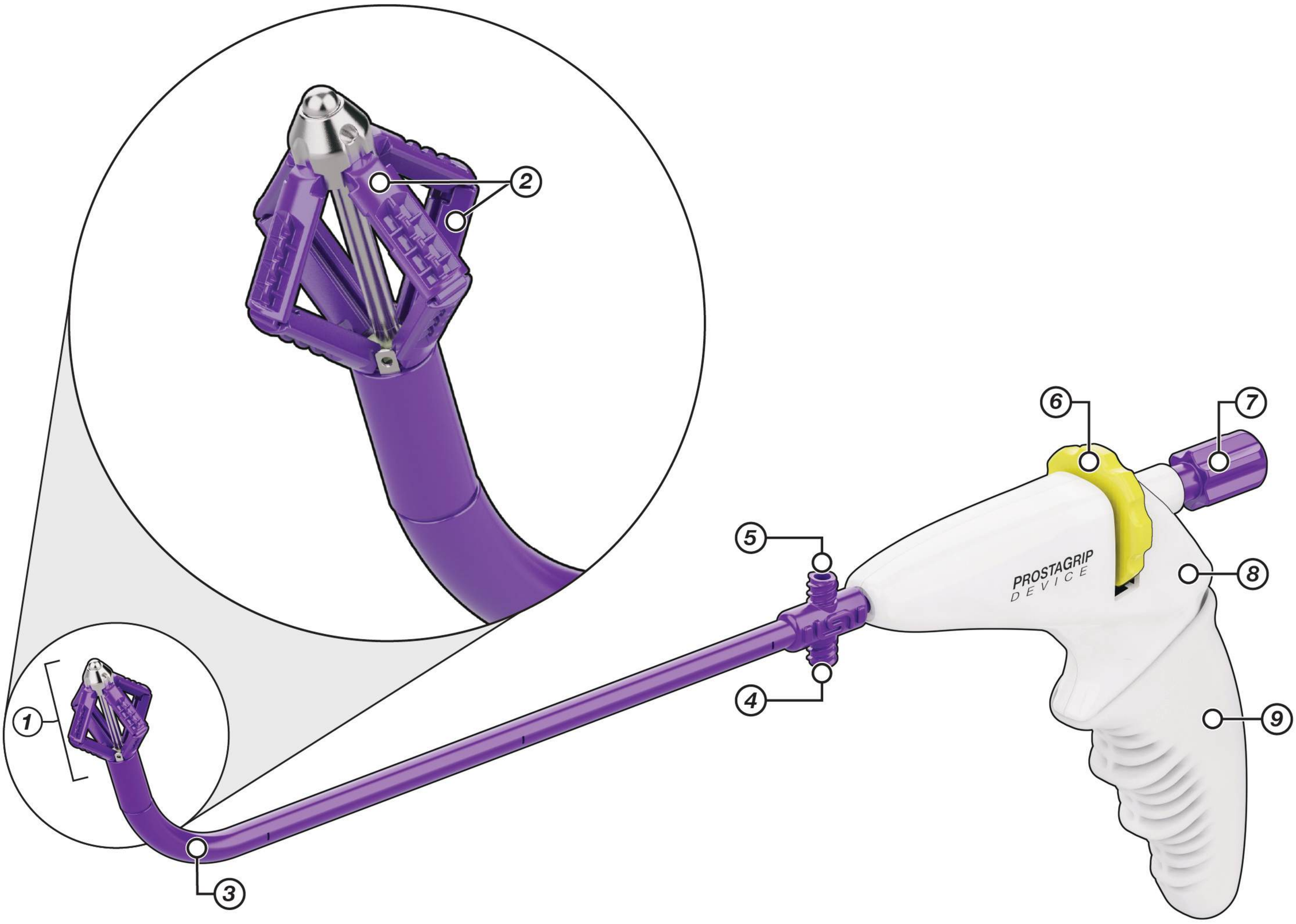
PROSTAGRIP™ DEVICE TECHNOLOGY GUIDE

READ THIS PRODUCT INSERT THOROUGHLY BEFORE USE

FIG. 1



1. *DEVICE TIP*
2. *EXPANDING GRIPPERS*
3. *CURVED SHAFT (22 Fr)*
4. *LOWER LUER PORT*
5. *UPPER LUER PORT*
6. *ROTATIONAL DIAL*
7. *EXPANSION KNOB*
8. *WHITE HANDLE*
9. *SOFT GRIP*

PROSTAGRIP™ DEVICE DESCRIPTION

Each sterile package includes one single-patient–use *PROSTAGRIP™ Prostatic Manipulator Device*. The *PROSTAGRIP™ DEVICE* features a rotating device tip ① that holds four purple radially expanding grippers ② on the distal end (patient's side) of its curved, 22 Fr shaft ③. A lower luer port ④ and an upper luer port ⑤ can provide fluid flow to and/or from the surgical site. The rotational dial ⑥ allows the device tip to rotate the prostate gland about the axis of the prostatic urethra. The purple expansion knob ⑦ on the white handle ⑧ is turned clockwise to deploy the grippers and counter-clockwise to retract the grippers back into the device tip. The white handle and soft grip ⑨ provide the surgeon with an ergonomic interface for control of the *PROSTAGRIP™ DEVICE*.

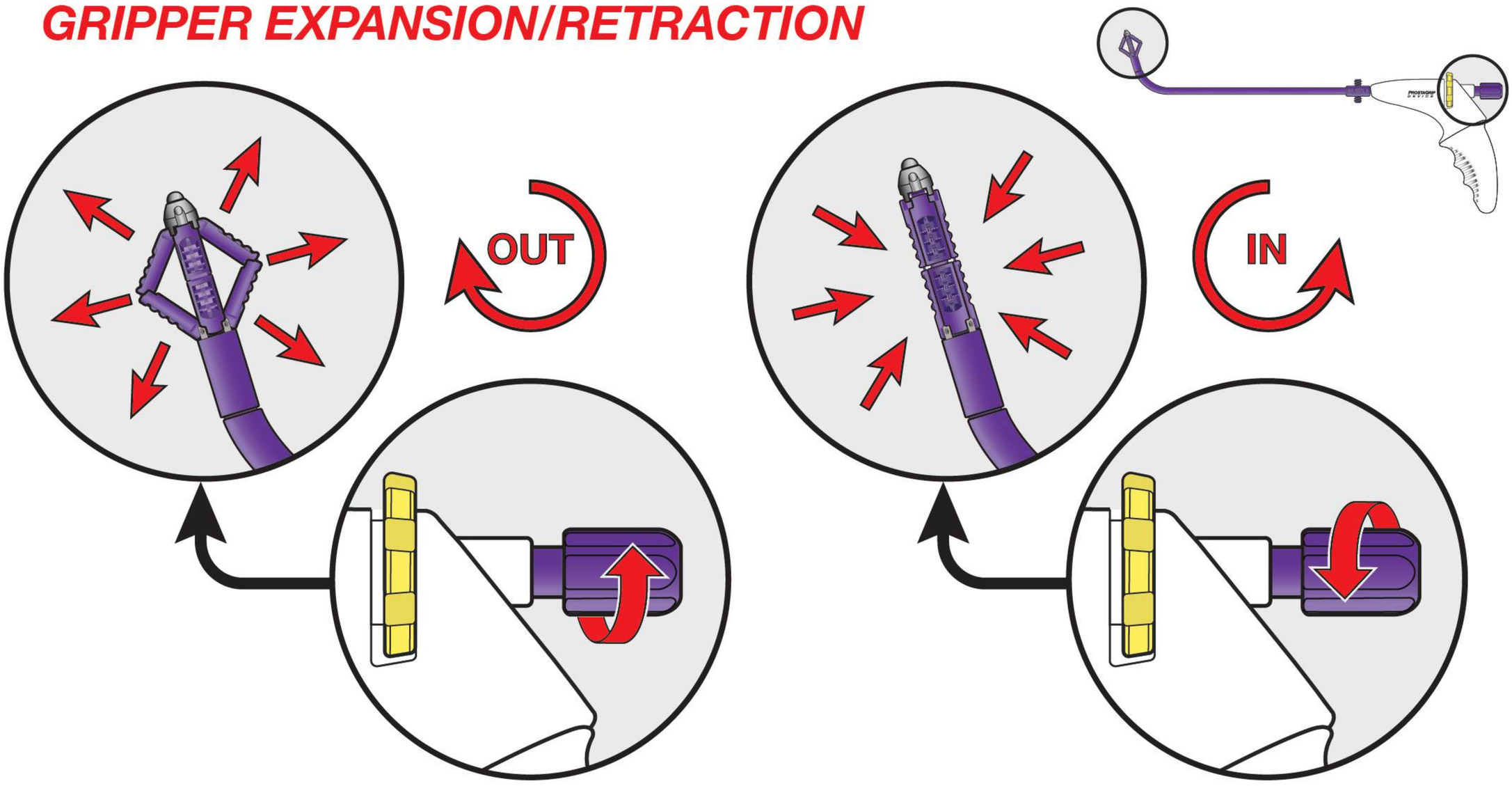
INDICATIONS

The *PROSTAGRIP™ DEVICE* is indicated for use in surgical procedures to facilitate the manipulation of the prostate.

