

Pristine Surgical Single-Use Sheath Kit

Instructions for Use

Single-Use Camera Heads	Compatible Single-Use Sheath Kits
89-10-6402 4 MM, 0°, 175 MM 89-10-6432 4 MM, 30°, 175 MM 89-10-6472 4 MM, 70°, 175 MM	89-24-6432 Conical Tip, 5.7 MM, 175 MM
89-10-6403 4 MM, 0°, 279 MM 89-10-6433 4 MM, 30°, 279 MM 89-10-6473 4 MM, 70°, 279 MM	89-24-6433 Conical Tip, 5.7 MM, 279 MM
89-10-6230 2.7 MM, 30°, 74 MM	89-24-6232 Conical Tip, 4.4 MM, 74 MM
89-10-6231 2.7 MM, 30°, 139 MM	89-24-6233 Conical Tip, 4.4 MM, 139 MM
89-10-6000 1.9 MM, 0°, 60 MM 89-10-6030 1.9 MM, 30°, 60 MM	89-24-6031 Conical Tip, 2.8 MM, 60 MM



PRISTINE SURGICAL

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Proprietary Information

The information contained in this guide is confidential and proprietary to the manufacturer and its affiliates. It is intended solely for the information and use of parties operating the equipment described herein. No part of this document may be distributed or disclosed in any form to third parties without prior written consent of the manufacturer.

The manufacturer reserves the right to revise this publication and to make changes from time to time without obligation to notify any person of such revisions or changes unless otherwise required by law.

DEVICE DESCRIPTION

The Pristine Surgical Single-Use Sheath Kit is comprised of a single-use obturator and a single-use sheath. The Pristine Surgical Single-Use Sheath Kit is provided sterile and may only be used once.

The Pristine Surgical Single-Use Sheath Kit is designed for use with Pristine Surgical 4K HDR Single Use Camera Heads.

INDICATIONS

The Pristine Surgical Single-Use Sheath Kit is indicated for use in minimally invasive endoscopic procedures to provide access and fluid flow to the surgical site.

WARNINGS AND CAUTIONS

Use of this equipment may present hazards to the user and/or patient. It is recommended to read this manual, the Single-Use Camera Head Quick-Start Guide, and the Camera System IFU thoroughly, especially the warnings and cautions, and be familiar with its contents before connecting and using this equipment. The words **warning**, **caution**, and **note** carry special meaning and, should be carefully reviewed:

Warning	Indicates risks to the safety of the patient or user. Failure to follow warnings may result in injury to the patient or user.
Caution	Indicates risks of improper use and/or damage to the equipment. Failure to follow cautions may result in loss of function or product damage.
Note	Indicates special information to clarify instructions or present additional useful information.



An exclamation mark within a triangle is intended to indicate and alert the user to the presence of important operating and maintenance instructions in the manual. This symbol is used to indicate Warnings and Cautions.



Warnings

To avoid potential injury to the user and the patient and/or damage to this device, please note the following warnings:

1. This equipment is designed for use by a qualified physician, having complete knowledge of the use of this equipment and the procedure to be performed. This device should only be used in compliance with the stated indications.
2. This device is provided sterile. Do not reuse or resterilize this device. Reuse of single use devices may pose health and/or safety risks, such as cross-contamination, an obstructed fluid path, or a restricted surgical portal.
3. Before use, carefully inspect the sterile barrier packaging to ensure it is not compromised and to ensure use is within stated shelf life. Do not use if the sterile barrier has been compromised as infection is possible. Do not use the device if the stated shelf life is expired.
4. Do not use if the device is damaged, as loss of function is possible which can lead to delays in the case. Ensure that no parts are missing or loose. Inspect the locking device for contaminants and damage to ensure a fixed and secure connection. Inspect all components of the stopcock for function or damage.

5. Before use, check the outer surface of this equipment to ensure that there are no rough surfaces, sharp edges, or protrusions that can cause injury. Always perform a pre-operative check.
6. After use, the device should be treated as regulated medical waste and processed according to local laws and hospital practices.



