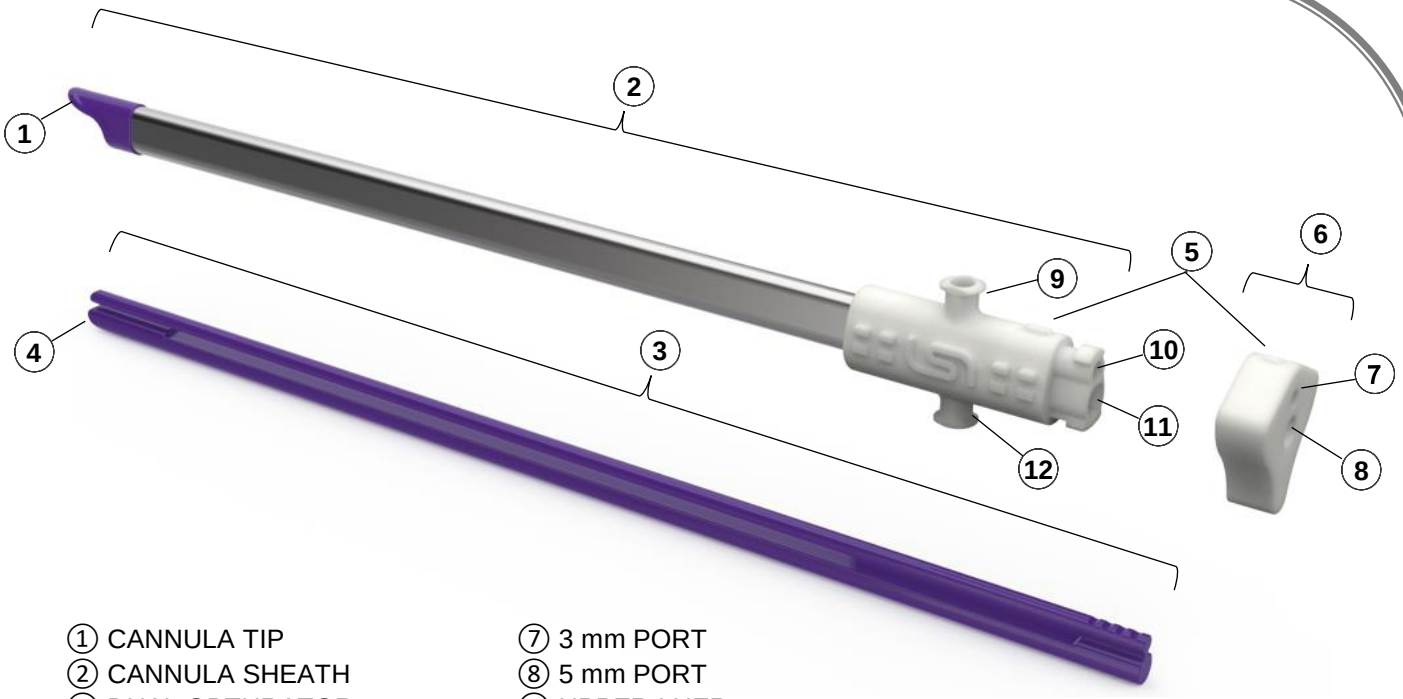
JNW URTRAC™ Instrument Guide

TECHNOLOGY GUIDE

READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE



① CANNULA TIP
② CANNULA SHEATH
③ DUAL OBTURATOR
④ ROUNDED TIP
⑤ ROTATIONAL INDICATOR (2X)
⑥ ROTATIONAL SEAL
⑦ 3 mm PORT
⑧ 5 mm PORT
⑨ UPPER LUER
⑩ UPPER LUMEN
⑪ LOWER LUMEN
⑫ LOWER LUER

JNW URTRAC™ DEVICE DESCRIPTION

The *JNW URTRAC™ Instrument Guide* is a sterilized, single-patient–use, dual-lumen cannula and obturator kit. Each kit comprises a dual-lumen cannula sheath, a dual obturator, and a rotational seal. The seal minimizes fluid loss through the surgeon side of the 3 mm and 5 mm ports.