USSOLUTIONS®

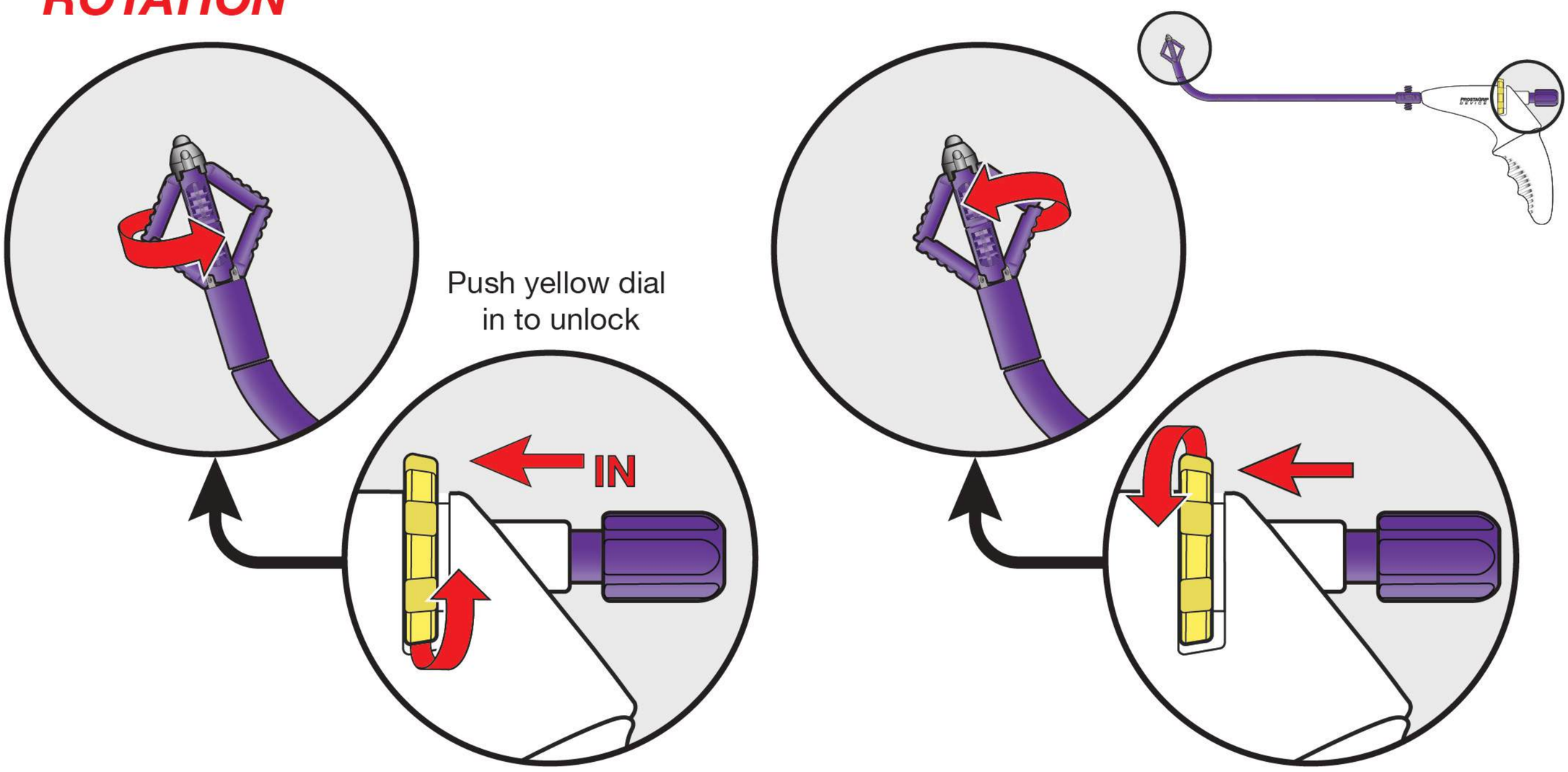
PROSTAGRIP™ DEVICE FUNCTIONS

GRIPPER EXPANSION/RETRACTION



Turn the purple expansion knob clockwise to expand out the purple grippers on the device tip; turn the expansion knob counter-clockwise to retract in the grippers. Prior to device removal from the prostate and patient, ensure that the purple grippers are fully retracted by turning the purple expansion knob counter-clockwise until it reaches a hard stop. Ensure the device moves easily within the urethra prior to its removal.

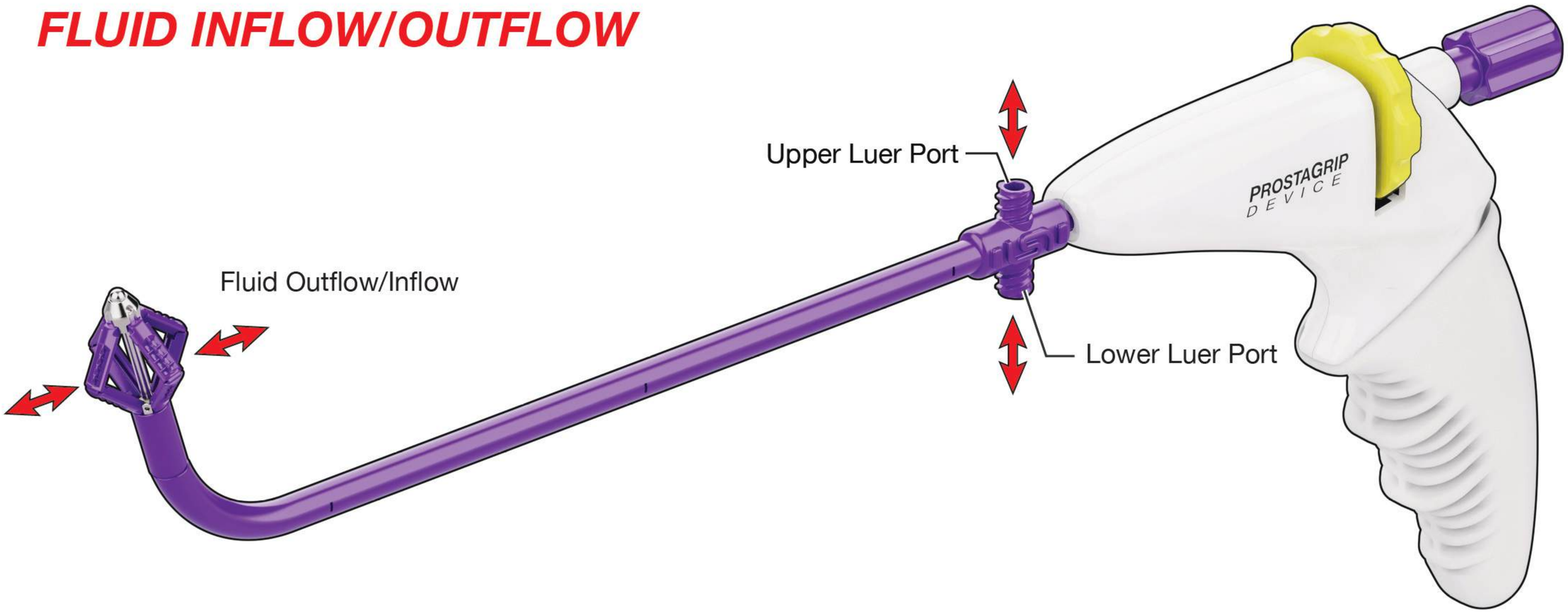
ROTATION



Push the yellow rotational dial forward to unlock. While maintaining forward pressure on the dial, rotate dial in either direction to rotate purple grippers. The yellow dial springs back to its locked position when released and holds the device tip in the desired orientation.

PROSTAGRIP™ DEVICE FUNCTIONS

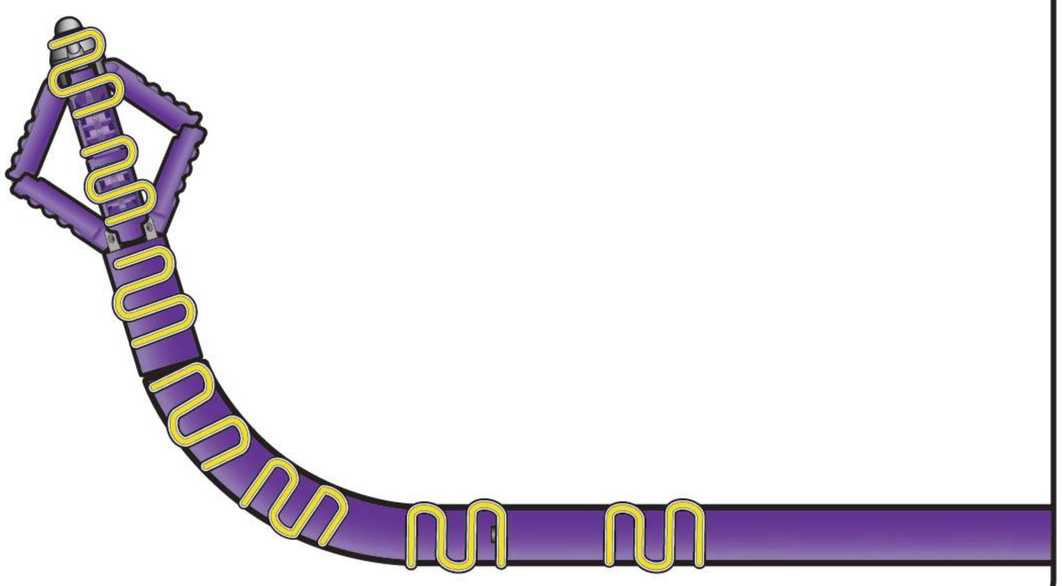
FLUID INFLOW/OUTFLOW



Fluid can be drained from and infused to the surgical site through the upper luer port and/or lower luer port if desired.

