NORFOLK VET PRODUCTS

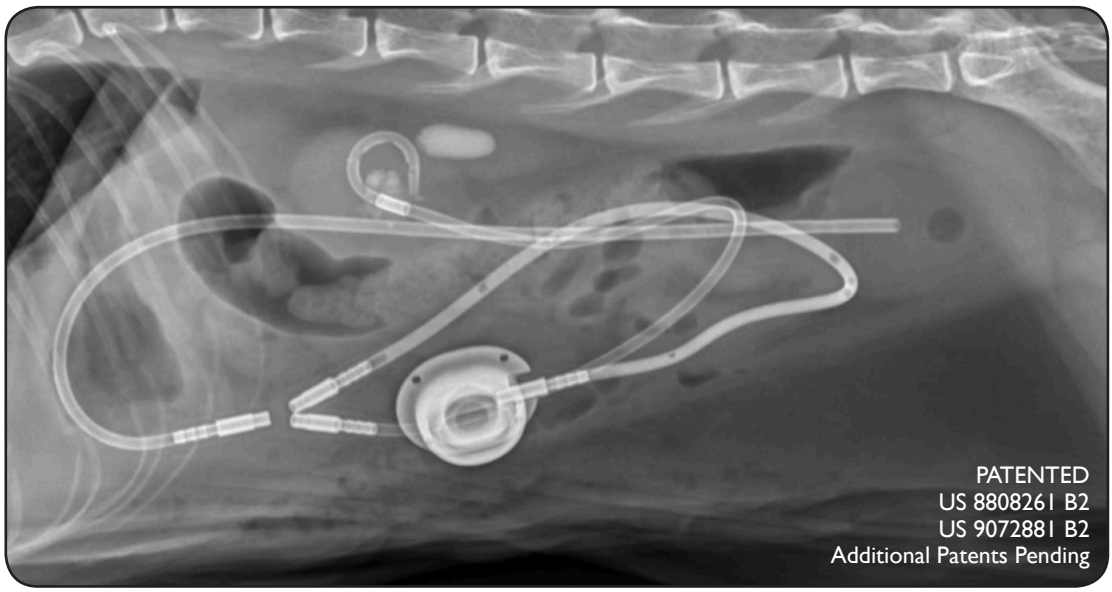
the SUB™ • a subcutaneous ureteral bypass system • making life easier for pets and vets •

SUB™ 3.0

A Subcutaneous Ureteral Bypass System

A Surgical Guide

provided by Drs. Allyson Berent and Chick Weisse



*The **New and Improved** Therapeutic Option for Dogs & Cats to Bypass Ureteral Obstructions*

Designed and Developed in Collaboration with Veterinarians

Specialty Medical Devices For The Veterinary Community

the SUB™
Veterinary Use Only

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SUB™ 3.0

A Subcutaneous Ureteral Bypass System

An Improved Therapeutic Option for Dogs & Cats Designed and Developed in Collaboration with Veterinarians

GUIDELINES WHEN USING THE SUBCUTANEOUS URETERAL BYPASS (SUB™)

provided by Allyson Berent, DVM, DACVIM and Chick Weisse, VMD, DACVS

The development of an indwelling subcutaneous ureteral bypass (SUB™) device (**Figure 1**) utilizes a combination locking-loop nephrostomy catheter attached via a 3-arm "Y-connector," or a 4-arm "X-connector," to a straight cystostomy catheter and a SwirlPort™. This port allows for subcutaneous access to the device for flushing and drainage of the system, as necessary.[1-12] A similar bypass device in humans has been used with extensive urinary tract malignancies, ureteral strictures secondary to renal transplantation, when ureteral stenting is ineffective, or when traditional surgery fails or is contraindicated.[13-15] It has been shown to reduce complications associated with externalized nephrostomy tubes and improve quality of life. The SUB™ device was first designed in 2009 for veterinary patients and has been used in thousands of cats to date. It has also been used in a small number of dogs.[7] The SUB™ 3.0 device contains a locking-loop design to prevent migration of the nephrostomy catheter, but this can also be placed down the ureter without the lock as a ureterostomy catheter for smaller renal pelvises. A port is placed in the subcutaneous space that is used for flushing and sampling of urine as needed. This port is a design unique to this system to help maintain long-term patency and have access for urine sampling. The SUB™ 3.0 was redesigned to decrease some of the most common complications seen with prior models (e.g. kinks), decrease procedure times, minimize the subcutaneous dissection needed for the 1.0 and 2.0 version, and to make the device easier for the operator to exchange, when needed.

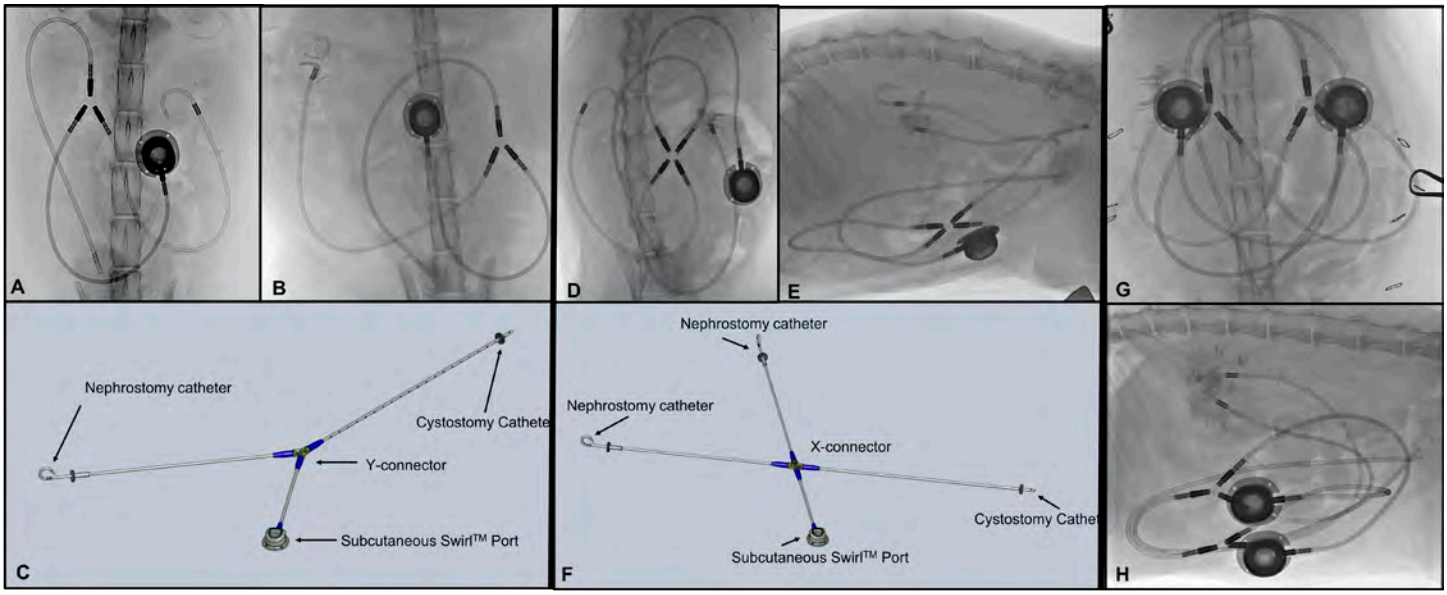


Figure 1: Schematic and Fluoroscopy image of the SUB™ 3.0 device (unilateral [A-C] and bilateral with "X-connector" [D-F], bilateral with 2 "Y-connectors" [G-H]). **A)** dorsoventral image after left sided SUB™ 3.0 placement. **B)** right sided SUB™ 3.0 placement with a locking-loop nephrostomy catheter. Notice the device is a ureterostomy catheter in Figure A, which is hooked up to a "Y-connector" with a straight bladder catheter and actuating tubing connecting the "Y-connector" to the subcutaneous port. **C)** Schematic of a unilateral SUB™ 3.0. **D)** Bilateral obstruction with an "X-connector" connecting bilateral nephrostomy/ureterostomy catheters to a single bladder catheter. **E)** Lateral fluoroscopic image of the bilateral device. **F)** Schematic of a bilateral SUB™ 3.0. **G-H)** Ventrodorsal and lateral fluoroscopic images of a bilateral obstruction using 2 3-way Y-connectors and 2 ports.

The use of the SUB™ device has been reported in various peer reviewed journals in both cats and dogs.[1-4] This device has been successfully placed and indwelling in patients since 2009. Traditionally, a shunting port was secured to the ventral abdominal wall, connecting the nephrostomy and cystostomy catheters directly (SUB™ 1.0 and 2.0)

(**Figure 2**), creating an artificial ureter, while also allowing sampling and flushing of the urinary system. In 2019, a modification of the SUB™ 2.0, named the SUB™ 3.0, was trialed in an attempt to further minimize some of the complications seen after evaluation of a large number of cats over a 10-year period; specifically kinking of the tubing at the entry to the body wall. By creating the SUB™ 3.0 (**Figure 1**) the tubing of the nephrostomy and cystostomy catheters remain indwelling within the abdomen and a 3rd catheter is connected to a port, which allows for access to the system without impacting urine flow if a kink were to occur. All 3 catheters are then connected in the abdomen to a "Y-connector". After more than a year of follow-up on a large number of cases in the authors' practice, as well as other key opinion leaders with great experience in SUB™ device placement, not a single kink was identified, and the rates of infection, mineralization and peri-operative blood clot occlusions did not increase over that time. Similar follow-up protocols were employed to that recommended for SUB™ 2.0.

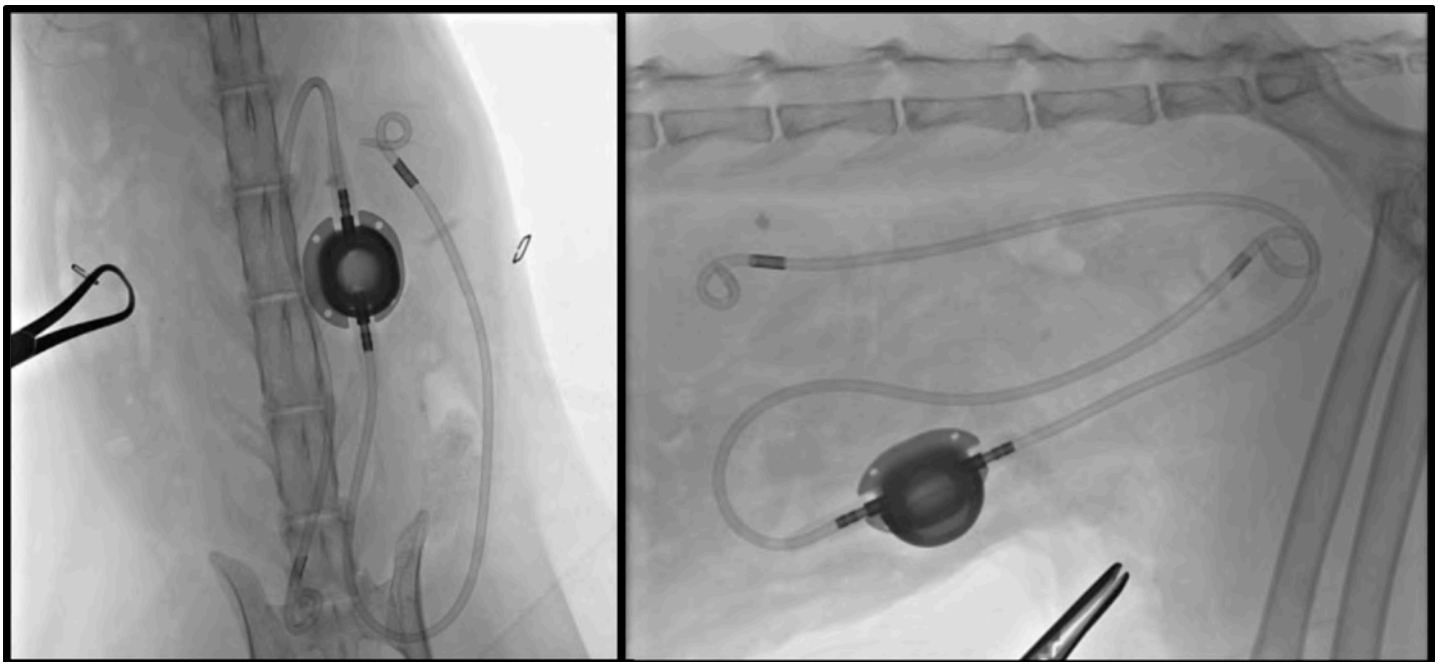


Figure 2: Subcutaneous ureteral bypass (SUB™) device 2.0. Lateral and Ventrodorsal images of a left sided device after placement.

