NORFOLK VET PRODUCTS

Speciality 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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v1801

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.

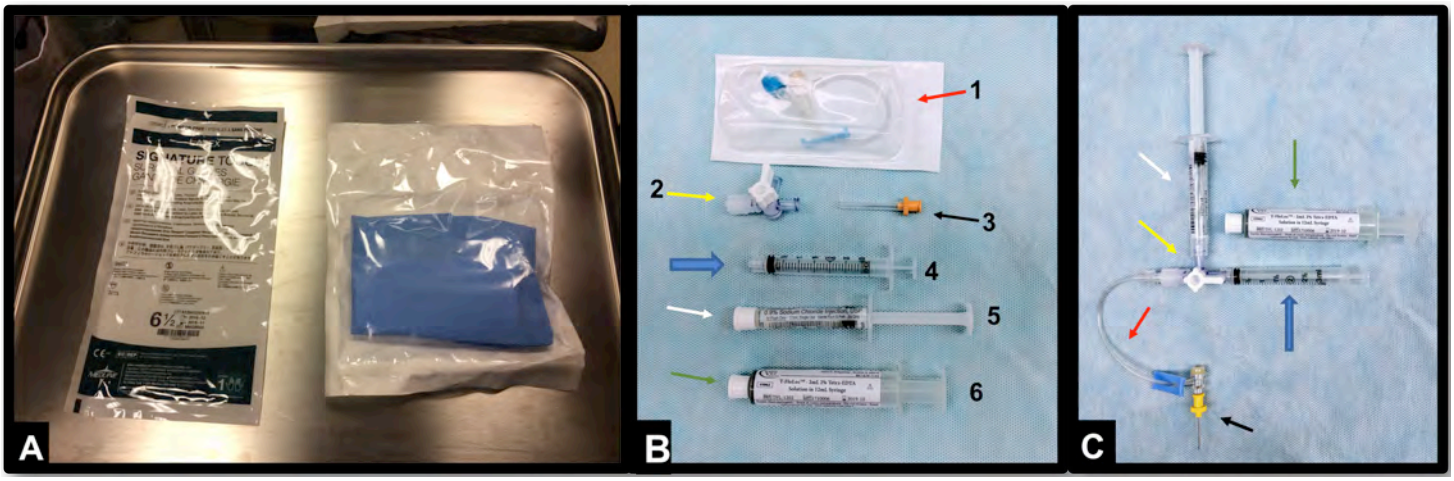


Figure1: Set Up of the SUB Flush Kit. A) sterile gloves and the flush kit. B) The parts in the SUB Flush Kit. 1. T-port Connector, 2. 3-way Stop-Cock, 3. 22G Huber Needle, 4. 3mL Syringe, 5. 2.5 mL Serile Saline in 3mL Syringe 6. 2mL Tetra-EDTA (***T-FloLoc™***) in 12mL Syringe. C) All of the parts attached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

