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IFU-006, rev. 02
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INSTRUCTIONS FOR USE

Surgical Drills, Drill Stops, and Tissue Punches

CAUTION

U.S. federal law restricts the products mentioned herein, for sale by or on the specific order of a dental professional.

Disclaimer of Liability

Users of any products ("Products") sold by (a) Paragon Implant Company, LLC or produced by (b) Paragon Implant Mfg., LLC or (c) any company that manufactures products for Paragon Implant Mfg., LLC (collectively, (a)-(c) are referred to as "Paragon"), shall make their own determination regarding the selection of Products that are suitable for each specific application and circumstance, and shall have full responsibility over the use of any such Products. Paragon has no control over either the selection or use of its Products, which are the sole responsibility of the user. Paragon disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damage(s) arising out of or in conjunction with any errors in professional judgment or in practice in the selection or use of Products. Users are advised and obliged to study the latest news and developments in implant dentistry, and to frequently review. www.paragon-implant.com for any updates or information related to Products and/or their specifications.

Product Description:

Surgical Drills, Drill Stops and Tissue Punches are reusable devices designed to prepare an osteotomy for a dental implant procedure.

The Surgical Drills and Tissue Punches are designed to prepare osteotomies using a powered device and include a shank with a latch-lock fitting that meets ISO 1797-1 standard for attachment to a dental handpiece. Follow the handpiece manufacturer's instructions for inserting and locking the Surgical Drills and Tissue punches into a handpiece spindle. Surgical Drills and Tissue Punches are made of heat-treated S420 Series stainless steel and are coated with a Diamond Like Carbon (DLC). Surgical Drills should be replaced after 30 osteotomies, or when cutting efficiency declines, or if corrosion or other damage is observed. Tissue punches should be replaced when cutting efficiency declines or if corrosion or other damage is observed.

Drill Stops of varying length and diameter are designed to attach to Surgical Drills and aid in the accuracy and precision of the osteotomy depth. The Drill stops are made of Titanium alloy (Ti-6Al-4V ELI) and are anodized to indicate diameter and bone level placement. Drill Stops should be replaced if they become damaged or worn and can no longer be identified or affixed to step drills.

The Surgical Drills, Drill Stops, and Tissue Punches are intended to be used in conjunction with the placement of the following Paragon Implant dental implant systems:

- GEN5™
- GEN5+™

Patient target group and intended user:

Surgical Drills, Drill Stops, and Tissue Punches are used to place GEN5 and GEN5 implants used in fully or partially edentulous patients who do not have the conditions listed in the contraindications mentioned in this document. It is recommended that practitioners should have a sound working knowledge of dental implantology and instruction in the handling of the Products. In addition, using the Products safely requires strict adherence to the instructions and procedures shown in this and any additional product specific *Instructions for Use* (IFU), technical brochures and catalogs.

Intended Use:

The Surgical Drills and Tissue Punches are intended for use during surgical placement of dental implants that are in the mandible and maxilla in support of and the retention of overdentures, single-unit or multiple-unit, screw- or cement-retained prostheses.

Drill Stops are used in conjunction with Surgical Step Drills to allow for a precise and accurate osteotomy depth.

Indications for Use:

Tissue punches may be used optionally to remove a circular section of mucosa from an edentulous location in the maxilla or mandible prior to producing an osteotomy.

Surgical Drills cut into maxillary or mandibular bone to create implant specific osteotomies for Endosseous dental implant placement.
The Surgical Drills include:

- A Pilot Drill to provide a starting position for the following Step Drills.
- Step Drills to form the osteotomy of the corresponding implant size.
- Crestal Drills to expand the crestal bone portion of the osteotomy.
- A Lindemann drill to support additional vertical and horizontal preparation of bone, when required.

The Drill Stops are intended to be attached to the surgical step drills for aiding in the accuracy and precision of the osteotomy depth. The Drill Stops are not intended to work with the pilot drill, Lindemann drill, or crestal drills.

