Instructions For Use

Blue Sky Bio, LLC Pterygoid Implant System

English Blue Sky Bio, LLC TAD

Blue Sky Bio, LLC
800 Liberty Dr
Libertyville, IL 60048 USA

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 for	STERILE R	Sterilized using Gamma Radiation
	Do not use if package is damaged	LOT	Batch code
MR	MR Conditional		Use by date
NON STERILE	Non-sterile	MD	Medical device
UDI	Unique device identifier		Date of manufacture
	Single sterile barrier system with protective packaging inside		Name and address of the implantation healthcare institution / provider
31	Date of implantation	?	Patient name or Patient ID
	Information website for patients	eIFU Indicator	Electronic Instructions For Use

Instructions for Use

Blue Sky Bio, LLC Pterygoid Implant System

Indications for Use

BIO| Pterygoid System is intended for surgical placement in the bone of the upper jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. Implants may be used with single-stage or two-stage procedures, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. BIO | Pterygoid implants can be placed bicortically in cases of reduced bone density. BIO | Pterygoid implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.

Contraindications

Implants should not be placed anytime when there are general contraindications associated with elective oral surgery.

Absolute and relative contraindications include, but are not limited to: cardiac and vascular disease, bleeding disorders, psychological disorders, uncontrolled diabetes mellitus, mineral, bone, or connective tissue disorders, renal disease, hepatic disease, auto-immune disorders, decreased immune function due to disease or medications, infectious disorders, and adverse conditions caused by medications. Further relative contraindications include poor oral hygiene, bruxism, malnutrition, alcoholism, tobacco usage, and history of radiation therapy.

In addition, the patient needs an adequate volume of residual bone for the placement of implants of sufficient size and number to support the anticipated functional loads to which the patient will subject these implants.

Warnings

The BIO| Pterygoid implant system is not intended for placement in maxillary or mandibular areas where there is inadequate bone present for these implants. BIO | Pterygoid implants are only to be used splinted in combination with at least one other implant. Implants should be placed and restored only by practitioners who are licensed and trained to perform these procedures. Adequate preoperative studies should be performed to examine the anatomic structures and to assess the biomechanical, functional, and aesthetic requirements of each case. Radiographs or other diagnostic reviews should be performed to determine position and topography of the maxillary sinus, nasal cavities, inferior alveolar nerve, mental foramen, natural tooth positions and other anatomical features that may affect implant placement or prognosis.

Surgical placement of pterygoid implants is straightforward for an experienced clinician and can be performed under local anesthesia in a dental office. However, the challenges of pterygoid implant placement are the learning curve and technique sensitivity associated with the procedure and proximity to certain vital anatomic structures. Clinicians must understand surgical anatomy before placement of implants in this region. Additionally, use of cone beam computed tomography (CBCT) imaging is recommended during treatment planning.

Consultation between the surgeon, restorative dentist, and dental laboratory is essential for success. Risks of implant placement and restoration include, but are not limited to: infection, implant failure, loss of bone and soft tissue, unfavorable aesthetic result, anesthesia, dysesthesia and paresthesia in the oral and facial areas, perforation of the sinus lining, sinus infection, dislodgement of implants and instruments in the surrounding structures, damage to adjacent teeth, non-restorable implants, fracture of implants or restorative components, and loosening of implants or restorative components.

Each implant system has unique measuring characteristics to allow full seating of the implant to the desired depth. In some instances, drill length reference lines measure longer than the stated length of the implant. It is recommended that the implant surgeon be thoroughly familiar with the specific measurement system being utilized and provide a suitable safety margin adjacent to any teeth and vital structures. Failure to recognize the difference between the actual length of the drill and radiographic measurements can result in permanent injury to the nerves or other vital structures by drilling beyond the depth intended, potentially resulting in permanent numbness to the lower lip and chin or other injuries.

Each implant system has specific design characteristics for mating implants, abutments, prosthetic components, and instrumentation. Combining instruments and components that are not configured or dimensioned for correct mating can lead to mechanical failure of components, damage to tissue, or unsatisfactory aesthetic results.

One-hundred percent success cannot be guaranteed. Lack of adequate quantity and/or quality of remaining bone, infection, inadequate surgical technique, poor patient oral hygiene, and generalized disease are some potential causes for failure of osseointegration, both immediately after surgery or after osseointegration is initially achieved. Pre-operative hard tissue or soft tissue deficits may yield a compromised aesthetic result or unfavorable implant angulation. With respect to children, routine treatment is not recommended until completion of alveolar growth has been verified.

Precaution - MRI Safety Information

MR Conditional

Warning: The RF safety of the device has not been tested. The patient may only be imaged when ensuring the following conditions are met.

