NORFOLK VET PRODUCTS

Specialty Medical Devices For The Veterinary Community

the SUB™ FLUSH KIT

A Special Flush Kit with T-FloLoc™ for use with the SUB System

INSTRUCTIONS FOR USE

provided by Drs. Allyson Berent and Chick Weisse

A New Option for Preventing Occlusion and Biofilm Formation in the SUB System

designed and developed in collaboration with veterinarians

the SUB™
Veterinary Use Only

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a guide to the use of the

SUB™ FLUSH KIT

A Special Flush Kit with T-FloLoc™ for use with the SUB System

GUIDELINES / INSTRUCTIONS FOR USING THE SUB™ FLUSH KIT

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

The development of an indwelling SUB device (Figure 1) using a multi-fenestrated locking-loop nephrostomy catheter attached via a dual-armed shunting port to a multi-fenestrated locking-loop cystostomy catheter provides renal pelvis drainage, avoiding trauma and complications associated with ureteral surgery or manipulation.[1-5]A similar bypass device in humans has been used for human patients with extensive urinary tract malignancies, ureteral strictures secondary to renal transplantation, when ureteral stenting is ineffective, or when traditional ureteral stenting or ureteral surgery fails or is contraindicated.[4-6] In humans[6-8], that device has reduced complications associated with externalized nephrostomy tubes and improved patient quality of life. The SUB device for veterinary patients contains a subcutaneous shunting port to permit periodic flushing and sampling of urine; this is a design unique to this system to help maintain long-term patency and infuse material to minimize biofilm formation and mineralization.

The SUB device has been placed in thousands of cats and has been recently reported in 174 feline ureters.[5] This device has remained functional and indwelling for over 7.5 years in many feline patients. It is important for the operator to have appropriate training with this device prior to considering its use on a clinical patient. Please contact us prior to use (Allyson.Berent@gmail.com or Chick.Weisse@gmail.com).

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 urine sample is obtained for analysis and culture, followed by infusion of a novel solution called tetrasodium ethylenediaminetetraacetic acid, also called tetra-EDTA or T-FloLoc. This substance helps prevent occlusion with stone material and treats/prevents biofim formation. This procedure typically does not require any sedation or anesthesia, is performed using ultrasound guidance with minimal restraint, and can be performed more routinely if necessary in patients at high risk for encrustation or infection.

