



Instructions for Use

Deployment Skid Cannula Access Tool

This Instructions for Use is intended exclusively for distribution within the United States.

In an effort to best meet the needs of our customers and minimize waste, these Instructions for Use are being provided in electronic format. This document is subject to change; the most current version of this IFU is available online. If unsure if using the latest revision, please reprint the IFU at www.anikaifu.com. If a paper copy is preferred it may be requested, free of charge, by contacting Anika Therapeutics, Inc. at www.anikaifu.com. The onus resides with the user to ensure that the most up to date IFU is used.

Products may not be available in all markets. Product availability is subject to the regulatory clearance in individual markets. Please contact your local representative if you have questions about product availability in your area.

R ONLY

Caution: Federal Law restricts this device to sale by or on the order of a physician.

Read these instructions completely prior to use.

DEVICE DESCRIPTION

The Deployment Skid Cannula Access Tool (Skid) is a reusable surgical stainless steel cannula access tool, designed to facilitate passage of delivery instruments and implants through commercially available non-rigid arthroscopic cannulas. The device is a semi-circular partial tube that can be inserted into the proximal opening of a cannula to open or bypass fluid control valves so that Anika instruments and implants can pass more easily into the arthroscopic surgical site. The Skid is rounded and blunted distally to avoid damage to the cannula and valves. These instruments are designed for repeated use, with proper care and handling.

INSTRUCTIONS FOR USE

Prior to surgery, confirm that the Skid easily passes through the non-rigid cannula to be used, as individual manufacturers valve configurations vary. The Skid is to be used with non-rigid cannulas with an inner diameter of 10mm or larger.

Introduce Skid into distal opening of non-rigid cannula. Advance slowly allowing the distal tip of the Skid to center on valve construct. Continue advancing to dilate and open valve. Fluid flow out of the cannula will temporarily increase as valve is opened. Pass instruments and implants through the passage created by the Skid. Remove Skid to allow valve elements to return to their normal functional position. Skid may be utilized in a handle-superior or handle-inferior orientation, per surgeon preference. Arthroscopic visibility may be enhanced in the handle-inferior orientation.

WARNINGS AND PRECAUTIONS

This product is provided NON-STERILE. The product must be properly cleaned and sterilized before each use. Remove and discard any plastic shipping materials before cleaning and sterilizing the instruments. The surgeon shall be thoroughly familiar with the implants, instruments, and surgical technique prior to performing the procedure. The Skid should be regularly inspected for any signs of wear or damage.

CLEANING

Cleaning the Skid by hand rather than by mechanical cleaning will prolong the life of the instrument. Clean all surfaces and crevices, of all debris, using a soft bristle brush or cleaning stylet. Remove all traces of blood or other residues immediately. Do not allow these to dry. The Skid should be cleaned while submerged in warm water with an appropriate neutral pH detergent. Always follow the manufacturer's instructions when preparing and using detergents. Do not use steel brushes as they can accelerate wear and corrosion of the instrument. Rinse instrument thoroughly with distilled water. Dry instrument immediately after cleaning.

STERILIZATION

Recommended parameters for steam sterilization are as follows:

<u>Cycle</u>	<u>Temperature</u>	<u>Minimum Exposure Time</u>
Vacuum	270° F/ 132° C	4 minutes











Recommended dry time is 30 minutes.

Parameters may vary based on manufacturer, installation, or maintenance of sterilization equipment. On-going testing must be performed by the user to confirm inactivation of all forms of microorganisms.

The Skid should be processed in double wrapped configuration using an FDA (or applicable regulatory agency) cleared sterilization wrap. Sterilizing in liquid solutions is not recommended.

Do not sterilize at temperatures greater than 275° F/ 135° C.

Note: Anika does not define the maximum number of uses appropriate for reusable instruments. The useful life of these devices depends on many factors, including the method and duration of each use and handling between uses. Careful inspection and functional test of the instrument before use is the best method of determining the end of useful life.

	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician		Medical device
	Non-sterile		Unique device identifier
	Date of manufacture		Do not use if package is damaged and consult instructions for use
	Lot number		Keep dry
	Catalog number	 <small>www.anikaifu.com</small>	Consult electronic instructions for use

FOR FURTHER INFORMATION

If further information on this product is needed, please contact Anika Customer Service at 1-888-721-1600 in the U.S., or an authorized representative.

Legal Manufacturer



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