EZ-TRAX™

Product Manual

User's Guide

Innovative Sterilization Technologies
7625 Paragon Road, Suite A
Dayton, OH 45459
www.iststerilization.com

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PURPOSE & SCOPE

This document was prepared to provide instructions for the handling, maintenance and reprocessing of the **EZ-TRAX™** Containment Device.

Instructions provided in this Instructions For Use (IFU) document have been validated by Innovative Sterilization Technologies. Validation testing was based on recognized industry, (i.e. AAMI, AORN, FDA, etc.), guidelines.

The **EZ-TRAX™** Containment Device IFU was developed using standard equipment and practices common to healthcare facilities. Healthcare facilities should only use reprocessing equipment and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the FDA for the validated parameters and cycles.

It is the responsibility of the healthcare facility to ensure that these instructions are performed using the appropriate equipment and materials, and that personnel have been adequately trained. Equipment and processes should be validated and routinely monitored.

INDICATIONS FOR USE

510(k) Number K192487
Device Name: **EZ-TRAX™** Containment Device

Indications for Use
The **EZ-TRAX™** Containment Device is intended for use as an accessory in healthcare facilities to organize, enclose, reprocess, transport, and store medical devices between surgical and other medical uses. The **EZ-TRAX™** Containment Device is not intended on its own to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterile barrier system.

Validated Cycle Times for Dynamic Air Removal Steam Sterilization Cycles

Cycle	Temperature	Exposure Time	Drying Time
Dynamic Air Removal	270° F/132° C	4 minutes	Per Applicable MFG IFU-Ref. Note 1

NOTE 1: Healthcare facilities should follow the dry time specified by the manufacturer of the sterile barrier used.

Sterilization validations included a worst case **EZ-TRAX™** and a medical device challenge set comprising of:

- Lumen dimensions (3) 1mm x 500mm
- Conjoined/mated surfaces: forceps, clamps, bending pliers, ratchet handles, retractors
- Cannulated: drill bits, taps, guides, screwdrivers, cannulated screws
- A total weight of 42 lbs (**EZ-TRAX™** Containment Device + sterile barrier system + medical device load) as a worst case challenge to the system. Healthcare facilities should not exceed 25 pounds (**EZ-TRAX™** Containment Device + sterile barrier system + medical device load).

DEVICE SUMMARY

The **EZ-TRAX**™ Containment Device:

- The **EZ-TRAX™** is offered in various sizes.
- Includes bases with dividers, lids, and brackets fabricated from a variety of materials commonly used to enclose, protect, and organize non-sterile medical devices.
- Is not intended to maintain sterility, but it is intended to be used in conjunction with a legally marketed, validated, FDA cleared sterile barrier system.
- Protects the interior components during transportation, sterilization, and storage.
- Is composed of intrinsically stable metals and thermoplastic polymers. The base and lid are composed of anodized aluminum with stainless steel handles. The dividers are composed of aluminum and the posts are composed of medical grade thermoplastic polymers.
- Base and lid are fully perforated with an evenly distributed pattern The sides of the base are partially perforated. The bases are used with locking lids.
- Is designed to process medical devices via steam sterilization within standard autoclaves found in hospitals and healthcare facilities. The **EZ-TRAX**™ is designed in such a way to withstand repeated steam sterilization cycles.

