Instructions For Use

Blue Sky Bio, LLC Reusable Instruments

English	Blue Sky Bio, LLC Reusable Instruments
Le français	Instruments médicaux réutilisables Blue Sky Bio, LLC
Deutsch	Blue Sky Bio, LLC-Wiederverwendbare medizinische Instrumente
Italiano	Strumenti medici riutilizzabili Blue Sky Bio, LLC
Español	Instrumental médico reutilizable Blue Sky Bio, LLC
Svenska	Blue Sky Bio, LLC Återanvändbara medicinska instrument
Ελληνικά	Επαναχρησιμοποιούμενα ιατρικά εργαλεία Blue Sky Bio, LLC
Português	Instrumentos médicos reutilizáveis Blue Sky Bio, LLC

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CE 0297

REF	Catalog number	Rx Only	Caution federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner
	Caution, consult accompanying documents	LOT	Batch code
	Manufactured for	MD	Medical device
	Do not use if package is damaged	EU REP	Authorized Representative in the European Union
NON STERILE	Non-sterile		Date of manufacture
UDI	Unique device identifier		Electronic Instructions For Use
	Information website for patients		

English (en)
Blue Sky Bio, LLC Reusable Instruments

Indications For Use

Blue Sky Bio reusable instruments, including surgical drills, used as an accessory with endosseous dental implants are intended to prepare the osteotomy and assist in surgical and prosthetic steps for the placement of Blue Sky Bio endosseous dental implants in the maxilla or mandible by licensed dental professionals.

Intended users: Licensed Dental Clinicians.

Device-specific intended uses

- **Drills:** Prepare the site for placement of endosseous dental implants.
- **Drivers & adapters:** Used to screw prosthetic components in place.
- **Pins:** Temporarily retain a laboratory-printed surgical drill guide during drilling of an osteotomy for a dental implant site; pins are removed immediately after use during surgery.
- **Bone condensers:** compact bone graft material at a surgical site.
- **Drill Bits (zygomatic):** Used to drill an osteotomy and prepare the site for zygomatic implant placement surgery. (For US and Canada Sales only)
- **Probe (zygomatic depth probe):** Used to check the depth of the prepared site for zygomatic surgery. (For US and Canada Sales only)
- **Zygomatic retractor:** Retracts tissues enveloping the zygomatic arch (muscles and mucoperiosteal flaps) to enhance the surgical view during zygomatic implant placement surgery. (For US and Canada Sales only)
- **Gauge:** Aids in the evaluation of the surgical dental implant site**.**
- **Pterygoid osteotome:** Used to initiate an osteotomy and determine the depth of the pterygoid plate. (For US Sales only)
- **Tissue punch:** Used to remove gingival tissue on top of crestal bone when preparing the site for implantation. (For US Sales only)
- **Abutment removal screw:** Instrument used to remove a seated abutment from an implant. (For US and Canada Sales only)
- **Component organizer cassette:** Plastic, autoclavable cassette used to hold and organize instruments and drills. Cassettes are not a sterile barrier. (For US Sales only)
- **Digital reference scanbody:** Used with an intraoral scanner as an optical impression transfer to digitally capture the position and orientation of dental implants or abutments; and are placed temporarily and removed immediately after the scan. (For US and Canada Sales only)
- **Implant mount:** Inserted into the implant to carry and place the implant into the implant site**.**
- **Bur:** used to prepare site for Zygomatic Implant placement surgery. (For US Sales only)

Supplied condition & reprocessing: Reusable accessories are supplied **non-sterile** and must be **cleaned and steam-sterilized** prior to use. End-of-life is determined by wear or damage; remove from service if cutting efficiency is reduced or if deformation, corrosion, or cracks are present.