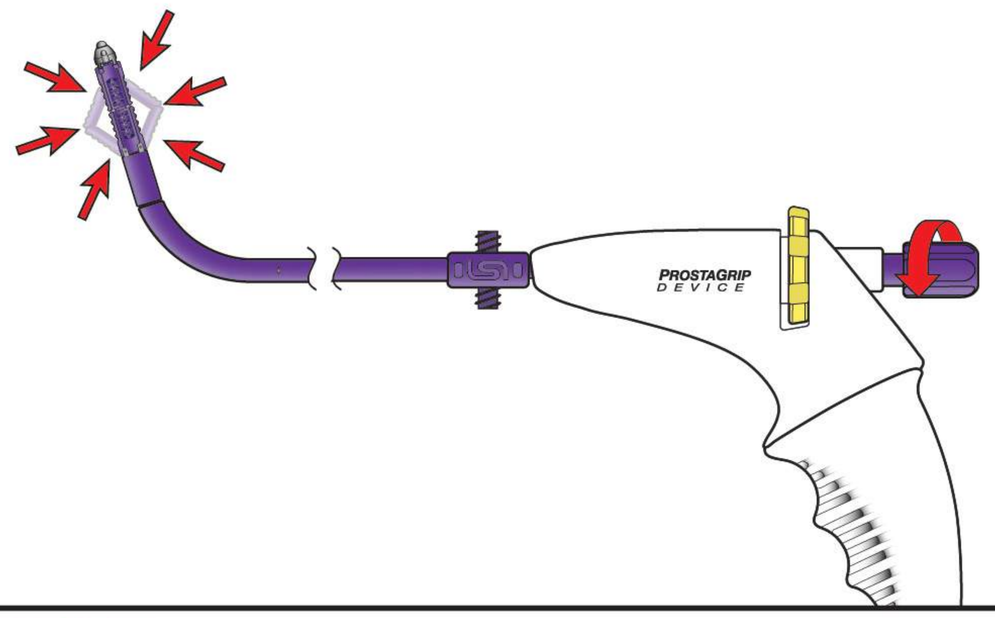
PREPARATION & PLACEMENT

1 LUBRICATE



LUBRICATE device tip and shaft with water-soluble lubricant while the grippers are fully expanded.

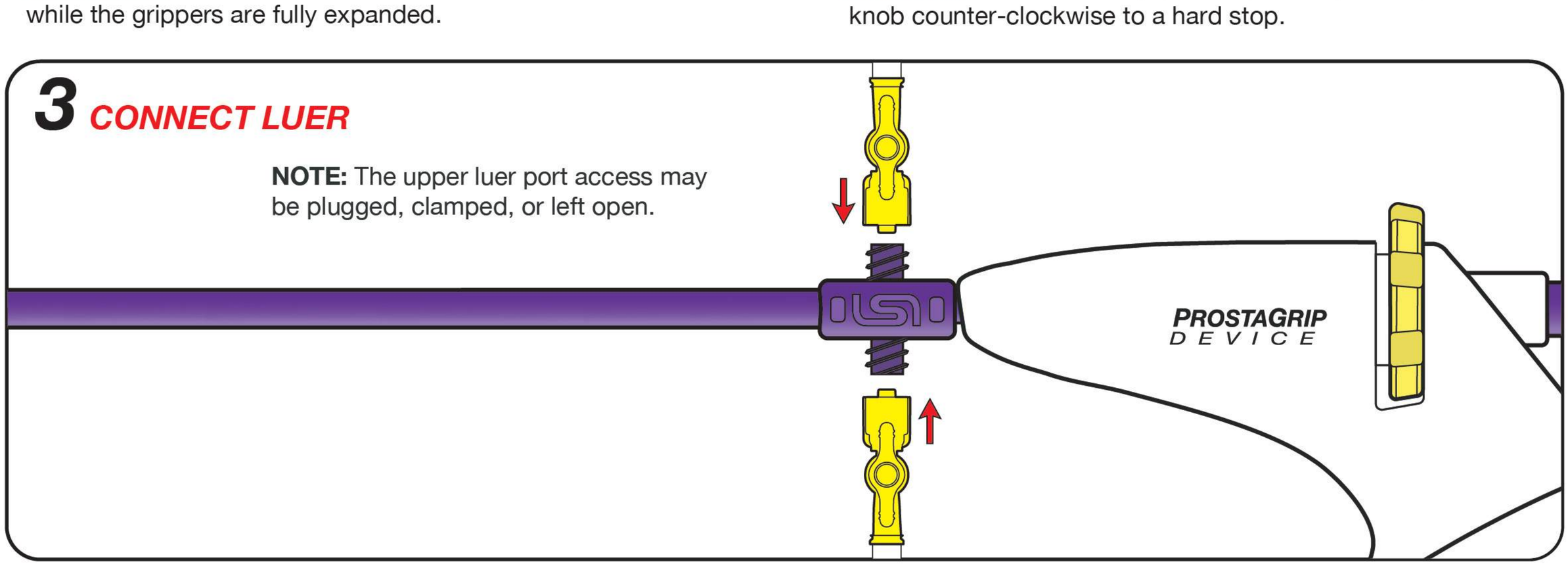
2 RETRACT



RETRACT the lubricated grippers by turning the expansion knob counter-clockwise to a hard stop.

3 CONNECT LUER

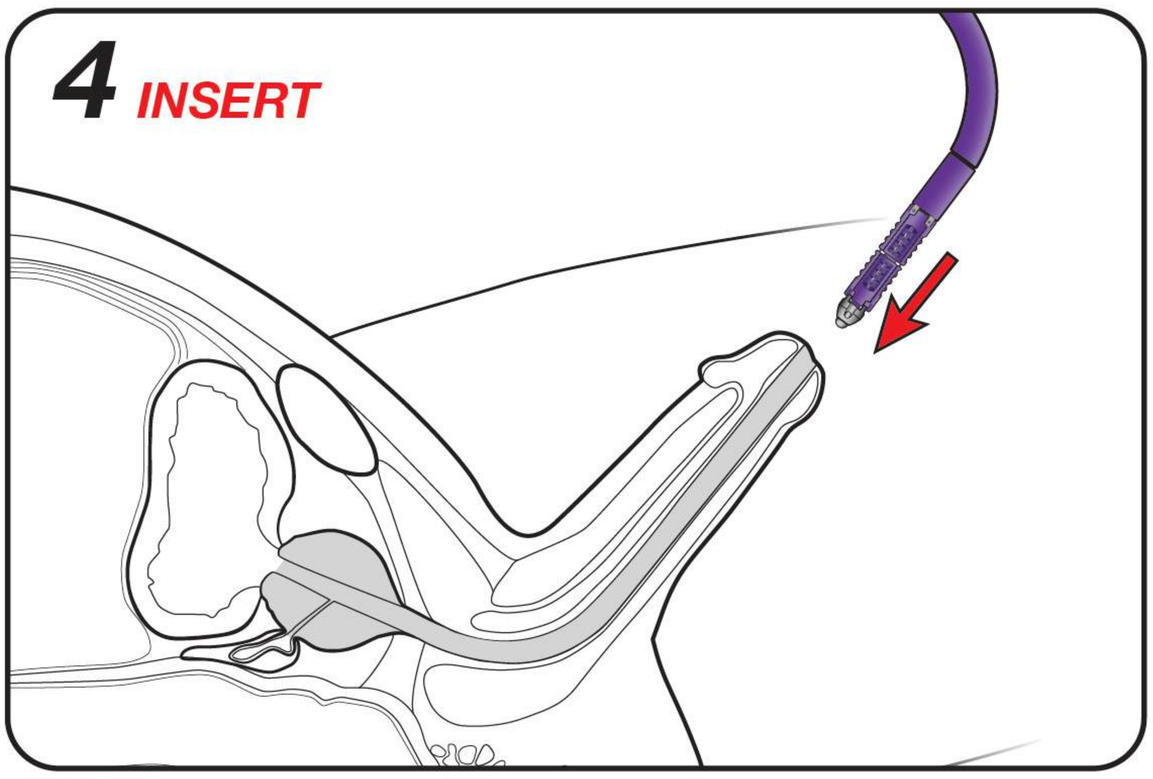
NOTE: The upper luer port access may be plugged, clamped, or left open.



CONNECT a stopcock with standard luer fitting to the luer port(s) to infuse or drain fluids at the surgeon's discretion.