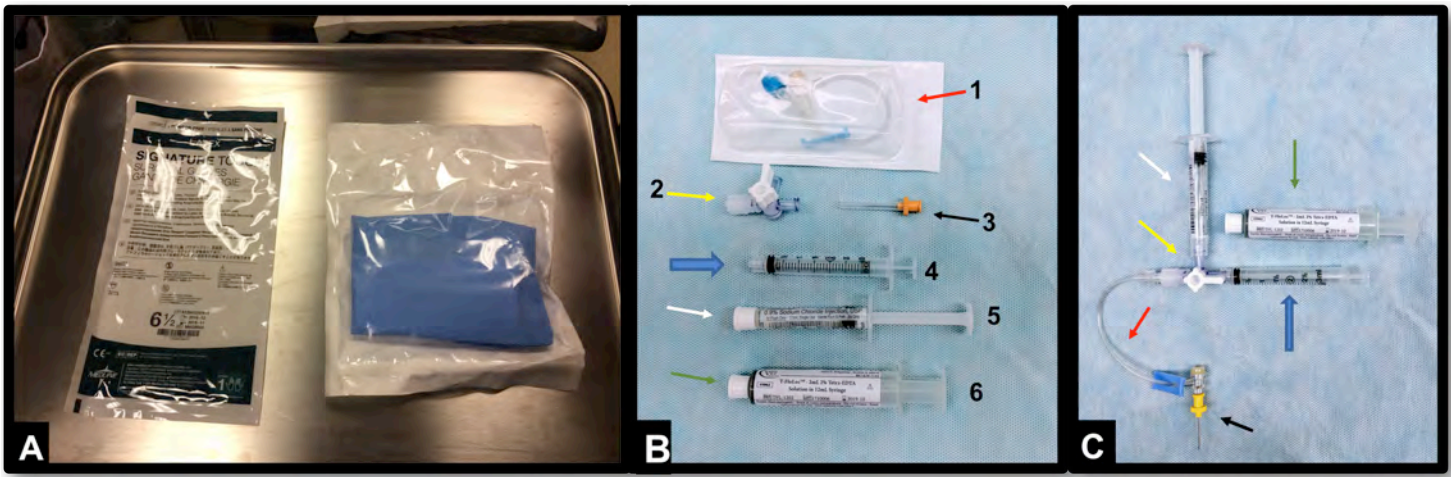


Figure1: Set Up of the SUB Flush Kit. A) sterile gloves and the flush kit. B) The parts in the SUB Flush Kit. 1. T-port Connector, 2. 3-way Stop-Cock, 3. 22G Huber Needle, 4. 3mL Syringe, 5. 2.5 mL Serile Saline in 3mL Syringe 6. 2mL Tetra-EDTA (***T-FloLoc™***) in 12mL Syringe. C) All of the parts attached properly to the system for flushing.

The ***SUB Flush Kit*** has been designed to include everything you will need to perform this procedure. The pack is sterile and the content should be put together using sterile gloves as depicted in Figure 1. The patient is positioned in dorsal recumbency in a V-trough to facilitate port access and ultrasonography. The following materials are included (Figure 1a-c).

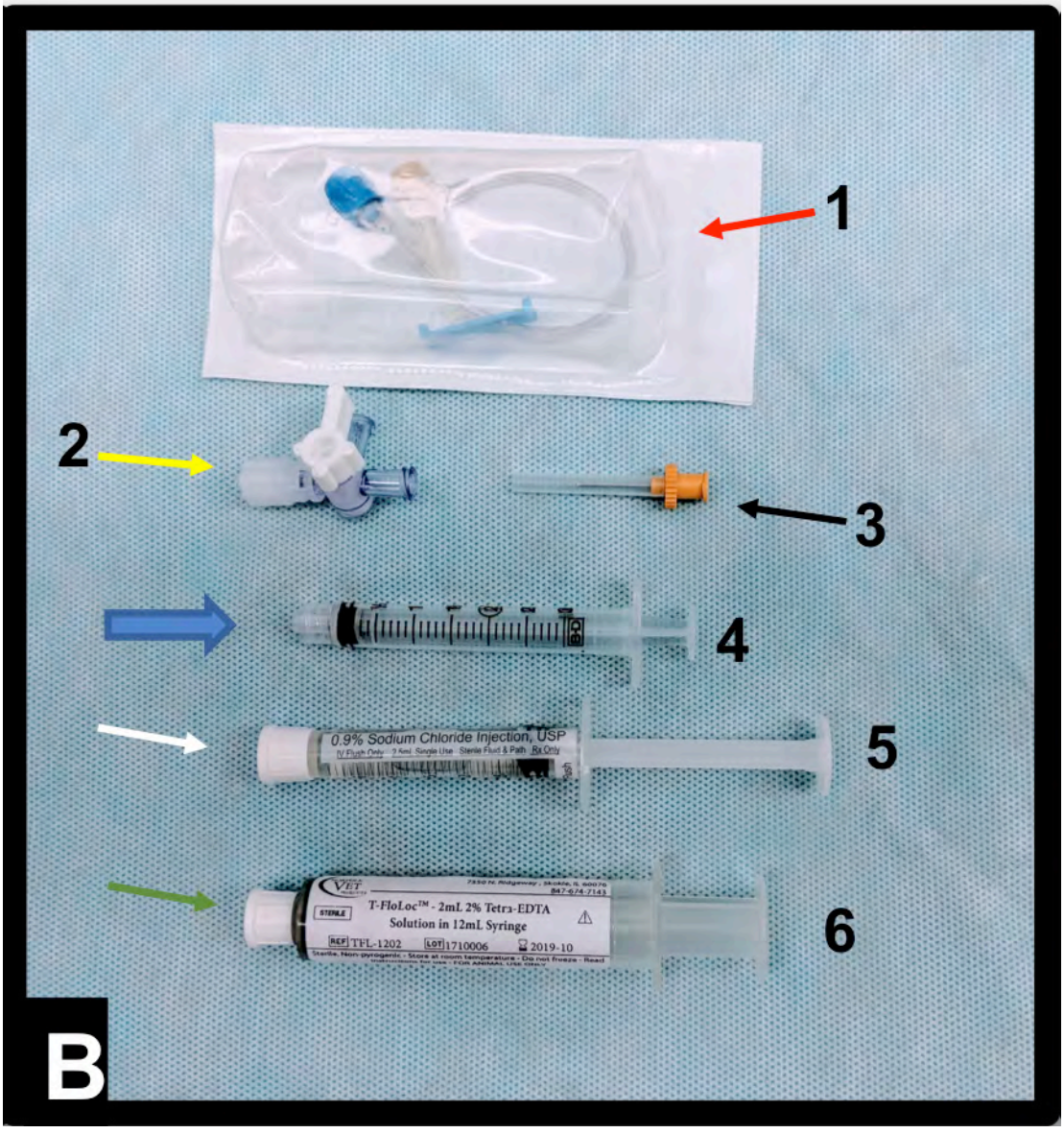
In addition you will need a clipper to clip the fur over the SUB port, and scrub solution to adequately scrub the skin over the SUB port so that the procedure is done in a sterile manner (Figure 2; Page 3). Prior to flushing, the renal pelvis sizes should be measured and recorded using ultrasound guidance.