Instructions

Device-specific Instructions

- **Drill bits:** Review the site anatomy and planned implant size/position. Refer to the manufacturer's website for the specific drill sequence for each implant type and size. Use pilot drill, then successive drills per sequence at 1000–2000 RPM without a surgical guide and at 800-1200 RPM with a surgical guide with copious irrigation. Employ intermittent cutting and avoid continuous contact that may increase heat. Monitor osteotomy dimension to avoid over-/under-preparation. Drills should be used for up to 100 uses or if the cutting efficiency is reduced or the coating shows signs of wear. Follow cleaning and sterilization below.
- **Drivers & adapters:** Choose the appropriate driver tip geometry to match the implant system
- **Pins:** Use a 2mm diameter drill through the designated hole in the surgical guide and place pins to stabilize the surgical guide. Ensure that the surgical guide does not move. After the surgery is completed remove the pins and clean and sterilize according to the instructions below.
- **Bone condensers:** Chose a bone condenser that is slightly smaller than the osteotomy and use gentle force to insert the bone graft granules into the surgical site.
- **Drills (zygomatic):** Drills should be chosen based on the diameter and the length of the planned implant. Drilling speed should not exceed 2000 RPM in a pumping motion with copious irrigation, Drills should be used for up to 100 uses or if the cutting efficiency is reduced or the coating shows signs of wear. Follow cleaning and sterilization below. (For US and Canada Sales only)
- **Probe (zygomatic depth probe):** Place into zygomatic osteotomy to probe the extent of the osteotomy and select the appropriate zygomatic implant. (For US and Canada Sales only)
- **Zygomatic retractor:** Raise a mucoperiosteal flap and expose the zygoma. Then insert the Zygomatic retractor and place the tip on the lateral surface of the zygomatic bone. During retraction maintain contact of the tip of the retractor with the zygoma to prevent injury of the surrounding structures. (For US and Canada Sales only)
- **Gauge:** place into the osteotomy to determine trajectory.
- **Pterygoid osteotome:** Place onto maxillary tuberosity in the planned trajectory of the pterygoid implant. With a mallet, gently tap to advance until it reaches the pterygoid bone. (For US Sales only)
- **Tissue punch:** With gentle steady pressure, penetrate the soft tissue to the depth of the underlying bone. Once the incision is complete, remove the punched tissue disk and expose the underlying bone. (For US Sales only)
- **Abutment removal screw:** Locate the abutment internal screw channel thread the retrieval screw clockwise until it bottoms out against the apical portion of the implant thread and separates the abutment from the implant. (For US and Canada Sales only)
- **Component organizer cassette:** Place instruments according to the marked locations in the organizer. Cassettes are not a sterile barrier and prior to sterilization, the cassettes are required to be enclosed by a pouch 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. (For US Sales only)
- **Digital reference scanbody:** Confirm implant system and platform size. Choose the matching scanbody. Remove healing abutment and ensure the internal surface of the implant is clean of debris. Insert the scanbody and make sure it is fully seated and properly oriented. Then screw down the fixation screw with appropriate driver. Hand tighten with light finger pressure only. Then scan with an optical scanner. (For US and Canada Sales only)
- **Implant Mount:** Confirm implant system and platform size. Choose the matching implant driver. Attach driver to implant and insert implant into the osteotomy. Avoid using torque higher than 60Ncm.

- **Burs:** Fixate the tip of the zygomatic bur in a stable position and, with a lateral movement, create a channel in the lateral wall of the maxillary sinus at 1000 RPM, using copious irrigation. The width of the channel should be slightly larger than the width of the selected zygomatic implant. (For US Sales only)

Contraindications

Use is contraindicated when general contraindications to elective oral surgery exist or when adequate bone volume is lacking for the planned implant size. Do not use with incompatible systems.

Warnings

- 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.
- 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.
- Precautions must be taken to avoid the swallowing or aspiration of components used in implant dentistry.

Precautions

- Verify component compatibility and correct drill length markings prior to use.
- Inspect cutting edges and surface coating. Replace drills if surface coating is worn or if cutting edges are damaged, or cutting efficiency is reduced.
- All instruments should be inspected for damage (i.e. surface coating, cracks, etc).

Cleaning and Sterilization

Cleaning and sterilization apply to all reusable instruments and drills. Perform the complete, validated process below before first use and after each use.

Cleaning instructions for reusable instruments:
1. Rinse with cool-to-lukewarm water for two-and-one-half minutes.
2. For all parts place in an ultrasonic cleaner with an enzymatic detergent diluted with tap water per the manufacture's guidelines.
3. Sonicate for 10 minutes.
4. Rinse with tap water for three minutes.
5. Inspection and Functional Check:
    - Examine for corrosion, pitting, cracks, burrs, loss of cutting efficiency, or deformation.
    - Confirm free rotation of latch-type shanks and correct engagement.
    - Remove from service any damaged or dull drill; end-of-life is determined by wear and damage during use.

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.; EN ISO 17665 and national guidance in the EU).

Method of Supply

Blue Sky Bio, LLC surgical drills and instruments are supplied non-sterile unless stated otherwise on labeling.

Surgical drills and instruments are manufactured from medical-grade stainless steel and/or titanium alloy. Cassettes are made from polyphenylsulfone (PPSU) or Stainless steel. Scanbodies are made from medical grade Titanium alloy or polyetheretherketone (PEEK).

Caution

Federal law restricts this device to sale by or on the order of a licensed Clinician (Rx Only).

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.

The hard copy of the IFU can be made available immediately through email, fax or direct mail free of cost.

Complaints and Adverse Events & Reporting

Please report any complaints or serious incidents to Blue Sky Bio customer service at (718) 376-0422 or https://blueskybio.com/pages/support.

Please report any serious incident to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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