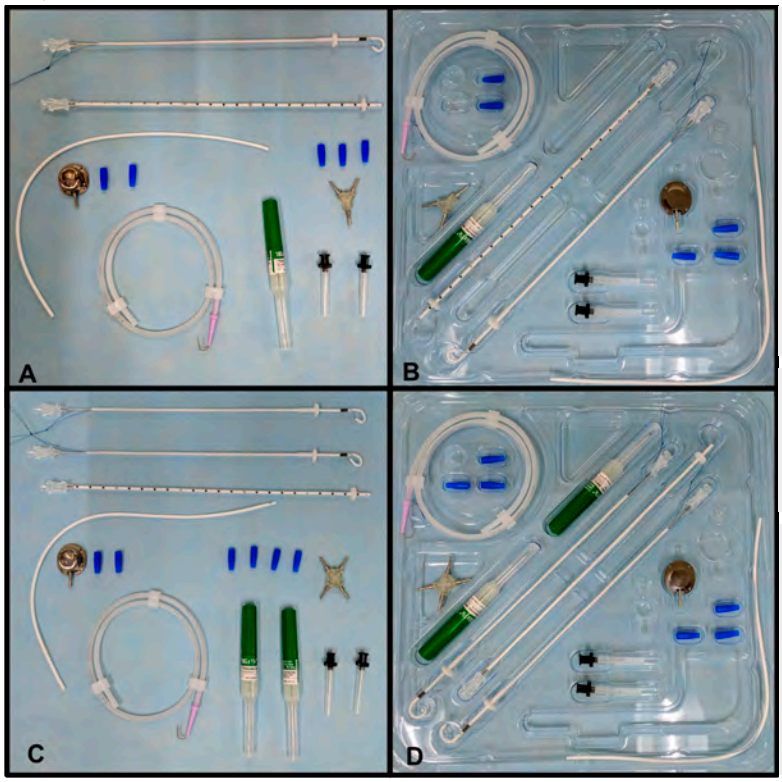
Prior to placing a SUB™ device on a clinical patient, it is important for the operator to have appropriate training. Please contact Norfolk Vet Products prior to use if you have any questions as training labs and videos are available. The details of the procedure are described in detail below.

Complications (Table 1, Page 17) encountered with the SUB™ device 1.0 and 2.0, as published in a recent article on 174 SUB™ devices placed in 134 cats over a 9 year period,[1] are expanded upon at the end of this manual. These complications include: 1) **leakage** at the nephrostomy/cystostomy tube exit or shunting port. This issue has been resolved with the addition of the Dacron cuff design to the renal capsule and bladder wall, respectively. The most common place for leakage is at the junction of the port and the catheter, or the catheter to the "Y" piece, where the locking string of the nephrostomy tube is secured. If this string is not properly trimmed, or at all exposed, leaking will occur. Please follow instructions VERY carefully to avoid this. 2) **hemorrhage/blood clots** during nephrostomy tube placement (<5%) can occur within the renal pelvis. This is likely due to catheter trauma to a renal blood vessel as the parenchyma is punctured or trauma to the renal pelvis during nephrostomy tube or guidewire manipulation. We have also seen blood clots develop in the urinary bladder after a concurrent cystostomy is performed for the removal of bladder stones. Care should be taken to avoid mucosal trauma. Blood clots in the bladder can occlude the end of the cystostomy tube post-operatively. 3) system **occlusion** with blood clots (5-8%), purulent debris (<1%), or stones (24% at a median of 463 days post-op) (with the new recommendation of flushing the system through the shunting port routinely with tetra-EDTA [**T-FloLoc™**] every 3 months, occlusion of the catheter is now documented in only 13% of cases at a median of 476 days), 4) **kinking** of the catheter during, or after, placement (up to 15% with prior versions, and 0% with the SUB™ 3.0), and 5) chronic UTIs (reported up to 31% pre-op and 8% post-op with

SUB™ 1.0 and 2.0 [with the use of tetra-EDTA [**T-FloLoc**™] every 3 months this rate has gone down to 0% [post-op chronic UTIs]). Most of these complications can be avoided with careful placement, sterile technique during surgery and device flushing, thorough leak testing upon completion of the procedure (see below), proper long-term management of hypercalcemia and stone disease, and routine flushing with t-EDTA.

The use of a SUB™ device for feline and canine patients with a ureteral obstruction can be considered a functional option for the treatment of all causes of ureteral obstruction. There is far more information on its use in feline[1] than canine patients[7] to date, and ureteral stents are still considered a less invasive and highly effective treatment option for canine patients, in the authors' practice.[1-7,10] The literature would support that this device is considered to have less short- and long-term complications in cats compared to all other alternatives when appropriate training is obtained.[1-12,18,19] Care should be taken, as the longest device has been indwelling for 9.0 years so outcomes beyond this point cannot be ascertained. Also, the reported literature with the highest number of cases and longest follow-up time is out of the authors' practice, documenting both a learning curve, and success with broader expertise. Outcomes may differ based on operator experience and variable pre- and post-operative supportive care regimens. In addition, the SUB™ 3.0 has been used exclusively by the authors for over 1-year, where the current reported literature over a 10-year period was with the SUB™ 1.0 and 2.0.

EQUIPMENT NEEDED



SUB™ KIT CONTENTS

SUB3-2001K - for use in cats and small dogs
- 1 x 6.5F x 20cm Locking Loop Catheter w/Stiffening Cannula
- 1 x 7F x 23.1cm Bladder Catheter w/Stiffening Cannula
- 1 x 7F x 30cm Polyurethane Catheter Tubing
- 1 x Low-Profile SwirlPort
- *1 x 3-way "Y" Connector*
- 1 x 18G x 1.25" IV Catheter
- 1 x 0.035" J-Tip Guidewire
- 5 x Blue Boot Catheter Connectors
- 2 x 22G x 0.75" Posi-Grip Huber Point Needle

SUB3-2002K - for use in larger dogs
Same as SUB3-2001K, but with:
- 1 x 6.5F x *35cm* Locking Loop Catheter w/Stiffening Cannula
- 1 x 7F x *38.1cm* Bladder Catheter with Stiffening Cannula

SUB3-3001K - for use in cats and small dogs
Same as SUB3-2001K, but with:
- 2 x 6.5F x 20cm Locking Loop Catheter w/Stiffening Cannula
- *1 x 4-way "X" Connector*
- 2 x 18G x 1.25" IV Catheter
- 6 x Blue Boot Catheter Connectors

Figure 3: Equipment for SUB™ 3.0 for a unilateral (Y-connector) or bilateral (X-connector) device. **A-B)** Unilateral device with a "Y-connector" outside of the packaging (A) and inside the tray (B). Notice the pigtail nephrostomy catheter and the straight bladder catheter. **C-D)** Bilateral device with an "X-connector" outside of the packaging (C) and inside the tray (D).

1. 6.5F Locking Loop Catheter(s) (kidney(s)) with Silicone/Dacron Disk and Silicone Sleeve w/Stiffening Cannula, fenestrations, and radiopaque marker band. The cannula goes over the guidewire during installation.
2. 7F Catheter (bladder) with a fixed Silicone/Dacron Disk, fenestrations, depth markings in 1cm increments, and Stiffening Cannula.
3. 7F Catheter Tubing for connection from subcutaenous port to Y/X Connector.
4. Low-Profile SwirlPort™. This should be flushed with saline using a Huber point needle to ensure patency prior to implantation.
5. 3-way "Y" Connector or 4-way "X" Connector for catheter attachment.
6. 18-gauge over-the-needle catheter(s).
7. 0.035" x 45cm J-tip Guidewire.
8. Blue Boots for catheter securement to port and Y/X Connectors.
9. 22G non-coring Huber point Needles for port flushing.
10. Cyanoacrylate Tissue Glue - NOT INCLUDED in the SUB™ Kit. *Cat. No. GLU*
11. SUB™ Flush Kit (see Page 14, 20) - NOT INCLUDED in the SUB™ Kit. *Cat. No. SFK-22*

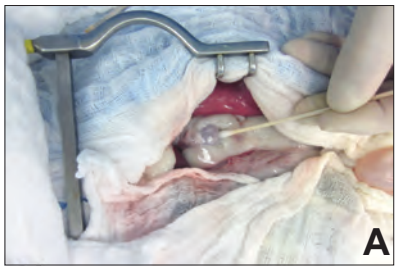
by Allyson Berent, DVM, DACVIM and Chick Weisse, VMD, DACVS

PREPARATION

Before proceeding with the surgery, each part of the system should be prepared by flushing the catheters, wires and port with sterile saline to ensure patency and to make sure each piece is damp. The catheters should be straightened out over the hollow cannulas.

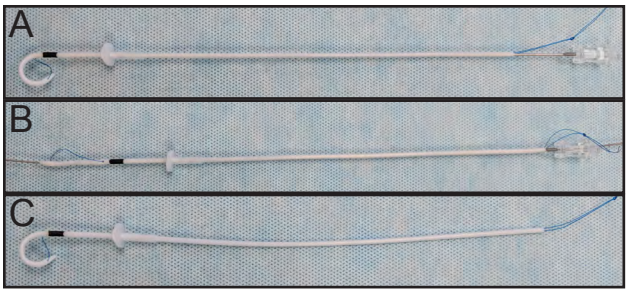
THE LAPAROTOMY

A ventral midline laparotomy is performed in order to expose the bladder apex and the affected kidney. The peri-renal fat is gently and bluntly dissected off the caudal pole of the kidney exposing a 1-2 cm region of renal capsule (**Figure A, right**).



PLACING THE LOCKING LOOP NEPHROSTOMY CATHETER

The nephrostomy catheter should be prepared: The hollow cannula is placed inside the pre-flushed 6.5 French locking-loop catheter (pre-loaded with the Dacron cuff and silicone sleeve). The system should be flushed with sterile saline.