EQUIPMENT NEEDED - INCLUDED IN SUB FLUSH KIT

1. 1 x T-Port Connector
2. 1 x 3-way Stop-Cock
3. 1 x 22G or 20G Huber Point Needle
4. 1 x 3mL Syringe
5. 1 x 2.5mL Sterile Saline in 3mL Syringe
6. 1 x 2mL ***T-FloLoc™*** in 12mL Syringe
7. Surgical Instructions (1 per Case of 5 kits)

ADDITIONAL EQUIPMENT NEEDED - **NOT** INCLUDED IN SUB FLUSH KIT

1. Sterile Gloves
2. Clipper to clip fur over the SUB Port
3. Scrub Solution to clean skin over the SUB Port



Ultrasound-Guided Flushing of the SUB (Figure 2,3): should be done through the shunting port using a Huber needle (Figure 1b,c; Figure 2). An extension set with a 3-way stop-cock is used with one empty syringe for urine sampling and one syringe filled with sterile saline (ultrasound-guidance). The shunting port is palpated under the skin and the flat silicone insertion site is isolated (Figure 2A). Using sterile technique, the Huber needle is advanced through the skin, into the silicone diaphragm until metal is reached. This must be done in a perpendicular manner (Figure 2A). Once the needle is inside the shunting port, a urine sample is obtained (Figure 2E). If no urine is withdrawn then the needle is either not deep enough into the access port, at the wrong angle, or the system is occluded on both ends.

