Buckeye Medical Technologies, LLC
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Instructions For Use:

Caution: Federal law restricts the sale of this device to a licensed dentist.

This temporary device is a passive device that aids in creating an esthetic emergence through the gingiva during the healing period. No occlusal forces are to be placed on the device. The device is held in place via a hand-tightened retaining screw. Over-tightening of the screw could result in failure of the device.

Disclaimer of Liability:
The user of the AnatotempSC anatomic dental implant healing abutment family of components must determine whether the clinical situation warrants the application of such a system. It is the sole responsibility of the user to determine clinical usage. Buckeye Medical Technologies, LLC disclaims any liability whether implied or expressed and shall not be held liable for indirect, direct, punitive, or other damages arising out of or in conjunction with errors in practice or judgment in the use of any Buckeye Medical Technologies, LLC components. Users are obligated to keep abreast of all new information regarding usage, news, and developments in implant dentistry. Users must constantly review the Anatotemp website for all the latest updates and recommendations for usage. Buckeye Medical Technologies, LLC has no control over the usage of its products which are the sole responsibility of the end user. Buckeye Medical Technologies, LLC assumes no liability whatsoever for damage and/or unforeseen outcomes or results arising thereof.


Do Not Reuse

Caution: Federal law restricts the sale of this device to a licensed dentist.


Use by date

Sterilized using irradiation.


Consult instructions for use


Do not use if packaging is damaged

1) Indications For Use:
The AnatotempSC anatomic dental implant healing abutment is a pre-manufactured healing abutment intended for use with endosseous root-form dental implants to aid in prosthetic rehabilitation. The abutment is a temporary device that aids in creating an esthetic emergence through the gingiva during the healing period. The single use, sterilized device is used by dental professionals during the dental implant healing process and is removed prior to permanent prosthetic placement. Anatotemps are compatible with the following implant systems:

Implant Brand and Type	Implant Platform Size
Implant Direct Legacy	3.5mmD, 4.5mmD, 5.7mmD
Implant Direct ReActive	3.5mmD, 4.3mmD, 5.0mmD
Implant Direct RePlus	3.5mmD, 4.3mmD, 5.0mmD
Implant Direct RePlant	3.5mmD, 4.3mmD, 5.0mmD, 6.0mmD
Implant Direct SwishPlus	4.8mmD, 6.5mmD
Implant Direct InterActive	3.0mmD, 3.4mmD
Implant Direct SwishActive	3.0mmD, 3.4mmD
Blue Sky Bio Quattro	Regular Platform (RP)
Nobel Biocare NobelActive CC	Wide Platform (WP)
Ditron Dental ULT & MPI	Internal Hex

2) Contraindications:
Buckeye Medical Technologies, LLC's AnatotempSC anatomic dental implant healing abutments take the place of conventional round dental implant healing abutments. The AnatotempSC anatomic dental implant healing abutments are used to assist in the creation of an esthetic emergence through the gingiva during the healing period. Six anatomic shapes, mimicking the cross-sectional anatomy of teeth, provide an ideal healing environment to create anatomic soft tissue shape and contour. AnatotempSC anatomic dental implant healing abutments can be placed at the first or second stage implant surgery procedure. AnatotempSC anatomic dental implant healing abutments are used in the treatment of the partially edentulous patient. No occlusal forces are to be placed on the components. The AnatotempSC is held in place with an abutment screw that is hand tightened (<10Ncm). The AnatotempSC must be completely seated on the dental implant platform and engaged with the internal connection. An AnatotempSC that is not completely seated and secured with an abutment screw may be at risk of fracture. The AnatotempSC anatomic dental implant healing abutment may be adjusted with conventional dental composite armamentarium to obtain ideal fit and seating. No dental material should be added to the components themselves. AnatotempSC anatomic dental implant healing abutments are contraindicated in any environment in which dental implant fixtures would be contraindicated. Anatotemps should not be used in patients with a sensitivity or allergy to methacrylate-like plastics. Anatotemps are contraindicated in the completely edentulous patient (any clinical scenario where occlusal forces would be encountered by the component) and in patients with uncontrolled parafunctional habits (i.e. bruxism, clenching, grinding.)