Locking Loop Nephrostomy Catheter

A) Catheter with a hollow cannula prior to straigtening. There is a radiopaque mark that allows the operator to observe the end of the last hole of the pigtail catheter under fluoroscopy.

B) The hollow trocar is advanced, straightening the catheter, and placed over a guidewire (0.035").

C) The hollow cannula is removed and the pigtail is made at the distal end of the catheter as the string is locked in place.

With the aid of fluoroscopy, the nephrostomy catheter is placed using the modified-Seldinger technique (**Figure 4, 5, 6**). An 18-ga over-the-needle catheter is used to puncture the renal pelvis from the caudal pole of the kidney (if pelvis is > 8mm). If the pelvis is < 8mm, then a ***ureterostomy catheter*** is typically placed by passing the guidewire down the ureter and removing the locking string from the catheter so that the catheter can be gently placed passively in the ureter instead of coiled in the renal pelvis (**Figure 6**). This is expanded upon below. Once a flash of urine is obtained in the 18-ga catheter (**Figure 4A**), the needle is removed and the T-port with a 3-way stop-cock and 2 of the 3mL syringes (one is empty and one is filled with a 50% contrast:saline solution) are attached in order to perform a pyelocentesis and antegrade ureteropyelogram (**Figure 4B, 5A, 6A**), respectively. With the empty syringe, a urine sample is obtained for culture. The 50% diluted sterile iodinated contrast (iohexol) material is then injected into the renal pelvis to perform an antegrade ureteropyelogram (**Figure 5A, 6A**) to document the ureteral obstruction and guide the placement of the guidewire. The ureter is monitored using fluoroscopy to document patency (partial or complete obstruction) and obstruction location.

Then, a 0.035" J-tip guidewire is advanced through the 18-ga catheter and coiled inside the renal pelvis (**Figure 5C**) being careful to avoid perforation of the renal pelvis or the ureter. This wire can be straightened using digital retraction of the wire, or using the introducer. Once the entire "J"-tip is within the renal pelvis (**Figure 5C**), the 18-ga catheter is removed over-the-wire while the wire is carefully secured with a pick-up instrument or hemostat at the renal capsule to avoid losing wire access (**Figure 4D**).

Next, the 6.5 Fr catheter, with the hollow cannula, is advanced over the guidewire into the renal parenchyma (**Figure 4D-F, 5D, 6C, 6D**). Once it enters the renal pelvis, the hollow cannula is retracted as the catheter is advanced over the guidewire creating a pigtail inside the renal pelvis (**Figure 4F, 5D-F**). Care is taken to ensure the black radiopaque marker is inside the renal pelvis as that marks the last fenestration of the catheter, which should always be within the renal pelvis, not the renal parenchyma (**Figure 5D-F**). The kidney should be held securely as the catheter is advanced

over the wire, intermittently monitoring with fluoroscopy, so that the kidney does not push away from you as you advance the catheter. The kidneys are often fibrotic and hard to advance the catheter into.

Once the catheter is in the pelvis, gentle twisting and pinning of the cannula and wire will help facilitate advancing the catheter into the kidney or ureter smoothly. If the pigtail is in the pelvis then the locking string is gently pulled to coil the pigtail inside the pelvis. It is important to avoid making it too tight where it could kink at a fenestration of the loop. The string is then clamped with a hemostat at the junction of the string and catheter to maintain tension on the string and keep the loop. Be sure not to clamp the catheter itself, but just the string at the junction of the catheter and the string. Keeping the hollow cannula in the straight part of the catheter, the Dacron cuff and silicone sleeve are gently advanced down the nephrostomy catheter to the renal capsule to keep the catheter snug in the renal pelvis (**Figure 4G**). Using the hollow cannula, drain contrast from the nephrostomy tube and fill with contrast under fluoro to ensure proper placement, filling, and drainage, with no leak outside of the kidney or ureter. (**Figure 5E,F**) Then remove the hollow cannula and apply the sterile cyanoacrylate glue between the Dacron and the renal capsule, which aides to provide security and prevent leakage (**Figure 4G**).

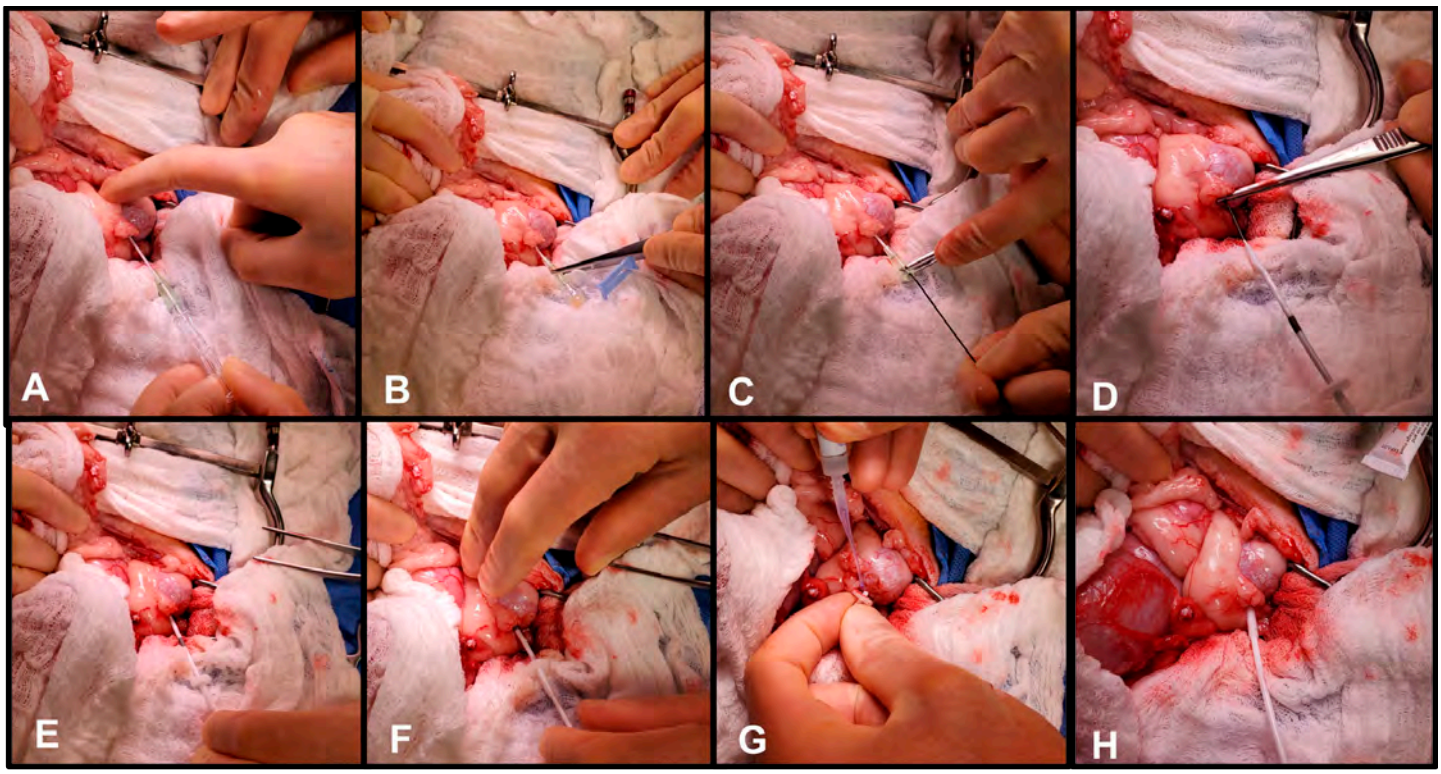


Figure 4: Intra-operative images during left sided SUB™ device placement in a cat. Cranial is to the top of the image.

A) 18-gauge IV catheter is used to puncture the renal pelvis through the caudal pole of the right kidney after fat dissection.

B) A pyelocentesis and antegrade pyelogram is being performed using contrast material on the stop-cock.

C) 0.035" "J-tipped" guidewire is advanced into the catheter and coiled inside the renal pelvis while the catheter is being removed over the guidewire.

D-F) Locking-loop nephrostomy catheter is advanced over the guidewire and into the renal pelvis.

G) Dacron cuff being glued to the renal capsule.

H) Silicone sleeve seen against the Dacron cuff on the renal capsule.

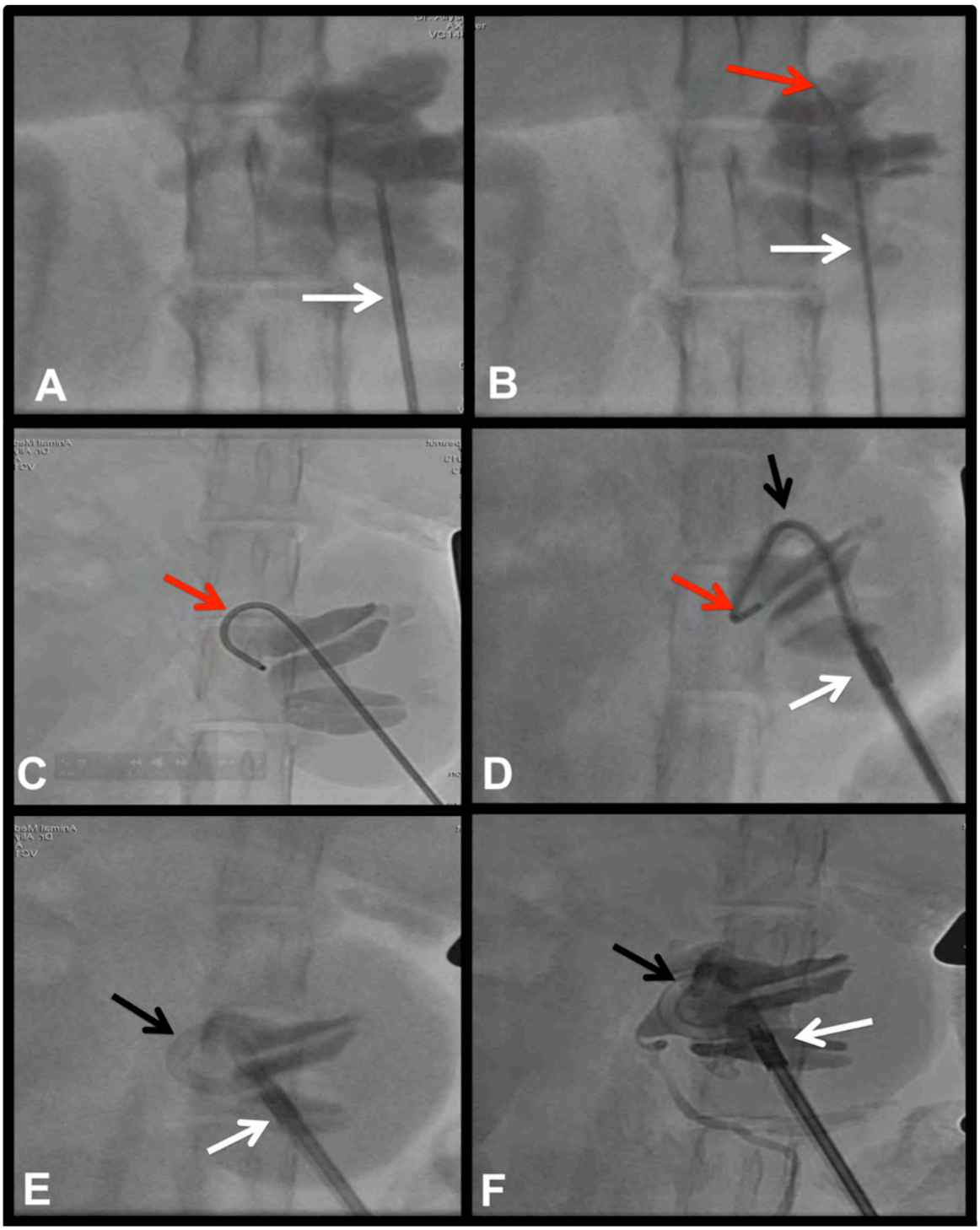


Figure 5: The Modified-Seldinger technique being used for locking loop nephrostomy access

A) 18-ga IV catheter (white arrow) being placed into the caudal pole of the renal pelvis and a pyelogram being performed.