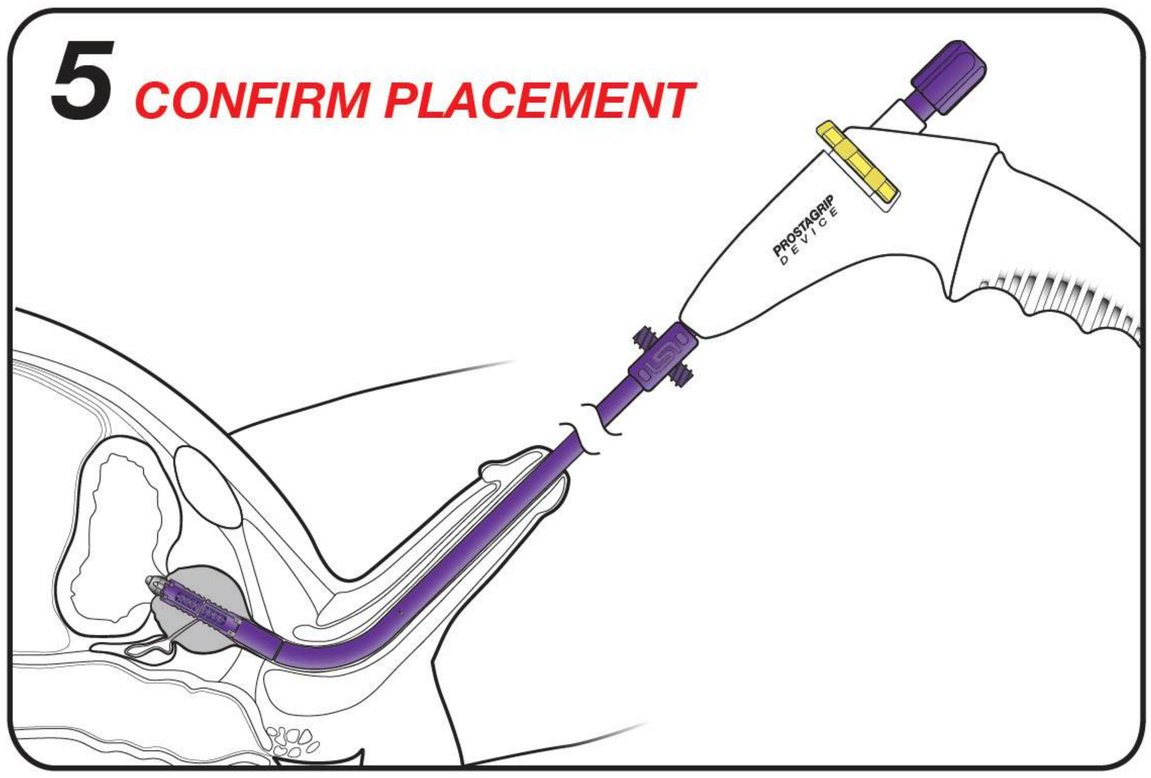
PREPARATION & PLACEMENT

4 INSERT



INSERT the *PROSTAGRIP™ DEVICE* through the urethra to the surgical site; use routine urethral preparation technique prior to *PROSTAGRIP™ DEVICE* insertion. **NOTE:** The grippers are intended to gently engage and distract tissue structures under appropriate visualization.

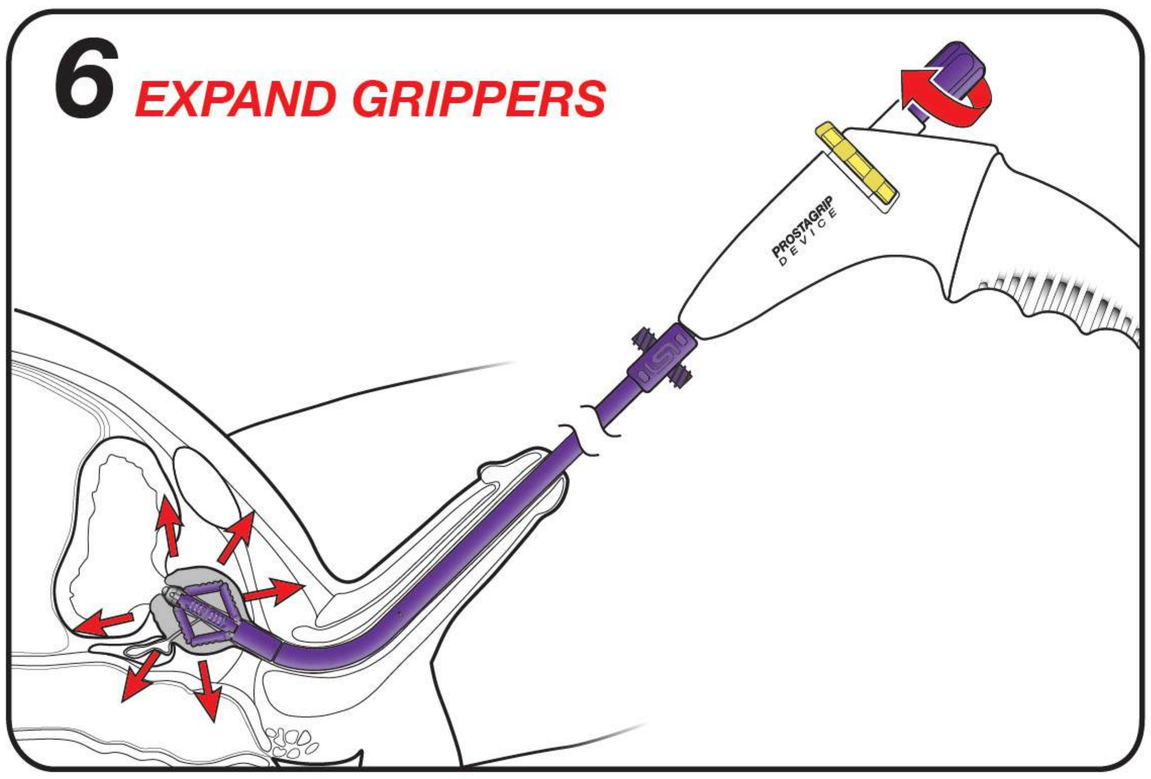
5 CONFIRM PLACEMENT



CONFIRM PLACEMENT of the *PROSTAGRIP™ DEVICE* in the desired location under visualization and/or by palpation. **NOTE:** This device is intended to move or manipulate tissue as an aid to visualization and dissection; it is not intended to directly dissect tissue.

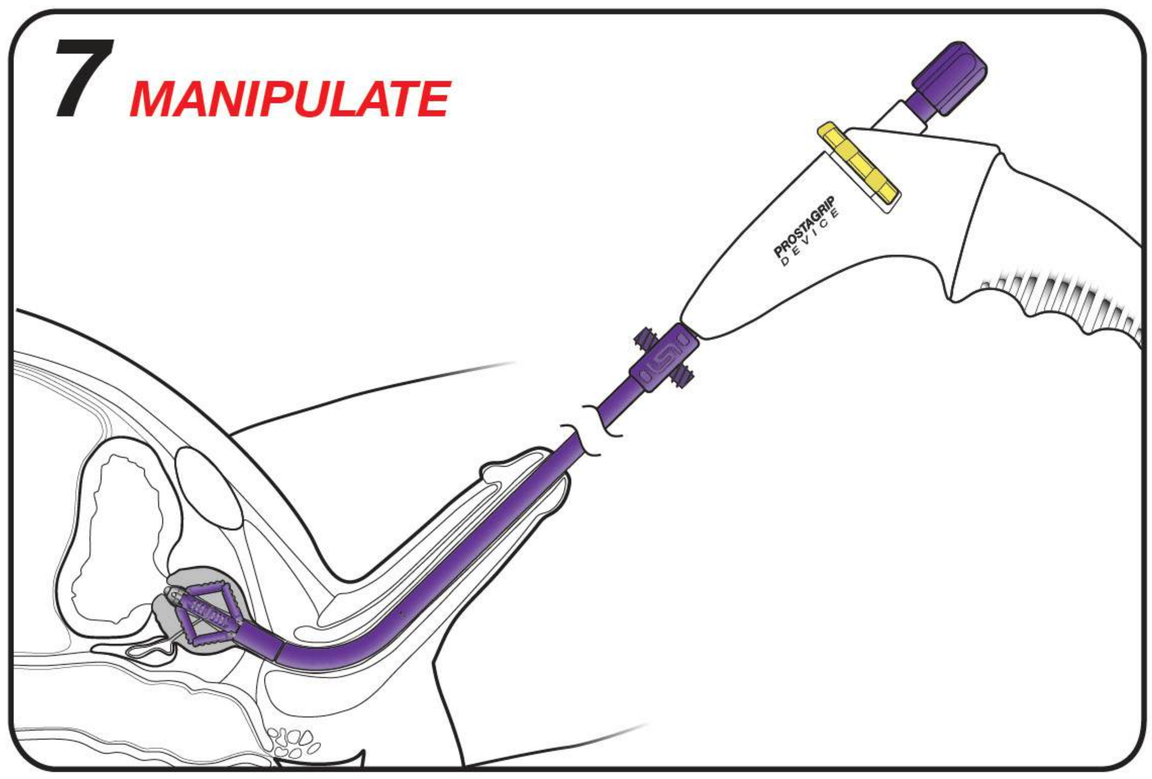
OPERATIVE USE

6 EXPAND GRIPPERS



EXPAND GRIPPERS by turning the expansion knob clockwise to engage the targeted tissue per the surgeon's discretion.