Cautions

To help prevent improper use and/or damage to this device, either of which could potentially result in risk to the patient, please note the following cautions:

1. The sheath tube and obturator rod can be bent or broken. Do not subject the sheath to impact or excess bending forces. Handle instruments carefully.
2. Be aware that not all instruments selected based on width and working length will be compatible in combination.
3. Never reprocess or reuse these Single-Use devices.

Note: The warranty is void if any of these warnings or cautions are disregarded.

Note: Report any serious event, as defined in the European Medical Device Regulations (EU MDR 2017/745) or local legislation, involving the device to the manufacturer and, if applicable, to the national Competent Authority of the Member State or local jurisdiction.

Note: Federal law (United States of America) restricts this device to use by, or on the order of, a physician.

SYMBOLS AND DEFINITIONS

A list of applicable symbols is presented below:

Symbol	Definition	Symbol	Definition
	Reference or Catalog Number		Operating Instructions
	Manufacturer		Lot Number
	Date of Manufacture		Quantity
	Warning/Caution		Available by Prescription Only
	Do not use if package is damaged		Medical Device
	Do not reuse		Use-By Date
	Do not resterilize		Sterile – Sterilized by Ethylene Oxide
	Magnetic Resonance Imaging Unsafe		Double Sterile Barrier System
	Temperature Range		Pressure Range
	Humidity Range		Keep Dry
	Non-pyrogenic		

UNPACKING, INSPECTION AND SETUP

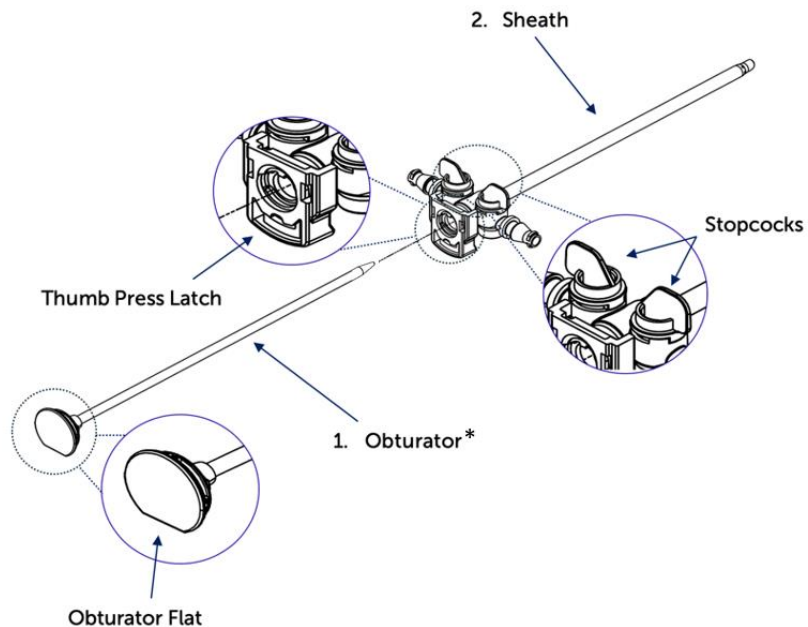
The Pristine Surgical Single-Use Sheath Kit may only be used with a compatible Pristine Surgical Single-Use Camera Head (89-10-6XXX).

The Pristine Surgical Single-Use Sheath Kit is provided in a sterile package within the shipping box. The device should be used only if the packaging and labeling are intact and there are no signs of damage. Carefully remove from the shipping box and inspect the sterile barrier for signs of damage or deterioration. Verify the expiration date has not lapsed. If there are signs of damage or deterioration, or if the expiration date has passed, do not use.

To facilitate delivery of the Pristine Surgical Single-Use Sheath Kit to the sterile field, the device is packaged in a Double Sterile Barrier System. Use aseptic handling techniques to ensure device sterility is maintained during unpackaging and delivery to the sterile field.

DIRECTIONS FOR USE

1.1 Sheath and Obturator



*The diagram above features a conical obturator. There is no variation in set-up for sharp obturator sheath kits.