B-C) A 0.035" J-tip guidewire (red arrow) advanced through the catheter and coiled inside the dilated renal pelvis.

D) The locking loop nephrostomy catheter (black arrow) is advanced over the guidewire and hollow cannula inside the renal pelvis allowing a curl to form over the wire (red arrow) within the renal pelvis. The white arrow is the radiopaque marker which marks the last hole of the multi-fenestrated loop, ensuring the entire loop is within the renal pelvis.

E) Once the radiopaque mark is within the renal pelvis (white arrow), the wire and hollow cannula are removed, the string is locked.

F) A pyelogram is performed to confirm no leakage and appropriate catheter placement. Notice the pigtail catheter loop is tight and locked with the mark (white arrow) within the large dilated pelvis.

PLACING THE NEPHROSTOMY TUBE DOWN THE URETER FOR PELVISES ~<8mm (FIGURE 6)

When a renal pelvis is smaller than ~8 mm, the authors have found it easier and safer to place the nephrostomy catheter down the ureter instead of coiling it in the renal pelvis (**Figure 5 and Figure 6**). This needs to be done very carefully using fluoroscopic guidance to avoid ureteral or caliceal perforation. The nephrostomy catheter is prepared by cutting the locking string at the loop and removing it from the top of the catheter. We do not want to lock a loop down the ureter, so this is now more of a gentle curved ureterostomy catheter that takes the curve of the proximal ureter (**Figure 6D**).

Instead of puncturing from the caudal pole (6 o'clock position) of the kidney, we aim more caudolaterally. The approach is to initially dissect the fat off of the caudolateral aspect of the kidney to expose the renal capsule, aiming for the ureter. Then, puncture with the over the needle catheter from the 5 o'clock (left side) or 7 o'clock (right side) position (**Figure 6A, 6E**). Once a flash of urine is obtained then a ureteropyelogram is performed. Using a 0.035" ***angle-tipped hydrophilic guidewire (not included in SUB™ kit)***, through the 18-ga catheter, the ureter is cannulated (**Figure 6B**). The wire is left down the ureter and the IV catheter is removed over the wire. If the renal pelvis is under 5mm, then a 22-ga IV catheter can be used to puncture the pelvis, and a 0.018" angle-tipped hydrophilic wire can be used to cannulate the ureter. Once that 0.018" wire is in the ureter, then the 22-ga catheter is removed over the wire and the 18-ga catheter (without the needle) is advanced over the 0.018" wire into the proximal ureter. The 0.018" wire is then removed and replaced with the 0.035" angle-tipped hydrophilic guidewire down the ureter through the 18-ga IV catheter. The 18-ga IV catheter is then removed over the 0.035" wire being careful not to remove the wire, and the nephrostomy catheter is advanced over the wire (**Figure 6C**), down the ureter, being passed off the hallow cannula once the cannula pierces through the renal parenchyma and into the renal pelvis, as described above. Once the catheter is in the ureter and the black mark is within the pelvis (**Figure 6D**), the Dacron cuff and silicone sleeve is advanced to the renal capsule and glued to the renal capsule, as described above.

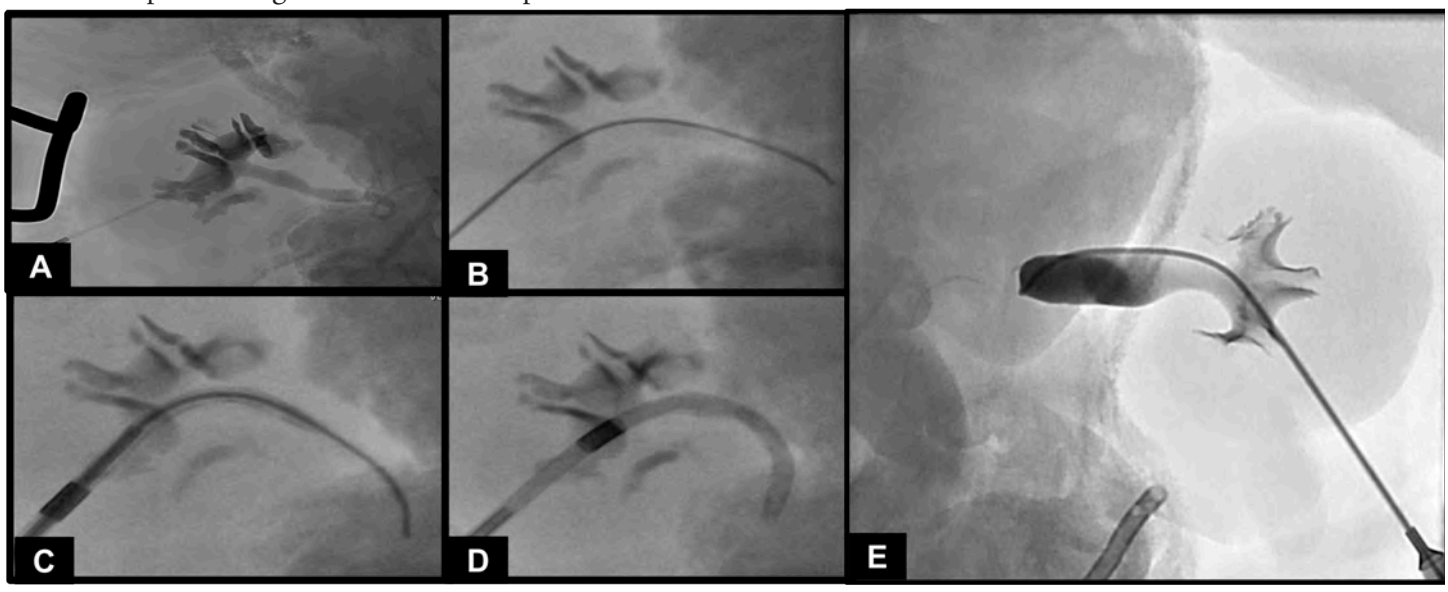


Figure 6: Placing the nephrostomy catheter down the ureter

A) Pyelogram of a renal pelvis with a ureteral obstruction using a 22-ga IV catheter.

B) 0.018" angle-tipped hydrophilic guidewire going down the right ureter and the 22-ga catheter removed and replaced with an 18-ga IV catheter over the 0.018" guidewire.

C) A 0.035" angle tipped hydrophilic guidewire is advanced through the 18-ga IV catheter and the 18-ga IV catheter is removed over the wire and the nephrostomy catheter is advanced over the 0.035" guidewire down the proximal ureter.

D) The black mark is noted to be well within the renal pelvis during a pyelogram and the guidewire is removed.

E) Puncturing the right renal pelvis from a caudolateral approach directly with an 18-ga catheter with a 0.035" guidewire the immediately advanced down the proximal ureter to the level of a ureteral stricture.

PLACING THE CYSTOSTOMY CATHETER (FIGURE 7)

The urinary bladder catheter is now placed (**Figure** 7). First, 3-0 Monocryl® in a purse string suture pattern is made at the apex of the bladder (**Figure** 7**A**). Care is taken to ensure this is the pinnacle of the bladder apex and the catheter does not sit too close to the ventral surface of the bladder where the urachal remnant is found. This could cause bladder irritation if that occurs. If there will be bilateral SUBs implanted, then each catheter should be placed just off the midline of the apex so both fit as close to the apex as possible. In the center of this purse string, cautery is used to puncture a small hole into the bladder lumen (**Figure** 7**B**) making sure to pierce the bladder mucosa. Using cautery helps to avoid post-operative hematuria, which could result in a blood clot on the tip of the bladder catheter.

The catheter is then prepared with the hollow cannula in the center, and the catheter is advanced inside the small cystotomy to seed into the urinary bladder lumen (**Figure** 7**C**). If the bladder size is very small, the tip of the catheter can be trimmed to ensure the length of the catheter inside the bladder does not come into contact with the bladder trigone, as this can be irritating to the patient. The catheter is advanced until the Dacron disk is against the serosal surface of the bladder, and the purse-string suture is secured and tied around the catheter (**Figure** 7**C**). Sterile saline (10-20mL) is attached to the hollow cannula to keep the bladder full during suturing.

Sterile cyanoacrylate glue is used to further secure the Dacron to the serosal surface of the urinary bladder (**Figure** 7**D, E**). Using 3-0 monocryl suture, the Dacron disk is sutured to the bladder wall (full thickness) using 3 or 4 sutures (**Figure** 7**F**). Notice how the suture is passed through both the superficial silicone ring and the deeper Dacron disk (**Figure** 7**F**). Once secure, saline is infused through the hollow cannula and the seal is leak tested. Once satisfied with no leak, the hollow cannula is removed and the bladder will empty.

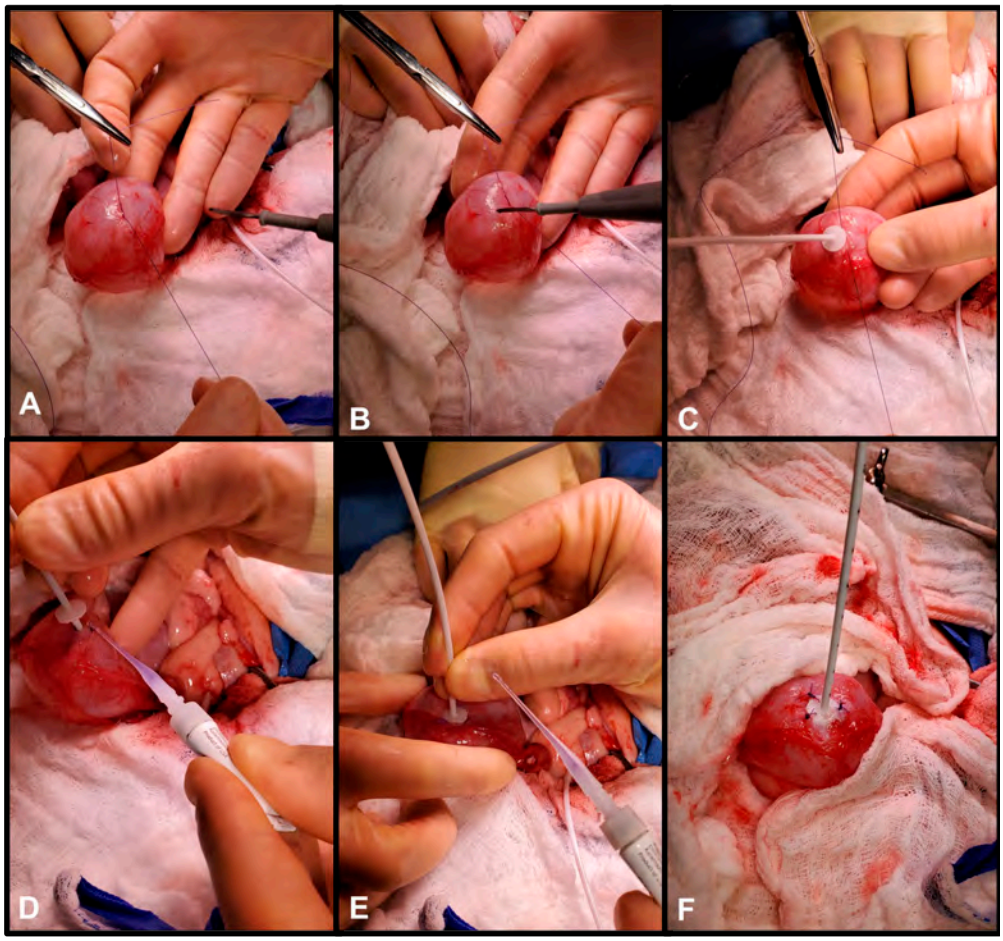


Figure 7: Placing the cystostomy catheter

A) A purse string suture is made at the apex of the bladder.

