

ZIRLUX PROSTHETIC COMPONENTS – INSTRUCTIONS FOR USE

IMPORTANT INFORMATION – PLEASE READ

Caution: U.S. federal law restricts this device to sale by, or on the order of, a licensed dentist or physician.

■ General Information

The Zirlux Prosthetic Components System consists of prosthetic components, and related accessories packaged under the Zirlux brand name for use by qualified, licensed clinicians and laboratory technicians fully trained in their application. Zirlux devices may be associated with the following product families:

Zirlux Prosthetic Components (*compatible with various implant systems and platform sizes*)

For specific product identification and contents, please refer to individual product labels.

For detailed information on the specifications and intended use of a particular product, please refer to the following user manuals:

Zirlux Prosthetic Components Restorative Manual DOC #3027285

■ Disclaimer of Liability

The guidelines presented herein are not adequate to allow inexperienced clinicians to administer professional implant treatment or prosthetic dentistry, and are not intended to substitute for formal clinical or laboratory training. Zirlux devices should only be used by individuals with training and experience specific to their clinically accepted application.

Zirlux is not liable for damages resulting from treatment outside of our control. The responsibility rests with the provider.

PROSTHETIC COMPONENTS

■ Description

Zirlux Prosthetic Components, consisting of abutments, screws, analogs, copings, and related restorative accessories, are manufactured from titanium alloy, gold alloy, or polymers. Zirlux Prosthetic Components are shipped non-sterile (except for multi-unit abutments). For product-specific descriptions and sterility information, please refer to the individual product labels and appropriate Zirlux catalogs and/or user manuals.

■ Indications for Use

Zirlux Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.

Multi-Unit Abutments are intended to provide support and retention for multi-unit screw-retained restorations. The 30-degree multi-unit abutments must be used within 45 degrees of parallelism for a splinted restoration. The 17-degree multi-unit abutments must be used within 32 degrees of parallelism for a splinted restoration.

■ Contraindications

Zirlux Abutments

- Wall thickness less than 0.5 mm
- Gingival margin diameter less than 0.5 mm wider than implant
- Angle corrections of more than 20 degrees
- Less than 0.5 mm margin height
- Less than 4 mm abutment height

Multi-Unit Abutments

- Wall thickness less than 0.5 mm
- Greater than 45 degrees divergence from parallel for a splinted restoration when using 30-degree multi-unit abutments
- Greater than 32 degrees divergence from parallel for a splinted restoration when using 17-degree multi-unit abutments

■ Warnings

A Zirlux abutment is intended to be used on an individual patient only. The reuse of such device on another patient is not recommended due to the risks of cross-contamination or infection. Angled abutments are not recommended for the posterior region of the mouth.

■ Adverse Effects

The following adverse effects have been observed when using prosthetic components and accessories:

- Components used in the patient's mouth have been aspirated or swallowed.
- The abutment screw has fractured due to application of excessive torque.
- The abutment is not adequately secured due to inadequate application of torque.

■ Precautions

Zirlux abutments may only be used for their intended purpose in accordance with general rules for dental/prosthetic treatment, occupational safety, and accident prevention. Zirlux abutments must only be used for dental procedures with the implant systems they were designed for. If the indications and intended use are not clearly specified, treatment should be suspended until these considerations have been clarified. All components that are used intraorally must be secured to prevent aspiration or swallowing.

■ Side Effects

No side effects, according to current knowledge.

■ Sterility

Multi-Unit Abutments are shipped sterile. They should not be resterilized. They are for single use only, prior to the expiration date. Non-sterile abutments and screws must be cleaned, disinfected, and sterilized prior to clinical use, according to a validated method.

The recommended disinfection process is based on ANSI/AAMI ST79 guidelines, as follows:

- **Disinfection:** Immerse abutments in disinfectant¹, rinse with distilled water and dry.
The recommended sterilization process is based on the ANSI/AAMI/ISO 17665-1 and ANSI/AAMI ST79 guidelines, as follows:
- **Sterilization:** Gravity-fed sterilizers: Autoclave in sterilization pouch for 30 minutes at 121°C (250°F)². Devices are to be used immediately after sterilization.

NOTE: The validated procedures require the use of FDA-cleared sterilization trays, wraps, biological indicators, chemical indicators, and other sterilization accessories labeled for the sterilization cycle recommended. The healthcare facility should monitor the sterilizer for the facility according to an FDA-recognized sterility assurance standard such as ANSI/AAMI ST79.