The cannula tip ① provides protection for a videoscope and allows the cannula sheath ② to gently move along sensitive tissue. The dual obturator ③ has a rounded tip ④ that is inserted into the cannula sheath to facilitate controlled, smooth passage to the surgical site. After removing the dual obturator and aligning both rotational indicators ⑤, the rotational seal ⑥ is placed on the surgeon side of the cannula sheath. The 3 mm port ⑦ and 5 mm port ⑧ are accessible only when the rotational indicators are aligned. Rotating the rotational seal clockwise about the 3 mm port closes the 5 mm port to maintain fluid pressure in the cannula sheath. Fluid is infused into the surgical site through the upper luer ⑨ and along the upper lumen ⑩. Fluid from the surgical site passes through the lower lumen ⑪ and out through the lower luer ⑫. Each luer connection can optionally be fitted with a stopcock to control inflow and outflow (not provided).

INDICATIONS

The *JNW URTRAC™ Instrument Guide* is indicated for use as a dual-lumen multipurpose cannula.

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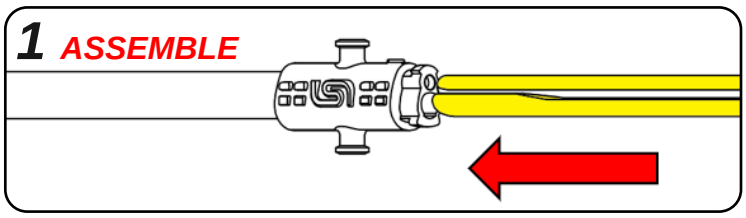
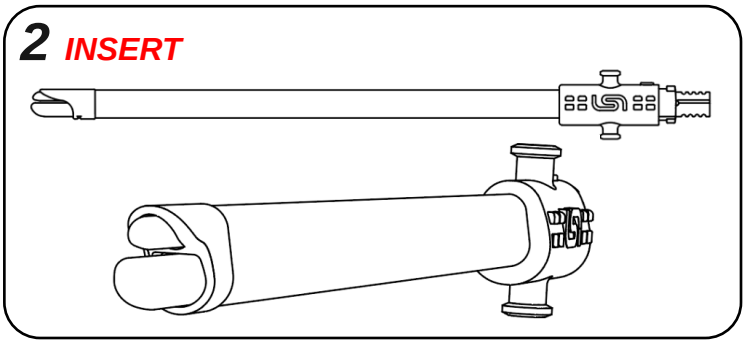
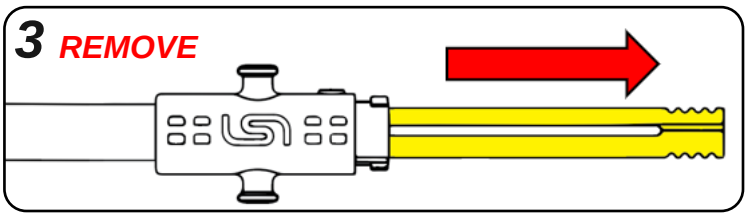


1. ***ASSEMBLE*** the dual obturator into the cannula sheath.

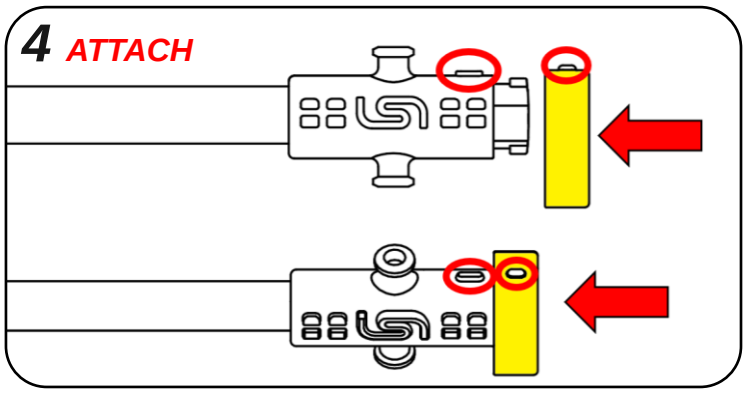


2. ***INSERT*** the dual obturator and cannula sheath into the surgical site.