B) Electrocautery is used to make a puncture in the center of the purse string into the bladder lumen.

C) The bladder catheter is advanced through the incision with the hollow cannula in place. Then the purse string is secured around the catheter and tied

D-E) The Dacron cuff is then glued to the apex of the bladder.

F) The Silicone/Dacron cuff is sutured to the bladder in 2 interrupted sutures using Monocryl.

ATTACHING THE CATHETERS AND TESTING THE SYSTEM (FIGURES 8, 9, 10, AND 11)

Next, the catheters are attached to the "Y-connector" inside the abdomen (**Figure 8**). No catheter is passed through the body wall at this point. Each of section of catheter (kidney(s), bladder, and actuating tubing to the port) should have the blue boot placed with the tapered end inserted proximally on the catheter away from the "Y/X-connector" (**Figure 8A**). The bladder and kidney catheters are often cut shorter to appropriately fit the abdomen of the particular patient. The 2-arms of the "Y" are typically placed caudally and attached to the kidney catheter laterally and the actuating tubing medially (**Figure 8A, Figure 1A, 1B**), respectfully. The bladder catheter is connected to the one arm that is facing cranially. Once all 3 catheters are secured onto the "Y-connector" and advanced up onto the metal step of the connector (**Figure 8A**) then the actuating tubing can be passed through the body wall on the ipsilateral side to the ureteral obstruction.

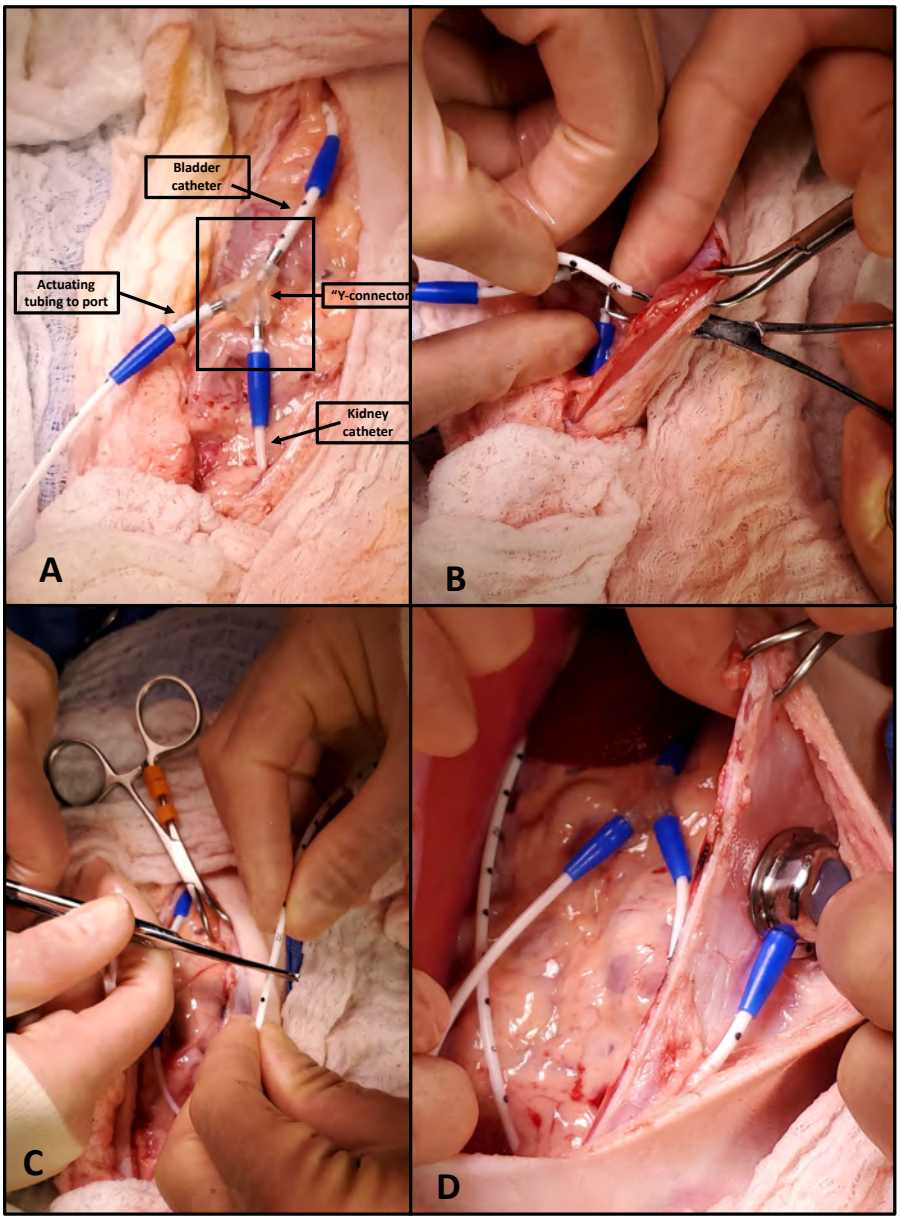


Figure 8: Connecting the "Y-connector" within the abdomen (cranial is the top of each image)

A) The "Y-connector" is connecting the kidney catheter, bladder catheter and actuating tubing that is going to the port. Notice all catheters are advanced up onto the final step of the metal barbs and they are pre-loaded with the blue boots for all connections.

B) The actuating tubing is being passed through the body wall on the ipsilateral side of the kidney catheter.

C) The actuating tubing is being cut to ensure it is not too long as the length suits the size of the cat's abdomen well.

D) The actuating tubing is being connected to the port and there is enough space between where the tubing comes through the body wall and where the port will be secured (approximately 2-3 finger lengths or 4 cm).

If the nephrostomy catheter has the locking-loop pigtail maintained and the string is locked with a hemostat, there are 2 options: 1) this string is locked with the "Y-connector" similar to that recommended for the SUB™ 2.0 (**Figure 9**), or 2) the string is cut flush with the catheter and the lock is not maintained as once the pigtail is well seeded inside the renal pelvis the lock is likely no longer necessary. This is done carefully to avoid a site of leakage. As the string sticking out of the catheter is the most common cause for device leakage.

If you would like to maintain the lock then the blue boot is advanced onto the catheter by pinning the string with your fingers and advancing the boot over the string. Once the boot is on the catheter (tapered end in first), then the string is re-locked with the hemostat. Fluoroscopy is used here to ensure the pigtail is not too loose or too tight prior to securing the lock onto the barbs of the "Y-connector". Then the first barb of the "Y-connector" is advanced into the catheter. Once the first barb is within the catheter lumen, the string will be wedged between the barb and the catheter,

which will lock the string. A #11 blade is then used to cut the string flush with the catheter end, against the metal barb (**Figure 9**), being careful to avoid having any excessive string out of the catheter, as this can be a site of leakage. Then the catheter is advanced over all of the barbs so that it is snug (**Figure 8A**).

The string should not be hanging out of the end of the catheter once it is advanced onto the connector pin. This makes an incomplete seal and a site that can leak

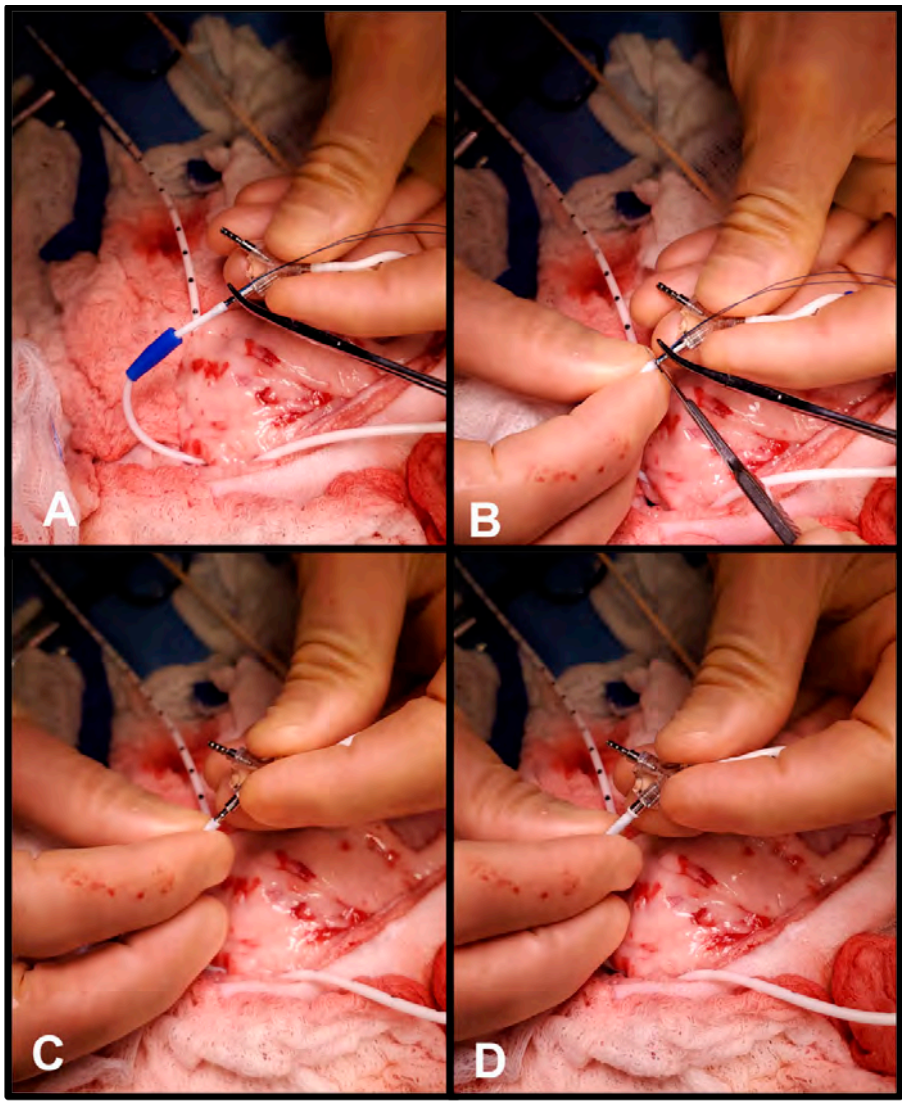


Figure 9: Attaching the nephrostomy catheter to the Y-Connector while maintaining the locking string

A) The string is wedged between the first rung of the barb on the shunting port and the catheter to maintain the lock.

