RETROPERC™

Flexible Ureteroscopy-Guided Retrograde Nephrostomy Wire Puncture Set

Manufactured for:

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LBL-01, Rev E

INDICATIONS FOR USE

Used to gain precise percutaneous access to the kidney by means of controlled fine wire puncture from within the collecting system. This set and suggested procedure are particularly well-suited for gaining percutaneous access to an unobstructed, non-dilated collecting system when pursuing a planned course of endourological intervention. Fluoroscopic control is necessary throughout this procedure. Intended for one-time use.

HOW SUPPLIED

Supplied sterilized by ethylene oxide gas in peel-open packages. Store in a dark, dry, cool place. Avoid extended exposure to light.

SET CONTAINS

- 2.7 French (0.97 mm) radiopaque TFE sheath 91 cm long with plastic pin vise actuator housing 0.019 inch (0.52 mm) stainless steel mandrel wire with distal 29 cm narrowed to 0.0175 inch (0.44 mm) diameter with puncture tip, total wire length 163 cm
- Coaxial microintroducer catheter: Outer catheter 5.0 French, 30 cm long; inner dilator 3.0 French (1.0 mm).

***CAUTION:* Sterile if the package is unopened or undamaged. Do not use if package is damaged.**
***CAUTION:* Federal Law (USA) restricts this device to sale by or on the order of a physician.**

WARNINGS

- For single use only. Do not reuse, reprocess or resterilize.
- After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.
- Use of this device should be restricted to use by or under the supervision of physicians trained in urologic and percutaneous renal access procedures.
- Excessive force or tension applied to the puncture wire or other instruments may cause laceration of the kidney
- In the event of kinking of the puncture wire or catheters, gently remove from patient. Do not re-use.
- Use in the setting of infection or anticoagulation may cause severe illness or death.

ACCESSORIES (not included)

- Flexible ureteroscope
- Ureteral access sheath
- Fluoroscopy
- 0.038 inch (0.97 mm) kink-resistant standard working wire guide, x 2
- Cystoscopy bed with padded lithotomy stirrups (suggested position)

SUGGESTED INSTRUCTIONS FOR USING RETROPERC™ FLEXIBLE URETEROSCOPY-GUIDED RETROGRADE NEPHROSTOMY WIRE PUNCTURE SET

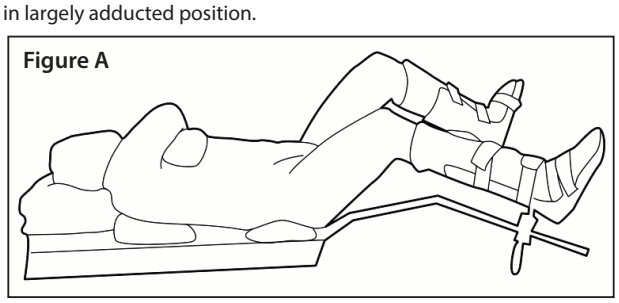
1. Review CT images of kidney and flank anatomy. Consider potential upper, mid, and lower pole tracts and their relation to adjacent organs and distance to skin. Select safe puncture tract with adequate margin for safety.

   ***CAUTION:* Patients without a safe tract, such as adjacent retrorenal organs, are not candidates for this procedure.**

   NOTE: In patients with BMI above 40 kg/m² or significant hydronephrosis it is difficult to direct the puncture wire to emerge at the flank. Such patients are poor candidates for this procedure.

   NOTE: Ureteral stent is placed 7-10 days prior to procedure to dilate ureter for easier and safer ureteral access sheath placement.
2. Mark the posterior axillary line (PAL) and 12th rib with sterile skin marker.
3. Suggested position is Barts 'flank-free' modified supine[1] position (**Figure A**). Patient is placed in lithotomy position with slight (15 degree) elevation of ipsilateral shoulder and hips, with ipsilateral arm resting across the chest over a pillow, gently taped in position. Pad all pressure points including peroneal nerves. Ensure that the patient and all limbs are resting in a neutral position with legs maintained in largely adducted position.

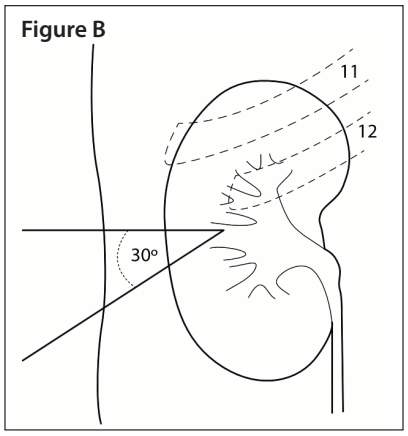
Figure A



4. Perform retrograde pyelogram. Place a 0.038 inch (0.97 mm) wire guide into renal pelvis with aid of a cystoscope. Remove cystoscope and carefully place ureteral access sheath over wire guide into ureter under fluoroscopic guidance.