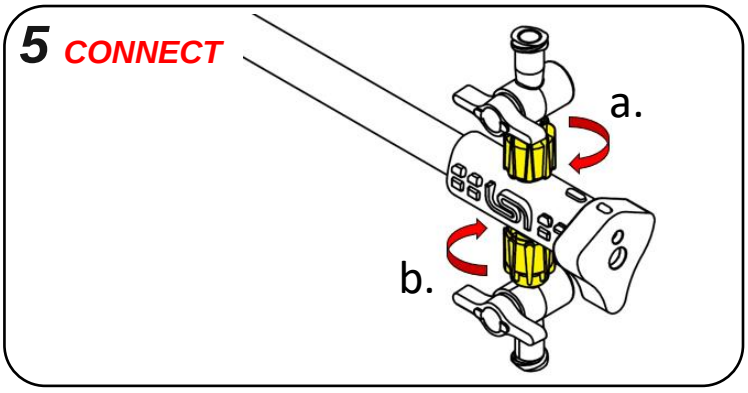
NOTE: Use standard dilation technique and apply lubrication as needed to facilitate gentle device insertion.



3. ***REMOVE*** the dual obturator from the cannula sheath when the cannula is positioned at the desired surgical site.

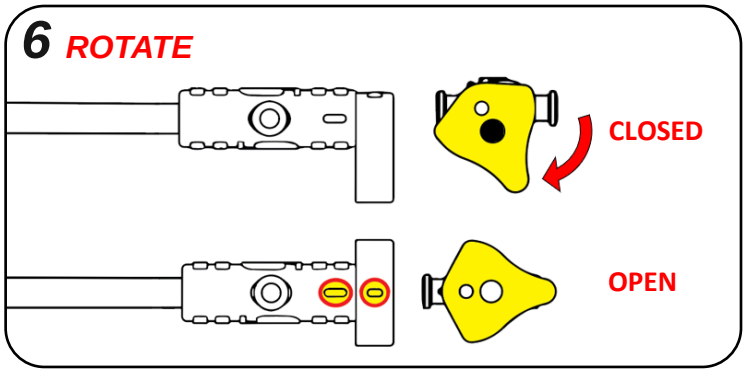


4. ***ATTACH*** the rotational seal to the surgeon end of the cannula sheath. Ensure that the indicators at the top of the rotational seal and cannula sheath are properly aligned.



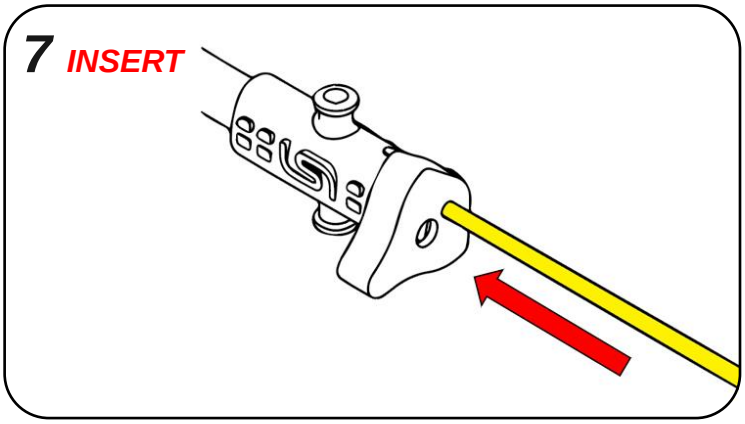
5a. ***CONNECT*** a stopcock with a fluid source to the upper luer of the cannula sheath if desired.