- **MRI**
Zirlux abutments have not been evaluated for safety and compatibility in the MR environment, and have not been tested for heating or migration in the MR environment. They can distort images obtained via magnetic resonance imaging (MRI).

■ **INSTRUCTIONS FOR USE — ZIRLUX TITANIUM ABUTMENTS**
Zirlux Titanium Abutments are prefabricated, screw-retained intraoral abutments intended to be connected directly to an endosseous implant for retention of a cemented dental prosthesis. They may be indicated for single- and multiple-tooth restorations. Titanium abutments are machined from titanium alloy and attached to the implant fixture with a titanium screw compatible with the restorative instrumentation of the specified implant system.

Capture Implant Placement
Take an implant-level impression utilizing the preferred technique (direct, indirect, or intraoral scan). Submit the impression to the laboratory.

- Laboratory — Fabricate the Restoration**
- 1) Follow pouring procedures for the appropriate die stone to produce a working model and articulate with a bite registration.
 - 2) Select the appropriate Zirlux Titanium Abutment based on the system, platform size, location, and occlusal clearance of the implant seated in the patient’s mouth.
 - 3) Seat the abutment completely into the implant analog on the working model, making sure that the anti-rotational features of the connection interface are fully engaged and the contours of the emergence profile (if applicable) are esthetically oriented.
 - 4) Insert the Zirlux Titanium Screw (provided) into the abutment’s screw access hole and hand-tighten using the appropriate driver.
 - 5) Fabricate the restoration using conventional casting or CAD/CAM techniques. Veneer as necessary. If a screw-retained hybrid restoration is indicated, lute the ceramic crown to the titanium abutment.

- Deliver the Final Restoration**
- 1) Seat the titanium abutment or screw-retained hybrid restoration completely into the implant, making sure that the anti-rotational features of the connection interface are fully engaged and the contours of the sculpted emergence profile are esthetically oriented.
 - 2) Insert the Zirlux Titanium Screw (provided) into the screw access hole and hand-tighten using the appropriate driver. It is strongly recommended that a radiograph of the connection site be taken to confirm complete seating of the abutment or hybrid restoration before proceeding.
 - 3) Using the appropriate driver in conjunction with a properly metered torque wrench, tighten the abutment or hybrid restoration to the implant manufacturer’s recommended torque value.
 - 4) Fill the screw access hole with cotton, Teflon tape, gutta-percha, or other suitable material.
 - 5) If the restoration is of a screw-retained hybrid design, cover the screw access hole with flowable composite, and cure. Otherwise, follow applicable cementation procedures to affix the definitive restoration to the abutment.

■ **INSTRUCTIONS FOR USE — ZIRLUX MULTI-UNIT ABUTMENTS**
Zirlux Multi-Unit Abutments are prefabricated, screw-retained intraoral abutments intended to be connected directly to endosseous implants in partially or fully edentulous patients for the retention of cast or milled bar overdentures. For implant-supported prostheses, six or more implants are recommended in the maxilla, four or more in the mandible. If clinical conditions dictate fewer implants, an implant-retained, tissue-supported prostheses is indicated. Multi-unit abutments are machined from titanium alloy, and are available with a variety of collar heights to achieve optimal emergence from shallow or deep gingival wells. Each Zirlux Multi-Unit Abutment is delivered sterile, suspended in an aseptic vial from a plastic carrier color-coded to indicate the restorative platform of the seated implant.

Straight multi-unit abutments lack any anti-rotational features at the implant-abutment interface. The apical portion of a straight multi-unit abutment is threaded for integration with the internal cavity of a seated implant. For abutment delivery, the occlusal surface features a male hex head compatible with the multi-unit driver recommended by the implant manufacturer. Angled multi-unit abutments of 17 degrees or 30 degrees enable clinicians to compensate for the divergence of seated implants or to otherwise accommodate an angled path of insertion. Angled multi-unit abutments feature an anti-rotational connection interface specific to the matching implant platform, and are attached to the implant fixture with an angled multi-unit abutment screw compatible with the restorative instrumentation of the specified implant system. Both straight and angled multi-unit abutments feature a female connection port at the coronal apex, to allow for the attachment of a screw-retained or fixed-removable dental prosthesis with a multi-unit restorative screw (Zirlux Prosthetic Screw).