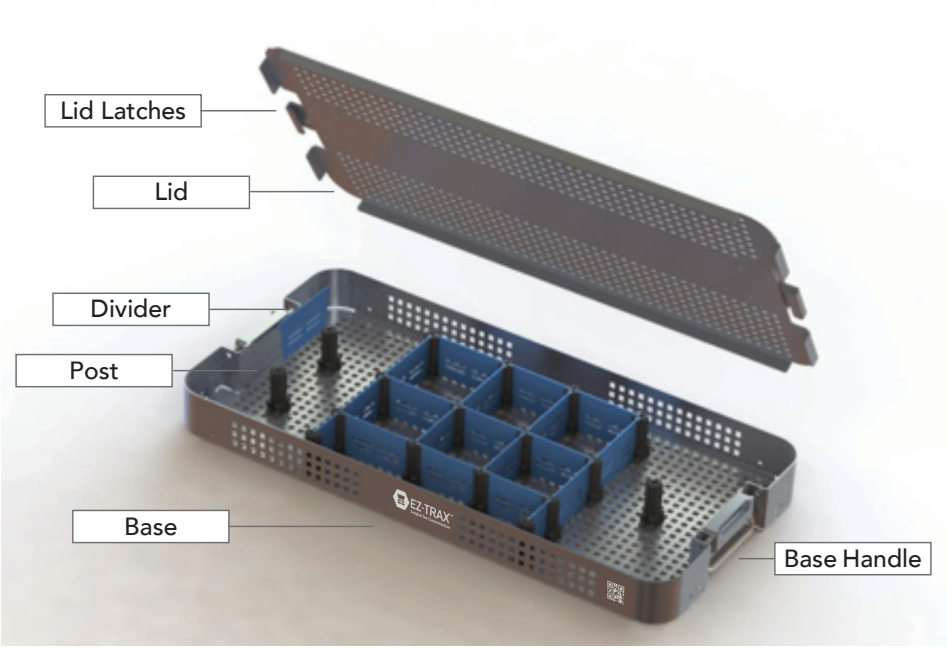
Base – metal tray with perforated sides and bottom, used to organize medical devices.

Base Handles – allow for safe handling and removal of the sterile contents during aseptic presentation.

Lid – perforated metal lids that fit on base to ensure medical devices maintain their position during transportation and handling.

Lid Latches – secures the lid to the base.

Posts & Dividers – used to configure layouts which allow for organization and protection of the medical devices.



WARNINGS & PRECAUTIONS

1. All reprocessing agents must be thoroughly rinsed off utilizing critical water.

    - Mineral residues from hard water, as well as higher contamination with microorganisms and endotoxins, can result in staining of the device or prevent effective reprocessing.
    - **Critical water**: water that is extensively treated (usually by a multistep treatment process that could include a carbon bed, softening, DI, and RO or distillation) to ensure that the microorganisms and the inorganic and organic material are removed from the water; a final submicron filtration could also be part of the treament process. This water is mainly used for the final rinse and steam generation.

2. Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials will damage the surface and finish of instruments. Soft bristled, nylon brushes and pipe cleaners should be used.

3. Cleaning agents with a low pH levels (<6.5) or high pH levels (>8.5) are not recommended. Exposure to non-neutral pH levels will cause damage to polymer components and will strip protective coatings from metals, especially aluminum.

4. Saline and cleaning/disinfection agents containing aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine or iodide are corrosive and should not be used.

5. Facilities must comply with the following steam quality requirements:

    - Steam dryness between 97% and 100%.
    - Noncondensable gases (e.g., air) at a level (less than 3.5% v/v condensate) that will not impair steam penetration into sterilization loads.
    - Steam that is too dry can contribute to superheating and, consequently, to suboptimal steam sterilization conditions. Steam that is too wet can lead to wet packs after sterilization and compromise sterility.

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6. Cool drafts from air ducts or other air currents should be avoided during the cooling phase to avoid post-sterilization moisture caused by rapid cooling syndrome.

7. Keep dissimilar metals separated during sterilization to resist corrosion.

8. Personnel should wear appropriate PPE per recommended industry guidelines.

POINT-OF-USE PREPARATION AND REPROCESSING

For optimal reprocessing results, do not allow contaminated medical devices to dry within the **EZ-TRAX™** prior to reprocessing.

Visible debris should be removed from the surfaces, crevices, mating surfaces and all other hard-to-clean areas. Dried on soil is difficult and sometimes impossible to remove with mechanical cleaning processes.

Follow your internal facility policies for the handling and transportation of contaminated medical devices to the designated reprocessing area.

Personnel should wear appropriate PPE per recommended industry guidelines.

CLEANING

Thorough cleaning and rinsing are the most important steps in preparing medical devices for reuse.