5b. ***CONNECT*** a stopcock to the lower luer of the cannula sheath if desired.



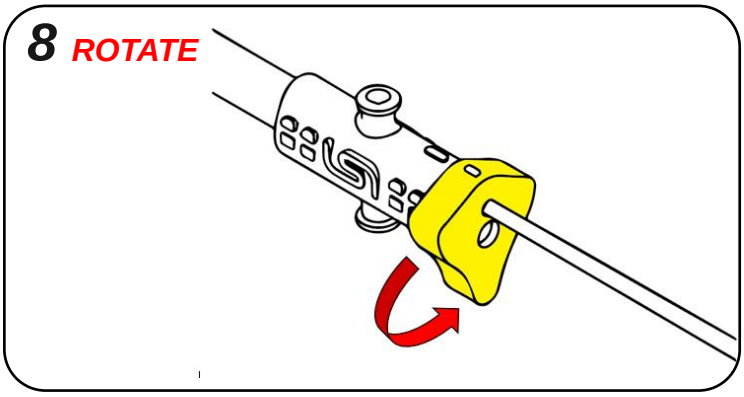
6. ***ROTATE*** the rotational seal clockwise to restrict the flow of fluid from the 5 mm port as needed.

NOTE: Reference the rotational indicators at the top of the rotational seal and cannula sheath to determine whether the seal is opened or closed.

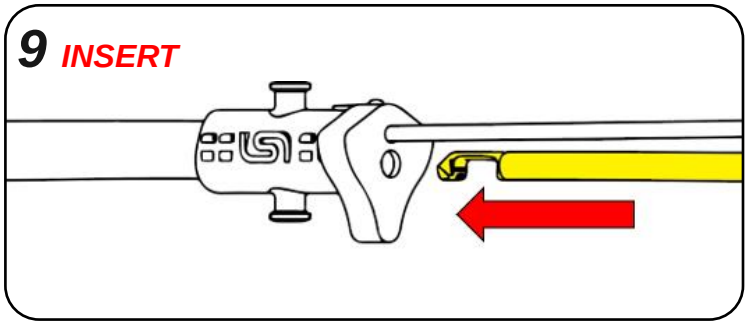


7. *INSERT* the desired scope through the 3 mm port of the cannula sheath.

NOTE: Apply lubrication as needed to facilitate scope insertion.
NOTE: DO NOT force the scope through the seal. The 3 mm port is intended to accommodate a 3 mm scope. Immediately remove the scope from the cannula sheath if excessive resistance is encountered during scope insertion. Excessive force on the scope can significantly damage the scope.

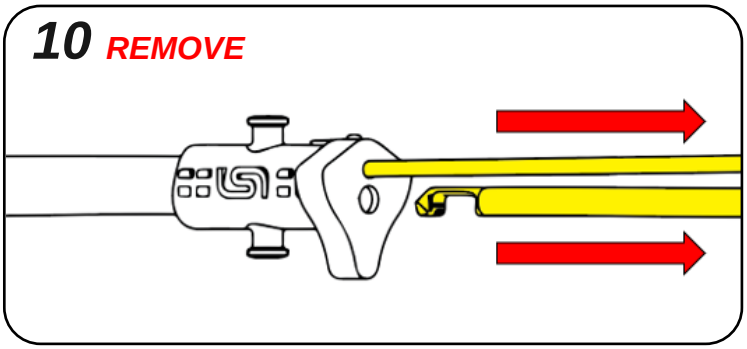


8. *ROTATE* the rotational seal counterclockwise using the scope as a rotational center to access the 5 mm port of the cannula sheath.

