

Contour Healer® Temporary Abutment

Caution: Federal law restricts this device to sale by or on the order of a dentist. This insert contains important information on the use of the Contour Healer. The company recommends that all dental professionals responsible for temporary abutment deployment read and understand this information before use of the device.

Description: The Contour Healer, LLC product line includes pre-manufactured dental abutments intended to serve as a temporary dental prosthesis during the healing process until a permanent crown is fabricated. They are directly connected to the endosseous dental implant by a screw. These devices are single-use and available to fit multiple platforms. This product line was designed to provide advantages over the existing products for this indication [see summary section below].

The temporary abutments are fabricated from medical grade PEEK Classix [polyetheretherketone] applicable for use in temporary abutments. The screw is medical-grade 316 stainless steel. The temporary abutments have a contoured shape with interfaces to match endosseous implants with various platform sizes.

Sizes: Abutment diameters 9.0 mm x 7.5 mm x 9.3 mm, Abutment / implant diameter 5.0, 4.3, 4.5, 3.5 and 5.7mm, Implant abutment connection 3.4 mm

Indications: The Contour Healer Temporary Abutment is intended for use with root-form endosseous dental implants to aid in prosthetic rehabilitation. The abutment is a provisional restoration that aids in creating an esthetic emergence through the gingiva during the healing period. The device is intended for single restorations in adults and should only be used for ninety days.

The Contour Healer Abutment is compatible with the following implant systems: Nobel Conical / Active Connection, Hiossen Standard Connection, Straumann RC Bone Level and Biomet 3i. Zimmer [Screw-Vent Dental Implant System], Nobel Biocare [Replace HA Coated Implant, Replace TiUnite Endosseous Implant, Nobel Biocare Endosseous Implants, and Groovy Implants], BioHorizons [BioHorizons Tapered Internal Implant System]

The stem [implant-abutment interface] of the Contour Healer identifies the proper compatible system.

The Contour Healer Temporary Abutment is not to be used as a final abutment. The Contour Healer Temporary Abutment is not to be used on occlusion. The Contour Healer Temporary Abutment is not to be used as a cast-too abutment.

Warnings: Implant surgery and restoration involve complex dental procedures. Appropriate and adequate training in proper technique is strongly recommended prior to implant use. Improper technique can result in implant failure, loss of supportive bone, or both.

Excessive mobility, bone loss, or infection may indicate the implant is failing. Any implant which appears to be failing should be treated or removed as soon as possible. If removal is necessary, curette any soft tissue from the implant site and allow site to heal as though it were an atraumatic extraction.

Overload is one of the key contributors to implant failure, particularly in the molar region where occlusal loads are typically the highest. Ensure the implant size is appropriate for the occlusal load.

Potential excessive loading conditions may include: inadequate number of implants; inadequate implant length, diameter, or both; excessive cantilever length; incomplete abutment seating; occlusal interferences causing excessive lateral forces; patient parafunctions such as bruxing; improper dental laboratory casting procedures; inadequate prosthesis fit; and trauma from patient habits and accidents.

Precautions Single-use only; do not reprocess. Contour Healer temporary abutments are provided non-sterile; autoclave before use [see below]

Do not dry-heat sterilize Contour Healer Temporary Abutments. Instruct the patient to see a trained dental professional immediately if any of the following occur: Looseness of the prosthesis, Infection or exudate around the implant, Pain or any other unusual symptom that the patient has not been told to expect.

To minimize heat generation during intraoral preparation, intermittent cutting (approximately 15 seconds in duration) under copious irrigation is recommended.

Do not over-tighten the screw. Over-tightening could strip the threads or break the implant. Appropriate tightening of the screw is essential to prevent premature loosening. The retaining screw should be hand-tightened only, using the corresponding drivers to match the implant system being used.

For optimal positioning: If using a Tri-Lobe abutment, place one cam to the facial. If using an internal hex, place a flat edge to the facial. If adjustment / reduction is necessary, polish using a brownie, fine acrylic bur or sof-flex disc. Do not reduce the abutment length or diameter; this may make the abutment unable to withstand expected load forces.

Summary of Device Features: The most difficult stage of implant surgery is to manage the peri-implant soft tissue contour. Shape and form of the peri-implant tissues are equally as important as other important factors such as bone quantity/ quality, primary stability, and bone to implant contact. The new abutment serves as a template to easily shape the soft tissue to proper form and allows the natural contours to be maintained without compromising the stability of the newly placed implant. The restorative phase is easier as the tissues are ready to be impressed along with the impression coping on the implant.

An abutment extends above the gum and is the transgingival component. These specially designed abutments provide for a more esthetic gingival contour during the restorative phase than can be achieved with a standard healing abutment having the typical conical design. Another important factor for implant success/survival is the ease of cleaning of the implant restoration. The soft tissues that are molded with this healing abutment allow for a precise soft tissue-implant crown interface facilitating peri-implant maintenance and home care.

Potential adverse reactions: The following complications may occur: edema, hemorrhage, hematoma, infection, inflammation, and local and generalized allergic reaction.

Storage: Store under ambient conditions of temperature and humidity in a cool, dry place

Product Packaging: The label on the outer packaging for each abutment contains a lot number that should be recorded in the patient's file to ensure complete traceability of the abutment.

Preparation:

Cleaning: 1. Disassemble two-piece components. 2. Rinse in cool to lukewarm water for three minutes. 3. Place in an ultrasonic cleaner with an enzymatic detergent diluted with tap water per the manufacturer's guidelines. 4. Sonicate for ten minutes. 5. Rinse components with tap water for three minutes.

Sterilization: 1. Clean components per instructions above. 2. Dry completely and place in proper sterilization pouch. 3. Sterilize within the following parameters: a. Pre-vacuum [steam] at 132°C [270°F] for 4 minutes. 4. Allow device to cool to room temperature before opening the package [to prevent condensation].

Caution: These are the minimum steam sterilization times and temperatures required to achieve a 10⁻⁶ sterility assurance level (SAL).

Exceeding these sterilization parameters may result in damage to plastic components. Verify the calibration of your unit to ensure recommended temperatures are not being exceeded.

Method of Use:

Technique for Screw-retained Temporary Healing Cap 1.

Place the Temporary Abutment onto the implant body so that the Tri-Lobe or external hex of the abutment aligns and mates with the inner configuration of the implant and press into place. 2. If adjustment / reduction is necessary, polish using a brownie, fine acrylic bur or sof-flex disc. 3. The abutment should be reduced to ensure it remains out of occlusion during the healing period. 4. Following the modifications, place the abutment onto the implant and secure in place with the retaining screw using the corresponding driver to match the implant system being used. Hand-tighten only. 5. Block out the screw access hole with a cotton pellet and seal with temporary material.

Made with pride in the USA

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