Contraindications:

In general, contraindications are applicable for GEN5 and GEN5+ implant surgery related patients with the following circumstances:

- Patients who are medically unfit for an oral surgical procedure.
- Patients who are allergic or hypersensitive to stainless steel, diamond-like carbon (DLC) coating, and/or Titanium alloy (Ti-6Al-4V ELI).
- Patients In whom adequate sizes, numbers or desirable position of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients with inadequate bone volume unless on augmentation procedure can be considered.

Caution: The Surgical Drills should not be used in conjunction with electrosurgery.

Caution: Drill Stops are not represented to be "non-pyrogenic".

Warnings:

The drills are to be used according to the Instructions for Use. Not doing so may result in the following circumstances:

- Device breakage
- Unintended embedded pieces in the patient
- Aspiration of devices

- Swallowing of devices

Unless specified in Product Instructions for Use, only use original Paragon Products.

Failure to recognize actual lengths of drills relative to radiographic measurements can result in permanent injury to nerves or other vital structures. Drilling beyond the depth intended from lower jaw surgery may potentially result in permanent numbness to the lower lip and chin or lead to a hemorrhage on the floor of the mouth.

Undesirable Side Effects:
The use of these devices constitutes an invasive treatment which may be associated with typical side effects such as, but not limited to, inflammation, infection, bleeding, hematoma, pain, and swelling. Depending on its location of use it may, in rare cases, lead to fenestration or fracture of bone, perforation of neighboring structures, sinusitis, or sensory/motor disturbances. During use of this device, the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex.

Precautions:
One hundred percent of implant success cannot be guaranteed. Implant treatment may lead to bone loss, biological or mechanical failures.

Storage and Handling:
Surgical Drills, Drill Stops, and Tissue Punches must be stored in a dry place, at room temperature, in their original packaging. Surgical Drills, Drill Stops, and Tissue Punches are provided in non-sterile vials. It is recommended to use the devices immediately after end-user sterilization. Keep the devices in their sterilization packaging and in a dry and clean environment prior to use. Check the packaging and device integrity prior to usage.

Note: Please check that the end-user sterilization packaging is compatible with the sterilization parameters for the device.

Warning: Use of non-sterile components may lead to infection of tissues or infectious diseases.

Caution: Do not use the device if packaging is damaged in any way (e.g., cracked vial, broken seal, or illegible text on the vial label).

Disposal:
Products to be disposed of must be treated and decontaminated as dental surgery waste in compliance with the relevant local healthcare guidelines, country and government legislation or policy, and environmental requirements.

Recycling or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable.

Surgical Procedures & Techniques for Implant Placement:
- *Pre-Operative Treatment Planning:*

During the pre-operative stage, availability of bone-height and bone-width, soft tissue thickness, and the planned trajectory of the implant must be determined. Appropriate radiography should be used to determine bone availability, optimal implant location while avoiding anatomically compromised structures such as the mandibular nerve canal, maxillary sinuses, and adjacent teeth with their convergent or divergent root system. Oral palpation can be used to provide clinical feedback as to the condition of the surrounding gingiva and alveolar ridge. Care should be taken when determining the final depth of the osteotomy as the drill point often extends past the posted length of the drill, by up to 1mmL.

- *Surgical Site Preparation:*

After the planning stage is completed, the clinician will follow standard implant site preparation procedures to gain access to the underlying bone. Follow the drill sequence as shown in the included table below for the various implant diameters and procedural steps to follow based on patient's bone density (dense or soft) and volume, in those respective areas.

- Ensure all drills are sharp prior to the start of the surgery. In cases where multiple implant sites are planned, it is advisable to have additional narrow diameter drills sterilized in case the demand arises during surgery. (Instrumentation are not supplied sterile).
- For planned procedures that require bi-cortical stabilization of implants, the clinician is advised to drill to full depth of the final dense bone type drill sequence for the specific size of implant to be placed. This is to prevent the apex of the implant from stopping at the opposing cortical plate, with its undersized osteotomy, and not being able to seat the implant to correct planned depth and consequently the stability of the implant.
- During site preparation, the clinician determines if the planned procedure may take place based on bone quality, quantity, and soft tissue thickness.

