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 *PRO-SPEC™ Instrument Tray* is a reusable sterilization 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 instruments during sterilization. All components are perforated for steam penetration. The tray can hold CrossRoads surgical instruments. The *PRO-SPEC™ Instrument Tray* does not include allograft wedges.

INDICATIONS

The *PRO-SPEC™ Instrument Tray* is used in healthcare facilities to store and organize CrossRoads surgical instruments and components during sterilization and during implant/prosthetic treatment. The *PRO-SPEC™ Instrument Tray* is not intended on its own to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, FDA-cleared sterilization wrap. Sterilization validation for the worst-case *PRO-SPEC™ Instrument Tray* included surgical instruments such as inserter handles, tamps, and trials. The *PRO-SPEC™ Instrument Tray* is validated for a maximum load of 18.7 lbs (tray + instruments).

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

Dimensions do not exceed:
20.546" length x 10.022" width x 3.978" 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 *PRO-SPEC™ Instrument Tray*. 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.

CARE AND CAUTION

PRO-SPEC™ Instrument Tray is provided non-sterile to the end user and intended for reuse. Instruments provided non-sterile to the end user must be cleaned and sterilized before each use in accordance with the instructions below.

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.

- All components of the *PRO-SPEC™ Instrument Tray* are provided non-sterile.
- *PRO-SPEC™ Instrument Tray* may be stored at room temperature.
- Packaging and devices should be inspected to ensure there is no damage. If the packaging or integrity has been compromised, contact the manufacturer for further instructions.
- All devices must be thoroughly cleaned per the following validated instructions below consistent with ANSI AAMI ST98.
- Do not stack trays in a mechanical washer.
- Do not stack the *PRO-SPEC™ Instrument Tray* with other trays and / or systems during steam sterilization.
- CrossRoads Extremity Systems devices must be cleaned separately from CrossRoads Extremity Systems Instrument trays. Lids should be removed from trays for the cleaning process, if applicable.
- Organizational trays are not intended to maintain sterility.
- Long, narrow cannulations, blind holes, and intricate parts require particular attention during cleaning.
- Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on CrossRoads Extremity Systems instrumentation.
- Stacking of terminally sterilized devices during storage may be performed in accordance with the sterile barrier (FDA-cleared wrap) manufacturer's Instructions for Use.

CLEANING

1. **Disassemble** all components as per manufacturer instructions (if appropriate). Open all hinged instruments.
2. **Rinse** with cold tap water to remove gross contamination.
3. **Bathe** in an enzymatic detergent solution prepared per manufacturer directions for 10 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 two minutes; use a syringe to repeatedly flush any very narrow lumens.
6. **Rinse** thoroughly /flush with deionized / reverse osmosis (RO/DI) water.
7. **Sonicate** for a minimum of 15 minutes in an enzymatic detergent solution prepared per manufacturer directions.
8. **Rinse** thoroughly /flush with RO/DI water for a minimum of two minutes.
9. **Dry** with a clean, soft, absorbent, disposable cloth.
10. **Visually inspect** for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary reclean until it is visibly clean. 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.

NOTE: Brushes (i.e. pipe cleaners) could be used for cleaning most lumens; however, the use of a syringe to flush narrow lumens with diameters less than or equal to 0.041 inches is recommended. Clean trays only with neutral pH detergents approved for use with anodized aluminum.

The recommended steam sterilization conditions for **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. Any instruments which are disassembled for cleaning and sterilization must be reassembled prior to use.

These recommendations are consistent with AAMI TIR 12, ANSI/AAMI/ISO 17665-1 and ANSI/AAMI ST79 and have been developed and tested using specific equipment on the system devices.

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.

The recommendations provided above have been validated by the medical device manufacturer as being capable of preparing a non-sterile CrossRoads Extremity Systems medical device. It remains the responsibility of the processor to ensure that the processing is actually performed, using equipment, materials and personnel in the reprocessing facility, and achieves the desired result. This requires verification and routine monitoring of the process. Likewise, any deviation by the processor from the recommendations provided should be properly evaluated for effectiveness and potential adverse consequences.

All users should be qualified personnel with documented expertise, competency and training. Users should be trained on hospital policies and procedures along with current applicable guidelines and standards.

Users should don appropriate personal protective equipment (PPE) when processing devices in accordance with the Department of Environmental and Occupational Health and Safety's (OSHA) bloodborne pathogen guidelines.

OTHER SUPPLIES AND EQUIPMENT NEEDED

- FDA-cleared wrap

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Symbols

Refer to package labels to determine which symbols are relevant to the device in the package.

Note: For recognized manufacturer, refer to the product label.

	Caution consult accompanying documents
	Catalogue number
	Consult instructions for use
	Contents of package
	Lot number
	Manufacturer
	Prescription only - device restricted to use by or on the order of a physician