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STERILIZATION TRAYS INSTRUCTIONS FOR USE

Caution: Federal law restricts the products mentioned herein, for sale by or on the specific order of a dentist.

Description

Paragon sterilization trays are divided into the following types:

- Complete Surgical Kit
- Basic Surgical Kit
- Standard Surgical Kit
- Drill Stop Kit
- Prosthetic Kit

The Surgical, Drill Stop, and Prosthetic Kits are reusable perforated instrument cassette systems, composed of an outer case (base), cover (lid), and insert, that is designed to hold dental instruments in place during transport, steam sterilization, and storage. The Surgical Kits are designed to support Paragon implant/prosthetic placement protocols, as well as hold various dental instruments such as: Surgical Drills, Drill Stops, Paralleling Tools, Implant Drivers, Drill Extender, Prosthetic Drivers and Torque Wrenches.

The insert contains markings and colors to indicate either the surgical workflow or the position of the instruments within the cassette.

The Standard and Basic Surgical Kits includes a removable stainless-steel pan, which functions as a storage receptacle for used surgical instruments.

Indications for Use

The Sterilization Trays are designed to hold various dental surgical and prosthetic instruments to organize, steam sterilize and transport the instruments between uses. The kit is to be enclosed in an FDA cleared steam sterilizable pouch large enough to fit a tray, and sterilized in an FDA cleared sterilizer for the following cycles:

1. Gravity Steam Cycle – At 132°C for 15 minutes with a 30-minute dry time
2. Pre-vacuum Steam Cycle – At 132°C for 4 minutes with a 20-minute dry time

- The kits are intended for sterilization of non-porous loads
- The tested kit represents the worst-case validated load of 497.1 grams

Model Name	Model (Catalog) Number	Max # of Instruments	Total Mass (g)	Vent to Volume Ratio (cm-1)
Complete Surgical Kit; Basic Surgical Kit	CSK; BSK	55	497.1	0.01043
Standard Surgical Kit	SSK	N/A	372.1	0.01043
Drill Stop Kit	DSK	20	37.5	0.9009
Drill Stop Kit Empty	Not available	N/A	31.2	0.9009
Prosthetic Kit Empty	PKE	N/A	120.3	0.03324
Prosthetic Kit	Not available	20	497.1	0.03324

Contraindications

In general, contraindications are applicable for implant related patients:

- Who are medically unfit for an oral surgical procedure
- Have allergies or hypersensitivity to chemical ingredients in the following material: titanium alloy (Ti-6Al-4V ELI) titanium, aluminum, vanadium)
- With inadequate bone or soft tissue volume unless an augmentation procedure can be considered
- In whom adequate sizes, numbers or desirable position of implants or abutments are not reachable to achieve safe support of functional or eventually para-functional loads
- The cantilever conditions are such that they extend >30mm in length between two adjoining implants or restorative distal cantilevers

Warnings

It is strongly advised that the Surgical Kits, Drill Stop Kit, and Prosthetic Kit are used only with Paragon recommended instruments and components. The storage and organization of non-Paragon instruments and components can lead to mechanical and/or instrumental failure.

All components, instruments, and tooling used in surgery must be maintained in good condition and care must be taken that the instrumentation does not damage implants or other components.

If cracking, flaking, peeling discoloration or other visual signs of degradation are observed on the subject device, discontinue use.

Follow the relevant Instructions for Use for any individually packaged instrument used in combination with the sterilization tray, such as torque wrenches.

Undesirable side effects

The placement of a dental implant constitutes an invasive treatment which may be associated with typical side effects such as inflammation, infection, bleeding, hematoma, pain, and swelling. Depending on the location, placement of the implant may also lead (in rare cases) to bone fracture, perforation of neighboring structures, sinusitis, or sensory/motor disturbances. During placement of this device the pharyngeal (gag) reflex may be triggered in patients with a sensitive gag reflex. During the submerged healing period, bone may grow over the cover screw. In some cases, cover screws may get exposed prematurely.

Dental implants are the substructure of a multi-component system that replaces teeth and as a result, the implant recipient may experience side effects like those associated with teeth, such as mucositis, calculus, peri-implantitis, fistulas, ulcers, soft tissue hyperplasia, soft and/or hard tissue recession/loss.

Precautions

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

Universal precautions for the handling of contaminated or biohazardous materials should be observed.

Processing/Reprocessing Instructions

Point of Use: The Sterilization Tray is delivered non-sterile and must be cleaned and sterilized prior to use. Not following the cleaning and sterilization instructions may accelerate normal product aging.

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. Automated cleaning may not be effective. A thorough manual cleaning process is recommended.

Preparation for Manual Cleaning

If the tray contains dental instruments, remove them from the tray, clean and disinfect separately before sterilizing and reassemble in the cleaned tray. Disassemble the tray into its individual components: base, cover, insert, Drill Stop Kit, and (if applicable) stainless steel pan. Note: Refer to assembly/disassembly instructions for the tray in the Appendix section.

