Instructions For Use

Blue Sky Bio, LLC Zygomatic Implant Systems

English Blue Sky Bio, LLC Zygomatic Implant Systems

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

English

Blue Sky Bio Zygomatic Implant Systems Instructions for Use

Indications

Blue Sky Bio Zygomatic Implant System is indicated for surgical installation in the zygoma region, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Blue Sky Bio zygomatic implants are recommended for the posterior (pre-molar/molar) region, one implant on each side, with at least two standard dental implants in the anterior region to support a fixed restoration. Blue Sky Bio zygomatic implants may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

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.

Warning

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 esthetic 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. 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, 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. These implants should not be used on patients with known hypersensitivity or allergic reaction to titanium alloys.

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

The Blue Sky Bio Zygomatic Implant System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Blue Sky Bio Zygomatic Implant System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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. Please refer to our web site for the specific sequence of drills for each implant type and size. 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.

Procedural Precautions, Prosthetics

Especially important is proper stress distribution through passive adaptation and fitting of the bridge to the implant abutments, adjusting occlusion to the opposing jaw, and avoiding excessive transverse loading forces. Immediate loading and immediate temporization require additional precautions and are not suitable for all cases. Because of the small size of prosthetic components, care must be taken that they are not swallowed or aspirated by the patient. Angled abutments and unsplinted narrow implants should not be used in the posterior area of the mouth.

Instructions for Abutments for Restoration of Blue Sky Bio Implants

After adequate osseointegration the implants should be uncovered, if necessary, and the cover screw should be removed. The internal part of the implant should be irrigated, freed from 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.

If the abutment is modified at chair side, it is advisable to make an impression and make a preliminary model to identify any undercuts prior to making the final impression. A carbide or diamond bur can be used with copious irrigation to remove the undercuts.

The indexing feature of the abutment (e.g. hexagon or square) should match the internal indexing feature of the implant. Adequate seating can be verified with a radiograph.

If the abutment is modified in a laboratory, proper orientation of the abutment into the implant should be identified by means of a transfer jig or any other transfer device. Final abutment 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.

Abutments should not be over-prepared, and the retention of restoration and the strength off the abutment should be taken into consideration. It is recommended that less than 50% of the structure of customizable abutments and less than 30% of straight abutments be removed. Modifying the abutment at the junction with the implant is not recommended.

A restoration should be fabricated and inserted, while making sure that the restoration is stable and occlusal load is appropriate. One piece implants require intraoral modification of the abutment portion of the implant. The implant should not be overprepared to avoid fracture of the implant.

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, and abutment screws are non-sterile and must be sterilized prior to use. See steam sterilization procedure below.

Moist Heat (Steam) Sterilization Recommended Procedure:

1. Place the device in a medical-grade paper/plastic steam-sterilization peel pouch compliant with EN ISO 11607-1 (or FDA-cleared for steam sterilization), sized to allow adequate seal margins and compatible with 121 °C gravity-displacement cycles.
2. Load Sterilizer (Gravity-Displacement) with pouches in a way that steam can circulate freely
3. Set sterilization parameters: 30-minute exposure at minimum of 121 °C (250 °F)
4. Run Sterilization cycle for the full 30-minute exposure at the set temperature
5. Allow 15 minutes of drying time before opening the sterilizer

Licensed Dental Clinicians are responsible for validating and routinely controlling their sterilization process and for ensuring their sterilization equipment is installed, maintained, and routinely monitored in accordance with the sterilizer manufacturer's instructions and applicable professional standards and local regulations (e.g., ANSI/AAMI ST79 and CDC guidance in the U.S.).

Method of Supply

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

Caution

Federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

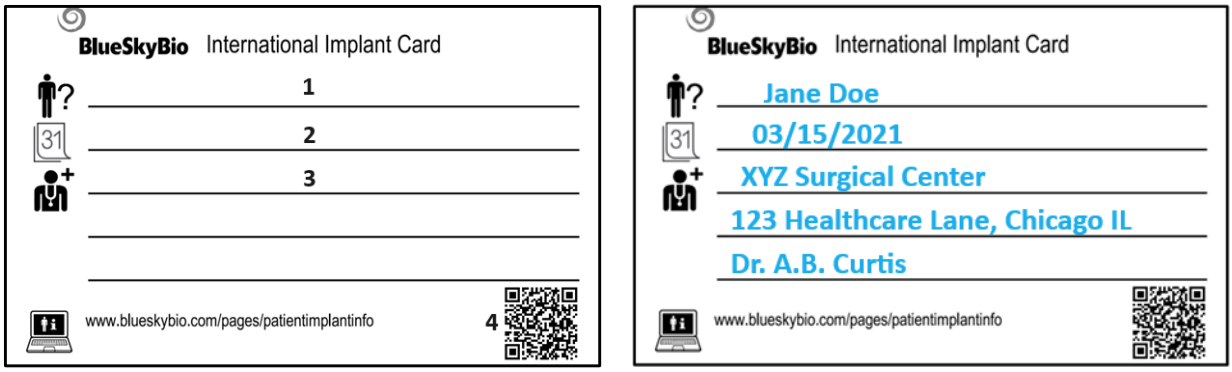
Disposal

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.

Manufactured by:

:Blue Sky Bio, LLC
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Libertyville Il 60048 USA