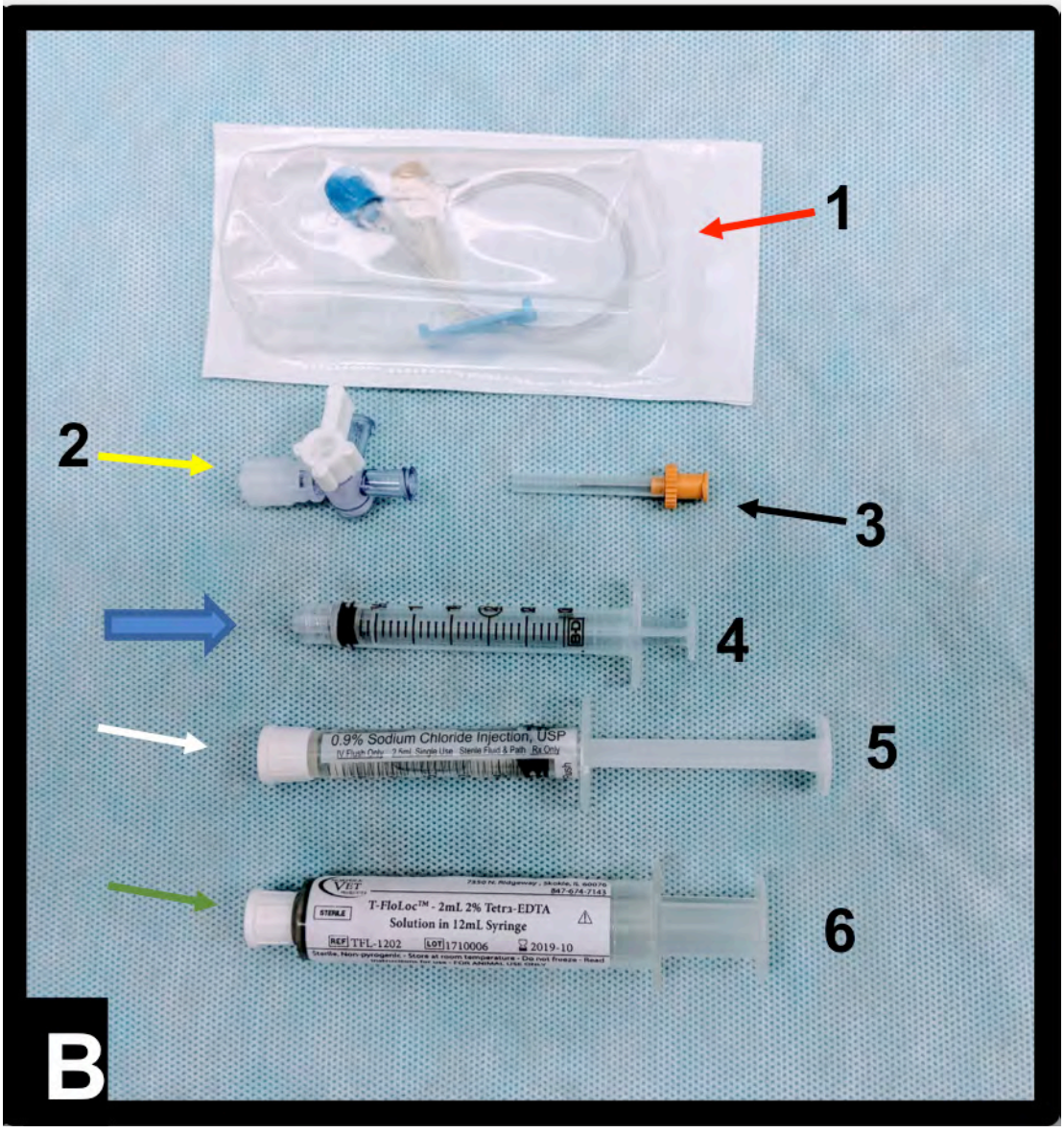
In addition you will need a clipper to clip the fur over the SUB port, and scrub solution to adequately scrub the skin over the SUB port so that the procedure is done in a sterile manner (Figure 2; Page 3). Prior to flushing, the renal pelvis sizes should be measured and recorded using ultrasound guidance.

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.

