



Instructions For Use

Surgical and Prosthetic Instrumentation Containers

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

Description

Paragon Surgical and Prosthetic Instrumentation Containers are divided into the following types:

- Complete Surgical Kit (CSK)
- Standard Surgical Kit (SSK)
- Drill Stop Kit (DSK)
- Prosthetic Kit (PKE)

The Surgical Drill, 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 organize and store instruments during a procedure, transportation and storage. The Surgical Kits are designed to hold various dental instruments such as: Surgical Drills, Drill Stops, Paralleling Tools, Implant Drivers, Drill Extender, Prosthetic Drivers and Torque Wrenches after relevant *Instructions for Use* have been followed to clean and sterilize used instruments such as Surgical Drills, Drill Stops, torque wrenches, etc.

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

Intended Use

The dental instrumentation containers are intended to organize and store various cleaned and sterilized surgical and prosthetic instruments.

Indications for Use

The containers are not indicated for containing surgical and prosthetic instruments during sterilization. The containers are indicated to be cleaned and sterilized prior to placement in the sterile field, where they may be loaded with cleaned and sterilized surgical and prosthetic instruments. Cleaned and sterilized instruments may be loaded into the containers for transportation or storage purposes.

Warnings

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

For storage and transportation, ensure that all instruments are properly cleaned and sterilized before placing them into the containers according to the relevant *Instructions for Use* and that the containers are cleaned and sterilized before storing/transporting the instruments.

For patient procedures, ensure that all instruments and containers are properly cleaned and sterilized before being placed into the sterile field for assembly according to the relevant *Instructions for Use*.

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 dental instrumentation container, such as Surgical Drills, Drill Stops, torque wrenches, etc.

Precautions

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

Storage and Organization Instructions

Point of Use: The Surgical and Prosthetic Containers are 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 following the relevant instrument's *Instructions For Use*.

Preparation for Manual Cleaning

If the container contains instruments, remove them from the container, and clean and sterilize separately. Disassemble the container into its individual components.

Reprocessing Instructions

Cleaning can be performed manually or in an automatic washer.

Warning: Cleaning and sterilization are required for all instrumentation containers prior to being placed in the sterile field for instrument loading. Surgical and Prosthetic Containers must be sterilized empty. All instruments must be cleaned and sterilized before they are loaded into the sterile container within the sterile field.

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: Instrumentation Containers should be cleaned as soon as possible after use. If cleaning cannot be performed immediately, the containers 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 containers or 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 container, begin cleaning by rinsing disassembled container under warm, running tap water for approximately three minutes.
2. Scrub the interior and exterior surfaces, lumina, and cavities of the tray with a soft-bristled, nylon brush or lint free cloth until all visible soil is removed.
3. Immerse tray in a bath of warm enzymatic cleaning solution for 10 minutes.
4. Scrub the interior and exterior surfaces, lumina, and cavities using an appropriately sized soft-bristled, nylon brush for at least three minutes or until all visible soil is removed.

5. Rinse the exterior and interior surfaces with lukewarm tap water for at least one minute to remove cleaning solution and visually inspect the instrument for gross soil. Repeat steps 3-5 if gross soil is observed.
6. Fully immerse the tray into an ultrasonic bath containing an enzymatic-based cleaning solution (e.g. neodisher® MediZym) and sonicate/treat 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) for approximately 5 minutes.
2. Scrub interior and exterior surfaces, lumina, and cavities using an appropriately sized soft-bristled, nylon brush for at least 3 minutes or until all visible soil is removed.
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 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 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 container 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	<ol style="list-style-type: none"> 1. Open the container enclosure. 2. Place the insert into enclosure. 3. Insert Drills Stop Kit or Stainless-Steel Pan into the slot on the organizer insert. 4. Close the container and place it in suitably sized sterilizable pouch.
DSK	<ol style="list-style-type: none"> 1. Slide on the container cover until centered over drill stop slots and place in suitably sized sterilizable packaging.
PKE	<ol style="list-style-type: none"> 1. Close the container and place it 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: Do not stack trays during sterilization.

Steam Sterilization Parameters: Sterilize the containers 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 organize and store cleaned and sterilized dental instrumentation. Maintain packaging integrity. Check before usage. For Surgical and Prosthetic Instrumentation, 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(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.

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
	Catalogue Number	ISO 15223-1
	Batch Code	ISO 15223-1
	Consult <i>Instructions for Use</i> or consult electronic <i>Instructions for Use</i> 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.

