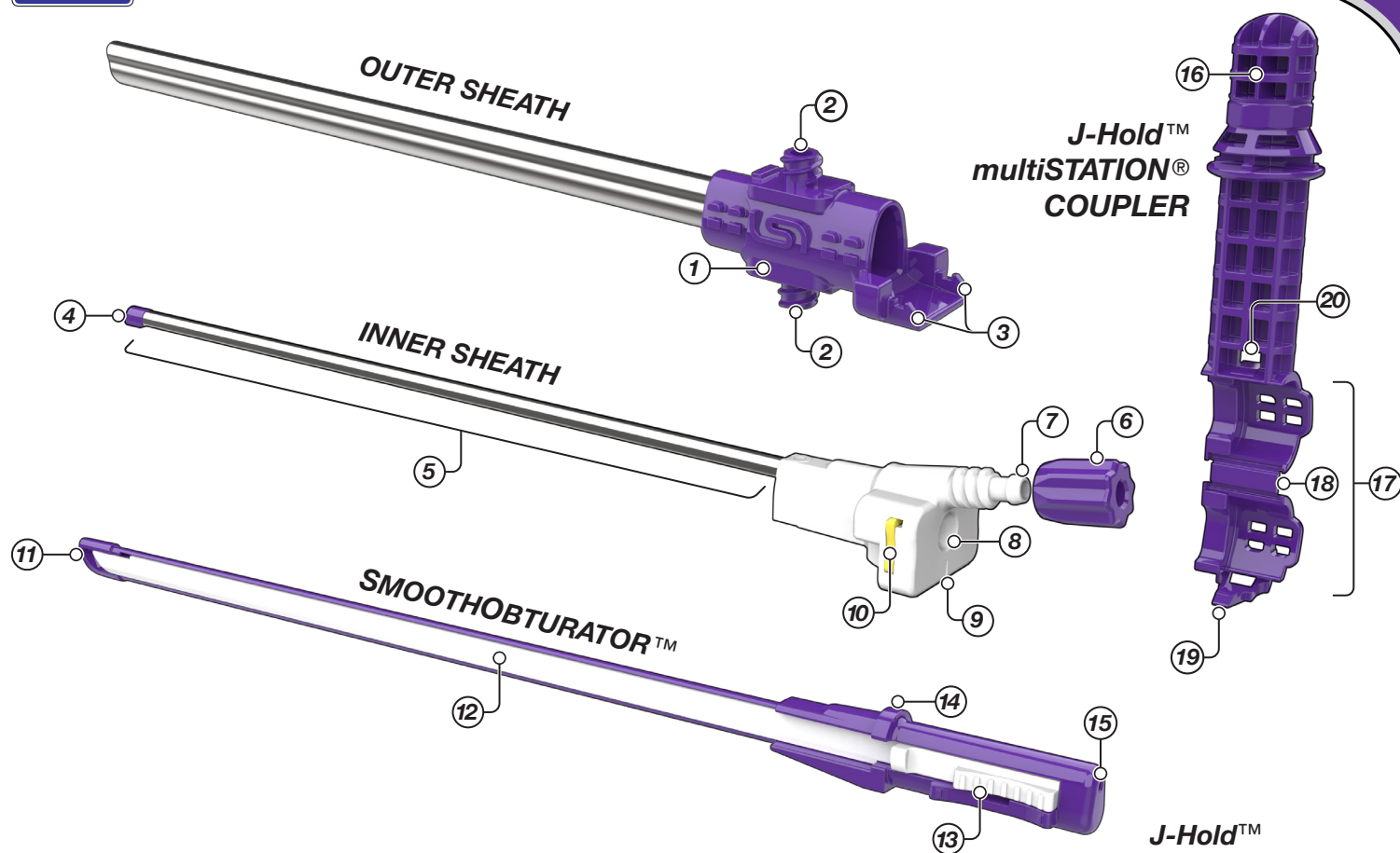


JNW μ ITUS™ INSTRUMENT GUIDE TECHNOLOGY GUIDE

 READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 1



OUTER SHEATH

- ① Textured Hub Grip
- ② Upper and Lower Connector
- ③ Locking Tabs

INNER SHEATH

- ④ Purple Tip
- ⑤ 3mm Conduit
- ⑥ Scope Lock
- ⑦ 3mm Port
- ⑧ 5mm Port
- ⑨ Suture Notch
- ⑩ Seal Door