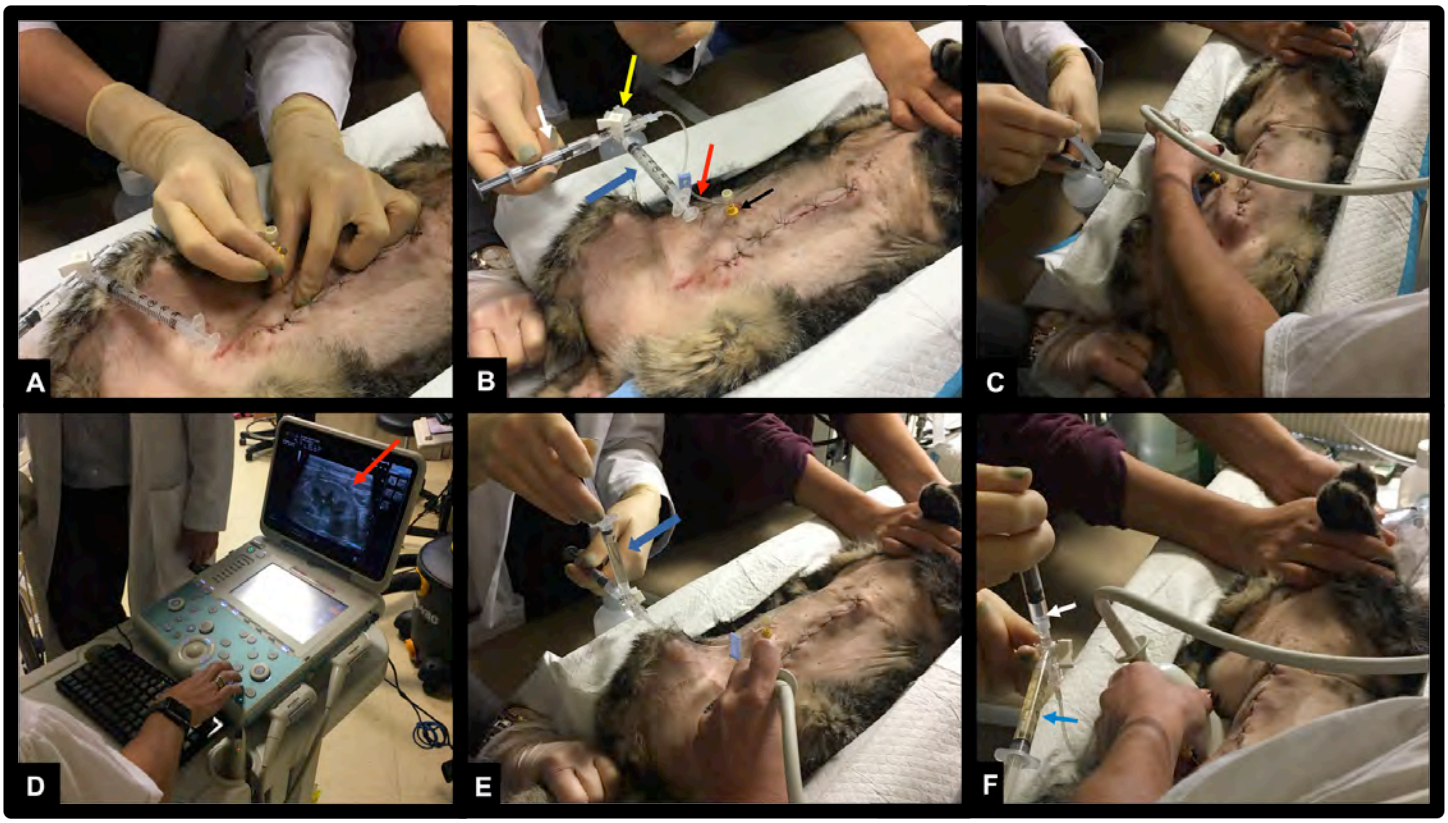


Figure 2:The flushing procedure.The cat is placed in dorsal recumbency and the port site is clipped and aseptically prepared and scrubbed using chlorohexidine surgical scrub. A) The Huber needle is inserted into the port using sterile technique and sterile gloves. Once metal is hit with the needle (black 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.

