Small Joint Reaming System
Instructions for Use

900-01-012 Rev G
April 2023

Description
The Small Joint Reaming System is composed of reamers and Kirschner wires (K-wires) used for the preparation of small joints in the hand and foot for fixation following trauma or an osteotomy. The K-wire is offered in a 0.062” diameter and a 6”length. The non-cannulated reamers are offered in diameters up to 14mm and the cannulated reamers are offered in diameters up to 24mm in diameter. The K-wires and non-cannulated reamers are intended for single use only.

Implant Materials
All reamers and k-wires are made from medical grade stainless steel.

Indications
The Small Joint Reaming System is indicated for use in the preparation of the small joints in the hand and foot for trauma and reconstructive purposes.

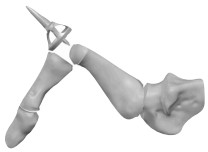
Contraindications
Use of Trilliant instruments is contraindicated in cases of active or suspected infection or in patients who are immunocompromised; or in patients with certain metabolic diseases.

Warnings
1. Reamers and K-wires are to be treated as sharps.
2. Re-use of instruments indicated as single use can result in decreased mechanical and clinical performance.

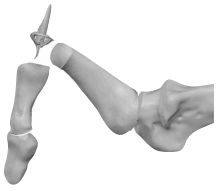
Maintaining Device Effectiveness
1. The surgeon should have specific training, experience, and thorough familiarity with the use of the required instrumentation.
2. The surgeon must exercise reasonable judgment when deciding which instrument to use for specific indications.
3. Failure to use dedicated, unique Trilliant Surgical instruments for every step of the surgical technique may compromise the integrity of the instrument or implanted device, potentially leading to patient injury.
4. Carefully inspect the instruments before and after each procedure to assure they are in proper operating condition. Instruments that are faulty, damaged, worn or suspect should not be used.
5. The Small Joint Reaming System should be used in a sterile environment.

Instructions for Use, Non-Cannulated Reamers

1. Expose the joint and fully release any ligaments.
2. Determine the appropriate size reamers.



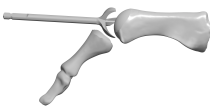
3. Using a wire pin driver, resurface the proximal head of the joint with the concave reamer until the desired correction is achieved. Make sure to initiate the reamer down the center axis of the joint.



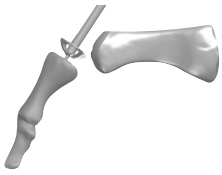
4. Using a wire pin driver, resurface the distal base of the joint with the convex reamer until the desired correction is achieved. Make sure to initiate the reamer down the center axis of the joint.
5. Reduce the joint and apply the desired fixation.

Instructions for Use, Cannulated Reamers

1. Expose the joint and fully release any ligaments.
2. Determine the appropriate size reamers.
3. Using a wire pin driver and an 0.062” diameter K-wire, insert the K-wire down the central axis of the proximal head of the joint to be reamed.



4. Place the appropriate sized concave reamer over the K-wire and resurface the proximal head of the joint until the desired correction is achieved using a powered drill. Remove the K-wire.



5. Using a wire pin driver and an 0.062” diameter K-wire, insert the K-wire down the central axis of distal base of the joint to be reamed.
6. Place the appropriate sized convex reamer over the K-wire and resurface the distal base of the joint until the desired correction is achieved using a powered drill. Remove the K-wire.
7. Reduce the joint and apply the desired fixation.

Cleaning

Trained personnel must perform cleaning and mechanical inspection prior to sterilization. Compliance is required with the equipment manufacturer's user instructions (manual and/or machine cleaning, ultrasound treatment, etc.) and recommendations for chemical detergents. For validated cleaning instructions, please reference document 900-06-011, Small Joint Reaming System Cleaning and Sterilization Protocol.

Packaging and Sterility

NON-STERILE PRODUCT

The Small Joint Reaming System can be packaged non-sterile and therefore must be sterilized prior to surgical use. Use of the sterilizer shall comply with the manufacturer's user instructions. The user facility must clean and disinfect instruments prior to sterilization per standard hospital procedures. Non-sterile devices are sterilizable by steam sterilization (autoclaving). The following parameters should be followed:

Sterilization Method	Pre-Vacuum Steam	Gravity Steam
Condition	Wrapped*	Wrapped*
Temperature	270°F (132°C)	270°F (132°C)
Time	4 minutes	30 minutes
Dry Time	Recommended 50 minutes**	Recommended 40 minutes**

* The system shall be packaged for sterilization by double wrapping in standard central supply wrap (i.e. Bio-Shield® Sterilization Wrap).
** Trilliant Surgical has validated the recommended sterilization cycle and dry time for trays. The dry time varies due to load configuration, wrapping method, and material.

CAUTION

Federal Law (USA) restricts this device to sale by or on the order of a physician.
Do not attempt a surgical procedure with faulty, damaged or suspect Trilliant Surgical instruments.
Inspect all components preoperatively to assure utility.

MRI Safety Information

The Small Joint Reaming System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Small Joint Reaming System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Symbols Glossary

Symbol	Description	Designation Number, ISO 15223-1:2021
	Catalog Number	5.1.6
	Batch Code	5.1.5
	Do not use if package is damaged	5.2.8
	Do not reuse	5.4.2
	Non-Sterile	5.2.7
	Device only to be sold on or by the order of a physician	N/A*
	Manufacturer	5.1.1
	Caution	5.4.4
	Consult instructions for use	5.4.3

*Symbol allowed under 21 CFR 801. The above symbols are outlined in ISO 15223-1:2021 Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements. Note: QTY is an abbreviation of "QUANTITY".

Please contact company for product inquiries and surgical techniques, or to report any adverse experience.

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