SMOOTHOBTURATOR™

- ⑪ Blunt Tip
- ⑫ Sliding Core
- ⑬ Obturator Latch
- ⑭ Position Indicator
- ⑮ Guide Wire Channel

J-Hold™ multiSTATION® COUPLER

- ⑯ Attachment Shaft
- ⑰ Hub Grip Pocket
- ⑱ Pocket Hinge
- ⑲ Pocket Hook
- ⑳ Pocket Latch

JNW μ ITUS™ INSTRUMENT GUIDE DESCRIPTION

The JNW μ ITUS™ INSTRUMENT GUIDE is a single-patient-use cannula and obturator kit. Each kit comprises an Outer Sheath, a removable Inner Sheath, a SMOOTHOBTURATOR™, a scope lock, a seal door, and a J-Hold™ multiSTATION® Coupler. The removable Inner Sheath provides a separate lumen for a 3mm endoscope. The J-Hold™ multiSTATION® Coupler enables attachment to the multiSTATION® System. The Outer Sheath has a textured hub grip ① on the surgeon side that features upper and lower connectors ② to facilitate fluid infusion and drainage of the surgical site. The locking tabs ③ engage with the seal door when inserted. The Inner Sheath incorporates a purple tip ④ at the end of a 3mm conduit ⑤. A 3mm endoscope can be inserted through the scope lock ⑥ and the 3mm port ⑦. The scope lock can be tightened to maintain the endoscope's rotation and axial position or loosened to allow rotation and translation of the scope, as desired. The surgeon side of the Inner Sheath also incorporates a 5mm port ⑧ to facilitate passage of a 5mm surgical instrument. The suture notch ⑨ beneath the 5mm port can be used to facilitate the passing of suture during Inner Sheath removal and reinsertion. To reduce fluid loss, the seal door ⑩ can close the 5mm port when not in use. The custom SMOOTHOBTURATOR™ has a blunt tip ⑪ and a sliding core ⑫ to facilitate smooth insertion along sensitive tissue. After pressing in and holding the obturator latch ⑬, the sliding core can be adjusted forward or backward. While in the fully forward position, the protruding edge of the sliding core aligns with the position indicator ⑭ to maintain the position of the SMOOTHOBTURATOR™ within the Outer Sheath, and the tip expands to cover the leading edge of the Outer Sheath. Moving the sliding core backward will allow the SMOOTHOBTURATOR™ to be removed from the Outer Sheath. The SMOOTHOBTURATOR™ has an integrated guide wire channel ⑮, allowing the assembled Outer Sheath with obturator to be inserted over a guide wire. The J-Hold™ multiSTATION® Coupler includes an attachment shaft ⑯ for connection to a separately available multiSTATION® Cannula Adapter. It also includes a hub grip pocket ⑰ into which the JNW textured hub grip is placed. The pocket hinge ⑱ allows the pocket to wrap around the hub grip such that the pocket hook ⑲ engaged with the pocket latch ⑳ secures the coupler in place. The hook and latch can be readily disengaged and reengaged as necessary.

INDICATIONS FOR USE

The JNW μ ITUS™ INSTRUMENT GUIDE is indicated for use as a dual-lumen multipurpose cannula.

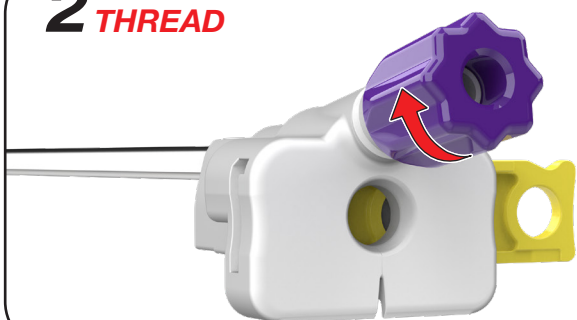
1 INSERT



1. **INSERT** the seal door from right to left into the slot on the surgeon side of the Inner Sheath.

NOTE: Ensure that the seal door is in the unlocked position (see FIG. 4).

2 THREAD



2. **THREAD** the scope lock clockwise to the 3mm port.