B) The string is cut with a #11 blade blunt with the metallic barb and no excessive string should be seen outside of the catheter.

C-D) The catheter is advanced onto the other barbs up to the stop step.

Next, the subcutaneous tissue on the ventral abdomen of the ipsilateral side of the obstructed kidney, para-incisional, is minimally dissected of fat to the ventral sheath halfway between the xiphoid and the pubis (**Figure 8D, Figure 11**). Once this area is clean of fat, a hemostat is used to pierce the ventral body wall in the caudal aspect of this space and the actuating tubing is gently clamped and passed through the body wall to connect to the SwirlPort (**Figure 8B**). It is important that the hole for the tubing is approximately 2-3 fingers wide, or approximately 4 cm, from the location of the port so that there is a gentle bending of tubing as it enters the body wall to avoid kinking (**Figure 8D, Figure 11**). Once the tubing is passed through the body wall it can be cut to fit the patient (**Figure 8C**), which is usually between 15-20cm. This gives more room for larger animals if needed to preserve length, but avoids excessive material in the abdomen which can lead to kinking.

Once the tubing is advanced through the body wall and the tubing is cut to the desired length, the 4th blue boot is advanced onto the end of the catheter and the catheter is then connected to the port (**Figure 8D, Figure 10C**). Now the system is closed and it can be leak tested. (**Figure 10B, 10C**) A Huber needle is inserted into the port connected to a T-port, 3-way-stop-cock, and 2 syringes; one filled with contrast and one empty (**Figure 10 C**).The system is first drained. Then the kidney and bladder catheters at the level of the "Y-connector" are compressed digitally (**Figure 10B**) as fluid is infused through the port to look for a leak at the "Y-connector". If no leak is confirmed, then the actuating tubing is compressed at the port (**Figure 10C**) as the system is infused to ensure no leak between the actuating tubing and the port. If no leak is detected, then the system is secure.

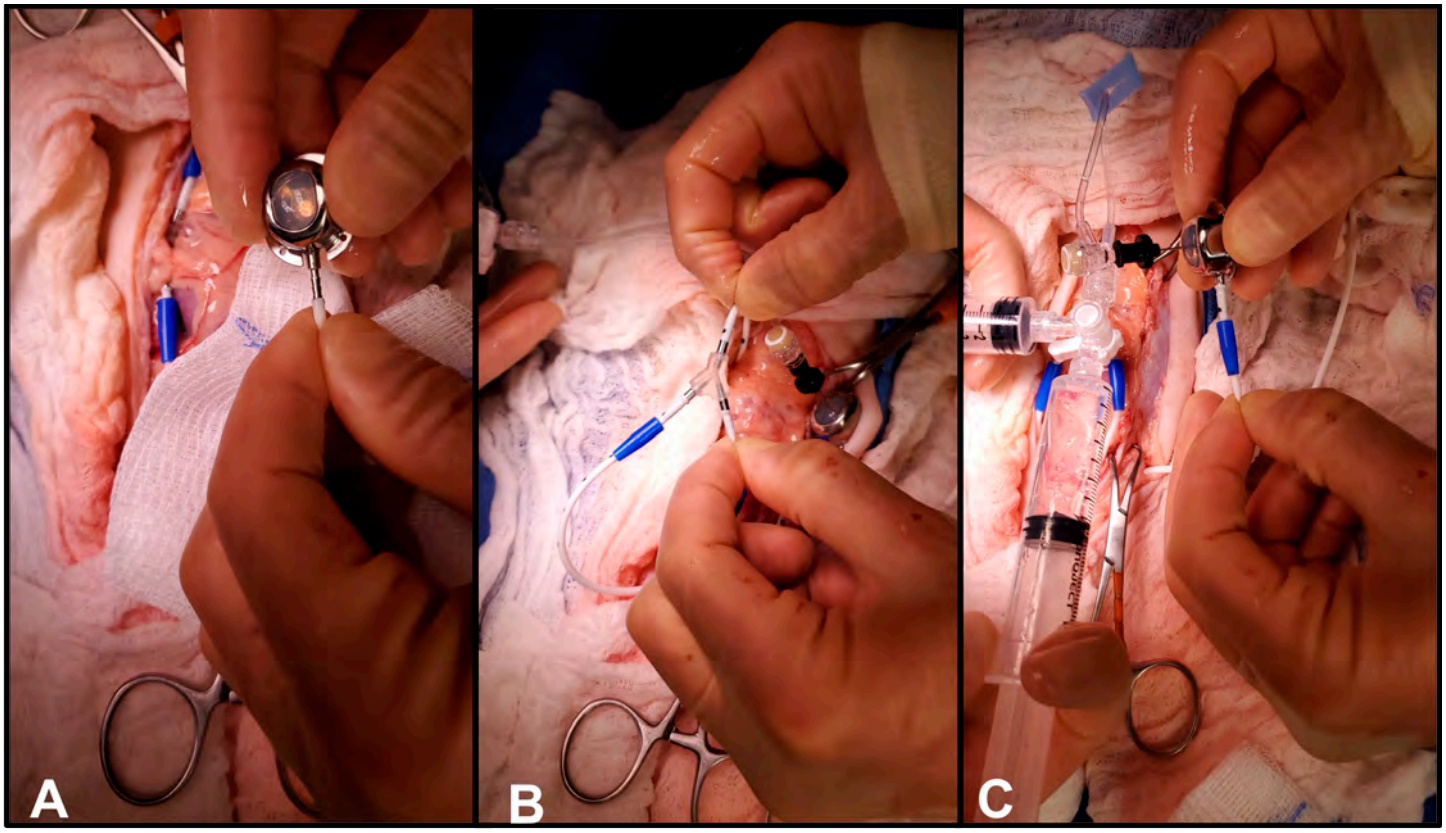


Figure 10: Leak testing the device

A) Port is connected to the actuating tubing once it is passed through the body wall.

B) Using a Huber needle, saline is infused into the system through the port while the kidney and bladder catheters are digitally compressed with your fingers at the "Y-connector". This is to ensure there is no leak in the connections. Then all blue boots are advanced onto the connector.

C) Then the port is assessed, and the actuating tubing is digitally compressed as the port is infused to ensure there is no leak at the port connection. Then the blue boot is advanced.

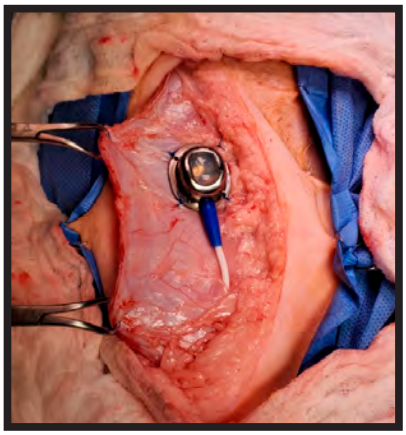


Figure 11: The port is placed on the ventral abdominal wall. The port should be half-way between the xiphoid and the pubis. The tubing should pass through the body wall approximately 4cm from the center of the port to ensure there is space between the port and the catheter.

Finally, using digital subtraction angiography (DSA), a contrast study is done confirming patency of the system from the port, through the actuating tubing, to the "Y-connector" and then up the nephrostomy/ureterostomy and down the cystostomy tube (**Figure 12**). Care should be taken to monitor that the renal pelvis and bladder fill and drain easily. The catheters need to be examined carefully at the renal capsule entry point, apex of the bladder entry point, and both sides of the shunting port for any leakage. In addition, all catheters should be examined for any kinks.

Once patency of the system is confirmed, the contrast is drained and the port is secured to the ventral body wall in the subcutaneous space using non-absorbable synthetic suture (3-0 Prolene) through the ventral rectus sheath to each of the four (4) eyelets of the port to secure it in place (**Figure 11**).

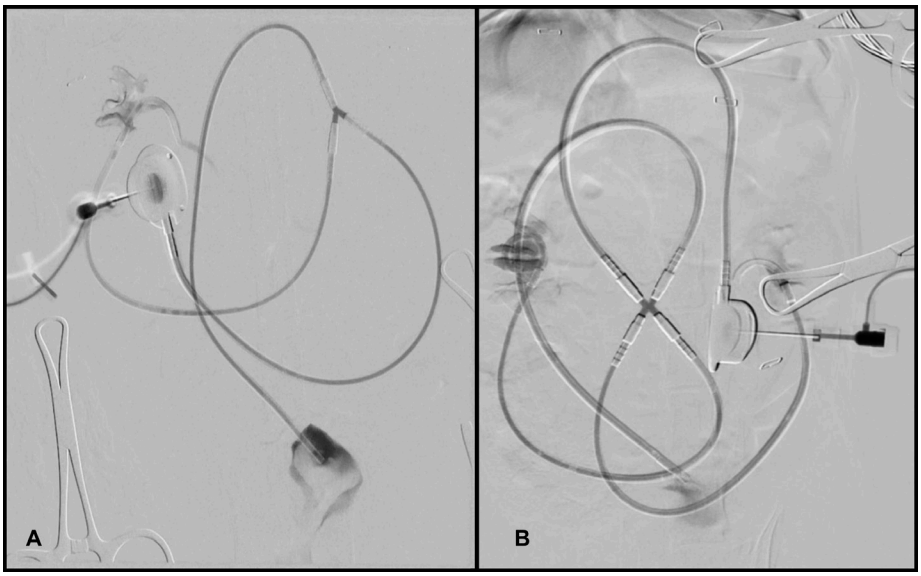


Figure 12: Ventrodorsal fluoroscopic images after SUB™ placement during digital subtraction angiography and contrast flushing of the devices

A) This is a unilateral device with a "Y-connector".

B) This is a bilateral device with an "X-connector".

The subcutaneous pocket is closed routinely and any dead space addressed using 3-0 monocryl suture. Topical bupivacaine is placed in the SQ pocket around the port to provide additional analgesia.

Next, the abdomen is flushed with warm sterile saline and the device is placed in a comfortable position in the abdomen. Prior to closing, ensure that all catheters are seated in place with both nephrostomy/ureterostomy tubes seated within the pelvis and the cystostomy tube within the bladder. The silicone sleeve should be abutting the Dacron cuff at the level of the renal capsule. Omentum is used to cover the entry site of the kidney and the bladder near the Dacron disk. The abdomen is then closed routinely.

Once complete, a fluoroscopy image is taken in both VD and lateral to ensure no kinks are seen and the catheter is well situated in the renal pelvis and urinary bladder (**Figure 1A, 1B**). The radiopaque marker on the nephrostomy catheter should always be within the renal pelvis and the Dacron disk can be seen at the margin of the caudal pole of the kidney and the apex of the bladder. Images in lateral can be taken with the legs in extension and flexion to ensure no kinks are seen.