- *Tissue Punch Operation:*

If surgical site preparation with a Tissue Punch is planned, select the diameter Tissue Punch corresponding to the diameter of the planned implant (4mm ID or 5mm ID) and proceed with incision at the site using a maximum speed of 250 RPM. Saline irrigation is optional. The speed used is determined by the clinician's preference and experience.

- *Drilling Operation:*

Drilling must proceed at a maximum speed of 2000 RPM or less, under copious irrigation, preferably with chilled saline solution. The speed used is determined by the clinician's preference and experience. During drilling, it is recommended to use an in-and-out motion without stopping the handpiece motor to allow the irrigation to flush away bone debris and cool the site. The surgical drills possess circumferential grooves at 7mm, 9mm, 11mm, 12.5mm, and 14mm above the drill point, indicative of standard bone-level implant placement depths. Drill shanks possess a circumferential color band at the base of the shank to indicate drill diameter and sequence. Following the proper drilling sequence specific to the implant diameter and depth is critical to long term implant stability.

- *Drilling with Drill Stops:*

Drill stops are offered in two diameters. Each diameter is offered with a 1mm supra-crestal implant placement and a bone-level implant placement. Drill stops are anodized to indicate diameter and placement. The following table summarizes the drill stops corresponding to drill size and placement.

Color	Placement Level	Corresponding Drill Size
Gold	Bone-level	2.3/2.0, 2.8/2.3, 3.4/2.8, 3.8/3.4
Green	1mm supra-crestal	
Rose Gold	Bone-level	4.4/3.8, 4.8/4.4, 5.1/4.8, 5.4/5.1
Blue	1mm supra-crestal	

To attach a drill stop to a surgical drill:
1. Select the drill stop corresponding to the surgical drill size and planned placement level.
2. Place the drill stop around the drill and slide it up to the length of the drill until it can no longer move.
3. Check to see that the retentive tines on the drill stop have engaged the fixation grove and that the drill stop is fixed in place. Proceed with drilling the osteotomy until the bottom of drill stop contacts the bone.

To remove a drill stop from a surgical drill, grasp the bottom of the drill stop and slide it off the fixation groove and then off the drill completely

Caution: When attaching or removing a drill stop from a surgical drill, keep fingers clear from edges of surgical drill to prevent injury.

Post-Operative Care: On the Implant Specialist's instructions, it is normally recommended that patients use a suitable, mouth wash (non-alcohol-based) while maintaining good oral hygiene during and post the healing phase.

Healing Time: Implants can heal for a period of two to four months or more prior to being restored. It is dependent on the bone volume, quality, as well as any type of compromising medical conditions. Paragon Implants have been cleared for immediate restoration.

Instructions: Consult *Instructions for Use* (IFU) notated by the symbol and other technically related sections on the website (https:/paragon-implant.com/IFU) for assistance.

Adverse Reactions:

Adverse events are to be reported by the user, or patient, to the manufacturer.

Cleaning and Sterilization Processing/Reprocessing:

All reusable instruments, including Surgical Drills, Drill Stops, and Tissue Punches are processed and packaged within a clean room environment. The reusable instruments, including the Surgical Drills and Drill Stops, are supplied in a non-sterile form unless otherwise indicated as sterile. Cleaning can be performed manually or in an automatic washer.

Caution: Prevent body fluids, hard and soft tissues from drying on the devices by minimizing the time before cleaning and reprocessing as soon as possible after use. If cleaning cannot be performed immediately, the surgical instruments should be kept moist and free of gross soil by using moistened, lint free wipes or rinsing in sterile water. Do not allow blood or debris to dry on the instruments.

Warning: Prior to each use and being placed intraorally, cleaning and sterilization are required for all reusable trays and instruments, including Surgical Drills and Drill Stops. All surgical instruments must be cleaned before they are loaded into the sterilization tray.

Warning: Always follow the indications, instructions and warnings provided by the supplier of the cleaning solution. Select only solutions intended for cleaning of medical devices made of a variety of metals and plastics.

Manual Cleaning and Drying:

Note: Enzymatic-based cleaning solutions must be diluted per the manufacturer's instructions. Acceptable enzymatic cleaning solution should have neutral pH.