The washer/disinfector manufacturer's IFU should be strictly adhered to. The washer/disinfector should be properly installed, qualified and regularly subjected to the manufacturer's maintenance and testing requirements. Use only cleaning agents recommended by the washer/disinfector manufacturer or noted as compatible with their equipment.

The following parameters and cycle were validated for mechanical cleaning:

Step	Time (mm:ss)	Temperature° F/C	Detergent
Pre-Wash	2:00	Cold Tap Water	n/a
Enzyme Wash	4:00	Cold Tap Water	Steris® Prolystica® 2X Concentrate Enzymatic Cleaner at 1/8 oz. per gallon (minimum effective concentration)
Detergent Wash	4:00	Cold Tap Water	Steris Prolystica 2X Neutral Cleaner at 1/8 oz. per gallon (minimum effective concentration)
Rinse	1:00	Cold Tap Water	n/a

All reprocessing agents must be thoroughly rinsed off utilizing critical water.

• **Critical water**: water that is extensively treated (usually by a multistep treatment process that could include a carbon bed, softening, DI, and RO or distillation) to ensure that the microorganisms and the inorganic and organic material are removed from the water; a final submicron filtration could also be part of the treament process. This water is mainly used for the final rinse and steam generation.

INSPECTION

K1 Medical LLC does not define the maximum number of uses for the **EZ-TRAX™**. Components are fabricated from a variety of intrinsically stable and corrosion resistant metals and thermoplastics. Repeated reprocessing has minimal effect on durability. End of life is normally determined by wear and damage during use.

Carefully inspect the **EZ-TRAX™** before use to ensure that all visible contamination has been removed. If contamination is detected repeat the mechanical cleaning process.

K1 Medical has established a visual inspection acceptance/failure criteria for determining the **EZ-TRAX™** use of life.

Visually inspect the **EZ-TRAX™** before use for signs of mechanical wear and damage. Signs of mechanical wear and damage may include:

- Corrosion and deformation (cracking, peeling, flaking, fracture, burrs, become brittle)
- Damaged Latches & Handles
- Damaged Post & Dividers
- Form, Fit, & Function Deficient Interfaces

If any of these inspection criteria are observed please discontinue use and contact K1 Medical for additional instructions.

PACKAGING & PREPARATION FOR STERILIZATION

Healthcare facilities should only use sterilizers and accessories that have been cleared by the FDA for the validated sterilization parameters and cycles. The applicable manufacturer's IFUs should always be followed.

The healthcare facility is responsible for the reassembly, inspection, and packaging of medical devices in a manner that will ensure steam sterilant penetration.

Medical devices should be prepared and sterilized according to the medical device manufacturer's IFU.

STERILIZATION

Healthcare facilities should only use sterilizers and accessories that have been cleared by the FDA for the validated sterilization parameters and cycles. The applicable manufacturer's IFUs should always be followed.

It is important that adequate cleaning be carried out prior to sterilization process.

It is the responsibility of the healthcare facility to ensure that the sterilization process is performed using qualified equipment, materials and personnel such that the recommended parameters and cycles are achieved.

Validated Parameters for Dynamic Air Removal Steam Sterilization Cycles

Cycle	Temperature	Exposure Time
Dynamic Air Removal	270° F/132° C	4 minutes

Sterilization validations included a worst case **EZ-TRAX™** and a medical device challenge set comprising of:

- Lumen dimensions (3) 1mm x 500mm
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Medical devices should be prepared and sterilized according to the medical device manufacturer's IFU.

Healthcare facilities should follow the sterile barrier system manufacturer's IFU for stacking requirements.

STORAGE BEFORE USE

Healthcare facilities should utilize professional organization guidelines, i.e. AAMI, AORN, CDC, to establish policies and procedures for determining shelf life/storage.

Healthcare facilities should follow the legally marketed, validated, FDA-cleared sterile barrier system manufacturer's IFU for shelf life requirements.

WARRANTY

What Is Covered. Innovative Sterilization Technologies (IST) warrants the original purchaser that the **EZ-TRAX™** conforms to the manufacturer's specifications and is free from defects in workmanship and material for a period of 30 days from the date of original purchase. If the original purchaser transfers the **EZ-TRAX™** containment device to another party, this Warranty will not be enforceable by the party to whom the product is transferred.