The axial tilt of a Zirlux Angled Multi-Unit Abutment (angular divergence from path of insertion) is designed and manufactured to lie along a plane of the implant connection geometry, as opposed to a corner or junction. To maximize the angle-correcting attributes of the multi-unit abutment, be sure to rotate the implant upon final seating so that one side of the internal connection geometry (flat or lobe) is oriented to serve as the base of angulation, in accordance with the restorative treatment plan.

- Place the Multi-Unit Abutment**
- 1) Select the appropriate Zirlux Multi-Unit Abutment based on platform size, endosseous implant angle, and depth of the soft-tissue well.
 - 2) Remove the lid from the aseptic vial and retrieve the abutment by lifting the plastic abutment carrier straight out. To maintain the sterility of the multi-unit abutment, be careful to handle only by the plastic carrier.
 - 3) (a) *For Straight Abutments:* Using the plastic carrier, seat the abutment into the implant and hand-tighten. Remove the plastic carrier by pulling the apex of the carrier toward the facial. (b) *For Angled Abutments:* Using the plastic carrier, seat the abutment into the implant until the anti-rotational features of the connection interface are engaged. Lift and rotate as necessary to orient the angle in the required direction. Hand-tighten

¹Refer to the disinfectant manufacturer’s instructions. ²ANSI/AAMI ST79

the Zirlux Angled Multi-Unit Abutment Screw using the appropriate driver. Twist the plastic carrier counterclockwise to remove.

NOTE: It is strongly recommended that a radiograph of the connection site be taken to confirm complete seating of the abutment before proceeding.

- 4) Using the appropriate driver in conjunction with a properly metered torque wrench, tighten the multi-unit abutment or angled multi-unit abutment screw to the implant manufacturer’s recommended torque value.











- Passive Temporization of Multi-Unit Abutments**
- 1) If the initial stability of the seated implant is insufficient for loading, cover each Zirlux Multi-Unit Abutment with a Zirlux Multi-Unit Temporary Healing Cap and hand-tighten with the Zirlux Prosthetic Screw provided, using the appropriate driver. Do not overtighten.
 - 2) Using the patient’s existing denture or other prosthesis, relieve the area directly above the placement of each temporary healing cap until the denture rests on the ridge.
 - 3) Follow procedures to reline the denture over the temporary healing caps, using soft relining material only. The temporized denture can be used during a healing phase until the implants obtain sufficient load-bearing stability.

Capture Multi-Unit Abutment Placement
When stability permits, take an abutment-level impression utilizing the preferred technique (direct, indirect, or intraoral scan). Submit the impression to the laboratory for the fabrication of a working cast and verification index.

Denture Protocol
Follow appropriate denture protocol in accordance with the patient-specific treatment plan. When trying in the various setups (e.g., verification index, occlusal rim, wax setup, retention bar), hand-tighten to the multi-unit abutments with prosthetic screws, using the appropriate driver. Start from the distal and move forward, alternating between sides of the ridge. Always confirm complete, passive seating, modifying the setup as needed.

- Deliver the Final Restoration**
- 1) Remove any temporary prosthesis.
 - 2) Confirm that each multi-unit abutment is tightened to the implant manufacturer’s recommended torque value.
 - For attachment-retained removable prosthesis:
 - 3) Follow procedures to seat the attachment component onto each multi-unit abutment. Tighten to the manufacturer’s recommended torque value.
 - 4) Line the prosthesis onto the attachment components and snap into place. Check comfort and occlusion, and make any necessary adjustments.
 - For screw-retained, fixed removable prosthesis:
 - 3) Line the prosthesis onto the abutments. Beginning with the midmost screw access channel, hand-tighten a Zirlux Prosthetic Screw into the multi-unit abutment. Repeat for each abutment, working outward and alternating left to right.
 - 4) Confirm appropriate seating. With the same middle-out, left-to-right technique, tighten each prosthetic screw to 15 Ncm.
 - 5) Check comfort and occlusion, and make any necessary adjustments.
 - 6) Fill each screw access channel with gutta-percha, silicone, or other suitable temporary material.

SYMBOLS

	Sterile with Gamma Radiation
	Non-Sterile
	Do not Reuse
	Do not Resterilize
	Use by (yyyy-mm)
	By Prescription Only
	Catalog Number
	Lot/Batch Number
	See Instructions For Use
	Date of Manufacture (YYYY/MM)

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