Note: It is recommended that the final rinse be performed with deionized, preferably distilled water.

Caution: Do not use cleaning agents containing hydrogen peroxide, chlorine or chloride. The active agents are corrosive to the drills. Using a detergent outside of the recommended neutral pH may adversely affect the finish of the drills.

Caution: Ensure drills are not in contact with one another or other metallic instruments when submerged in liquid during cleaning.

1. Begin cleaning by rinsing instrumentation under warm, running tap water for at least 3 minutes.
2. Scrub the interior and exterior surfaces, lumina, and cavities of the instrument with a soft-bristled, nylon brush or lint free cloth.
3. Flush the inner surfaces, cavities, and lumina (where applicable) at least once with 20mL of an enzyme-based cleaning solution (e.g. neodisher® MediZym) using a disposable 20mL syringe with an irrigation needle.
4. Immerse the instrument in a bath of warm enzymatic cleaning solution for 10 minutes.
5. Scrub the interior surfaces, lumina, and cavities (where applicable) using an appropriately sized soft-bristled, nylon brush for at least 1 minute.
6. Scrub the exterior surfaces and cavities (where applicable) using an appropriately sized soft-bristled, nylon brush for at least 1 minute.
7. Rinse the exterior and interior surfaces with lukewarm tap water for at least 20 seconds to remove the cleaning solution and visually inspect the instrument for gross soil. Repeat steps 4-6 if gross soil is observed.
8. Fully immerse the instrument(s) into an ultrasonic bath containing an enzymatic-based cleaning solution (e.g. neodisher® MediZym) and sonicate for 10 minutes.
9. Remove the components from ultrasonic bath and rinse exterior and interior surfaces thoroughly with cool, running, tap water for a minimum of 2 minutes.
10. Dry with lint-free, single-use wipes.

Automated Cleaning and Drying:

Note: Enzymatic and Alkaline cleaning solutions must be diluted per the manufacturer's instructions.

Note: Only FDA approved washer/disinfectors may be used under the following cleaning parameters.

Note: It is recommended that the final rinse be performed with deionized, preferably distilled water.

1. Begin cleaning by soaking the instrument (disassembled if applicable) in warm enzymatic cleaning solution (e.g. neodisher® MediZym) for approximately 5 minutes.
2. Flush the inner surfaces, cavities, and lumina (where applicable) two to three times (2x-3x) with 20mL of the enzyme-based cleaning solution using a disposable 20mL syringe with an irrigation needle.
3. Scrub the interior surfaces, lumina, and cavities (where applicable) using an appropriately sized soft-bristled, nylon brush for at least 1 minute or until all visible soil is removed.
4. Scrub the exterior surfaces of components with a soft-bristled, nylon brush or lint free cloth for at least 1 minute or until all visible soil is removed.
5. Thoroughly rinse all the outer and inner surfaces, lumina, and cavities (where applicable) with cool, running, tap water for a minimum of 20 seconds.
6. Place the components in a suitable rack or load carrier within the automatic washer ensuring that the rack or load carrier is oriented in a horizontal position.
7. Perform automatic cleaning that includes:
    - A 2-minute minimum pre-cleaning with cold water.
    - A 6-minute minimum cleaning with a mildly alkaline detergent intended for automated cleaning (e.g. neodisher® Mediclean).
    - A 2-minute minimum rinsing with cold water.
    - A 5-minute drying at a minimum of 66°C (150.8°F)
    8. Any residual moisture remaining after automatic cleaner drying cycle may be dried with lint-free, single-use wipe.

Sterilization:

All steam sterilizing packaging and sterilizing equipment are to be FDA cleared for use. When sterilizing multiple devices in one steam sterilization cycle, ensure that the packaging and equipment maximum load requirements are followed.

Caution: Ensure instruments and other devices made from different materials are not in contact during sterilization.

Warning: Steam Sterilization operating times may vary from unit-to-unit, especially when sterilizing multiple pouches. All steam sterilizers should comply with the requirements of, and be validated, maintained, and

checked in accordance with EN 285, EN 13060, ISO 17665-1, ANSI/AAMI ST79.