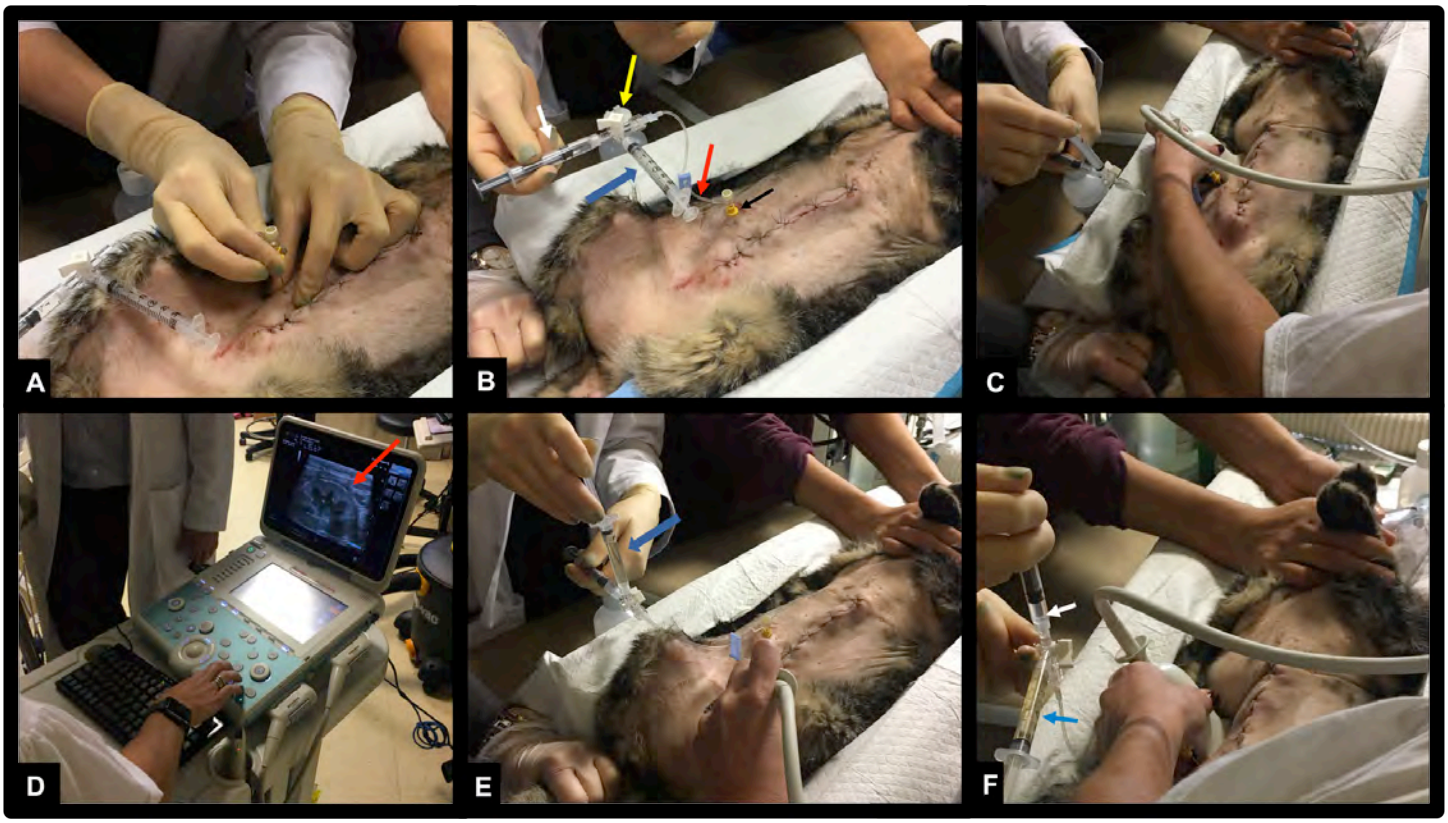


Figure 2:The flushing procedure.The cat is placed in dorsal recumbency and the port site is clipped and aseptically prepared and scrubbed using chlorohexidine surgical scrub. A) The Huber needle is inserted into the port using sterile technique and sterile gloves. Once metal is hit with the needle (black arrow) and the needle is within the well than the system is in place (B). The empty syringe (blue arrow), 3-way stopcock (yellow arrow), T-port (red arrow), and sterile saline (white arrow). C) Ultrasound is used to evaluate the renal pelvis and urinary bladder measuring size and evaluating for any pathology. D) ultrasound image of the kidney with the SUB coming through the caudal pole (red arrow). E) Urine being drained from the port (blue arrow). F) saline being infused into the system (white arrow), monitoring the kidney with ultrasound guidance.

Once urine is obtained (and submitted for urine culture and urinalysis) the sterile saline is carefully injected into the port while the renal pelvis is being monitored with ultrasound guidance (Figure 2F, Figure 3). Once saline is seen to enter the renal pelvis (usually confirmed by the presence of small air bubbles-Figure 3A) 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 VOLUME of saline to see fluid enter the urinary bladder through the SUB cystostomy tube (Figure 2F, 3B). Again, bubbles are usually seen (Figure 3B). 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) to ensure it is not being over-distended. Once patency is confirmed, then the urine sample is removed from the 3-way-stop-cock and the syringe with T-FloLoc is attached to the system. The saline should again be withdrawn from the system. Once the renal pelvis is drained empty, the flush solution is slowly flushed into the renal pelvis avoiding any overdistension. This is done in pulses to allow for the solution to drain down the SUB between each pulse. Typically 1-2 mL is infused if no distension is seen. 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.