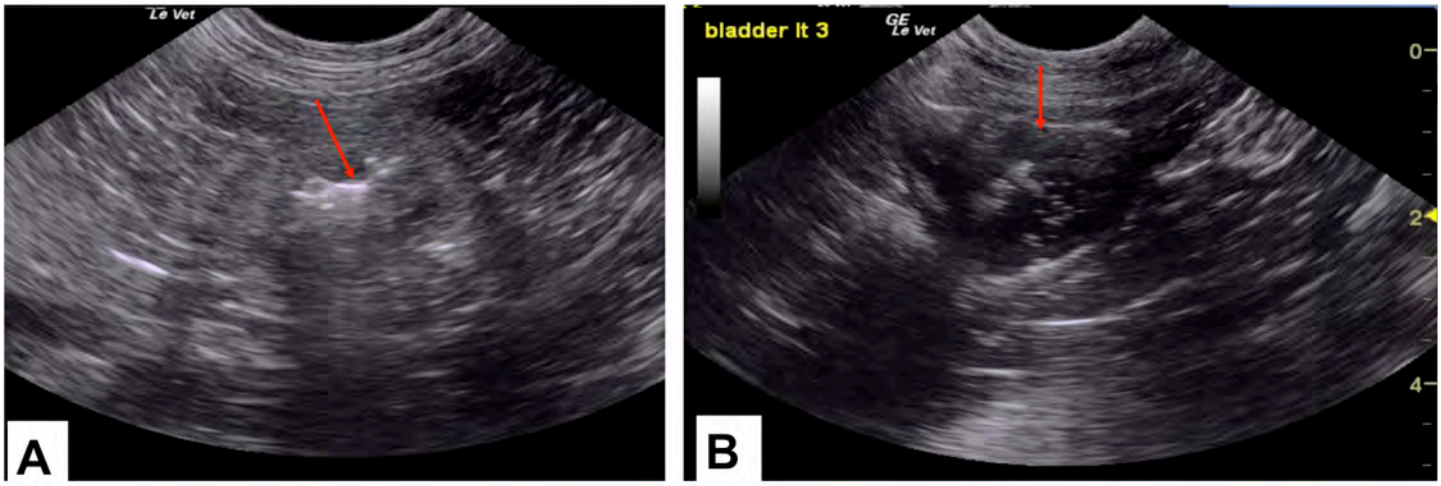


Figure 3: Ultrasound images of the kidney. (A) and the Bladder (B), during an infusion. Notice the blubbles (red arrows)

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.

