Instructions For Use

Blue Sky Bio, LLC TAD

English Blue Sky Bio, LLC TAD

Blue Sky Bio, LLC
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REF CATALOG NUMBER

DO NOT REUSE

CAUTION, CONSULT ACCOMPANYING DOCUMENTS

Rx Only CAUTION FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR PROPERLY LICENSED PRACTITIONER

MANUFACTURED BY

STERILE R STERILIZED USING GAMMA RADIATION

DO NOT USE IF PACKAGE IS DAMAGED

LOT BATCH CODE

USE BY DATE

NON STERILE NON-STERILE

DATE OF MANUFACTURE

MD MEDICAL DEVICE

UDI UNIQUE DEVICE IDENTIFIER

NON PYROGENIC

ELECTRONIC INSTRUCTIONS FOR USE

SINGLE STERILE BARRIER SYSTEM WITH PROTECTIVE PACKAGING INSIDE

Instructions For Use

Blue Sky Bio, LLC TAD System

Instructions for Use

Indications

The Blue Sky Bio TAD system is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth in adults and adolescents greater than age 12. Blue Sky Bio TAD system is used temporarily and is intended to be removed after orthodontic treatment has been completed.

Contraindications

Blue Sky Bio TAD screws should not be placed anytime when there are general contraindications associated with elective surgery.

Absolute and relative contraindications include but are not limited to: titanium alloy allergy, insufficient bone support, deciduous or mixed dentition, cardiac and vascular disease, bleeding disorders, psychological disorders, uncontrolled diabetes, bone or connective tissue disorders, renal disease, hepatic disease, auto-immune disorders, decreased immune function due to disease or medications, infectious disorders, adverse conditions caused by medications, poor oral hygiene and noncompliance, malnutrition, alcoholism, tobacco usage, and history of radiation therapy.

MRI Safety Information

Blue Sky Bio TAD has not been evaluated for safety and compatibility in the MR environment. The Blue Sky Bio TAD has not been tested for heating or migration in the MR Environment.

Warnings and Precautions

The Blue Sky Bio TAD system should be placed by practitioners who are licensed and trained to perform such procedures. Adequate preoperative studies should be performed to examine the anatomic structures and to assess the biomechanical and functional requirements for each case.

The Blue Sky Bio TAD system is a temporary device and in order to avoid possible osseointegration, it must be removed after treatment.

To prevent injury to any vital anatomical structures, Blue Sky Bio TAD should be inserted away from tooth roots, tooth buds, vessels, nerves and/or sinuses.

The applied orthodontic load to each Blue Sky Bio TAD should not exceed 300 grams.

All components of the system should be properly secured to prevent aspiration or swallowing.

Risks of Blue Sky Bio TAD placement include but are not limited to: infection, loss of bone and soft tissue, anesthesia, paresthesia, sinus infection, dislodgement of the devices into the surrounding anatomical structures, damage to adjacent teeth, fracture or loosening of Blue Sky Bio TAD before the end of the treatment.

Insertion Torque should not exceed 22.5 Ncm.

Follow Up Care

Patients should be instructed in appropriate oral hygiene and care. Periodic follow up appointments should be made to confirm and maintain adequate function of the Blue Sky Bio TAD and the health of the surrounding tissues.

Description

The head on the occlusal portion of the Blue Sky Bio TAD incorporates elements to which an orthodontic wire can be attached thus providing a fixed anchorage point for orthodontic movement of teeth. The collar has a smooth surface to minimize plaque accumulation and prevent soft tissue irritation. The threaded portion is designed for rapid insertion and provides stability and adequate retention once the screw is fully inserted. The apical tip has sharp threads with a self drilling feature.