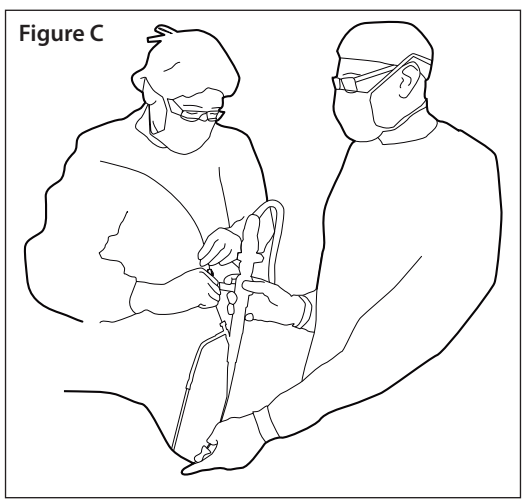
   CAUTION: Inspect the puncture wire provided in this set to be certain the wire tip does not protrude beyond the sheath but is about 1 mm inside the end of the sheath (The pin vise actuator is locked on the wire when shipped). It is equally important that the puncture wire point not be retracted more than 2 mm from the tip of the sheath.
5. Advance flexible ureteroscope into renal pelvis and perform bolus injection of contrast to delineate calyceal anatomy.
6. Advance the flexible ureteroscope under fluoroscopic guidance and direct vision into the selected posterior calyx. A posterior calyx in the middle or lower pole is preferred, depending on the procedure planned and CT scan review. Intercostal access is avoided due to twelfth-rib obstruction or puncture of adjacent viscera such as liver, spleen, or lung
7. Inject a bolus of contrast at this point if desired. Puncture trajectory between horizontal and 30 degrees below horizontal in the anterior-posterior (AP) plane is selected for successful wire puncture (**Figure B**).

Figure B



8. While the surgeon maintains position of the ureteroscope in the selected calyx, an assistant carefully inserts the puncture wire/TFE sheath ensemble into the ureteroscope working channel (**Figure C**) until the TFE sheath is observed exiting the tip of the ureteroscope.

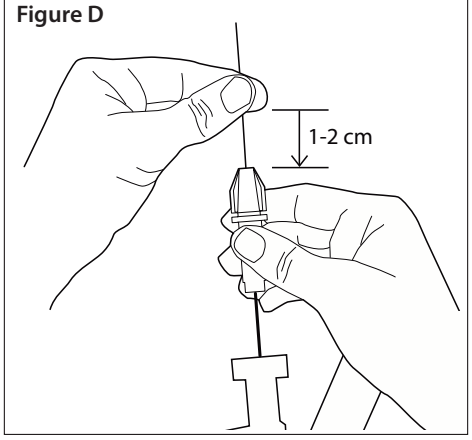
Figure C



9. The assistant firmly grasps the base of the pin vise actuator between the thumb and index finger and frees the puncture wire by twisting the cap in a counterclockwise fashion. Maintaining the thumb/index finger grasp on the pin vise actuator base, the assistant slowly advances the fine wire in 1-2 cm increments (**Figure D**) to perform the puncture into and through parenchyma, capsule, fat, muscle, fascia and skin. Place hemostat on wire tip at flank.

   WARNING: The flexible ureteroscope may back out of the selected calyx or "cobra" away from the calyx as the puncture wire is advanced. Failure to maintain ureteroscope tip at end of calyx during puncture wire advancement may cause infundibular puncture thus risking hemorrhage. Position of ureteroscope is confirmed with fluoroscopy during wire advancement.

Figure D



CAUTION: ***Close AP fluoroscopic imaging of the ureteroscope tip and guidance of the advancing puncture wire is necessary to ensure a puncture tract between horizontal and 30 degrees below horizontal. Selection of a posterior calyx usually prevents anterior puncture. Lateral imaging may be useful to confirm posterior trajectory.***

NOTE: The wire point may "tent" just beneath the skin exit site. A scalpel nick is sometimes necessary to deliver the wire through the skin.

10. Palpate the tip of the 12th rib and consider the location of wire emergence in relation to this. CT scan may be reviewed at this time to evaluate anatomy surrounding tip of 12th rib on CT images to ensure safe puncture tract.

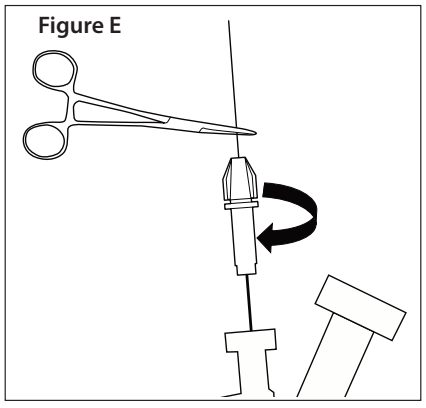
CAUTION: ***An exit site anterior to the posterior axillary line must not be used to develop a tract. Dilation of such a tract significantly increases the risk of puncturing adjacent viscera. Intercostal tracts are generally avoided. The wire must be withdrawn and the flexible ureteroscope repositioned so the puncture wire will exit in a preferred location.***

a. Extend skin incision to 5 mm. While supporting wire tip at flank with hemostat, further advance the wire into the ureteroscope until approximately 37 cm of wire is externally visible outside the flank.

