitly marked as sterile. Sterilization is required for all prosthetic components prior to being used intraorally.

3: *Packaging For Sterilization*: Enclose the product in FDA cleared steam sterilizable pouches and sterilize in FDA cleared sterilizer.

3.1: *Sterilization of non-sterile prosthetic components*:

3.1.1: *Sterilization of prosthetic components (Titanium, gold, and plastics)*: Steam sterilize using a gravity displacement cycle for 30 minutes at 121°C (250°F), 15-20 psig, and dry time: 15 minutes wrapped in a double pouch. Multiple piece products should be disassembled to individual components prior to sterilization.

3.1.2: Steam sterilize Zirconia abutments using a pre-vacuum cycle for 4 minutes at a temperature of 132°C (270°F) with a dry cycle of 20 minutes double pouched. When sterilizing multiple devices in one steam sterilization cycle, ensure that the sterilizer manufacturer’s maximum load requirements are followed.
3.2: Zest Prosthetics Sterilization: Please follow sterilization instructions provided with product.

4: Insertion Procedures for Abutments:

4.1: Patient Information: For items packaged in vials, 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 packaged in vials 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 the corresponding driver. 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, Zirconia, 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 the corresponding driver. If modifications are required, the following must be maintained: a maximum angle of 30° from the axis of the implant, a minimum wall thickness of 0.4mm, a minimum post height of 4mm and a minimum cuff height from the interface of 0.7mm.

The modifiable abutments are intended to be modified only by the company and/or chairside by the dentist using standard hand instruments only.

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 section 3 above.

4.5: Insertion of Abutments: Abutments are initially seated using the corresponding driver 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, unless otherwise specified on the label, 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.
1: Description, General: Surgical instruments, Surgical Drills, and Surgical Trays are surgical devices used to perform a dental implant or prosthetic surgical procedure following implant indications and contraindications for use. The surgical devices are reusable and are provided non-sterile but are capable of being cleaned and sterilized according to the instructions for use.

1.1: Description, Surgical Instruments: Tools comprised of guides (Titanium), manual drivers (Stainless Steel), handles (Stainless Steel), guide pins (Titanium), holders (Aluminum), tri-lobe positioning tools (Aluminum), sleeves (Titanium), fixture mount tools (Titanium), guide pins (Titanium), spring spacers (Titanium), abutment removal screws (Titanium), or other complementary tools which are used to aid in a surgical implant/prosthetic procedure.

1.2: Description, Surgical Drills: Tools comprised of one or more drills (Stainless Steel) used to create an osteotomy, or drivers (Stainless Steel) used to apply a torque, using a powered (active) device.

1.3: Description, Surgical Trays: The surgical trays are designed to hold various surgical devices in order to organize, steam sterilize, and transport them between uses. The trays are to be enclosed in an FDA cleared steam sterilizable wrap and sterilized in an FDA cleared sterilizer using the sterilization method specified below. The trays are intended for sterilization of non-porous loads, and the trays are recommended not to be stacked during sterilization. Implant Direct Sybron Manufacturing LLC does not make any lumen claims.

2: Preparation for Use: Surgical devices are packaged non-sterile and should be cleaned and sterilized (Note 3) prior to each use. Disassemble surgical devices prior to cleaning.

Cautions: Universal precautions for the handling of contaminated or biohazardous materials should be observed. The surgical devices are not designed for cleaning and disinfection in the fully assembled state. The surgical devices must be removed from the tray and the tray disassembled for adequate cleaning results. After cleaning and disinfection, per instructions below, the tray is reassembled and the instruments and drills can be loaded into the tray, per the packaging for sterilization instructions, and sterilized.

Note 3: Cleaning and sterilization instructions validated by Implant Direct Sybron Manufacturing LLC as per AAMI TIR 12, AAMI TIR 30, and FDA draft guidance document for processing/reprocessing medical devices in health care settings.

3: Processing/Reprocessing Instructions

3.1: Point of Use: Prevent body fluids, hard and soft tissues from drying on the surgical devices by minimizing the time before cleaning and reprocessing as soon as possible after use. Directly after use, wipe excess soil (as directed below) from the surgical devices. Automated cleaning may not be effective. Thorough manual cleaning process is recommended.

3.2: Preparation for Manual Cleaning: If the tray contains surgical devices, remove them from the tray, clean and disinfect separately before sterilizing them reassembled in the cleaned tray. Disassemble the tray into its individual components: base, lid, and (if applicable) insert. Note: Refer to assembly/disassembly instructions for the tray in appendix section.

3.3: Cleaning and Disinfection

3.3.1: Agents: Acceptable cleaning agents are specified in the cleaning instructions below.

