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IFU-009, rev. 02
2026-10-29

INSTRUCTIONS FOR USE

Paragon Implant Surgical and Prosthetic Instrumentation

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:

Paragon Implant Surgical and Prosthetic Instruments are surgical devices used to perform dental implant or prosthetic surgical procedures following implant indications and contraindications for use. The surgical devices are reusable and are provided non-sterile but are capable of being cleaned and sterilized according to these instructions for use.

Surgical and Prosthetic Instruments are comprised of:

- Drive-beam style torque wrenches (stainless steel, DLC coated), designed for high (implant insertion) and low (prosthetic fixation) torque ranges.
- Torque wrench inserts and ratchet/wrench extender (Stainless Steel, DLC coated), designed for compatibility with 4mm square, 2.5mm hex, and latch interfacing drivers.
- Drill extender (Stainless Steel, DLC coated) for use with a powered (active device).
- Various 2.5mm and 1.25mm Ruby-Ball Hex Drivers (Stainless Steel, DLC coated) are designed to be used manually or with a powered (active) device. All variations are designed with a corundum ball to retain a corresponding internal hex component.
- Various multi-unit and angled-screw channel abutment drivers (Stainless Steel, DLC coated) designed to be used manually or with a powered (active) device.
- Friction Fit Removal Tool (Stainless Steel, DLC coated, and Titanium Alloy).
- Parallel Guide Pins (Titanium Alloy, DLC coated), MUA Guide Pins (Titanium Alloy), and angle measuring guide (Stainless Steel, DLC coated).
- Analogue Insertion Tools (Stainless Steel, DLC coated) designed for laboratory use.

Some of the drivers are designed for use with a powered device and include a shank with a latch-type (contra-angle) fitting that meets ISO 1797-1 standard for attachment to handpieces. Follow the handpiece manufacturer's instructions for inserting and locking latch-type instruments into a handpiece spindle.

Patient target group and intended user:

The Paragon Implant Surgical and Prosthetic Instruments are used for surgical and restorative procedures 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, to use 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 Paragon Implant Surgical and Prosthetic Instruments are intended for use during surgical placement and complete restoration of root-form Endosseous dental implants.

Indications for Use:

High and low range torque wrenches are indicated for mandibular/maxillary implant insertion and fixation of restorative componentry, respectfully. Parallel Guide pins are indicated for placement in mandibular/maxillary osteotomies to guide drilling operations. Torque wrench inserts, drivers, and MUA guide pins, are indicated for the placement, fixation, and removal of restorative components. ACS Drivers are indicated for up to 25 degrees of angulation. The Friction Fit Removal Tool is indicated for removal of friction fit abutments from implants. Drill and Wrench/Ratchet extenders are indicated for extending range of latch-type instruments and 4mm square instruments, respectively.

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 an augmentation procedure can be considered.

Warnings:

Unless specified in Product Instructions for Use, only use original Paragon Products with Paragon Implant dental implant systems.

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:
Paragon Implant Surgical and Prosthetic Instruments 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 and Prosthetic Techniques:

- *Paralleling Guide Pins*:

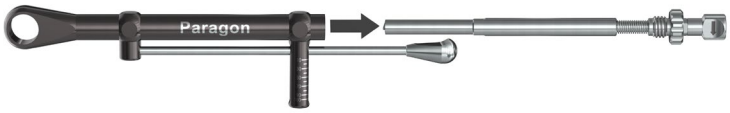
Paralleling guide pins may be inserted into the osteotomy following use of a 2.3/2.0 surgical drill or a 2.8/2.3 surgical drill to help visualize three-dimensional osteotomy axis.

Warning: A suture, floss, or other line should be drawn through the through-hole in the paralleling guide pin and tied down before placement. Failure to do so may result in aspiration or swallowing of the device.

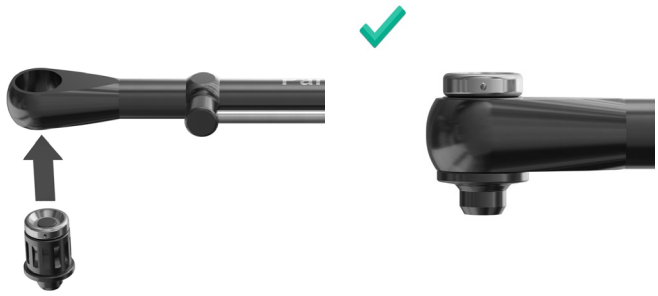
- *Torque Wrench Operation:*

The high and low range Torque Wrenches (TW-100 and TW-35) may be disassembled by turning the lock-nut counter-clockwise and removing the spring-loaded locking pin from the Torque Wrench body. Assemble the Torque Wrenches by fully inserting the spring-loaded locking pin back into the Torque Wrench body and turning the locknut clockwise until tightened.





The Torque Wrenches are designed to accept the circular, scalloped portion of a Driver or Torque Wrench Insert.



The direction of applied torque can be limited to clockwise or counterclockwise rotation by pulling the spring-loaded locking pin back, twisting until the indicator arrow points in the direction of the desired applied torque, and releasing the pin.



Caution: Always adjust the direction of the applied torque on a Torque wrench before inserting the driver, making sure that the locking nut and locking pin is fully seated. Failing to do so may result in the driver falling out of the Torque Wrench or the Torque Wrench not operating properly.

To apply torque with a drive-beam style Torque Wrench, grasp the Torque Wrench beam by the finger grip and apply torque. The dial on the torque wrench is designed to indicate the applied torque where the Torque Wrench beam aligns with the graduations on the dial.

Warning: Care should be taken not to over-torque implant during placement. Failing to do so may result in implant placement failure, and/or damage to surrounding tissues.

Caution: Always apply torque with the driver on the same vertical axis of the implant. Do not angulate the torque wrench or handpiece during torque application. Failure to do so may result in device, misalignment, detachment, and/or damage.

Warning: Care should be taken not to over-torque fixation screws or abutment screws (20 Ncm for temporary abutment fixation and 30 Ncm for permanent abutments). Failing to do so may result in damage to the implant, restorative component, and/or surrounding tissue.

- *Removing a Friction Fit Abutment:*

Insert the Friction Fit Removal tool into the abutment and turn clockwise until the abutment releases from the implant.

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 and Prosthetic Instrumentation, are processed and packaged within a clean room environment. The reusable instruments, including the Surgical and Prosthetic Instrumentation, are supplied in a non-sterile form. 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 and Prosthetic Instrumentation. 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

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