Thread length: 6mm & 9mm

Shaft length: 6,5mm & 9.5mm

Overall length: 10.4mm & 13.4mm

Major diameter 1.6mm & 1.8mm

Placement Procedure

An initial osteotomy is made using a 1.2 mm diameter drill at 800 RPM utilizing sterile saline irrigation to avoid overheating of bone. The recommended depth of the osteotomy is half of implant length of the selected Blue Sky Bio TAD. The osteotomy is made to avoid excessive insertion force which could cause breakage or failure of the Blue Sky Bio TAD.

The selected Blue Sky Bio TAD is placed into the driver and the tip of the screw is inserted into the osteotomy. A maximum speed of 20 RPM is used to advance the screw in the desired direction and to the desired depth making sure to avoid penetration of roots of adjacent teeth. If resistance is encountered, the position of the screw should be evaluated radiographically and if necessary, the Blue Sky Bio TAD should be redirected

Contraindicated Placement Sites

•Maxillary sinuses.

•Dental roots

•Mental foramen.

•Recent extractions.

•Sites with presence of any pathology.

Sterility

Blue Sky Bio TAD implants are supplied sterile and are for single use only prior to the labeled expiration date. Do not use implants if the packaging has been damaged or previously opened. Reusable instruments are supplied non-sterile and prior to their use, they must be cleaned and then sterilized according to the instructions provided for reusable instruments.

Cleaning instructions for reusable instruments

Rinse with cool-to-lukewarm water for two-and-one-half minutes. For all parts place in an ultrasonic cleaner with an enzymatic detergent diluted with tap water per the manufacture's guidelines. Sonicate for 10 minutes. Rinse with tap water for three minutes.

Steam Sterilization instructions for reusable instruments

Sterilize for a full 30-minute cycle on steam gravity autoclave at 121°C and additional 15 to 30 min drying cycle.

Method of Supply

Blue Sky Bio TAD screws are made out of medical grade titanium alloy.

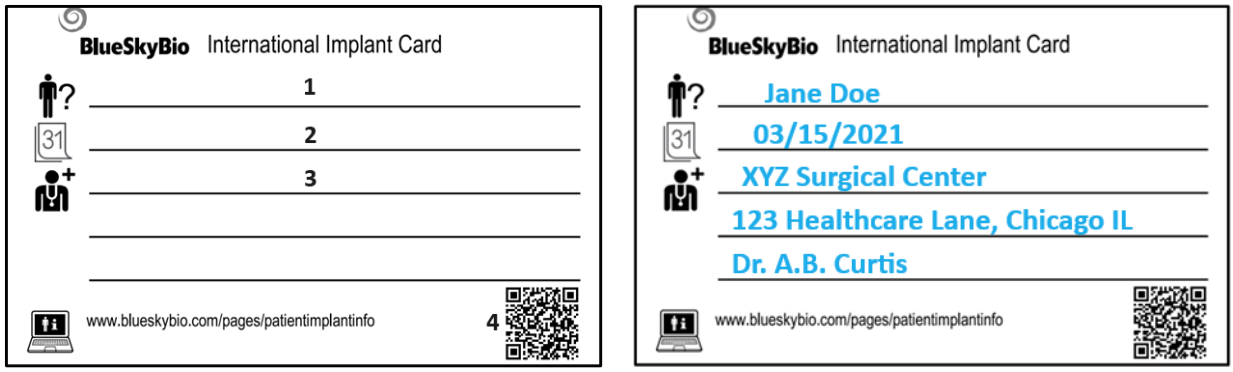
Caution

The sale of this device is restricted to, or by the order of licensed physicians or dentists.

Implant Card Instructions for Completion

An implant card has been provided with the implant device. It is intended to be completed by the healthcare provider; then giving to the patient.

1. Name of the patient or patient ID – To be completed by healthcare institution/provider
2. Date of implantation - To be completed by healthcare institution/provider
3. Name and address of the healthcare institution and provider - To be completed by healthcare institution/provider
4. Barcode to patient implant information – Present on Implant Card



Locations of text to be filled on the Left. Example of a completed implant card on the right with written information in blue.

Symbolling located on the device specific side of the implant card can be found on the first page of the IFU.