

## Disposable Cannula System

### Instructions for Use



STERILE EO

#### A. Device Description

The Disposable Cannula System is a disposable cannula and obturator set for use in general arthroscopic surgical procedures to provide operating portals during the insertion and removal of instruments. The contents are provided sterile, for single use only.

#### Contents

- 1 ea. – Disposable Cannula.
- 1 ea. – Disposable Obturator.

#### B. Indications

The Disposable Cannula System is intended for use in general arthroscopic surgery to provide operating portals during the insertion and removal of instruments. Sample procedural uses are indicated below:

##### Knee

- ACL repairs
- PCL repairs
- Extra-capsular repairs
  - Medial collateral ligament
  - Lateral collateral ligament
  - Posterior oblique ligament
- Patellar realignment and tendon repairs
  - Vastus medialis oliquous advancement
- Iliotibial band tenodesis

##### Shoulder

- Capsular stabilization
  - Bankart repair
  - Anterior shoulder instability
  - SLAP lesion repairs
  - Capsular shift of capsulolabral reconstructions
- Acromioclavicular separation repairs
- Deltoid repairs
- Rotator cuff tear repairs
- Biceps tenodesis

#### C. Contraindications

- Blood supply limitations and previous infections which may retard healing.
- Foreign-body sensitivity. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
- Foreign Body Reactions. See Adverse Effects-Allergic Type Reactions.

- The use of this medical device and the placement of hardware or implants must not bridge, disturb or disrupt the growth plate.
- Do not use for surgeries other than those indicated.

#### D. Adverse Effects

- Infections, both deep and superficial.
- Foreign body reactions.
- Adverse reactions to device materials are unlikely but may occur. Patient sensitivity to device materials must be considered prior to implantation.

#### E. Warnings

- A single use instrument must never be reused.
- Pre-operative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the device, are important considerations in the successful utilization of the implant device.
- This is a single instrument. Reuse of any component in this system could result in failure of the instrument to perform as intended and could cause harm to the patient and/or user.
- Patient sensitivity to the device materials should be considered prior to implantation. See Adverse Effects.

#### F. Precautions

##### U.S. Federal law restricts the Disposable Cannula System to sale by or on the order of a physician.

- Surgeons are advised to review the product-specific surgical technique prior to performing any surgery. Detailed surgical techniques in print and electronic formats are available. Or, contact your representative for an onsite demonstration.
- Prior to use, inspect the device to ensure it is not damaged. Do not use a damaged device.
- Excessive force should not be placed on the device.
- Careful attention should be paid to asepsis and avoidance of anatomical hazards.
- After use, this device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.
- The contents of this system are used to aid the delivery and removal of surgical instruments and should not be implanted.

#### G. Packaging and Labeling

- Device should be accepted if the factory packaging and labeling arrive intact.
- Contact Customer Service if package has been opened or altered.

#### H. Storage Conditions

All devices must be stored in the original unopened packaging, away from moisture and should not be used after the expiration date.

## I. Information

Surgeons are advised to review the product specific surgical technique prior to performing any surgery. Detailed surgical techniques are available in print and electronic formats. Or, contact your authorized representative for an onsite demonstration. If further information is needed, contact Maruho Medical Customer Service or your authorized representative.

	Catalog number
	Batch code
	Consult instructions for use
	Caution
	Date of manufacture
	Keep Dry
	Do not use if package is damaged
	Expiration date
	Do not reuse
	Sterilized by Ethylene Oxide gas
	Manufacturer
	Prescription use only

Maruho Medical, LLC  
200 Cobb Parkway N  
Building 200, Suite 210  
Marietta, GA 30062, USA  
1-888-404-3980 Customer Service