Device Name	The Blue Sky Bio Implant Systems
Static Magnetic Field Strength (B0)	≤ 3.0T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP) for all landmarks above umbilicus No excitation restrictions for all landmarks below the umbilicus
RF Transmit Coil Type	Extremity T/R coils permitted. Excludes Head T/R coil.
Operating Mode	Normal Operating Mode in the allowed imaging zone
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	Not evaluated for head landmark
Scan Duration	No specific constraints due to implant heating

NOTE: All metals generate image artifacts. Image artifacts in patients with metal implants do not pose a direct hazard to the patient or a performance issue. However, they can lead to misinterpretation of the results. Clinical judgement should be used in evaluation of artifacts and their possible impact on interpretation.

Procedural Precautions, Surgery

All efforts must be made to minimize damage to the host tissue. In particular, special attention must be paid to thermal and surgical trauma and to the elimination of contaminants and sources of infection. The surgical procedure requires a high degree of precision and care. Any divergence from the principle of least possible trauma at implant installation increases the risk of failure to establish osseointegration.

All drilling procedures should be performed at maximum 1000-2000 RPM with copious irrigation. The use of sharp drills, sufficient irrigation, an in-and-out drilling motion, short cutting cycles, waiting for the bone to cool, and use of pilot drills in successively increasing sizes are essential.

Special care should be taken to avoid over or under preparation of the osteotomy. Implants should be inserted in such a way that they are stable and lack any mobility. Excessive insertion torque (greater than 60 Ncm) may lead to damage to the implant or instruments and fracture or necrosis of the bone site.

All instruments used in surgery must be maintained in good condition and care must be taken that the instruments do not damage the implants or other components. Precautions must be taken to avoid the swallowing or aspiration of components used in implant dentistry. After the implant installation, the surgeon's evaluation of bone quality and initial stability will determine when implants may be loaded. An appropriate follow-up protocol should be followed.

NOTE: Consult Surgical Instructions for individual implant procedures and drill sequence. https://blueskybio.com/pages/instructions-for-use

Instructions for Abutments for Restoration of Blue Sky Bio Implants

BIO | Pterygoid implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

For BIO| Pterygoid implants, a final abutment with appropriate angulation should be selected. The indexing feature of the abutment (e.g. hexagon) should match the internal indexing feature of the implant. Adequate seating can be verified with a radiograph. Seating should be performed using an insertion driver compatible with the selected implant system and a torque wrench applying 30 Ncm of torque on the abutment or fastening screw.

In case of delayed loading, after adequate osseointegration the implants should be uncovered, if necessary, and the cover screw or protective healing cap should be removed. The internal part of the implant should be irrigated, free of debris, and dried. If necessary, a healing abutment should be placed and the tissue should be allowed to heal around the healing abutment. A final abutment that is compatible with the implant should be chosen and inserted as described above once the tissue has healed.

A restoration should be fabricated and inserted after the tissue has healed, while making sure that the restoration has a passive fit, is stable, and the occlusal load is appropriate.

Follow Up Care

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

Sterility

All 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.

Abutments, abutment screws, and instruments are supplied non-sterile and must be cleaned and sterilized prior to use. The recommended sterilization cycle is: moist heat (steam), gravity-displacement, wrapped, 30 minute exposure at 121 °C (250 °F), and 15 minutes of drying. Use a wrap that is FDA cleared for the indicated cycle.

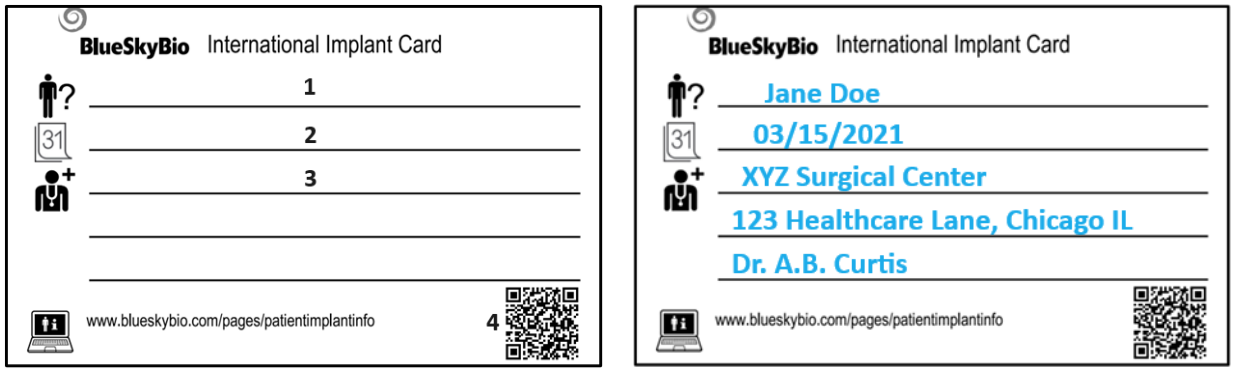
Method of Supply

Blue Sky Bio implants, abutments, and abutment screws are made out of medical grade titanium alloy (ASTM F136).

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

Disposal
The product should be disposed of in an environmentally friendly manner in accordance with local regulations. Hazardous waste of contaminated devices or sharp objects should be disposed of in suitable containers which meet the specific technical requirements.

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.

Please report any serious incident to the manufacturer

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