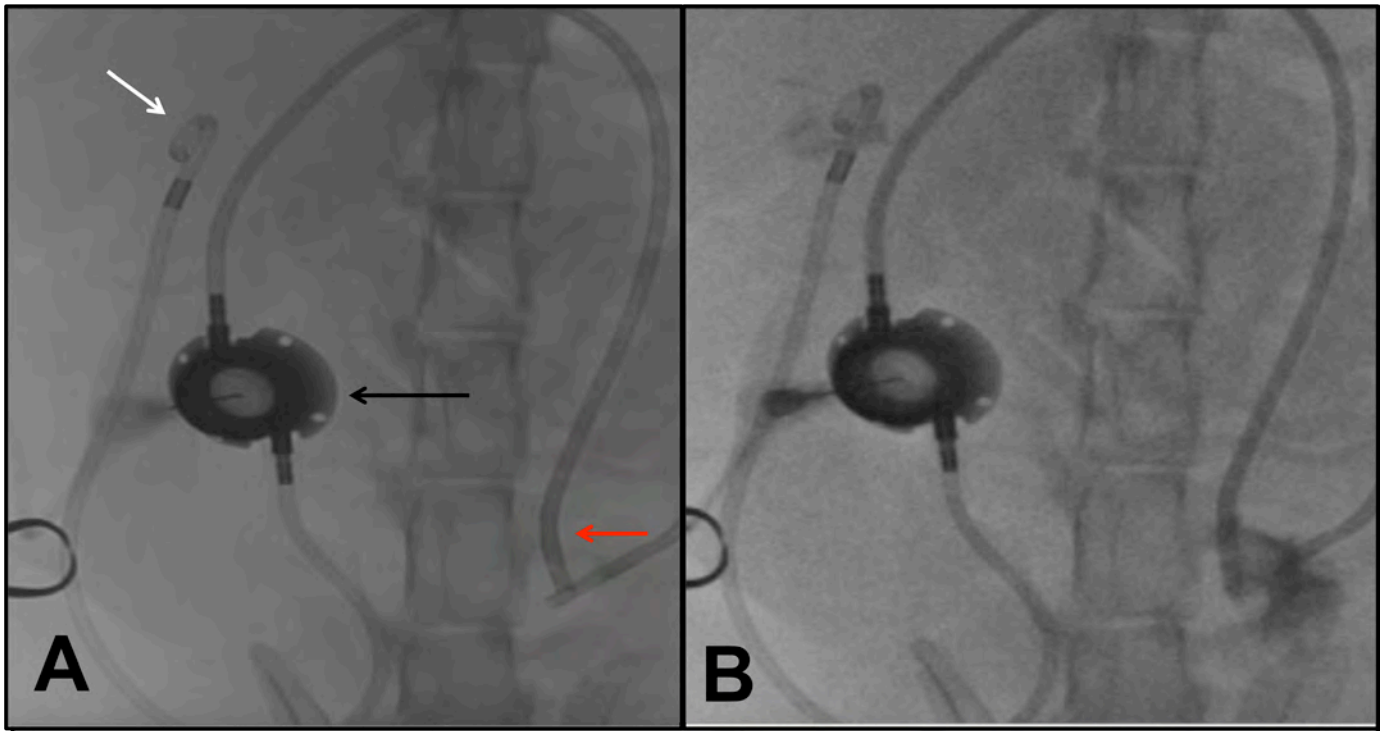


Figure 4 (A,B): Fluoroscopic images of a cat with bilateral SUBs in dorsal recumbency. A) not entire SUB system is visualized with the nephrostomy tube (white arrow), port (black arrow) and bladder catheter (red arrow). B) Contrast is infused into the system after urine is drained showing contrast in 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 (DSA), as long as the patient is not moving (Figure 4c). If the patient is not sedated then DSA 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.