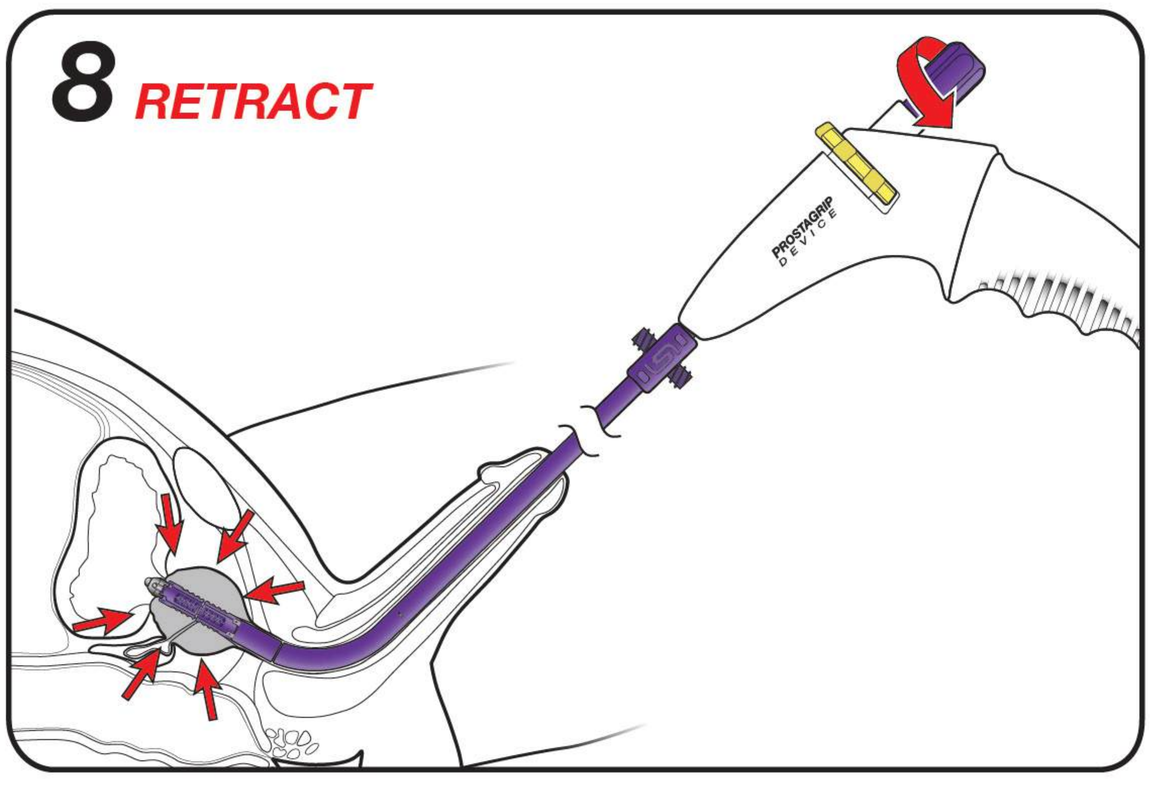
7 MANIPULATE



MANIPULATE the prostate and periprostatic tissue using the *PROSTAGRIP™ DEVICE* rotational dial with the grippers secured within the prostate.

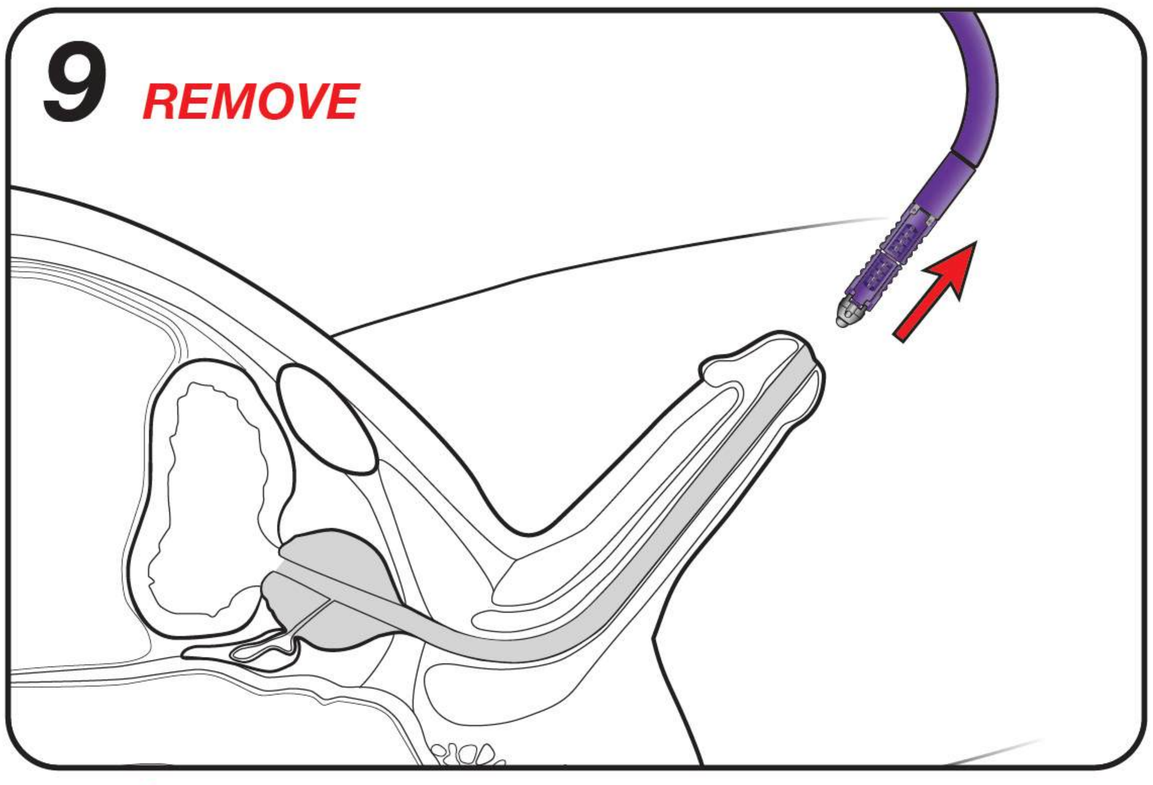
REMOVAL

8 RETRACT



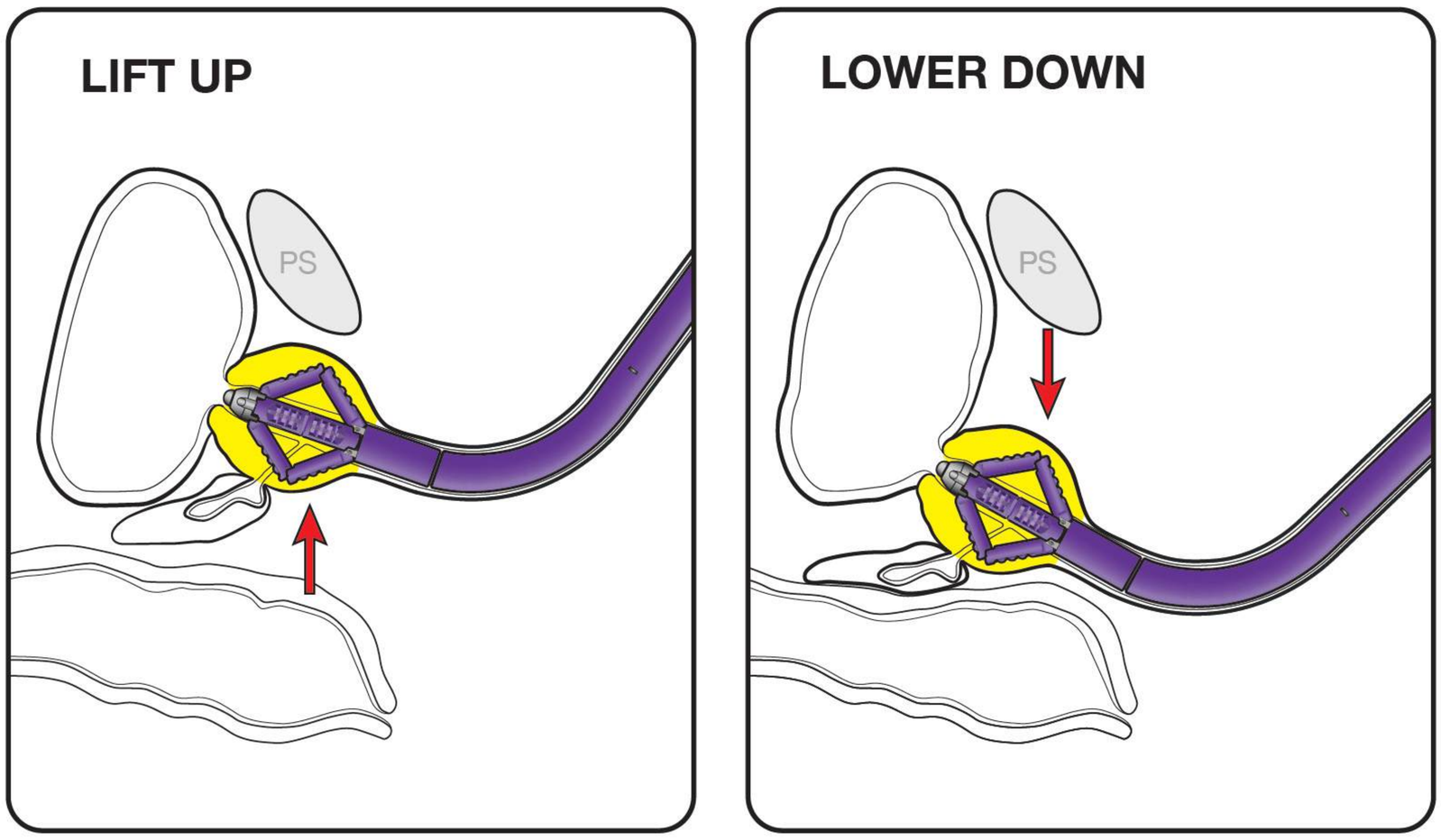
RETRACT the grippers by turning the expansion knob counter-clockwise to a hard stop. Ensure that the grippers are fully retracted by visualization, or release of the expanded tissue and/or confirming easy device tip passage through the