3) Single Use Packaging:
AnatotempSC anatomic dental implant healing abutments are designed for Single Use Only and reuse should not be considered or attempted.

4) Sterile Packaging:
AnatotempSC anatomic dental implant healing abutments are individually packaged in a PETG tray with a Tyvek seal and sterilized via an e-beam process. Users are advised to individually inspect tray and Tyvek seal to confirm that all components are intact. Do not re-sterilize.

5) Shelf Life:
AnatotempSC anatomic dental implant healing abutments are considered sterile for 5 years from the date of initial sterilization. The AnatotempSC expiration date is indicated by the hourglass symbol on the product label followed by the month and year of expiration.

6) Handling:
AnatotempSC anatomic dental implant healing abutments are packaged individually in a PETG tray with Tyvek seal that is then placed within an individual unit box. Anatotemps are to be stored in a dry environment at room temperature. Anatotemps are to be opened and placed directly on the sterile surgical field at the time of surgery.

7) Technique for AnatotempSC Placement:

7a) *Preoperative Patient Assessment, Treatment Planning, and Dental Implant Placement*:
Potential patients must be assessed to be candidates for dental implant placement both from a medical and anatomical standpoint per the Instructions For Use (IFU) of the specific dental implant company and type. Appropriate clinical and radiographic workup and implant placement treatment plan must be formulated. Guided surgery is recommended. Dental implants must be placed in bone with adequate density and adequate width and height away from vital structures such as the mandibular canal, adjacent teeth, and maxillary sinuses. The platform of the dental implant must be at bone level or the appropriate level as instructed in the specific implant IFU.

7b) *Patient Information*:
Individual unit box is opened and the component label is compared to the label on the Tyvek seal as well as the unit box label. Once confirmed for consistency, label is placed in the patient's chart. Instructions For Use are reviewed and saved in patient's record.

7c*) Placement Instructions*:
The individual AnatotempSC unit tray is removed from the unit box and while being held over the surgical field, the Tyvek seal is gently removed from the tray. Contents of the tray (AnatotempSC and abutment screw) are carefully dropped onto the surgical field. The abutment screw is then placed through the AnatotempSC and a .050" hex driver/thumb wrench is placed into the top of the screw. An oral pharyngeal partition is always placed in the oral cavity to block the oral pharynx from the surgical field. The dental implant platform and internal connection is rinsed and suctioned free of debris. The combined AnatotempSC/Screw component is transferred to the field with a hex wrench and placed on the implant platform. Digital manipulation is performed to engage the anti-rotational connection of the AnatotempSC and the internal anti-rotational connection of the implant making sure the anatomic position of the AnatotempSC is correct. Figure 1 below depicts the six anatomic AnatotempSC shapes, each with five positional markers, as well as the respective tooth positions. The three markers are always positioned buccal and the two markers positioned lingual or palatal. The abutment screw is then hand tightened (<10Ncm) while confirming complete seating of the AnatotempSC on the dental implant platform and anti-rotational engagement. Although the sizes of the components are based on an extensive anatomic tooth anatomy CT dimensional study, occasional minimal subtractive adjustment may be needed to verify complete seating. Positional markers should never be altered. Adding material to components is contraindicated.

7d) *Adjunctive Procedures*:
The AnatotempSC anatomic dental implant healing abutment can be placed at surgical stage 1 or surgical stage 2. The AnatotempSC anatomic healing abutments can also be used as a scan body or an impression body when utilizing an intraoral scanner or conventional impression. Contouring the gingiva to provide passive tissue fit is encouraged. Interproximal suturing is recommended.

Figure 1.