NOTE: Partially thread the scope lock to allow for subsequent endoscope insertion.

3 INSERT

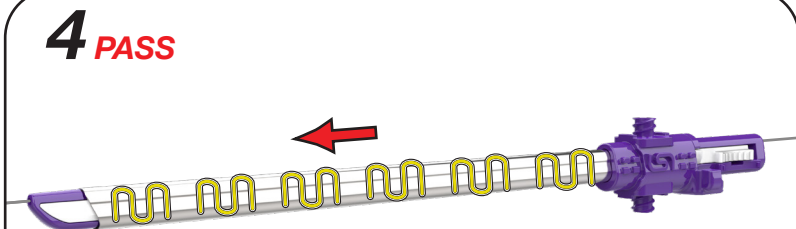


3. **INSERT** the *SMOOTHOBTURATOR*™ into the Outer Sheath.

NOTE: Ensure that the sliding core is in its backward position prior to insertion.

NOTE: After insertion, press in the obturator latch and adjust the sliding core into its forward position to extend the tip to cover the leading edge of the Outer Sheath (see FIG. 3).

4 PASS

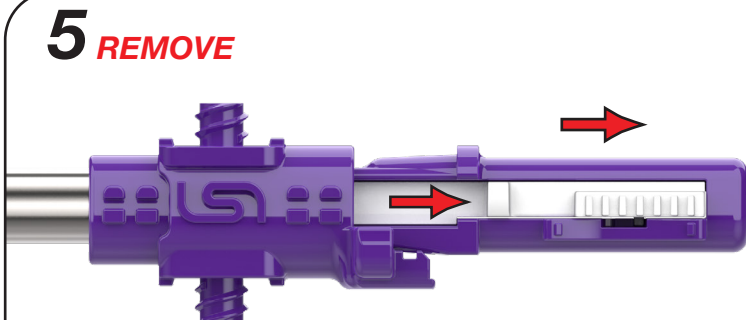


4. **PASS** the *SMOOTHOBTURATOR*™ and Outer Sheath into the surgical site.

NOTE: Use standard dilation technique and apply lubrication as needed to facilitate gentle device insertion.

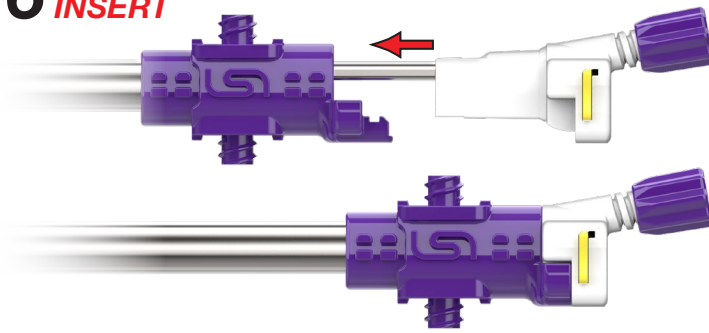
NOTE: If desired, the *SMOOTHOBTURATOR*™ and Outer Sheath may be passed to the surgical site over a guide wire.

5 REMOVE



5. **REMOVE** the *SMOOTHOBTURATOR*™ from the Outer Sheath by pressing in the obturator latch and adjusting it backward to retract the sliding core, then withdrawing the *SMOOTHOBTURATOR*™.

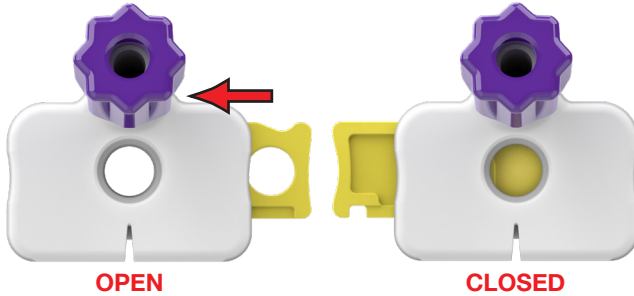
6 **INSERT**



6. **INSERT** the Inner Sheath into the Outer Sheath until the locking tabs engage.