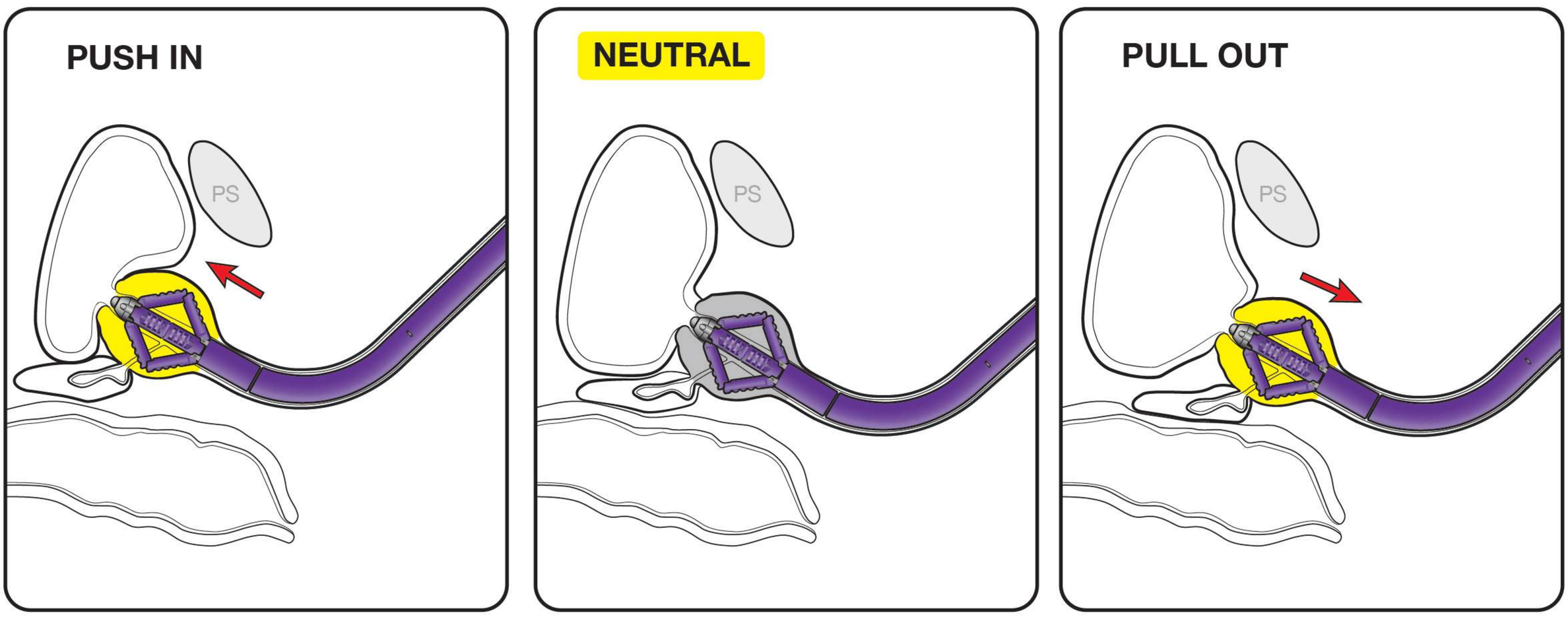
9 REMOVE

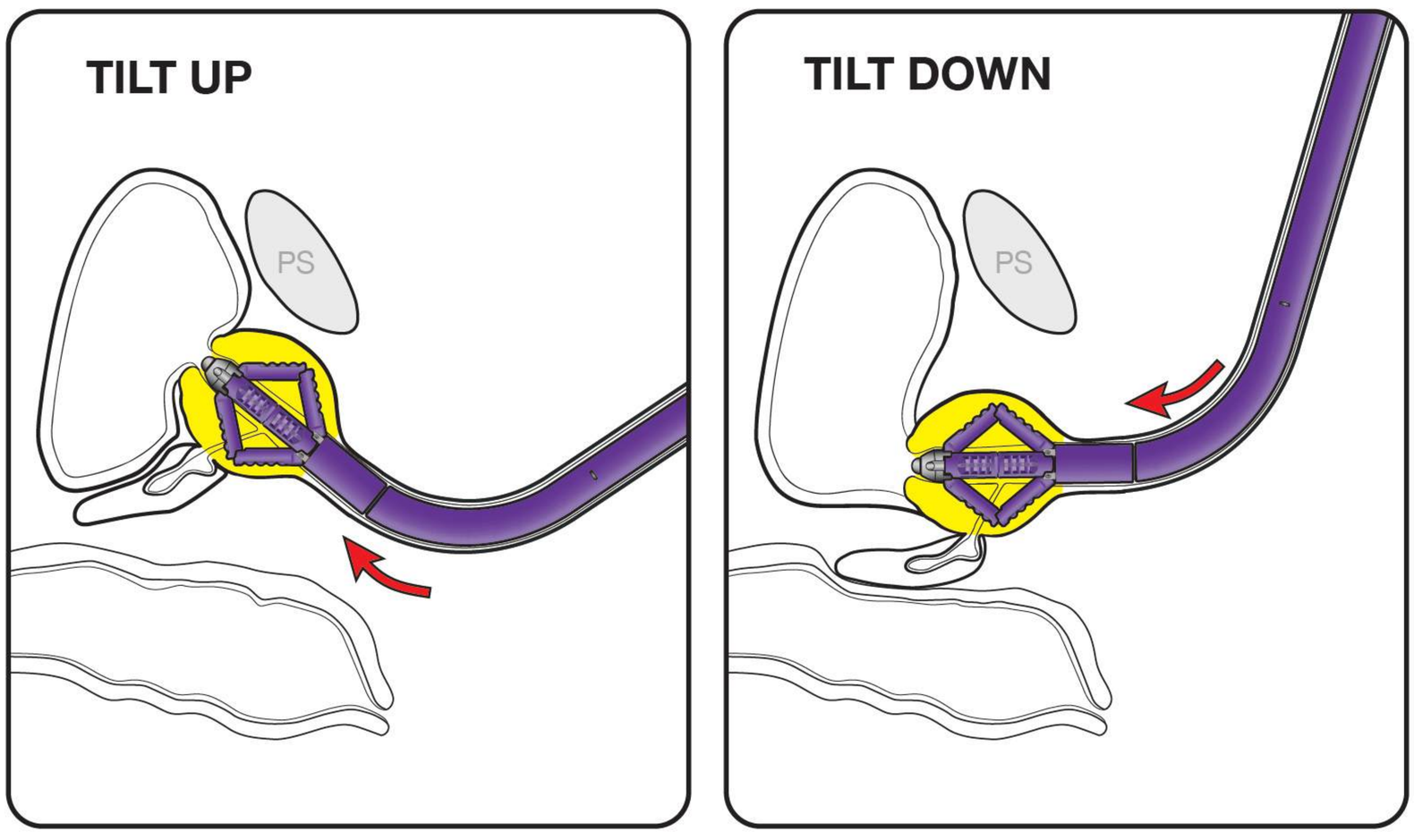


REMOVE the *PROSTAGRIP™ DEVICE* gently from the prostatic specimen and the surgical site with the grippers fully retracted.