FLUSHING OF THE SUB™ (FIGURE 13)

The details of performing a SUB™ flush and the follow-up recommendations are outlined in the SUB™ flush kit instruction for use manual (IFU). Current recommendations include flushing the device prior to discharge, at 1 week post-operatively, then at 1 month, and every 3 months thereafter. During the flushing procedures, a 0.5-1.0 mL discard sample of urine sample is obtained from the SUB™ 3.0 device due to the stagnancy of some fluid in the accessory catheter connection to the port. Then, another sample is taken for urine culture and urinalysis. Next, sterile saline is infused into the system using ultrasound guidance to ensure patency of all catheters. No more than 0.25-0.5mL of fluid should be infused to see bubbles in both the bladder and the renal pelvis. This saline can be pre-agitated (not usually needed) and flushed with vigor (not with excessive volume) to see the turbulence.

Following confirmation of patency in the renal pelvis and bladder, a novel solution called tetrasodium ethylenediaminetetraacetic acid (t-EDTA), or ***T-FloLoc™***, is gently infused into the system, monitoring the renal pelvis size to ensure it is not getting progressively bigger. We do this in small 0.25-0.5ml puffs allowing time for it to drain down the SUB™ before the next puff. We monitor the renal pelvis the entire time. If the pelvis gets smaller after each puff, then we infuse the entire 2mL syringe. If it does not get smaller, thae we stop the infusion and just allow the line to remain filled with the t-EDTA. This material helps prevent occlusion with stone material and prevent biofilm formation. It can also be used to clear partially mineralized devices[6] and to clear recurrent infections associated with biofilm in the authors' experience. This procedure typically does not require any sedation or anesthesia, is performed in dorsal recumbency using ultrasound guidance with minimal restraint, and can be performed more regularly in patients at higher risk for encrustation (e.g. hypercalcemic, history of device mineralization) or infection (e.g. pre-operative infection).

The ***SUB™ Flush Kit*** has been designed to include everything you will need to perform this procedure. The pack is sterile and the contents should be assembled using sterile gloves as depicted in **Figure 13**. The patient is positioned in dorsal recumbency in a V-trough to facilitate port access and ultrasonography. The following materials are included:

1) 1 x T-port Connector
2) 1 x 3-Way Stopcock
3) 1 x 22 or 20 Gauge Huber Point Needle
4) 2 x 3mL Syringe (empty)
5) 1 x 3mL Syringe w/2.5mL Sterile Saline
6) 1 x 12mL Syringe w/2mL T-FloLoc™

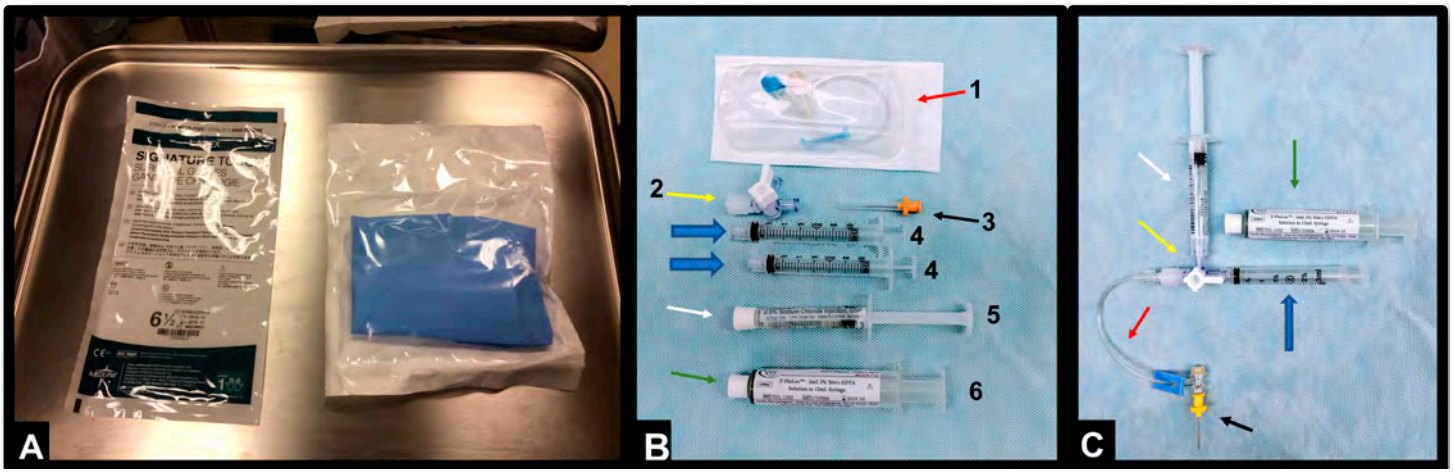


Figure 13 A-C: Set-up of the SUB™ Flush Kit

A) sterile gloves and the flush kit.

B) The parts in the SUB™ flush kit. 1: T-port connector, 2: 3-way stop-cock, 3: 20 ga Huber needle, 4: empty 3 mL syringe (one for discard and one for sample collection), 5: 2.5 mL sterile saline, 6: 2 mL of t-EDTA (T-FloLoc).

C) All of the parts attached properly to the system for flushing

In addition you will need a clipper to clip the fur over the SUB™ port and scrub solution to adequately scrub the skin over the SUB™ port so that the procedure is done in a sterile manner (**Figure 13**). Prior to flushing, the renal pelvis sizes should be measured and recorded using ultrasound guidance, and the urinary bladder should be examined for bladder stones, or any thickened tissue around the SUB™ catheter.

Ultrasound-Guided Flushing of the SUB™ (Figure 13) should be done through the port using a Huber needle. An extension set with a 3-way stop-cock is used with two (2) empty syringes for a discard sample and for a urine sample. The port is palpated under the skin and the flat silicone insertion site is isolated (**Figure 13**). Using sterile technique, the Huber needle is advanced through the skin and into the silicone diaphragm until metal is reached. This must be done in a perpendicular manner. Once the needle is inside the port, a urine sample is obtained (**Figure 13**). If no urine is withdrawn, then the needle may not be deep enough into the access port, may be at the wrong angle so not within the sampling well, the system may be occluded on both ends, or the bladder and renal pelvis may both be empty of urine (unlikely). Once urine is obtained, the first 0.5-1.0 mL is discarded as it was sitting stagnant in the actuating line. The next 1-2 mL is submitted for analysis. Next, the syringe with sterile saline is attached to the stop-cock and 0.25-0.5mL is carefully injected into the port with some vigor to create turbulence. This can be pre-agitated to make more bubbles but is usually not needed. This should ONLY be done while the renal pelvis is being monitored with ultrasound (**Figure 13**).

Once saline is seen to enter the renal pelvis (usually confirmed by the presence of small air bubbles-Figure 13) the fluid is withdrawn to avoid over distension. Next, the ultrasound probe should be placed over the bladder apex and the port should be flushed again using the SAME SMALL VOLUME of saline to see fluid enter the urinary bladder through the SUB™ cystostomy tube (Figure 10F, 11B). Again, bubbles are usually seen (Figure 11B). **Care must be taken NOT to overfill the renal pelvis during monitoring of the urinary bladder. The renal pelvis should ALWAYS be monitored during this procedure with ultrasound (or fluoroscopy) the ensure it is not being over-distended.** Once patency is confirmed, then the flush volume of saline is removed from the 3-way-stop-cock and the syringe with T-FloLoc™ is

attached to the system. Monitoring of the renal pelvis using ultrasound guidance is necessary. Once the renal pelvis is drained empty the flush solution is slowing flushed into the renal pelvis in puffs of 0.25-0.5 mL at a time to avoid any over-distension. This is done in pulses to allow for the solution to drain down the SUB™ between each pulse.

If the renal pelvis shows any distension, then stop the infusion until it resolves. If it does not resolve in a few seconds, then discontinue the flushing. This technique is only for prophylactic flushing. If the ***T-FloLoc*** solution is being used for treatment of mineralization or biofilm, please follow the appropriate protocol which is available through Norfolk Vet. Once the flush is complete, the needle should be removed from the port carefully.

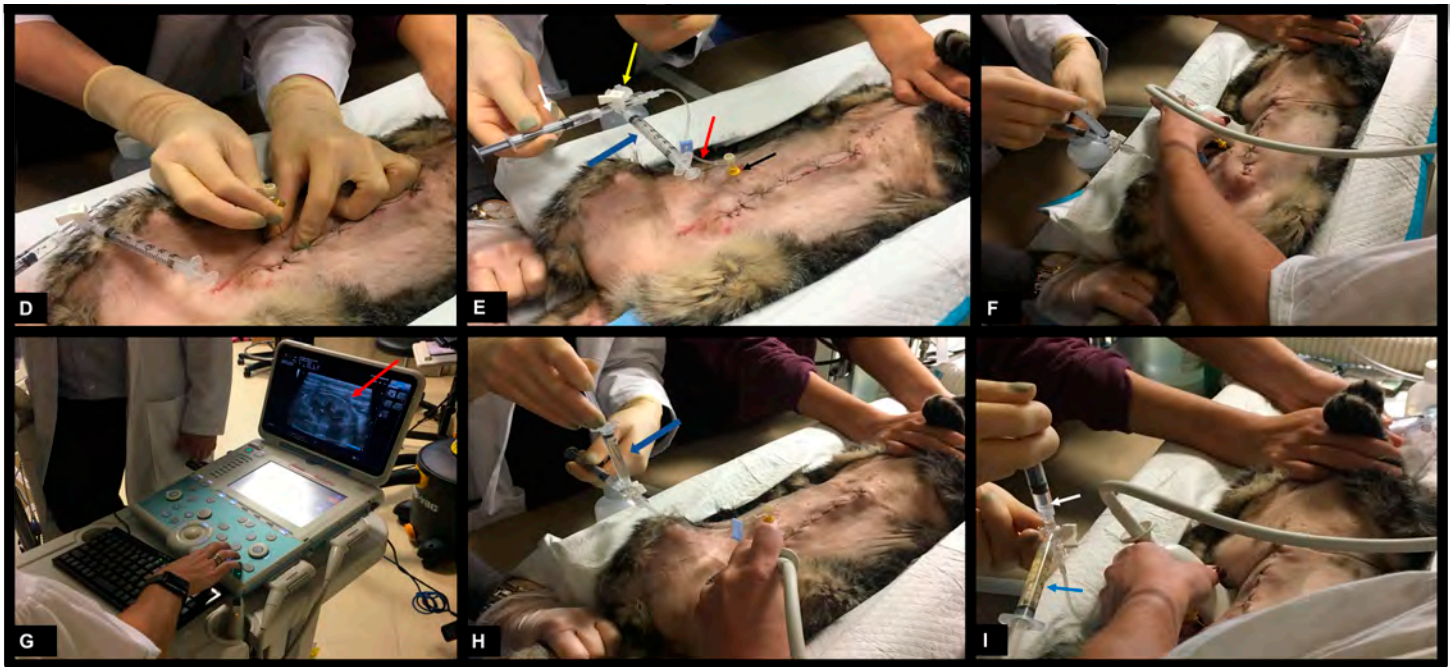


Figure 13 D-I: The flushing procedure

With the cat in dorsal recumbency the port site is clipped and aseptically prepared and scrubbed using chlorohexidine surgical scrub.

D) The Huber needle is inserted into the port using sterile technique and sterile gloves.

E) Once metal is hit with the needle (black arrow) and the needle is within the reservoir/well, then the system is in place. The empty syringe (blue arrow), 3-way stopcock (yellow arrow), T-port (red arrow), and sterile saline (white arrow).