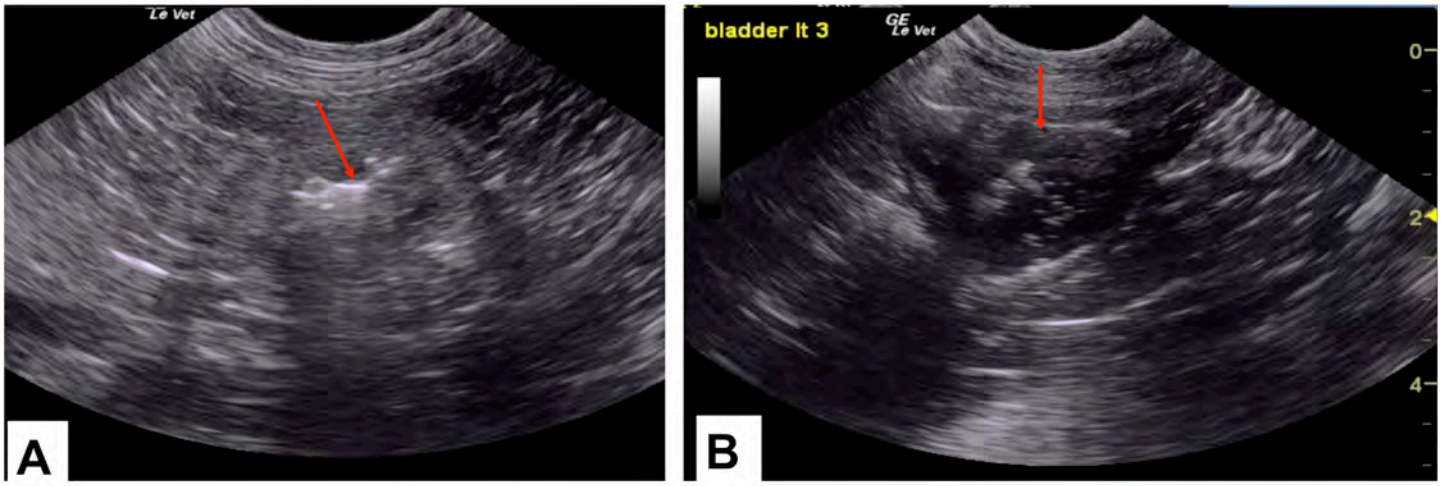


Figure 3: Ultrasound images of the kidney. (A) and the Bladder (B), during an infusion. Notice the blubbles (red arrows)

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 carefully removed form the port, and the procedure is complete.

Fluoroscopic Guidance Technique (Figure 4): 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 than you need 100% of iohexol (240-360mg/mL) in a 3 mL syringe connected to the T-port, 3-way stop-cock, and empty syringe system (Figure 1). 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.