PROSTATIC MANIPULATION SAGITTAL VIEW

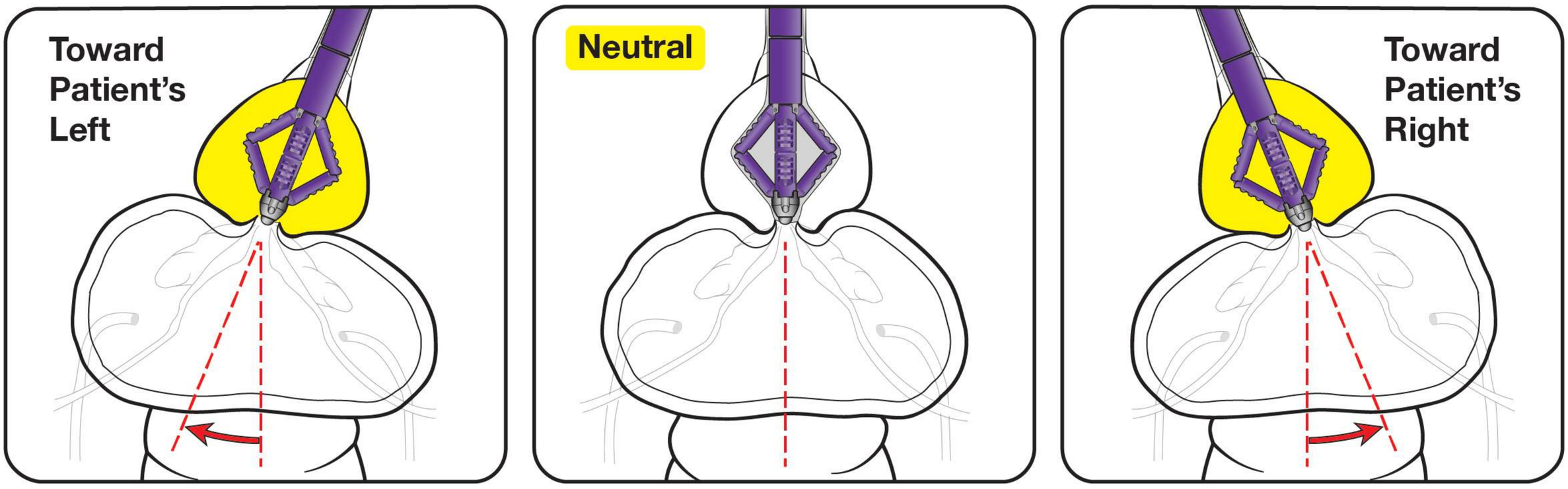




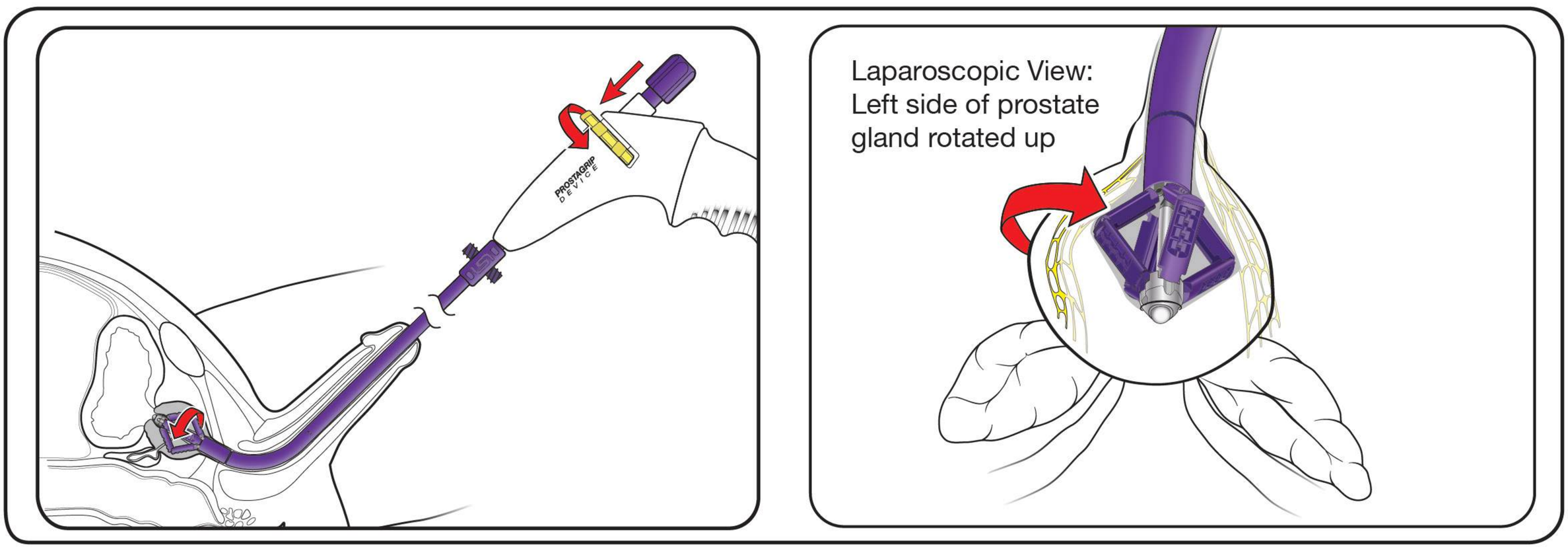


PROSTATIC ANGULATION

ANGULATION - Top (anteroposterior) view (with prostate & bladder in cross section)