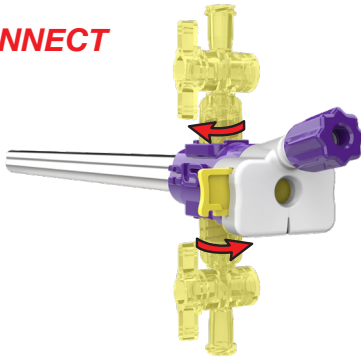
NOTE: Ensure that the seal door is in the unlocked position during insertion (see FIG. 4).

7a **SLIDE**



7a. **SLIDE** the seal door to the closed position to restrict fluid flow from the 5mm port as needed (see FIG. 6).

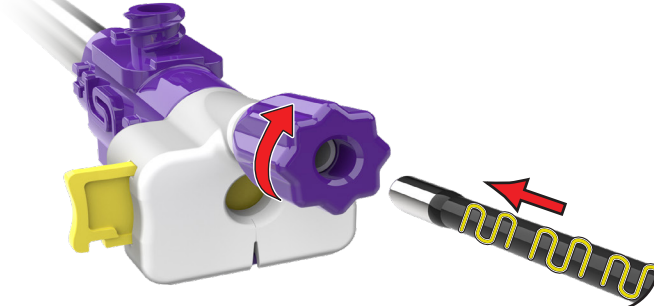
7b **CONNECT**



7b. **CONNECT** stopcocks to the upper and lower connectors for fluid infusion and drainage if desired.

NOTE: Fluid connectors not shown in subsequent images for simplicity.

8 **INSERT**



8. **INSERT** the desired scope through the 3mm port and the scope lock. Tighten the scope in place by rotating the scope lock clockwise.

NOTE: Apply lubrication as needed to facilitate scope insertion.

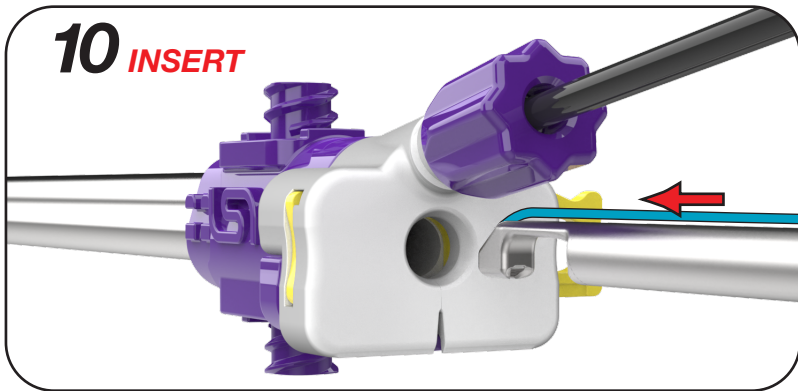
NOTE: DO NOT force the scope through the 3mm port. If excessive resistance is encountered, remove the scope immediately to prevent damage to the scope.

9 **SLIDE**



9. **ACCESS** the 5mm port by sliding the seal door to its open position.

10 INSERT

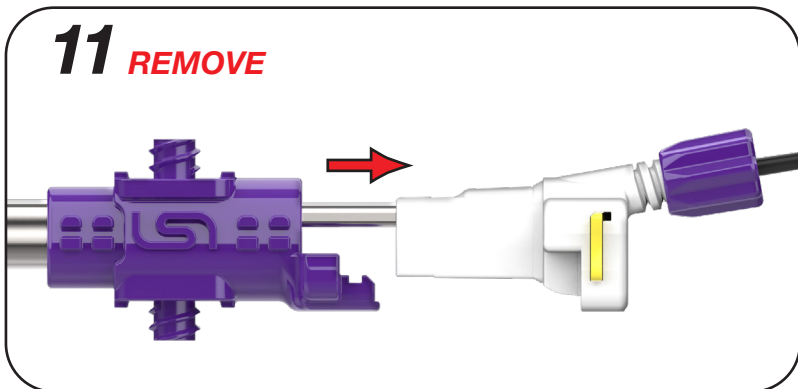


10. **INSERT** the desired device through the 5mm port. Utilize, adjust, and interchange devices through the 5mm port as needed.

NOTE: Apply lubrication as needed to facilitate device insertion.

NOTE: DO NOT force a device through the 5mm port. This port is intended to accommodate a 5mm device. If excessive resistance is encountered, remove the device immediately.