Reprocessing Instructions

The Surgical, Drill Stop, and Prosthetic Kits, and all reusable instruments, inclusive of surgical drills, drill stops, torque tools, and torque wrenches are processed and packaged within a clean room environment. Reusable trays and instruments are supplied non-sterile and must be cleaned and sterilized prior to each use. Cleaning can be performed manually or in an automatic washer.

Warning: Cleaning and sterilization are required for all reusable trays and instruments prior to being placed intraorally. All instruments must be cleaned before they are loaded into the tray for sterilization.

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.

Note: Trays and instruments should be cleaned as soon as possible after use. If cleaning cannot be performed immediately, the 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.

Manual Cleaning and Drying

Note: Enzymatic-based cleaning solutions must be diluted per the manufacturer's instructions.

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

1. After removing all instrumentation from the tray, begin cleaning by rinsing disassembled tray under warm, running tap water for 3 minutes.
2. Scrub the interior and exterior surfaces, lumina, and cavities of the tray with a soft-bristled, nylon brush or lint free cloth.
3. Immerse tray in a bath of warm enzymatic cleaning solution to soak for 10 minutes.
4. Scrub the interior and exterior surfaces, lumina, and cavities using an appropriately sized soft-bristled, nylon brush for a minimum of 3 minutes.
5. Rinse the exterior and interior surfaces with lukewarm tap water for a minimum of 1 minute to remove cleaning solution and visually inspect the instrument for gross soil. Repeat steps 3-5.
6. Fully immerse the tray into an ultrasonic bath containing an enzymatic-based cleaning solution (e.g. neodisher® MediZym) and sonicate for 10 minutes.
7. Remove the components from ultrasonic bath and rinse the exterior and interior surfaces thoroughly with cool, running, tap water for a minimum of 2 minutes.
8. 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 fully submerging the tray in warm enzymatic cleaning solution (e.g. neodisher® MediZym) to soak for 5 minutes.
2. Scrub interior and exterior surfaces, lumina, and cavities using an appropriately sized soft-bristled, nylon brush for a minimum of 3 minutes.
3. Thoroughly rinse all the outer and inner surfaces, lumina, and cavities with cool, running, tap water for a minimum of 1 minute.
4. Place the tray in a suitable rack or load carrier within the automatic washer ensuring that the rack or load carrier is oriented in a horizontal position.
5. Perform automatic cleaning that includes:
   - 2-minute minimum pre-cleaning with cold tap water.
   - A 6-minute minimum cleaning with a mildly alkaline detergent intended for automated cleaning (e.g. neodisher® Mediclean) in 43°C tap water
   - A 2-minute minimum rinsing in 43°C tap water
   - A drying at a minimum of 66°C (151°F) for 5 minutes.
6. Any residual moisture remaining after automatic cleaner drying cycle may be dried with lint-free, single-use wipe.

Inspection following cleaning: Users should inspect the kit for degradation. If cracking, flaking, peeling, discoloration or other visual signs of degradation are observed on the subject device, discontinue use.

Steam Sterilization

Preparation for Sterilization

Kit	Protocol
CSK BSK	1. Open the kit enclosure. 2. Place the insert into enclosure. 3. Insert available tools into corresponding labeled locations in the kit insert. 4. Insert DSK into slot on insert. Alternatively, place stainless steel pan into slot on insert. 5. Close Enclosure and place in suitably sized sterilizable packaging.
DSK	1. Slide open the kit cover. 2. Insert available drill stops into the corresponding labeled locations with the bottom of the drill stops at the bottom of kit. 3. Slide on the kit cover until centered over drill stops and place in suitably sized sterilizable packaging. Alternatively, insert the drill stop kit into slot on surgical kit organizer insert.
PKE	1. Open the kit. 2. Insert available tools into suitably sized cells. 3. Close the kit and place the kit in a suitably sized sterilizable packaging.

***Packaging for 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.

Note: Contact between instruments of dissimilar material should be strictly avoided during sterilization.
Note: Do not stack trays directly on top of or beneath one another during sterilization.
Note: A pouched tray angled on its side or edge promotes drainage.

Steam Sterilization Parameters: Sterilize the devices using the allowable parameters.

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

Inspection following sterilization*:* Visible signs of moisture or significant weight gain may be indicative of sterilization process failure or a barrier integrity issue. If the sterilization load has visible signs of moisture, on or within the load, the load should not be considered sterile and should be reassembled and re-sterilized, prior to use.
Note: Refer to assembly/disassembly instructions for the tray in the Appendix section.

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

Storage & Handling
It is recommended to use the devices immediately after sterilization. Keep the devices in their sterilization packaging and in a dry and clean environment prior to use. Maintain packaging integrity. Check before usage. Please refer to the sterilization packaging's *Instructions for Use*.

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 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.

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 with 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
REF	Catalogue Number	ISO 15223-1
LOT	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

Appendix:

Figure A. *The area of the surgical tray where the cover connects has flats on either side and a round protrusion in the center*

Figure B. *To either remove or replace the cover, rotate it so that the opening points down. The cover can then be lifted or reattached by sliding along the flats until snapping into place. Once in place, it can easily be rotated closed or open.*