Caution: After cleaning and drying, perform a visual inspection of all components for unacceptable remnant soil. If necessary, repeat the cleaning procedure to remove all soil before sterilization.

Caution: After cleaning and drying, perform a visual inspection of all components for unacceptable deterioration. Discard any components that fail a visual inspection.

Caution: Contact between instruments of dissimilar material should be strictly avoided during sterilization. For sterilization instructions using the surgical tray, please see the surgical tray instructions for use.

1. Following visual inspection, insert each component into a separate, sterilizable pouch that is FDA approved or meets the ISO 11607 suitability for steam sterilization up to at least 137°C (279°F). For sharp instruments, such as drills, double pouch before sterilization.
2. Label each sterilization pouch with information necessary to identify the device and seal.
3. Place the sealed sterilization pouch(es) into the steam sterilizer. The sterilization pouch should be oriented in a horizontal position.
4. Sterilize the device using either one of the following cycles and associated parameters:

Method	Conditions	Drying Cycle
Gravity Moist Heat Sterilization (Autoclave)	132°C (270°F) 15-20 psig 15 minutes	30 minutes
Pre-vacuum Moist Heat Sterilization (Autoclave)	132° C (270° F) 4 minutes	20 minutes

5. Use sterilized components immediately, otherwise follow the instructions for storage provided by the manufacturer of the sterilization accessories / storage containers.

Caution: If there are any signs of excess moisture or pooled water in the load at the end of the sterilization cycle, repackage and re-sterilize using a longer drying time.

Glossary of Packaging Labeling Symbols:

The following table describes the symbols which may be printed on the packaging label. Refer to the packaging label for the applicable symbols associated to the Product.

Symbol	Symbol Title	Symbol Source
	Non-Sterile	ISO 15223-1
Rx Only	Caution: U.S. federal law restricts this device to sale by or on the order of a dental professional.	21 CFR 801.109(b)(1)
	Date of Manufacture (YYYY-MM-DD)	ISO 15223-1
	Catalogue Number	ISO 15223-1
	Batch Code	ISO 15223-1
	Consult *Instructions for Use* or consult electronic *Instructions for Use* Follow the link to the eIFU: https://paragon-implant.com/IFU	ISO 15223-1
	Manufacturer	ISO 15223-1
	Do not use if package is damaged and consult Instructions for Use	ISO 15223-1
	Caution	ISO 15223-1
Qty:	Quantity	Paragon Implant Mfg., LLC

Australian Sponsor:
Paragon Implant Australasia Pty LTD
Suite C1.11 (Level 1) The Odeon
52 Lyons Road
Drummoyne, NSW 2047, Australia

GEN5 and GEN5+ Drill Sequence

Implant Diameter (mm)	Bone Type	Drill Type and Sizes										
		Pilot Drills SD1.8 or 2.0 Lindemann		2.3/ 2.0	2.8/ 2.3	3.4/ 2.8	3.8/ 3.4	4.4/ 3.8	4.8/ 4.4	5.1/ 4.8	5.4/ 5.1	Crestal Bone Drill
3.7	Soft	X	X	X	X							
	Dense	X	X	X	X	X						OPTIONAL
4.2	Soft	X	X	X	X	X						
	Dense	X	X	X	X	X	X					OPTIONAL
4.7	Soft	X	X	X	X	X	X					
	Dense	X	X	X	X	X	X	X				OPTIONAL
5.2	Soft	X	X	X	X	X	X	X				
	Dense	X	X	X	X	X	X	X	X			OPTIONAL
5.7	Soft	X	X	X	X	X	X	X	X	X		
	Dense	X	X	X	X	X	X	X	X	X	X	OPTIONAL

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Drills	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
CD3.3																														
CD3.7																														
CD4.2																														
CD4.7																														
CD5.2																														
CD5.7																														
SD1.8																														
SD2.3																														
SD2.8																														
SD3.4																														
SD3.8																														
SD4.4																														
SD4.8																														
SD5.1																														
SD5.4																														
LD2.0																														

*Each number (1-30) represents 1 osteotomy.

*Replace drills after 30 osteotomies.