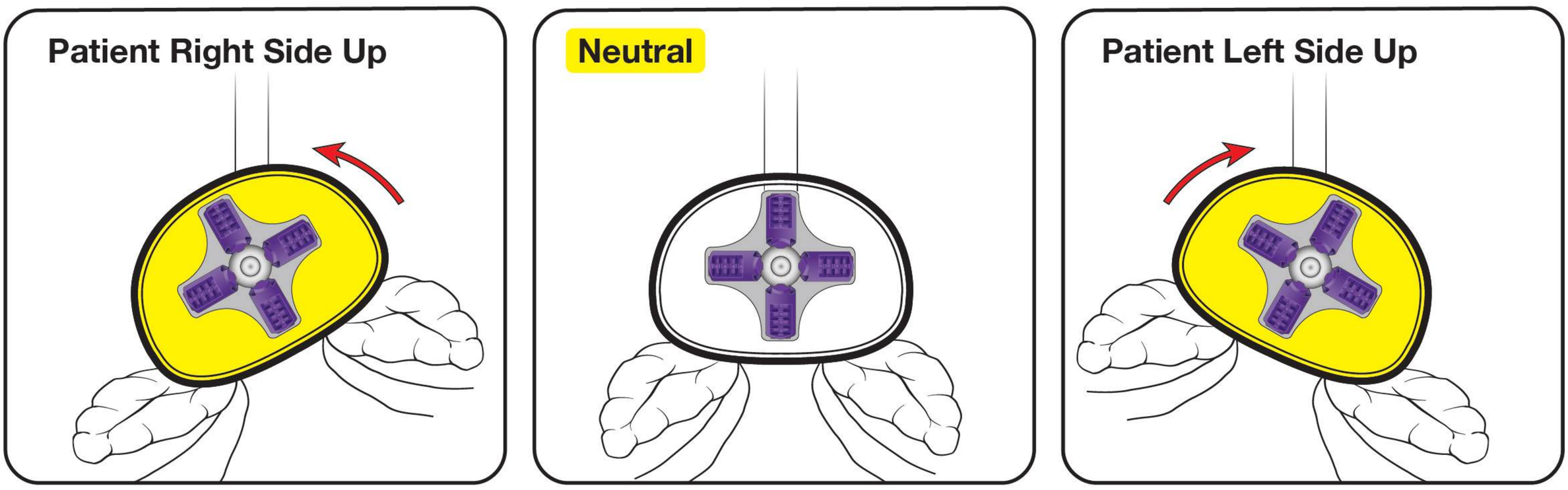


PROSTATIC ROTATION



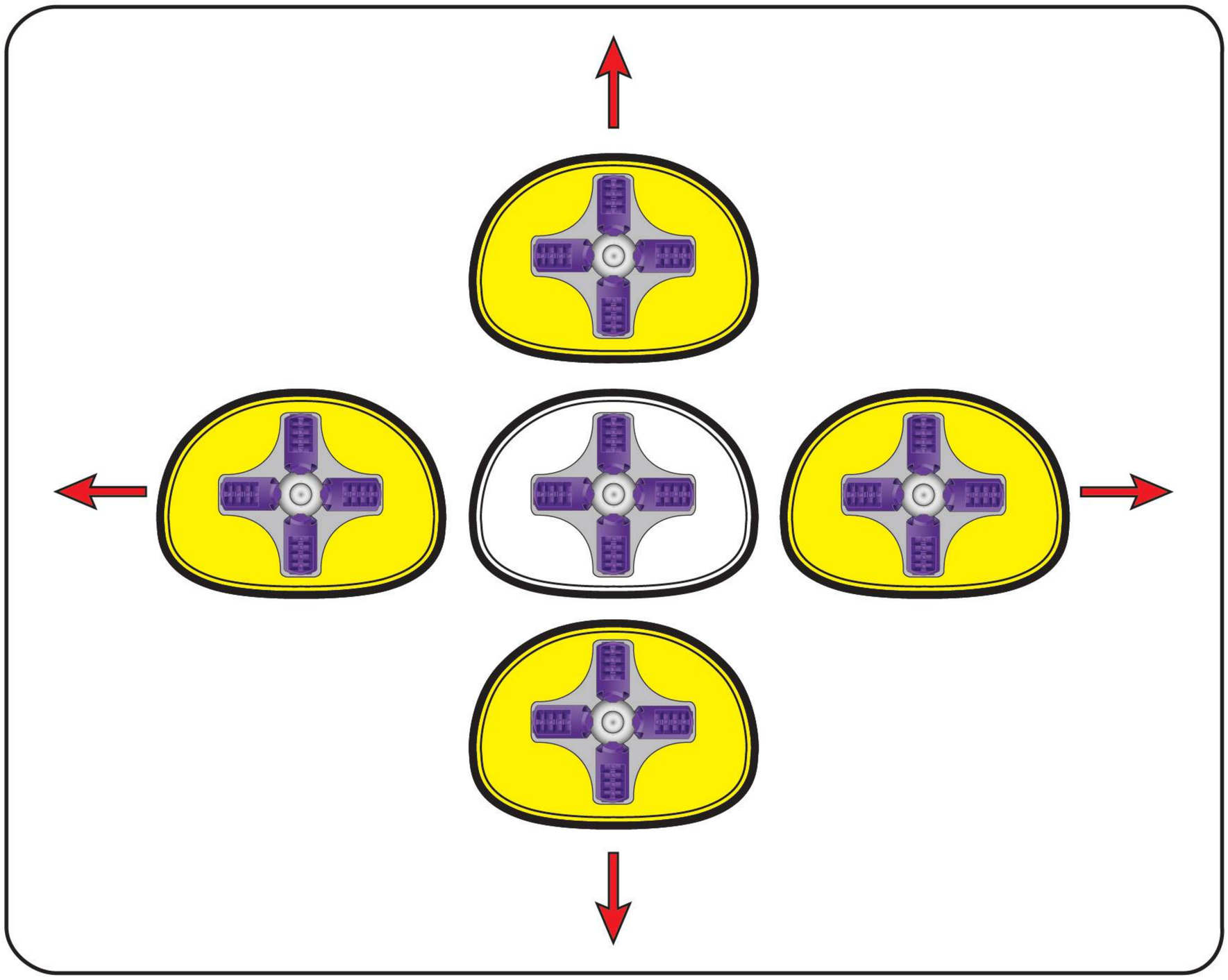
Rotate the prostate by pushing the yellow rotational dial forward to unlock, and maintaining forward pressure until the prostate is in the desired rotational position; release of forward pressure on the rotational dial locks the rotational dial and grippers in that position.

ROTATION - End view along the prostatic urethral axis

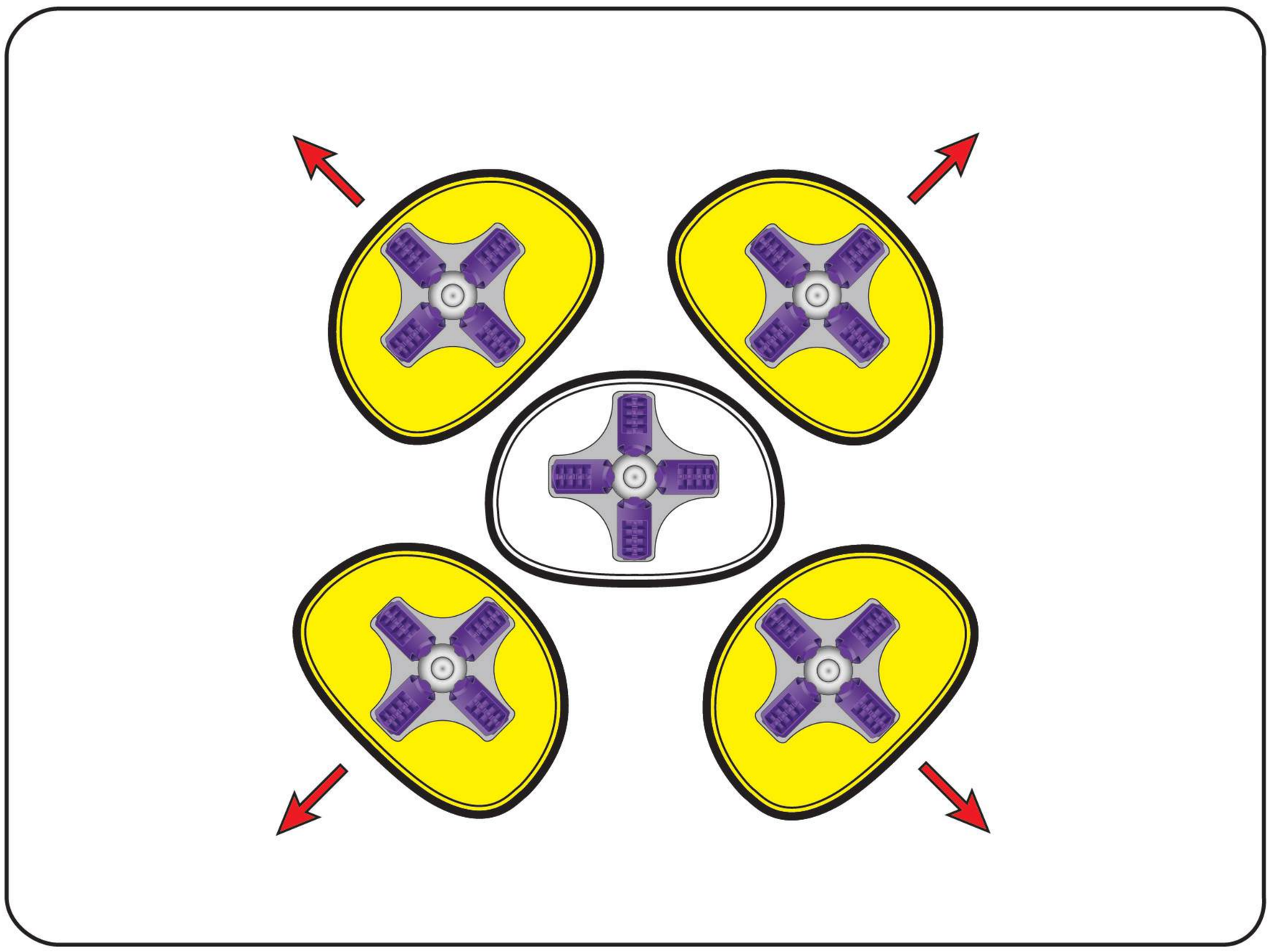


RADIAL DISTRACTION

End view along the prostatic urethral axis



The prostate can be moved from its anatomical location throughout the dissection process, per the surgeon's preference. Direct up-and-down and side-to-side movement is shown above.



The surgeon can also elect to use combinations of movement integrating up-and-down and side-to-side movement, shown above with rotation, along with any combination of specimen tilting, angulation, and/or pushing in or out.

ACTIONS:
After the *PROSTAGRIP™ DEVICE* is inserted into the surgical site and appropriately positioned within the prostate, turning the expansion knob clockwise will expand the grippers. The *PROSTAGRIP™ DEVICE* enables the surgeon to lift, lower, push in, pull out, tilt, and angle tissue to facilitate visualization and dissection. Rotating the rotational dial allows rotational positioning of the targeted tissue site.

CONTRAINDICATIONS:
- The *PROSTAGRIP™ DEVICE* is contraindicated for use under conditions that, in the surgeon's judgment, create unacceptable risk of patient injury during placement, use, and/or removal.
- The *PROSTAGRIP™ DEVICE* is not intended for use in patients who are contraindicated for retrograde urological procedures.
- The *PROSTAGRIP™ DEVICE* is contraindicated for use in patients who have the presence of tight strictures or anatomy that precludes gentle passage of the device.

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 before employing the *PROSTAGRIP™ DEVICE.*
- Applications other than for urologic procedures can result in damage to the *PROSTAGRIP™ DEVICE*, 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.
- As in all surgical procedures, avoid applying excessive or prolonged tension, compression, or torque on tissue.
- Do not reuse, reprocess, or resterilize this product. The *PROSTAGRIP™ DEVICE* 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 open (unsealed), unused, expired, or damaged *PROSTAGRIP™ DEVICE*.
- Each *PROSTAGRIP™ DEVICE*, along with packaging, must be inspected, handled, and disposed of consistent with standard, accepted medical device disposal procedures.
- The *PROSTAGRIP™ DEVICE* is not insulated against any electrical energy. When using electrosurgical device techniques, avoid contacting the *PROSTAGRIP™ DEVICE* 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.
- Avoid thermal, electrical, or laser damage to, or direct cutting against, the plastic grippers during tissue handling and dissection.
- Always ensure that the device tip is positioned as intended while expanding the grippers.

ADVERSE REACTIONS:
No documented adverse reactions.

FIG. 2 PRODUCT ORDERING — **SUPPLIED:** STERILE

	REORDER	PRODUCT	DESCRIPTION
 x 6	REF 081358	***PROSTAGRIP™ DEVICE***	*Box of (6) Devices*

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Symbol Glossary: www.lsisolutions.com/symbols

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