What We Will Do To Correct Problems. Should your **EZ-TRAX™** prove defective during this period, you must notify IST. You must permit IST to make such investigation, examination and tests as IST deems appropriate and, if requested to do so, you will return the product to the address set forth below. The manufacturer at its' sole obligation under this Warranty is, at its' option, to repair or replace the defective product or products, without charge for parts or labor. Postage, insurance or shipping costs incurred in presenting your **EZ-TRAX™** product for warranty service are your responsibility.

What Is Not Covered. This Warranty is contingent upon proper use and maintenance of the product; it does not cover products that have been improperly shipped, or that have been misused, abused, neglected, or improperly maintained, cleaned or stored, or that have been serviced other than by IST or that have been modified without the express approval of IST. Failure to follow the directions in the Instructions For Use (IFU) may constitute improper use or maintenance of the product and causes this Warranty not to apply. This Warranty does not extend to normal wear or to replacement items.

DEFINITIONS

cleaning: Removal of contamination from an item to the extent necessary for further processing or for the intended use.

containment device: Instrument case, cassette, or organizing tray intended for use in healthcare facilities for the purpose of containing reusable medical devices for sterilization.

critical water: Water that is extensively treated (usually by a multistep treatment process that could include a carbon bed, softening, DI, and RO or distillation) to ensure that the microorganisms and the inorganic and organic material are removed from the water; a final submicron filtration could also be part of the treament process. This water is mainly used for the final rinse or steam generation.

cycle, steam sterilization, dynamic-air-removal type: One of two types of sterilization cycles in which air is removed from the chamber and the load by means of a series of pressure and vacuum excursions (prevacuum cycle) or by means of a series of steam flushes and pressure pulses above atmospheric pressure (steam-flush pressure-pulse [SFPP] cycle).

exposure time: Period for which the process parameters are maintained within their specified tolerances. In a steam sterilization process, exposure time is the period during which items are exposed to saturated steam at the specified temperature.

healthcare facility: Specialized facility where professionals deliver services utilizing medical devices.

instructions for use (IFU): Written recommendations provided by the manufacturer that provide instructions for operation and safe and effective use of its device defined within the Food Drug & Cosmetic Act.

medical device: as defined within the Food Drug & Cosmetic Act as "...an instrument, apparatus, implement, machine, contrivance, implant,

in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

packaging system: Combination of the sterile barrier system and protective packaging.

pH level: Number denoting alkalinity or acidity. NOTE—The pH scale is logarithmic and runs from 0 to 14; the neutral point is 7. Numbers below 7.0 indicate acidity, and those above 7.0 indicate alkalinity.

reprocess: To prepare a device, instrument, or piece of equipment for reuse by any or a combination of the following processes: precleaning, cleaning, disinfection, sterilization, and rinsing at appropriate stages.

rinsing: Removal of any residue of cleaning agents and chemicals remaining after the cleaning process.

steam quality: Steam characteristic reflecting the dryness fraction (weight of dry steam present in a mixture of dry saturated steam and entrained water) and the level of noncondensable gas (air or other gas that will not condense under the conditions of temperature and pressure used during the sterilization process).

sterile barrier system: Minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use.

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sterility assurance level (SAL): Probability of a single viable microorganism occurring on an item after sterilization. SAL is normally expressed as 10-n. A SAL of 10-6 means that there is less than or equal to one chance in a million that a single viable microorganism is present on a sterilized item.

sterilization: Validated process used to render a product free from viable microorganisms.

sterilization cycle: Defined sequence of operational steps designed to achieve sterilization and carried out in a sealed chamber.

tray: Basket, with or without a lid, that has perforated sides or bottom, that holds instruments, and that is either enclosed in sterilization wrap or a pouch or placed inside a container for sterilization.

validation: Documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.

water quality: Descriptor of the levels of various impurities present in water.

MANUFACTURER & CUSTOMER SERVICE INFORMATION

info@onetray.com
or call 937.619.0138.