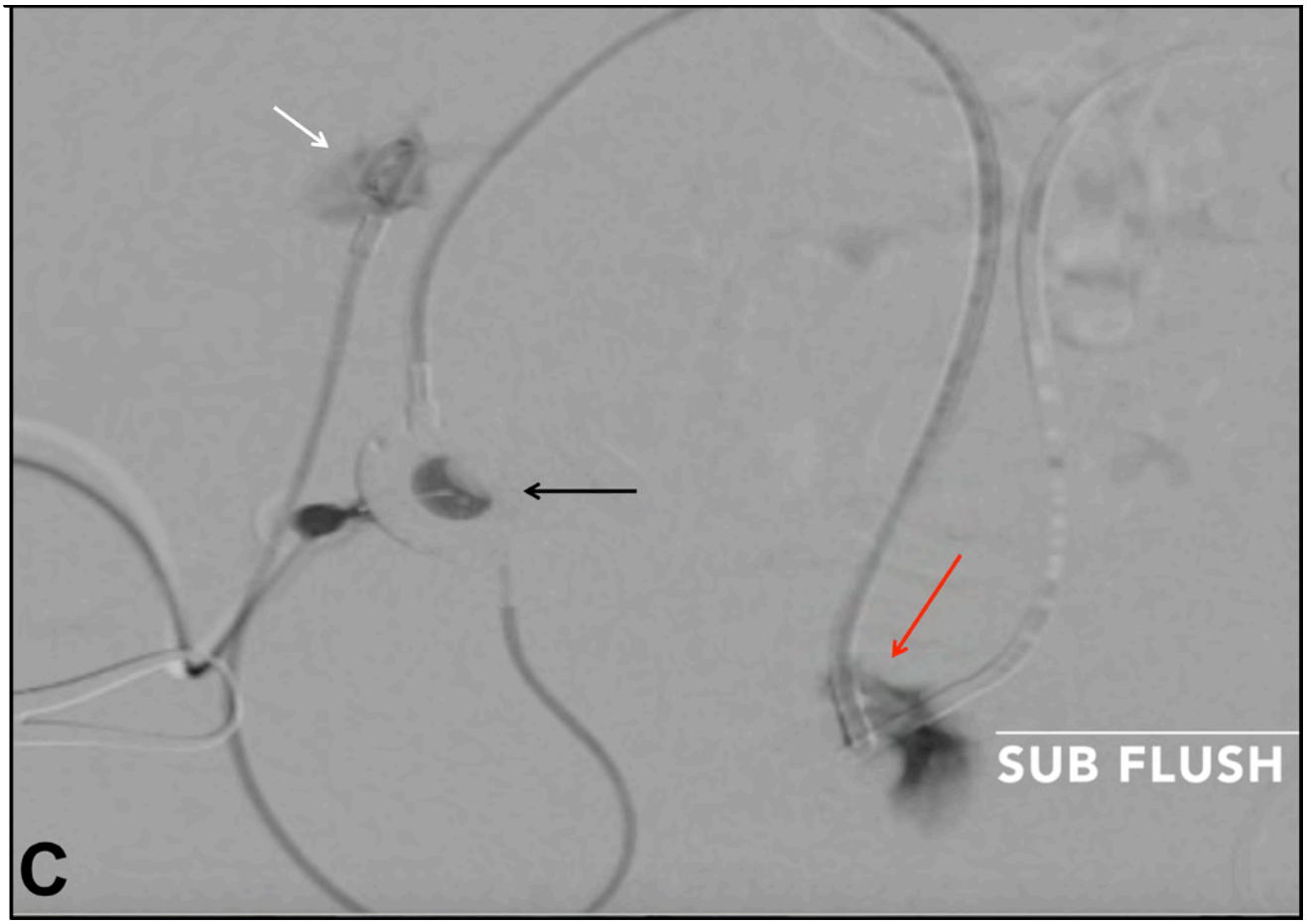


Figure 4C: Fluoroscopic images of a cat with bilateral SUBs in dorsal recumbency. C) Flush done under digital subtraction radiography (DSA) showing how much easier it is to see the contrast in the system. This can only be done with sedation or anesthesia as it requires a pause in breathing and movement.

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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1. Berent AC. Ureteral obstructions in dogs and cats: a review of traditional and new interventional diagnostic and therapeutic options. J Vet Emerg Crit Care. 2011; 21(2): 86-103.

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T-FloLoc™

Instructions for Use

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A. Description & Specifications

T-FloLoc™ 2% Catheter Lock/Flush Solution is a sterile, single-use, clear, colorless solution. It is free of preservatives, antibiotic, alcohol, and latex, and it is non-pyrogenic. T-FloLoc™ 2% is a chelating agent that functions as an anticoagulant, an antimicrobial, and anti-biofilm agent effective against bacteria and fungi.

B. Indications

Vascular Access Devices (VAD)

T-FloLoc™ 2% is indicated for locking vascular access devices with intermittent intravenous infusions or hemodialysis regimens. T-FloLoc™ 2% is intended to prevent bacterial colonization, the establishment of intraluminal biofilm, and to maintain catheter patency.

Subcutaneous Ureteral Bypass Devices

T-FloLoc™ is indicated for flushing a catheter or implanted device [SUB™, Subcutaneous Ureteral Bypass system] for drainage of the urinary tract. T-FloLoc™ 2% is periodically instilled into the device to maintain patency and prevent biofilm formation and encrustation within urinary tract devices.

C. Contraindications

T-FloLoc™ should not be used in patients with documented sensitivity to edetate.

D. Precautions

1. DO NOT use if the protective cap on the syringe has been broken and/or removed.
2. When drawing blood for sampling, aspirate the T-FloLoc™ lock solution and discard.
3. Use with caution in hypocalcemic conditions (recommend aspiration of the solution prior to infusion in hypocalcemic conditions).

E. Adverse Effects

T-FloLoc™ has no known adverse effects.

F. Installation of T-FloLoc™ 2%

Vascular Access Devices

1. Disinfect the septum of the needleless connector or injection port prior to any access of the VAD. A 10-sec scrub with chlorhexidine/alcohol or 70% alcohol is recommended. Disinfect the skin over the septum of an implanted port prior to access. A two-minute scrub with CHG/IPA is recommended.
2. Flush the device with 0.9% normal saline (2x catheter fill volume recommended). If flushing an implanted port, first access the port with a Huber point needle by advancing the needle through the skin and the silicone septum until reaching the base of the port reservoir, then flush with saline.
3. Using an aseptic technique, attach the T-FloLoc™ syringe to the access device. A zero, neutral, or positive displacement needleless connector is recommended for percutaneous catheters to prevent blood backup into the catheter on disconnection of the syringe.
4. Slowly inject the T-FloLoc™ into the access device to the fill volume of the device. The lock may

Continued on Reverse Side →

remain until the next infusion/withdrawal and does not need to be aspirated prior to the next infusion. Fill volumes for Norfolk Vet Products vascular access devices are available by calling 847-674-7143 or emailing info@norfolkvetproducts.com.