11 REMOVE



11. **REMOVE** the Inner Sheath (with the scope attached) from the Outer Sheath by sliding the seal door to the unlocked position.

NOTE: Always ensure that the Inner Sheath purple tip remains visible on the external display when manipulating or removing the Inner Sheath with the scope inserted.

NOTE: With the Inner Sheath removed, larger surgical instruments and/or tissue can be passed through the open bore of the Outer Sheath.

Using the J-HOLD™ multiSTATION® COUPLER (optional, sold separately)

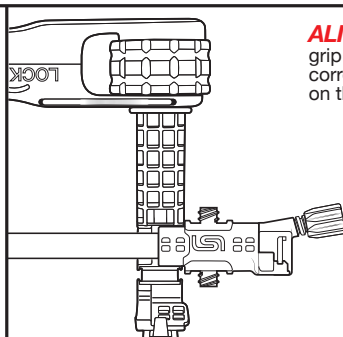
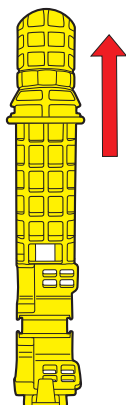
FIG. 2



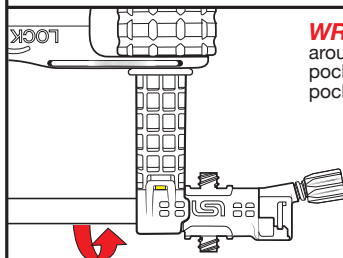
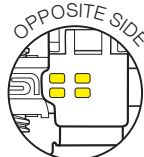
ORIENT the cannula adapter such that the "LOCK" label is upside down relative to the J-Hold™ attachment shaft.

INSERT the J-Hold™ attachment shaft into the cannula adapter and secure the J-Hold™ in place.

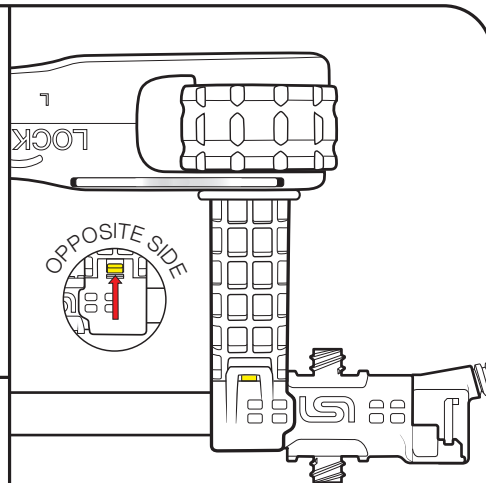
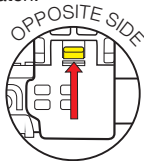
Refer to the multiSTATION® CANNULA ADAPTER Instructions For Use for additional information.



ALIGN the 4 holes in the hub grip pocket with the corresponding raised texture on the hub grip.



WRAP the hub grip pocket around the hub grip until the pocket hook has engaged the pocket latch.



UNLATCH the hub grip pocket by pressing up on the pocket hook, allowing the J-Hold™ to be removed from the hub grip.

ACTIONS

- The *JNW JUTUS™ INSTRUMENT GUIDE* is a cannula/coupler device that provides for ergonomic and repeatable simultaneous use of a 3mm diameter endoscope and a 5mm diameter shafted device while allowing for fluid infusion and drainage of the surgical site. The device is designed as an instrument guide with a removable Inner Sheath that, when inserted, establishes 2 independent lumens: one for the passage of an endoscope and one for the passage of a surgical device.

CONTRAINDICATIONS

- The *JNW JUTUS™ INSTRUMENT GUIDE* is contraindicated for use under conditions that, in the surgeon's judgement, create unacceptable risk of patient injury during placement, use, and/or removal.
- The *JNW JUTUS™ INSTRUMENT GUIDE* is not intended for use in patients who are contraindicated for retrograde urological procedures.
- The *JNW JUTUS™ INSTRUMENT GUIDE* is contraindicated for use in patients with tight strictures precluding passage of the device.
- The *JNW JUTUS™ INSTRUMENT GUIDE* is contraindicated for use in patients with large obstructing distal ureteral calculi.