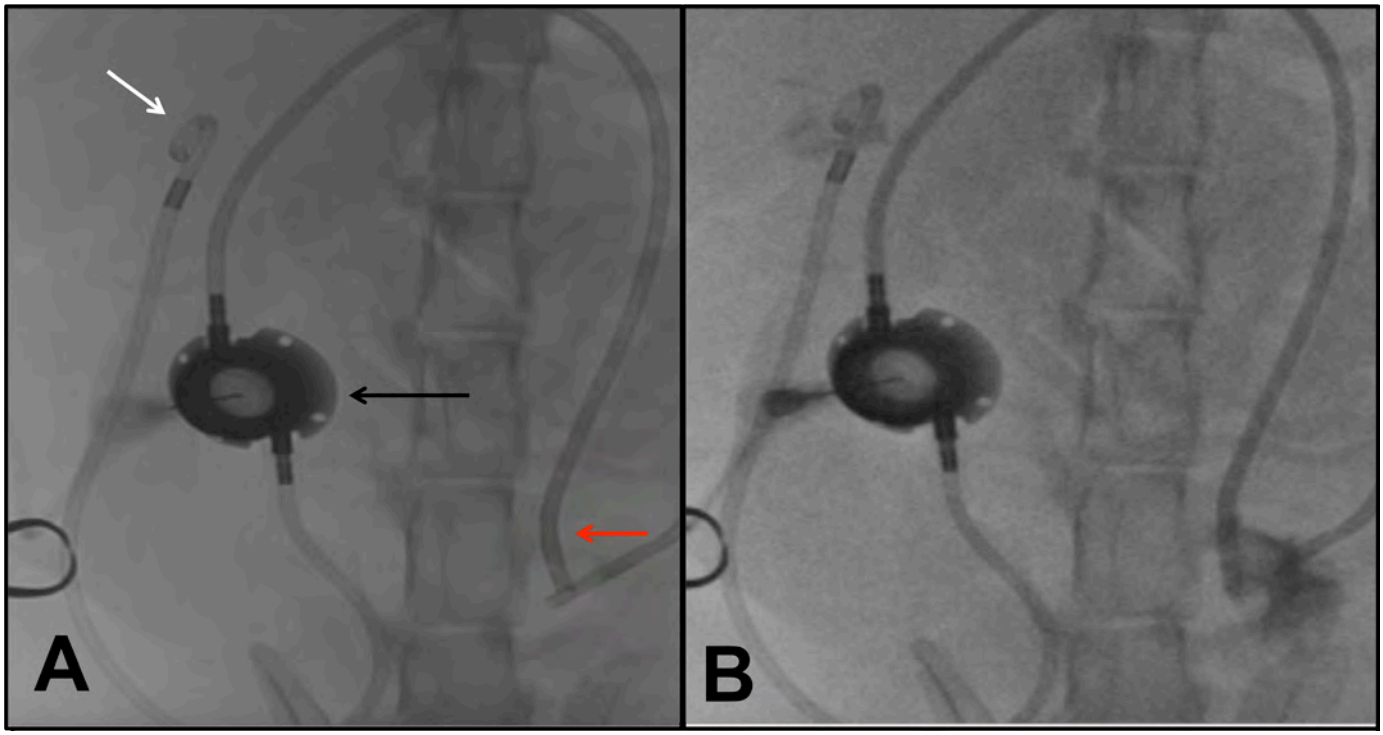


Figure 4 (A,B): Fluoroscopic images of a cat with bilateral SUBs in dorsal recumbency. A) not entire SUB system is visualized with the nephrostomy tube (white arrow), port (black arrow) and bladder catheter (red arrow). B) Contrast is infused into the system after urine is drained showing contrast in the renal pelvis, catheters and urine bladder confirming patency.

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 4). This is ideally done using digital subtraction radiography (DSR), as long as the patient is not moving (Figure 4c). If the patient is not sedated then DSR is more difficult so regular fluoroscopy is used (Figure 4a,b; Page 4). The pelvis should not be over-distended and the injection should be done slowly (0.5 ml at a time after 3 ml drainage). The renal pelvis and the urinary bladder should be monitored simultaneously (Figure 4b,c) to ensure both catheters are filling with contrast to the pelvis and bladder and there is no renal pelvis overdistension. Then all of the contrast should be easily withdrawn from the bladder and renal pelvis. Then the T-FloLoc syringe is mixed with 1 ml of contrast. This mixture is attached to the stop-cock and it too is infused into the system slowly, avoiding renal pelvis over-distension. This should be done in 0.5 ml increments with pauses allowing drainage of the material between each pulse to avoid over-distenion. 1-2 ml of total solution should be infused. The needle can then be carefully removed from the port, and the flush is complete.