F-G) Ultrasound is used to evaluate the renal pelvis and urinary bladder measuring size and evaluating for any pathology. Ultrasound image of the kidney with the SUB™ coming through the caudal pole (red arrow).

H) A discard sample and another urine sample is collected for analysis (blue arrow).

I) Saline being infused into the system (white arrow), monitoring the kidney with ultrasound guidance. Once patency is confirmed the t-EDTA is used to flush into the system, monitoring the kidney with ultrasound.

FLUOROSCOPIC-GUIDED FLUSHING OF THE SUB™ (FIGURE 12)

This technique is uncommonly used for routine SUB™ flushing, but can be useful for cases in which ultrasound-guided flushing is insufficient, unavailable or inconclusive. If the flush is being done under *fluoroscopic guidance*, then you need 100% of iohexol (240-360mg/mL) in a 3mL syringe connected to the T-port, 3-way stopcock, and empty syringe system. Ultrasound is not needed for the flush but should be used prior to the flush to get accurate renal pelvis size measurements to ensure proper function of the SUB™ device. The patient is placed under the fluoroscopic unit in dorsal recumbency, and the port area is clipped and scrubbed aseptically as described above. The fluoroscopy image should be aligned with the patient so that the kidney, port and bladder are seen in the image. After the urine sample is obtained, to ensure proper needle placement, the contrast solution is injected into the port. Careful monitoring of the contrast should be seen using fluoroscopy traveling from the port, up the catheter, to the kidney while the renal pelvis fills (**Figure 12**). Never infuse more contrast than the urine that you removed and ideally not more than 1-2 mL

slowly while watching. This is usually not done using digital subtraction angiography (DSA), as the patient is usually awake and moving. The renal pelvis and the urinary bladder should be monitored simultaneously (**Figure 12**) to ensure all catheters are filling with contrast to the pelvis and bladder and there is no renal pelvis overdistension. All of the contrast should be easily withdrawn from the bladder and renal pelvis. Then, the ***T-FloLoc***™ syringe is mixed with 1ml of contrast and is slowly infused, avoiding renal pelvis over-distension. This should be done in 0.25-0.5ml increments with pauses allowing drainage of the material between each pulse to avoid overdistension. The needle can then be removed from the port carefully and the flush is complete.

COMPLICATIONS AND PROGNOSIS (TABLE 1, PAGE 17)

The SUB™ device is an alternative for the treatment of ureteral obstructions and has been used regularly in many practices for the last 10-years, and has been met with some of the lowest peri-operatively morbidity and mortality rates of those reported in the literature.

Considering that over 85% of cats with a ureteral obstruction have concurrent nephroliths and the median number of stones per ureter was documented to be 4 in a recent study[18], a majority of cases seem to benefit from this approach in the authors' practice (stones, stricture and tumors regardless of location, size or number of obstruction sites).

The device should only be placed by those trained with the technique, as a higher complication rate can be seen when proper training is not pursued. These cases are technically challenging, pre- and post-operative management are incredibly important for the best outcomes, with over 93% of patients surviving to discharge and less than 25% of patients eventually succumbing to renal disease. The author's recommend all new users to consider a training course prior to use. The authors' have made a video of further explanation, and they are available for consultation via the email(s) above, as well as more details in the published literature[1] and a text book chapter.[5] The authors also recommend first practicing on a cadaver or using the ***3D printed silicone model*** that is available separately through Norfolk Vet Products prior to trying this technique on live animals with naturally occurring disease.

The acute decompression success rates are high (>98%), but training is mandatory. In a recent report in the authors' practice[1], patency of the device was evident long-term, followed for a median of 827 days (range: 1-2397), with improvement in the creatinine concentrations from a median of 6.8 mg/dL to 2.6 mg/dL, prior to discharge and 2.1 mg/dL at the time of first recheck. Complications reported in this large study are documented in **Table 1**.

Device leakage was only rarely seen in the intra- or peri-operative period and this complication has been eliminated since the use of SUB™ 2.0 and 3.0 in the authors' practice. This was almost always associated with a technical error of not cutting the locking string close enough to the catheter.

Kinking of the device was evident in the short- or long-term in 4.6-15% of cases with prior devices and has been reduced to 0% with the SUB™ 3.0. This was almost always a technical error where the entry of the device through the body wall was not far enough from the end of the blue boot and was noticed more commonly when the patient was moved into different positions (crouched vs laying extended).

Immediate post-operative occlusion of the device (median 3.5 days) was almost always associated with the development of a ***blood clot in either the kidney or bladder catheter***. This occurred in 8% of cases in the prior study, which is similar with the SUB™ 2.0 and 3.0. Half of these cases were easily addressed with infusion of 1 mL of tissue plasminogen activator (TPA) into the SUB™ port. The cases where this failed, an exchange of the catheter was required. This 2nd surgery prolonged hospitalization by 1 day.

Mineralization of the device was seen in 24.5% of cats in the long-term at a median of 463 days in the prior study.[1] Half of those cases (12%) developed a patent ureter and did not require a SUB™ catheter exchange. The other half did require an exchange, and their median hospitalization time was 2 days, with 100% survival to discharge. Since the start of prophylactic flushing using tetra-EDTA (T-FloLoc™), the rate of mineralization has declined to 12.7% with a rate of 4.5% that need an exchange of the device.

Dysuria, which is commonly seen in cats with double pigtail ureteral stents (38%)[9], was seen in 5-8% of cats with a SUB™ device alone. Most of these cats had a history of dysuria prior to SUB™ placement, negating the device as a primary cause.

Chronic urinary tract infections were documented in 8% of cats prior to routine use of t-EDTA and has gone down to 0% since the routine use of t-EDTA. This has been one of the most impressive findings with the use of this flushing solution.

Overall, the use of a SUB™ for feline and canine patients with a ureteral obstruction can be considered a functional option associated with an excellent prognosis. This is a technique that is best performed using fluoroscopic guidance to help avoid unnecessary complications. Many of the complications seen are technical and can be avoided with proper training and imaging. The biggest long-term complications are mineralization and infections, both of which are showing more promise with the prophylactic use of tetra-EDTA (T-FloLoc™). Again, operators should be well versed in interventional techniques and devices, the possible complications, and appropriately trained in the use of this device before trying this in a clinical patient. Pre- and post-operative management strategies may also play a role in the short- and long-term outcomes and education on the best management of these critical patients should be considered.

Complications	Intra-op (174 SUBs; 145 Episodes; 137 cats)	Peri-op (172 SUBs; 143 Episodes; 135 cats)	Short-term (165 units; 136 episodes; 128 cats)	Long-term (159 renal units; 131 episodes; 124 cats)	Total (2009-2015)	2.0 post t-EDTA 69 SUBs 55 Cats (2017-2019)	3.0 post t-EDTA 42 SUBs 38 Cats (2019-2020) (* 2 2.0's replaced w 3.0's)	Combo 2.0 and 3.0 111 SUBs 73 cats (2017-2020)
Bilateral					27%			52%
Leakage	2.3%	3.5%			5.7%	1.5%	0%	1%
Kinking	1.7%	0.6%		2.5%	4.6%	15%	0%	11%
Blood clot in device	2.3%	5.2%	2.4%	0.6%	8%	11.6%	4.7%	9%
Urethral obstruct/Cystotomy			2.3%	3.2%	5.4%	0%	0%	0%
Mineralization of device			0.6%	24.5%	24.2%	16%	7%	12.7%
Need for device exchange for mineralization					12.4%	7%	0%	4.5%
E-tube hemorrhage	1.4%				1.5%	0%	0%	0%
Fluid overload		4.2%			4.2%	9%	5%	9.5%
Dysuria		2.8%		5.5%	8.3%	9%	5% (all dilated with a 2.0 as well)	6.8%
Worsening Azotemia		1.4%			1.4%	0%	0%	0%
Chronic UTI				8%	8%	0%	0%	0%
Death prior to discharge	1.4%	4.9%	2.9%		6.2%	5.5%	5.2%	5.5%
Median (mean; range) follow-up time (days)					896 (1007, 0.25-2,988)	276 (342, 4-916)	204 (190, 4-412)	244 (283, 4-916)

TABLE 1. COMPLICATION CHART COMPARING THE SUB™ 1.0, 2.0 AND 3.0 FROM 2009-2020.

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Please email allyson.berent@gmail.com or chick.weisse@gmail.com if you have any questions or need additional information on the flushing procedure of the SUB™ device.

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Please email allyson.berent@gmail.com or chick.weisse@gmail.com if you have any questions or need additional information on the flushing procedure of the SUB™ device.

ORDERING INFORMATION

SUB™ 3.0 KITS (1 KIT PER BOX)

Catalog Number	Description
SUB3-2001K for use in cats and small dogs	- 1 x 6.5F x 20cm Locking Loop Catheter with Stiffening Cannula - 1 x 7F x 23.1cm Bladder Catheter with Stiffening Cannula - 1 x 7F x 30cm Polyurethane Catheter Tubing - 1 x Low-Profile SwirlPort™ - 1 x ***3-way "Y" Connector*** - 1 x 18G Over-the-Needle Catheter - 1 x 0.035" J-Tip Guidewire - 5 x Blue Boot Catheter Connectors - 2 x 22G x 0.75" Posi-Grip Huber Point Needle - Surgical Instructions
SUB3-2002K for use in larger dogs	- 1 x 6.5F x 35cm Locking Loop Catheter with Stiffening Cannula - 1 x 7F x 38.1cm Bladder Catheter with Stiffening Cannula - 1 x 7F x 30cm Polyurethane Catheter Tubing - 1 x Low-Profile SwirlPort™ - 1 x ***3-way "Y" Connector*** - 1 x 18G Over-the-Needle Catheter - 1 x 0.035" J-Tip Guidewire - 5 x Blue Boot Catheter Connectors - 2 x 22G x 0.75" Posi-Grip Huber Point Needle - Surgical Instructions
SUB3-3001K for use in cats and dogs, typically for obstructive neoplasia	- 2 x 6.5F x 20cm Locking Loop Catheter with Stiffening Cannula - 1 x 7F x 23.1cm Bladder Catheter with Stiffening Cannula - 1 x 7F x 30cm Polyurethane Catheter Tubing - 1 x Low-Profile SwirlPort™ - 1 x ***4-way "X" Connector*** - 2 x 18G Over-the-Needle Catheter - 1 x 0.035" J-Tip Guidewire - 6 x Blue Boot Catheter Connectors - 2 x 22G x 0.75" Posi-Grip Huber Point Needle - Surgical Instructions

SUB™ FLUSH KITS (5 KITS PER CASE)

Catalog Number	Description
SFK-22 for use with all shunting ports	- 1 x T-Port Connector - 1 x 3-way Stop-Cock - 1 x 22-Gauge Huber Point Needle - 2 x 3mL Syringe - 1 x 2.5mL Sterile Saline in 3mL Syringe - 1 x 2mL ***T-FloLoc™*** in 12mL Syringe*
SFK-20 for use with all shunting ports	- 1 x T-Port Connector - 1 x 3-way Stop-Cock - 1 x 20-Gauge Huber Point Needle - 2 x 3mL Syringe - 1 x 2.5mL Sterile Saline in 3mL Syringe - 1 x 2mL ***T-FloLoc™*** in 12mL Syringe*

NOTE: each flush kit is sterile packaged, suitable for sterile field use

**T-FloLoc™ can be ordered separately; call for details*