5. Each syringe is for single use only. Discard the syringe after use. Discard any unused portion. Do not reuse.

Subcutaneous Ureteral Bypass Devices (SUB™)*

1. If using a *SUB™ Flush Kit*, follow the *SUB™ Flush Kit Instructions for Use* for flushing with T-FloLoc™ 2%. If not, proceed to instruction #2.
2. Disinfect the skin over the septum of the implanted port prior to access. A two-minute scrub with CHG/IPA is recommended.
3. Using an aseptic technique, advance a Huber point needle through the skin and the silicone septum until reaching the base of the port reservoir. The Huber needle should be attached to a t-connector set fitted with a 3-way stopcock. This allows access to retrieve a urine sample with an empty syringe while also connecting a sterile saline syringe for flushing.
4. Attach an empty syringe (3-10mL) and a syringe (3-10mL) filled with 0.9% normal saline to the stop-cock.
5. Draw back urine to ensure patency and to avoid overfilling. Never infuse more solution than you can withdraw. Once a urine sample is retrieved, remove the sample and submit for culture.
6. Under ultrasound (or fluoroscopy), flush the device with 0.5mL 0.9% normal saline. Start with the ultrasound probe over the renal pelvis. Once saline is seen to enter the renal pelvis, withdraw the fluid to avoid over-distension.
7. Next, place the ultrasound probe over the urinary bladder and flush the port again with the same volume, 0.5mL, of 0.9% normal saline. Care must be taken to NOT overfill the renal pelvis during monitoring of the urinary bladder. The renal pelvis should ALWAYS be monitored during this procedure. Once saline is seen to enter the urinary bladder, withdraw the fluid to avoid over-distension.
8. Attach the T-FloLoc™ syringe to the stop-cock.
9. Slowly inject the T-FloLoc™ into the SUB™ Device. This should be done in pulses to allow for the solution to drain down the SUB between each pulse, typically 1-2mL if no distension is seen. Stop the infusion if any distension is observed in the renal pelvis and wait until it resolves. If it does not resolve in a few seconds, discontinue the flushing.
10. Once the flush is complete, remove the needle/syringe from the port.
11. Each syringe is for single use only. Discard the syringe after use. Discard any unused portion. Do not reuse.

*This technique is for prophylactic flushing only. If the T-FloLoc™ solution is being used for treatment of mineralization or biofilm, please follow the appropriate protocol available through Norfolk Vet.

G. Storage

T-FloLoc™ 2% should be stored at room temperature. Do not freeze.

References

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Note: This protocol is based on initial clinical experience presented at the Veterinary Interventional Radiology and Endoscopy (VIRIES) conference in 2017. Successful demineralization of a SUB device was accomplished in 8/10 devices and successful eradication of recurrent urinary tract infections was successful in 3/4 patients. The protocols recommended is what has been deemed to be safe and effective in this small groups of feline patients in the authors' experience.

T-FloLoc™ (Tetra-EDTA) Protocol for INFECTION

Provided by Drs. Allyson Berent and Chick Weisse

Precautions:

1. **Clip the port site and scrub using aseptic technique as usual when accessing the SUB™.**
2. **Follow instructions on SUB Flushing in *THE SUB™ FLUSH KIT or T-FloLoc™ IFUs.***
3. **Typically, DO NOT INFUSE MORE THAN 6-10 mL after emptying bladder. NEVER infuse more than you can remove. ALWAYS monitor renal pelvis using ultrasound or fluoroscopy during infusion. AVOID OVERFILLING THE RENAL PELVIS. Infuse in pulses and avoid using too much pressure to avoid overfilling pelvis. The goal is for the T-FloLoc™ to stay in the bladder and to coat the catheters as long as possible. Try to get the bladder empty through the SUB™ prior to infusion.**
4. **Must have pet on correct antibiotic before starting protocol. This material will clear the biofilm from the catheter but NOT the tissue of the bladder, ureter, and kidney. In addition, as the bacteria are released from the biofilm, systemic antibiotic therapy will help to kill the bacteria in the urine. If you cannot get on a proper systemic antibiotic, then the chance of success is likely lower to clear a recurrent infection associated with a biofilm on the catheters and in the urinary tissues. We recommend 3-7 days of appropriate antibiotic before starting this protocol so that you have a negative culture on the day of starting infusions. We continue antibiotics for a minimum of 4-6 weeks.**