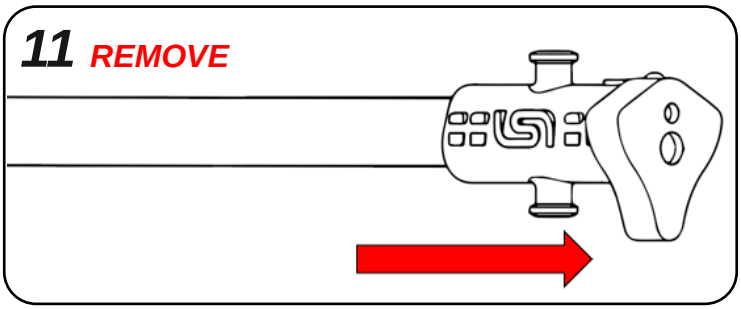


9. *INSERT* the desired device through the 5 mm port of the cannula sheath. Utilize, adjust, and interchange devices through the 5 mm port as needed.

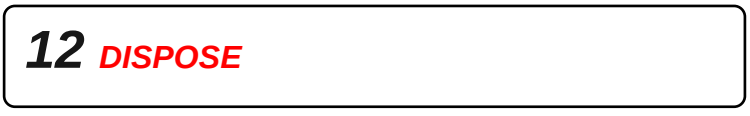
NOTE: Apply lubrication as needed to facilitate device insertion.
NOTE: DO NOT force the device through the seal. The 5 mm port is intended to accommodate a 5 mm device. Immediately remove the scope from the cannula sheath if excessive resistance is encountered during scope insertion.



10. *REMOVE* the 5 mm device and scope from the cannula sheath following the completion of the procedure.



11. *REMOVE* the cannula sheath gently from the surgical site.



12. *DISPOSE* of the device and associated components following standard, accepted medical device disposal procedures.

ACTIONS:

- The *JNW URTRAC™ Instrument Guide* is a Coupler/Cannula device that provides for ergonomic and repeatable simultaneous use of a 5 mm diameter shafted device and ~3 mm diameter scope. The Device is designed as an instrument guide to establish 2 independent lumens: 1 for the passage of scope and inflow of fluid and with integrated luer fitting, 1 for the passage of a device and out-flow of fluid and with integrated luer fitting.

CONTRAINDICATIONS:

- The *JNW URTRAC™ 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 URTRAC™ Instrument Guide* is not intended for use in patients who are contraindicated for retrograde urological procedures.
- The *JNW URTRAC™ Instrument Guide* is contraindicated for use in patients who have the presence of tight strictures precluding passage of the device.
- The *JNW URTRAC™ Instrument Guide* is contraindicated for use in patients who have the presence of large obstructing distal ureteral calculi.

WARNINGS:

- Federal (U.S.A.) 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 URTRAC™ Instrument Guide*.
- Applications other than for urologic procedures can result in damage to the *JNW URTRAC™ Instrument Guide*, rendering it unsuitable for continued use.
- 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 and a nonconductive distension medium and nonconductive irrigation fluid can potentially result in patient injury due to high-frequency current.
- Do not reuse, reprocess, or re-sterilize this product. The *JNW URTRAC™ 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 re-sterilization 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 URTRAC™ Instrument Guides*.
- Each *JNW URTRAC™ Instrument Guide*, along with packaging, must be inspected, handled, and disposed of consistent with standard, accepted medical device disposal procedures.
- The *JNW URTRAC™ Instrument Guide* is not insulated against any electrical voltage. When using electrosurgical device techniques, avoid contacting the *JNW URTRAC™ Instrument Guide* with all electrosurgical 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.

ADVERSE REACTIONS:

- No documented adverse reactions.

ORDERING INFORMATION

***JNW URTRAC™* PRODUCT ORDERING**			
	REORDER	**PRODUCT**	**DESCRIPTION**
 **X 6**	**REF** **081300**	***JNW URTRAC™ Instrument Guide***	Box of 6 Kits (1 Device per Kit)

LSI SOLUTIONS, Inc.
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