Do not use cleaning agents containing hydrogen peroxide, chlorine or chloride. The
active agents are corrosive to the surgical devices. Using a detergent outside of the recommended pH may adversely affect the finish of the surgical devices. Ensure surgical drills and instruments, made with different materials, are not placed together in a liquid during cleaning. Clean, sterilize, and maintain wrenches (P/N: TWM, TW30, TW35, BioTorq wrenches), LT/RA Latch Driver (P/N:58-100000), and Zest attachment system tools according to specific instructions provided with the products. The cleaning and sterilization instructions are different than the instructions detailed in this document.

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

3.3.3: Cleaning and Disinfection Instructions: Follow the sections listed in the table below for cleaning and disinfection.

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
<th>Surgical Instruments and Drills (See Note 4)</th>
<th>Surgical Tray (Disassembled) (See Note 4, Note 5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.3.3.1</td>
<td>Preliminary manual cleaning</td>
<td>Wipe Surgical instruments and Drills using a soft, disposable non-shedding wipe.</td>
<td>Wipe tray using a soft, disposable non-shedding wipe.</td>
</tr>
<tr>
<td>3.3.3.2</td>
<td>Cleaning</td>
<td>Soak in lukewarm enzymatic solution, per manufacturer’s instructions, for 20 minutes</td>
<td>Immerse the tray in concentrate enzymatic detergent, per manufacturer’s instructions, for 10 minutes</td>
</tr>
<tr>
<td>3.3.3.3</td>
<td>Routine Cleaning</td>
<td>Wash using broad spectrum cleaning solution</td>
<td>Immerse the tray in neutral detergent (per manufacturer’s instructions) and soak for 2 minutes.</td>
</tr>
<tr>
<td>3.3.3.4</td>
<td>Routine rinsing and drying</td>
<td>Rinse with water and dry</td>
<td>Rinse with tap water and dry with lint free cloth</td>
</tr>
<tr>
<td>3.3.3.5</td>
<td>Sonication</td>
<td>Prepare a neutral pH enzyme detergent solution per manufacturer’s instructions. Sonicate for 10 Minutes at a Frequency of 45 to 50 kHz</td>
<td>Prepare a concentrate enzyme detergent solution per manufacturer’s instructions. Sonicate for 10 Minutes at a frequency of 42 to 46 kHz</td>
</tr>
<tr>
<td>3.3.3.6</td>
<td>Rinsing</td>
<td>Rinse for 3 minutes with Reverse Osmosis (RO) or Deionized Water (DI)</td>
<td>Rinse for 3 minutes with Reverse Osmosis (RO) or Deionized Water (DI)</td>
</tr>
<tr>
<td>3.3.3.7</td>
<td>Additional sections</td>
<td>Repeat sections 3.3.3.5 and 3.3.3.6 with fresh RO/DI.</td>
<td>Repeat section 3.3.3.6 two times with fresh RO/DI for each rinse.</td>
</tr>
<tr>
<td>3.3.3.8</td>
<td>Final Drying</td>
<td>Dry using a clean, disposable, absorbent, non-shedding wipe</td>
<td>Dry using a disposable lint free cloth.</td>
</tr>
<tr>
<td>3.3.3.9</td>
<td>Inspection - Is soil or tissue or fluid visible on the surgical device?</td>
<td>Yes - repeat section 3.3.3.1 thru 3.3.3.8 above</td>
<td>Yes - repeat section 3.3.3.1 thru 3.3.3.8 above</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No - proceed to sterilize as instructed below (Section 4: Steam Sterilization)</td>
<td>No - proceed to sterilize as instructed below (Section 4: Steam Sterilization)</td>
</tr>
</tbody>
</table>

**Note 4:** Wrenches (P/N: TWM, TW30, TW35, BioTorq wrenches), LT/RA Latch Driver (P/N:58-100000), and Zest attachment system tools are provided with different cleaning and sterilization instructions. Please use the instructions for use provided with the wrenches, LT/RA Latch Driver, and Zest tools as they are different than the instructions in this document. The cleaning and sterilization instructions provided with these tools do not apply to Implant Direct surgical drills, Instruments, or trays.

**Note 5:** Cleaning: Prolystica 2X concentrate Enzymatic Detergent and Prolystica 2X neutral pH detergent were used to validate the manual cleaning process as per the manufacturer’s dilution instructions. Cleaning validations were performed using the micro BCA protein assay with device extraction. Process validation consisted of contamination, cleaning, and sterilization. The haemoglobin level was well below the acceptance criteria level of <2.2 µg/cm2. The protein level was well below the acceptance criteria level of
6.4 ug/cm².

4: Steam Sterilization for Surgical Devices

4.1: Packaging for Sterilization: Enclose the surgical device in FDA cleared steam sterilizable packaging and sterilize in an FDA cleared sterilizer. To avoid deformation, the surgical trays should not touch the walls of the steam sterilizer. When sterilizing multiple surgical devices in one steam sterilization cycle, ensure that the sterilizer manufacturer’s maximum load requirements are followed.