CAUTION: ***The wire must not be pulled at the flank since this could lacerate the kidney or act to "saw" the puncture tract.***

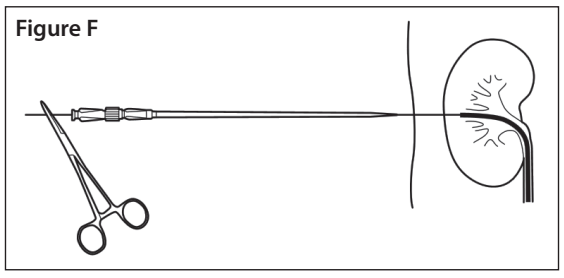
b. After 37 cm of wire is delivered out of the flank, twist the pin vise actuator cap in a clockwise fashion to the 'locked' position and place reinforcing hemostat clamp on the puncture wire just above the pin-vise actuator (**Figure E**).

Figure E



c. Load coaxial catheter over puncture wire at the flank and stabilize puncture wire tip behind coaxial catheter at the flank with hemostat (**Figure F**).

Figure F



d. Advance coaxial catheter until catheter tip reaches the flexible ureteroscope tip on fluoroscopy while holding the hemostat on puncture wire tip for stability.

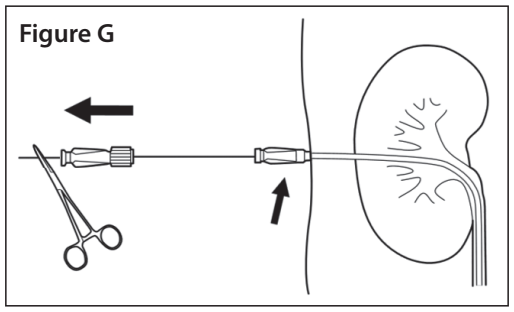
e. Carefully maintaining coaxial catheter tip-to-flexible ureteroscope contact and allowing no gap, gently draw the flexible ureteroscope downward while advancing the coaxial catheter until the coaxial catheter hub reaches the flank skin.

CAUTION: ***It is essential to maintain close approximation of the coaxial catheter tip to the flexible ureteroscope tip under fluoroscopy as this is performed. Failure to do so could result in laceration of the kidney with the puncture wire.***

f. Remove hemostat above pin vise actuator and twist pin vise actuator cap in a counterclockwise fashion to release the wire.

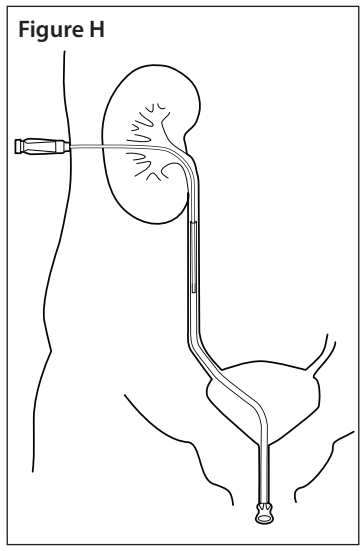
g. Twist upper coaxial catheter Luer hub in a counterclockwise fashion in relation to lower hub. Remove the inner dilator and puncture wire while maintaining position of outer catheter hub at flank skin (**Figure G**).

Figure G



h. Carefully remove the flexible ureteroscope, pin vise actuator and wire sheath, while maintaining both the outer catheter hub at the flank skin and the ureteral access sheath (**Figure H**).

Figure H



i. Advance 0.038 inch (0.97 mm) diameter working wire guide antegrade through the outer coaxial catheter until the wire emerges from the ureteral access sheath at the urethra.

j. Remove the outer coaxial catheter at the flank while maintaining the working wire guide position.

k. Advance a second 0.038 inch (0.97 mm) diameter wire retrograde through ureteral access sheath into renal pelvis.

l. Remove ureteral access sheath and secure working wire outside of urethra.

m. To opacify collecting system for nephrostomy tract dilation, a catheter may be placed retrograde over second wire if appropriate.

n. Proceed with planned endourological procedure.

REFERENCES

Bach C et al. "The Barts 'flank-free' modified supine position for percutaneous nephrolithotomy". *Urol Int.* 2012;89(3):365-8.

Wynberg JB et al. "Body mass index predicts outcome of ureteroscopy-assisted retrograde nephrostomy for percutaneous nephrolithotomy". *J Endourol.* 2014 Sep;28(9):1071-7.

Wynberg JB et al. "Flexible ureteroscopy-directed retrograde nephrostomy for percutaneous nephrolithotomy: description of a technique". *J Endourol.* 2012 Oct;26(10):1268-74.

US PATENTS

8,888,787 and 8,771,287.

REF	Catalog number		Do not re-use
Rx ONLY	For provision and use only at a licensed physician's direction and under medical supervision		Consult instructions for use
STERILE EO	Sterilized using ethylene oxide		Do not resterilize
	Do not use if packaging is damaged		Latex free