INSTRUCTIONS FOR USE

CrossRoads Screw System

MANUFACTURER

CrossRoads Extremity Systems
6423 Shelby View Drive, Suite 101
Memphis, TN 38134 USA
+1 901-221-8406

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

SYMBOLS

The following symbols are defined in ISO 15223-1: *Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements* and may be used on the device label. Refer to package labels to determine which symbols are relevant to the device in the package.

SYMBOL	SYMBOL TITLE (LOCATION IN STANDARD)	DEFINITION
	Caution (5.4.4)	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
REF	Catalog Number (5.1.6)	Indicates the manufacturer's catalog number so that the medical device can be identified.
	Consult Instructions for Use (5.4.3)	Indicates the need for the user to consult the instructions for use.
	Do not reuse (5.4.2)	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
LOT	Batch code (5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Manufacturer (5.1.1)	Indicates the medical device manufacturer.
STERILE R	Sterilized using irradiation (5.2.4)	Indicates a medical device that has been sterilized using irradiation.
	Use By Date (5.1.4)	Indicates the date after which the medical device is not to be used.
	Do not use if package is damaged (5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened.

DEVICE DESCRIPTION

Implants
The CrossRoads Screw System includes implants and the related instrumentation needed for implantation. The implants are made of biocompatible titanium alloy per ASTM F136 or stainless steel per ASTM F138. Implant components are provided sterile and are intended for single use only.

Instrument System
Instruments used with CrossRoads Screw System include the following: K-wires, K-wire dispenser, Drill bits, Head drills, Implant Driver, Driver Handles and a Depth Gauge.
Sterile instrument used with the CrossRoads Screw system include drill bits, head drills, and implant drivers. These instruments are provided sterile and intended for single use only.
Non-sterile instruments used with CrossRoads Screw System include the following: K-wires, K-wire dispenser, Drill bits, Head drills, Implant Driver, Driver Handles and a Depth Gauge. These instrument components are provided non-sterile and must be cleaned by the end user prior to use according to the directions contained herein.

INDICATIONS

The CrossRoads Screw System is indicated for fracture repair and fixation, osteotomy, joint fusion, reconstruction and arthrodesis of bones appropriate for the size of the device.

CONTRAINDICATIONS

Contraindications for the CrossRoads Screw System are as follows:

- Comminuted bone surface that would prevent proper screw placement.
- Pathological bone conditions that would prevent secure screw fixation
- Active or suspected infection
- Physiological or psychological conditions that limit the patient's ability and/or willingness to follow instructions during the healing process.
- Inadequate skin, bone, or neurovascular status
- Skeletally immature patients with open epiphyses
- Sensitivity to metals, including nickel.

Contraindications may be relative or absolute and are left to the discretion of the surgeon.

WARNINGS

- Surgeon familiarity with the device, instrumentation, and surgical technique prior to surgery is crucial to proper device installation.
- As with any implant system, the implants cannot be

expected to replace normal healthy bone or withstand the stress placed upon the device by full or partial weight-bearing or load bearing in the presence of nonunion, delayed union or incomplete healing. Therefore, it is important that immobilization of the treatment site using routine methods be maintained until bone healing has occurred.

- Reduction of the site should be achieved and maintained prior to implanting the device. The compressive force of the implant should not be relied upon to achieve closure or reduction of a fracture line.
- Drill bits are designed for use specifically with the supplied guides. Re-use or reprocessing may affect the compatibility with other instruments and usability of the instruments.
- If it is suspected that sterilization is compromised prior to implantation, another sterile implant should be used.
- The implants and sterile instruments are intended for single use only. Sterile product should not be re-sterilized.
- The CrossRoads Screw System has not been evaluated for safety and compatibility in the MR environment. The CrossRoads Screw System has not been tested for heating or migration in the MR environment.
- Do not use other manufacturer's instruments or implants in conjunction with the CrossRoads Screw System.
- Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together.

Dispose of used device in accordance with healthcare facility policy and local regulations.

COMPLICATIONS
Surgical procedures involving these devices should not be attempted by physicians unfamiliar with possible adverse clinical events which may occur during or after the procedure and could require additional surgery for implant revision.

The anticipated adverse device effects are the same as those anticipated devices and surgical techniques associated with the currently available screw fixation procedures.

