**MANUFACTURER**

CrossRoads Extremity Systems
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**CAUTION: Federal Law (U.S.) restricts this device to the sale, distribution, and use by or on the order of a physician.**

**DEVICE DESCRIPTION**

The subject *CrossRoads Tray System* is a reusable sterilization tray or organizing tray intended for use in health care facilities for the purpose of containing reusable medical devices for sterilization. It is composed of multiple pieces, designed to be integrated into a single unit which contains and protects the interior components during sterilization. All components are perforated for steam penetration. The tray can hold implants and instruments such as inserters, K-wire guides, fixation pins, reamers and ratcheting handles.

**INDICATIONS**

The *CrossRoads Tray System* is used in healthcare facilities to store and organize CrossRoads surgical instruments and components during cleaning/sterilization and during implant/prosthetic treatment. The CrossRoads Tray System are not intended on their own to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization pouch or sterilization wrap. Sterilization validations for the worst-case CrossRoads Tray System included surgical instruments such as drills, inserters, reamers, fixation pin, benders, and ratcheting handles. The CrossRoads Tray System is validated for a maximum load of 8.5 lbs (tray + instruments).

| | |
|---|---|
| **Method** | Steam Sterilization (Moist Heat Sterilization) |
| **Cycle** | Prevacuum |
| **Temperature** | 270 ˚F (132 ˚C) |
| **Exposure time** | 4 minutes |
| **Drying time** | 20 minutes |

The dimensions of the trays are as follows:
1. 20.60" length x 9.80" width x 2.00" depth.
2. 15.00" length x 9.80" width x 2.00" depth.
3. 10.00" length x 9.80" width x 2.00" depth.

**CONTRAINDICATIONS**

None

**WARNINGS**

Use of non-sterile devices may lead to infection of tissue or infectious diseases.

**POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS**

None known.

**PRECAUTIONS**

It is strongly recommended to use only CrossRoads instruments with the *CrossRoads Tray System*. The storage and organization of non-CrossRoads instruments and components can lead to mechanical and/or instrumental failure.

The manufacturer's instructions for use for any detergent / cleaning solution and or equipment and accessories to clean and /or dry the devices must strictly be followed where applicable. Do not deviate from the reprocessing instructions.

**HOW SUPPLIED, CLEANING AND STERILIZATION**

Instrument System

*CrossRoads Tray System* is provided non-sterile to the end user and intended for reuse. Prior to use and reuse following the cleaning and sterilization instructions.

Visually inspect each instrument for deterioration such as corrosion and worn components; ensure that the laser markings are legible. Visual inspection must be performed at each cleaning to determine if an instrument is acceptable for use. If an instrument is not acceptable for use, return to the manufacturer.

**CARE AND CAUTION**

- All components of the *CrossRoads Tray System* are provided non-sterile.
- *CrossRoads Tray System* may be stored at room temperature.

Instruments provided non-sterile to the end user must be cleaned and sterilized before each use in accordance with the instructions below.

**Cleaning**

1. **Disassemble** all components as per manufacturer instructions (if appropriate).
2. **Rinse** with cold tap water to remove gross contamination.
3. **Bathe** in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes.
4. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe.
5. **Rinse** with cold tap water for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumens.
6. **Bathe** in a detergent solution prepared per manufacturer directions for 5 minutes.
7. **Scrub** thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with detergent solution using a syringe.
8. **Rinse** thoroughly /flush with deionized / reverse osmosis (RO/DI) water.
9. **Sonicate** for a minimum of 10 minutes in an enzymatic detergent solution prepared per manufacturer directions.
10. Rinse thoroughly /flush with RO/DI water.
11. **Dry** with a clean, soft, absorbent, disposable cloth.
12. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary reclean until it is visibly clean.

The recommended steam sterilization conditions for **non-sterile implants and reusable instruments** are as follows:

**FOR PREVACUUM STEAM STERILIZATION ONLY:**

1. Double wrap the assembled tray in an FDA cleared wrap.

2. Autoclave according to the following parameters:

**Steam Sterilization – PREVACUUM**

| Cycle Type | Parameter | Minimum Set Point |
|---|---|---|
| Prevacuum 270 ˚F (132 ˚C) | Exposure Temperature | 270˚F (132˚C) |
| | Exposure Time | 4 minutes |
| | Dry Time | 20 minutes |

3. Sterilization is maintained until wrap opened or otherwise compromised. After sterilization, remove the component from its wrapping or container using accepted sterile technique with powder-free gloves.

Ensure that the component is at room temperature prior to use. Avoid contact with hard objects that may cause damage.

These recommendations are consistent with ANSI/AAMI ST79 guidelines and have been developed and tested using specific equipment.

Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

**OTHER SUPPLIES AND EQUIPMENT NEEDED**

- FDA cleared wrap

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