WARNINGS

- Federal law restricts this device to sale, distribution, and use by, or on, the order of a physician.
- Read all instruction manuals thoroughly. Before use, read these instructions and review the manuals/instructions for all other equipment that will be used during the procedure. Inadequate understanding of the techniques, complications, and hazards of surgical procedures can lead to patient harm or death.
- Users should be familiar with standard procedures and techniques for urologic procedures employing the *JNW JUTUS™ INSTRUMENT GUIDE*.
- During urologic procedures, exposure of open blood vessels to certain pressure conditions can lead to irrigation fluid being absorbed into the circulatory system, potentially resulting in water intoxication of the patient. Water intoxication can lead to patient injury, illness, or death.
- Failure to use nonconductive lubricant, nonconductive distension medium, and nonconductive irrigation fluid can potentially result in patient injury due to high-frequency current.
- Do not reuse, reprocess, or resterilize this product. The *JNW JUTUS™ INSTRUMENT GUIDE* is designed and intended for single-patient use only. The performance of this product after cleaning or other reprocessing has not been validated and is not supported by LSI SOLUTIONS®. Reuse, reprocessing, or resterilization may compromise the integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- Discard any opened (unsealed), unused, expired, or damaged *JNW JUTUS™ INSTRUMENT GUIDE*.
- Each *JNW JUTUS™ INSTRUMENT GUIDE*, along with packaging, must be inspected, handled, and disposed of consistent with standard, accepted medical device disposal procedures.
- The *JNW JUTUS™ INSTRUMENT GUIDE* is not insulated against any electrical voltage. When using electro-surgical device techniques, avoid contacting the *JNW JUTUS™ INSTRUMENT GUIDE* with all electro-surgical devices.

PRECAUTIONS

- Surgical procedures should only be performed by physicians having adequate training and familiarity with such techniques. In addition, medical literature should be consulted relative to techniques, complications, and hazards prior to the performance of surgical procedures. Inappropriate actions or use can lead to patient harm or death.
- Before instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility and ensure that electrical isolation or grounding are not compromised.
- Allowing irrigation fluid to reach temperatures of 43° C / 109° F can result in patient injury. Do not preheat the irrigation fluid above body temperature (37° C / 99° F).
- Do not forcibly advance or withdraw the device if resistance is encountered. If it becomes difficult to advance or withdraw the device, stop its motion and determine the cause of the resistance.
- Care must be taken when moving the *multiSTATION® CANNULA ADAPTER* while the *JNW JUTUS™ INSTRUMENT GUIDE* is inserted in the patient.
- Ensure the suture/suture tubes are visible while removing and re-inserting the Inner Sheath of the device.

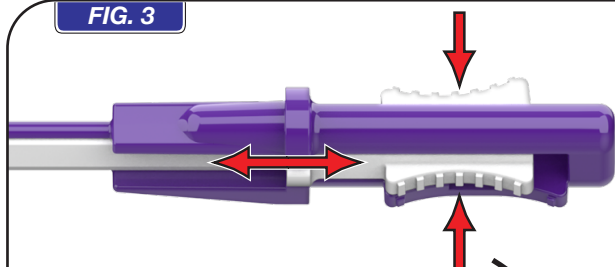
ADVERSE REACTIONS:

- No documented adverse reactions.

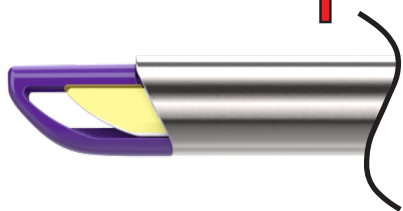
JNW JUTUS™ INSTRUMENT GUIDE PRODUCT ORDERING			SUPPLIED: STERILE
	REORDER	PRODUCT	DESCRIPTION
 x 6	REF 082150	JNW JUTUS™ INSTRUMENT GUIDE	Box of 6 Kits (1 Inner Sheath per Kit) (1 Outer Sheath per Kit) (1 SMOOTHOBTURATOR™ per Kit) (1 Scope Lock per Kit) (1 Seal Door per Kit) (1 J-Hold™ per Kit)
 x 1	REF 080415	multiSTATION® CANNULA ADAPTER	(1 CANNULA ADAPTER per Kit)