4.2: Limitations of Reprocessing

4.2.1: Proper processing/reprocessing has minimal effect on the surgical devices. End of life is determined by damage due to wear.

4.2.2: Clean and sterilize the surgical devices using the allowable parameters. Not following the cleaning and sterilization instructions may accelerate normal product aging. Ensure surgical drills and instruments made with different materials are not touching during sterilization.

4.3: Surgical Devices Sterilization Parameters:

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
<th>Surgical Instruments and Drills <em>(Note 6)</em></th>
<th>Surgical Trays- assembled with or without instruments <em>(Note 6)</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>4.3.1</td>
<td>Sterilization packaging</td>
<td>Enclose instruments and drills in FDA cleared steam sterilizable wraps or pouches <em>(Note 7)</em></td>
<td>Double wrap assembled trays in FDA cleared steam sterilizable wraps <em>(Note 7)</em></td>
</tr>
</tbody>
</table>
| 4.3.2   | Steam Sterilization Parameters | **Gravity**  
Time: 15 minutes  
Temperature: 132°C (270°F)  
Dry Cycle: 30 Minutes  
**Pre-Vacuum**  
Time: 4 minutes  
Temperature: 132°C (270°F)  
Dry Cycle: 20 Minutes | **Gravity**  
Time: 15 minutes  
Temperature: 132°C (270°F)  
Dry Cycle: 30 Minutes  
**Pre-Vacuum**  
Time: 4 minutes  
Temperature: 132°C (270°F)  
Dry Cycle: 20 Minutes, 4 pulses |

*Note 6*: Wrenches (P/N: TWM, TW30, TW35, *BioTorq* wrenches), LT/RA Latch Driver (P/N: 58-100000), and *Zest* attachment system tools are provided with different cleaning and sterilization instructions. Please use the instructions for use provided with the wrenches, LT/RA Latch Driver, and Zest tools as they are different than the instructions in this document. The cleaning and sterilization instructions provided with these tools do not apply to Implant Direct surgical drills, Instruments, or trays.

*Note 7*: Please check the sterilization packaging is compatible with the sterilization parameters for the device.

5: Handling and Inspection: Surgical devices are used as an aid for placement of Implant Direct products.

⚠️ Surgical devices should always be inspected before use and are to be replaced after excessive wear or damage. Do not use damaged or blunt surgical devices.

6: Storage: It is recommended to use the devices immediately after sterilization. Keep the devices in their sterilization packaging and in a dry and clean environment prior to use. Maintain packaging integrity. Check before usage. Please refer to the sterilization packaging’s instructions for use.

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

Disassemble:
1. Open the lid of the tray and fold back.
2. Remove surgical devices from the insert and base, if any.
3. Rotate the insert up and unsnap the insert from the base.
4. Remove the insert from the assembly.
5. Unsnap the lid from the base to disassemble.

Assemble:
1. Snap on the lid to the base and keep both the parts perpendicular to each other.
2. Place the insert in between the base and the lid and snap in.
3. Assemble surgical devices in the insert and base, if needed.
4. Close the lid by lowering the lid. It automatically locks on to the base when lowered.
<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Manufacturer's symbol" /></td>
<td>Manufacturer's symbol</td>
</tr>
<tr>
<td><img src="image" alt="Use by date" /></td>
<td>Use by date</td>
</tr>
<tr>
<td><img src="image" alt="CE mark" /></td>
<td>CE mark</td>
</tr>
<tr>
<td><img src="image" alt="Sterilized using gamma irradiation" /></td>
<td>Sterilized using gamma irradiation</td>
</tr>
<tr>
<td><img src="image" alt="Do not re-use" /></td>
<td>Do not re-use</td>
</tr>
<tr>
<td><img src="image" alt="Rx Only" /></td>
<td>Caution: Federal law restricts this device to sale by or on the order of a dentist</td>
</tr>
<tr>
<td><img src="image" alt="Consult instructions for use" /></td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td><img src="image" alt="Do not use if packaging is damaged" /></td>
<td>Do not use if packaging is damaged</td>
</tr>
<tr>
<td><img src="image" alt="Caution" /></td>
<td>Caution</td>
</tr>
<tr>
<td><img src="image" alt="Catalog Number" /></td>
<td>Catalog Number</td>
</tr>
<tr>
<td><img src="image" alt="Non-sterile" /></td>
<td>Non-sterile</td>
</tr>
<tr>
<td><img src="image" alt="Authorized Representative in Europe" /></td>
<td>Authorized Representative in Europe</td>
</tr>
</tbody>
</table>

Authorized Representative in Europe
Emergo Europe
Prinsesgracht 20
2514 AP The Hague
The Netherlands

IFU-001
Rev: 19
CO: 5232