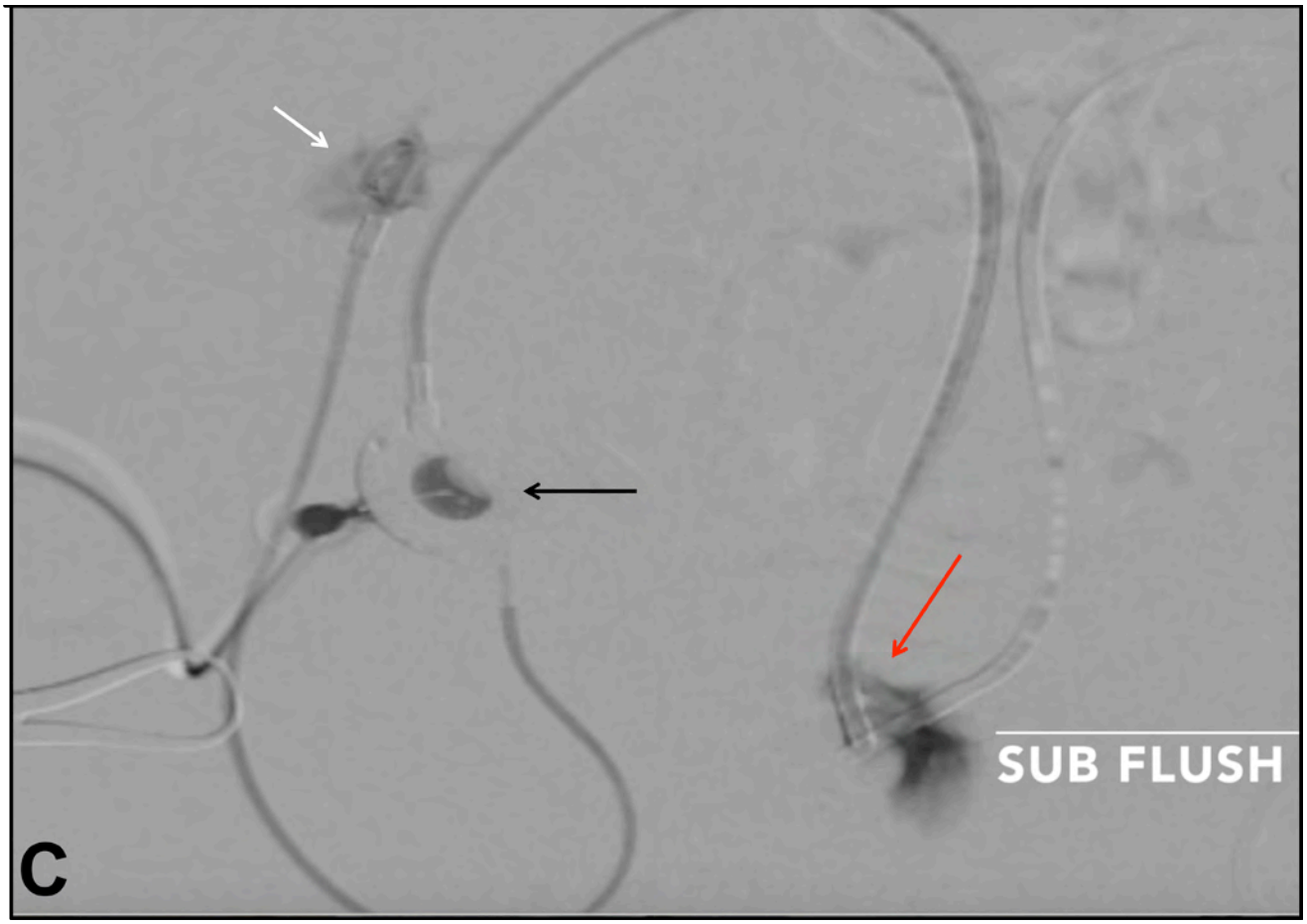


Figure 4C: Fluoroscopic images of a cat with bilateral SUBs in dorsal recumbency. C) Flush done under digital subtraction radiography (DSR) showing how much easier it is to see the contrast in the system. This can only be done with sedation or anesthesia as it requires a pause in breathing and movement.

NOTES:

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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.

SUB™ FLUSH KIT CONTENTS (5 PER CASE)

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
- 1 x 3mL Syringe
- 1 x 2.5mL Sterile Saline in 3mL Syringe
- 1 x 2mL ***T-FloLoc™*** in 12mL Syringe
- Instructions For Use (1 per Case of 5 Kits)

SFK-20 - option for Swirl and Large Shunting Ports
- 1 x T-Port Connector
- 1 x 3-way Stop-Cock
- 1 x 20-Gauge Huber Point Needle
- 1 x 3mL Syringe
- 1 x 2.5mL Sterile Saline in 3mL Syringe
- 1 x 2mL ***T-FloLoc™*** in 12mL Syringe
- Instructions For Use (1 per Case of 5 Kits)

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