Using the SMOOTHOBTURATOR™

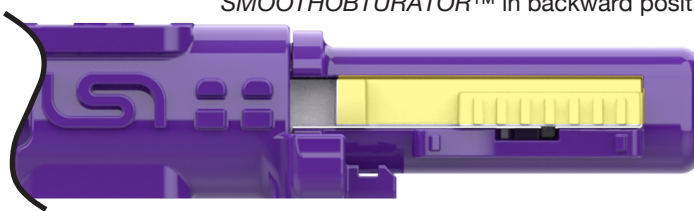
FIG. 3



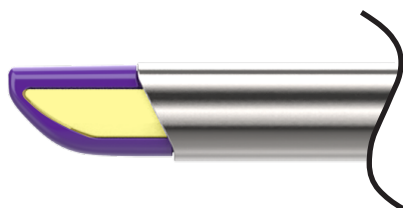
Pressing in and holding the obturator latch allows the sliding core to be adjusted forward or backward, facilitating cannula insertion and SMOOTHOBTURATOR™ withdrawal, respectively.



SMOOTHOBTURATOR™ in backward position

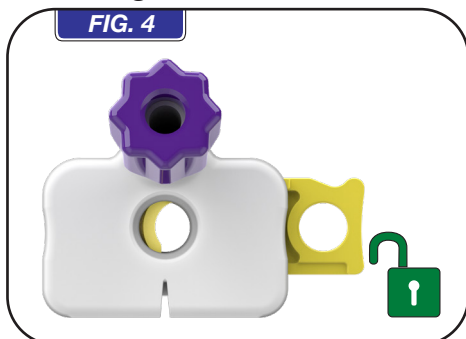


SMOOTHOBTURATOR™ in forward position



Using the Seal Door

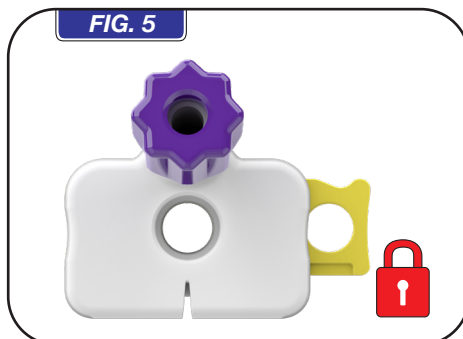
FIG. 4



Seal Door unlocked

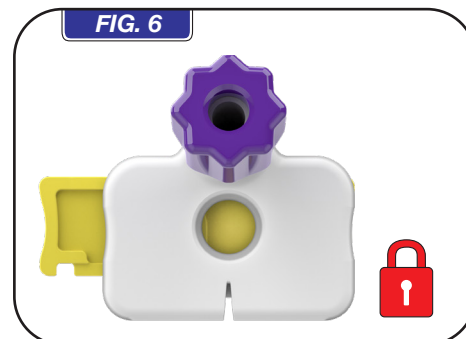
* The inner sheath can only be inserted or removed in the unlocked position.

FIG. 5



Seal Door open and locked

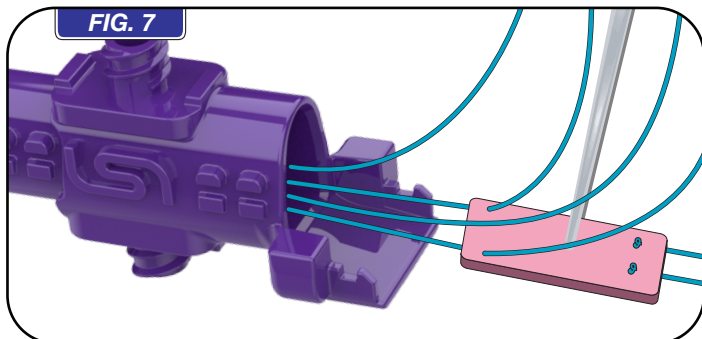
FIG. 6



Seal Door closed and locked

JNW μITUS™ INSTRUMENT GUIDE TECHNIQUE PEARLS

FIG. 7



Tissue structure shown being passed to the surgical site through the open bore of the Outer Sheath.

FIG. 8



Suture can be passed through the suture notch to facilitate Inner Sheath removal and reinsertion.

LSI SOLUTIONS®

Patents: www.lsisolutions.com/patents

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Symbol Glossary: www.lsisolutions.com/symbols



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