ADVERSE EVENTS
The following list includes potential complications typically associated with fixation devices.

- Prolonged healing
- Failure or breakage of the implant or part of the implant
- Damage to nerves and vessels
- Infection, painful, swollen or inflamed implant site
- Loosening or dislocation of the implant requiring revision surgery
- Edema
- Delayed union or malunion
- Allergic reaction(s) to implant material(s)
- Muscle tendon impalement and excessive operative bleeding
- Nonunion pseudoarthrosis development and persistence and failure of the bone regenerating satisfactorily
- Loss of bone mass
- Venous thrombosis, pulmonary embolism, cardiovascular problems
- Inability to compress the bone surface due to poorly fixated implant

Adverse Events related to CrossRoads Screw System
No additional risks are associated with CrossRoads Screw System.

HOW SUPPLIED, CLEANING AND STERILIZATION
Implants
The implants are provided sterile to the end user. Implant packaging and implants should be inspected to ensure there is no damage. If the implants' packaging or implants' integrity has been compromised, contact the manufacturer for further instructions.

Instrument System
Certain instruments are provided sterile to the end user. Sterile Instrument packaging and instruments should be inspected to ensure there is no damage. If the sterile instruments' packaging or instruments' integrity has been compromised, contact the manufacturer for further instructions.
Some instruments may be provided non-sterile to the end user and 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).**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 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.

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.

The minimum recommended steam sterilization conditions for **non sterile reusable instruments** are as follows:

FOR PREVACUUM STEAM STERILIZATION ONLY:

1. Double wrap the assembled tray in a CSR wrap or similar type non-woven medical grade wrapping material.

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	20-30 minutes

3. 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.

RECOMMENDED PROCEDURE

Steps for application of the CrossRoads Screw System are as follows (Note: Screw diameters and their size-matched instruments are provided below in Table 1 below):

1. Hold the fusion site securely and insert the appropriate K-wire across the site.
2. Select the appropriate diameter screw for the procedure. Slide the Depth Gauge over the K-wire and measure for screw length. The gauge should be flush against bone.
3. If desired, drill a pilot hole using the appropriate drill bit for the selected screw diameter. Slide the drill bit over the K-wire; drill until just across the fusion site. Do not drill a pilot hole for placement of the snap-off screw.
4. If desired, drill a countersink to seat the headed screws fully. Slide the head drill over the K-wire; rotate until the appropriate depth is achieved. A countersink is not necessary for the snap-off screw.
5. Confirm the screw diameter and length.
6. Attach the appropriate driver (star, hex or snap-off) to the appropriate driver handle (cannulated AO or snap-off). Slide the cannulated screw over the K-wire and drive the screw into bone until the head is flush with the surface. For solid or snap-off screw placement, first remove the K-wire then drive into bone as above.
7. Place multiple screws by repeating these steps.
8. Remove the K-wire and close.

Screw diameter	Pilot drill	Head drill	Driver	K-wire
Headed				
2	1.7	3.8	#8 star	0.9
2.5	2.0	3.8	#8 star	0.9
3	2.2	4.9	#10 star	1.1
3.5	2.7	4.9	#10 star	1.1
4.0	3.2	6.0	#15 star	1.4
5.0	3.5	8.0	#25 star	2.0
6.5	4.9	8.0	#25 star	2.0
Headless				
2.5	2.0	2.4	1.6 hex	0.9
3.0	2.2	2.8	2.0 hex	0.9
3.5	2.7	3.4	2.5 hex	1.4
4.3	3.2	4.2	2.5 hex	1.6
7.0	4.9	7.1	#25 star	2.0
Snap-off				
2.0	NA	NA	Snap-off	1.1
2.7	NA	NA	Snap-off	1.1

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.

MR SAFETY INFORMATION

The Crossroads Screw System has not been evaluated for safety and compatibility in the MR environment. These systems have not been tested for heating, migration, or image artifact in the MR environment. The safety of the Crossroads Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

OTHER SUPPLIES AND EQUIPMENT NEEDED

- Standard OR equipment used in patient preparation and surgical exposure.
- Power drill with AO connection.

REMOVAL

1. Expose the implant site and head of the implant.
2. Once exposed, engage the appropriate driver into the screw head. Turn counterclockwise until the screw is free from bone.

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