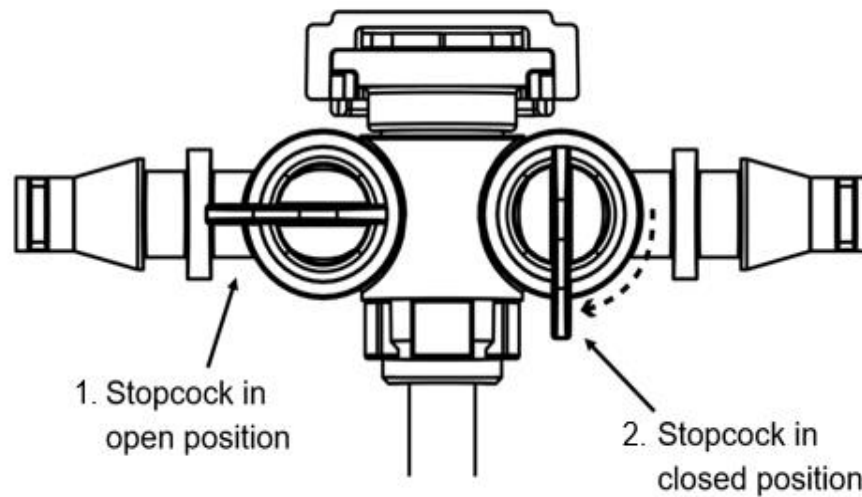
To introduce an obturator into the sheath:

1. Insert the obturator, lining up the flat end of the obturator (1) handle with the thumb press latch of the sheath (2).
2. When the obturator is fully inserted into the sheath, the latch will click into the closed position, locking the obturator in place.
3. To remove the obturator, push the thumb press latch to activate the click mechanism and release the obturator. Remove the obturator from the sheath gently.



Never use force to insert the obturator. If obturator is resistant, check for correct size and alignment.

1.2 Stopcocks



The Pristine Surgical Single-Use Sheath features dual stopcocks, which may be used to control the fluid inflow and outflow.

Each stopcock features a rotatable control lever; the position of this lever will indicate whether the stopcock is allowing inflow/outflow to proceed:

1. The stopcock is open, and fluid will flow through the valve unobstructed, when the handle lies perpendicular to the sheath/endoscope (parallel to the fluid path).
2. The stopcock is closed when the handle lies parallel to the sheath/endoscope (perpendicular to the fluid path).

STORAGE AND OPERATING CONDITIONS

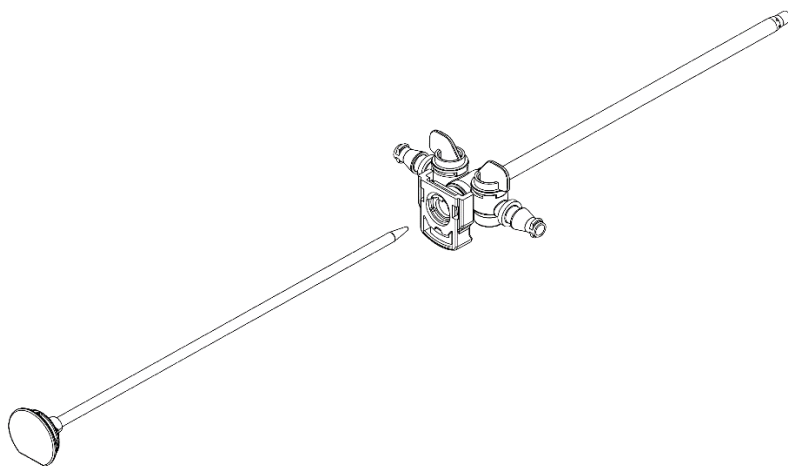
These sterile devices must be stored in the original unopened packaging, away from moisture and should not be used after the expiration date specified on the label. Specified storage and operating conditions for the Sheath Kit are as follows:

	Temperature	Humidity	Pressure
Storage	-40°F to 122°F [-40°C to 50°C]	10% to 90%, non-condensing	50.0 kPa to 106.0 kPa
Operating	50 °F to 86 °F [10°C to 30°C]	30% to 75%, non-condensing	70 kPa to 106 kPa

MAINTENANCE AND DISPOSAL

The Pristine Surgical Single-Use Sheath Kit does not contain any user serviceable components and there is no maintenance requirement as it is disposed of after one use.

After use, the device should be treated as regulated medical waste and processed according to national and local laws and regulations.



89-24-6XXX Pristine Surgical Single-Use Sheath Kit



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