WEEK 1:

Day 1: focused urinary tract ultrasound, CBC/CHEM, remove urine for urine cytology, urinalysis and urine culture, remove and quantify all urine from SUB(s) through the port, infuse up to 75% of that volume under ultrasound guidance to fill the kidney, catheters and bladder OR until the pelvis is getting some dilation (not more than about 6-10 mL total given VERY slowly). Do this under sedation if the patient is not compliant so that the patient can be in dorsal recumbency and immobile for 20-30 minutes (usually sedation is NOT needed). If patient is compliant, keep bladder small so that they do not urinate for 1-2 hours, and remove litter box from cage for 1-2 hours. Repeat drainage and infusion 2-4 hours later.

Day 2: Same infusion procedure as above with a urine cytology (no need for culture or UA)

Day 3: Same infusion procedure as above with urinalysis, cytology and culture.

Day 4: Same infusion procedure as above with a urine cytology (no need for culture or UA)

Day 5: Same infusion procedure as above with urinalysis, cytology and culture, and renal panel

WEEK 2:

Day 8-10: Renal panel, urinalysis, cytology and culture, then remove and quantify all urine from SUB(s) port, infuse 75% of that volume under ultrasound guidance to fill the kidney, catheters and bladder (not more than 6-10 mL total). Do this under sedation if not compliant (usually sedation not needed) so that the patient can be in dorsal recumbency and immobile for 20-30 minutes. Remove litter box for 1-2 hours. Do not repeat same day.

WEEK 3:

Day 15-17: Renal panel, urinalysis, cytology and culture, then remove and quantify all urine from SUB(s) port, infuse 75% of that volume under ultrasound guidance to fill the kidney, catheters and bladder (not more than 6-10 mL total). Do this under sedation if not compliant (usually sedation not needed) so that the patient can be in dorsal recumbency and immobile for 20-30 minutes. Remove litter box for 1-2 hours. Do not repeat same day.

WEEK 4:

Day 22-24: Renal panel, urinalysis, cytology and culture, then remove and quantify all urine from SUB(s) port, infuse 75% of that volume under ultrasound guidance to fill the kidney, catheters and bladder (not more than 6-10 mL total). Do this under sedation if not compliant (usually sedation not needed) so that the patient can be in dorsal recumbency and immobile for 20-30 minutes. Remove litter box for 1-2 hours. Do not repeat same day.

WEEK 5: **STOP ANTIBIOTICS******

Day 29-31: Antibiotics should have been stopped 1-3 days prior to this visit. Renal panel, urinalysis, cytology and culture, then remove and quantify all urine from SUB(s) port, infuse 75% of that volume under ultrasound guidance to fill the kidney, catheters and bladder (not more than 6-10 mL total). Do this under sedation if not compliant (usually sedation not needed) so that the patient can be in dorsal recumbency and immobile for 20-30 minutes. Remove litter box for 1-2 hours. Do not repeat same day.

WEEK 6: OFF Antibiotics for 1-week

Day 36-38: Renal panel, urinalysis, cytology and culture, then remove and quantify all urine from SUB(s) port, infuse 75% of that volume under ultrasound guidance to fill the kidney, catheters and bladder (not more than 6-10 mL total). Do this under sedation if not compliant (usually sedation not needed) so that the patient can be in dorsal recumbency and immobile for 20-30 minutes. Remove litter box for 1-2 hours. Do not repeat same day.

WEEK 8:

Day 50-65: Renal panel, urinalysis, cytology and culture, then remove and quantify all urine from SUB(s) port, infuse 75% of that volume under ultrasound guidance to fill the kidney, catheters and bladder (not more than 6-10 mL total). Do this under sedation if not compliant (usually sedation not needed) so that the patient can be in dorsal recumbency and immobile for 20-30 minutes. Remove litter box for 1-2 hours. Do not repeat same day. Then every 3 months thereafter: renal panel urinalysis, cytology and culture, then remove and quantify all urine from SUB(s) port, infuse 1.5 ml per SUB device as long as that much or more is removed prior to infusion.

WEEK 12:

Day 78-80: CBC/CHEM, urinalysis, cytology and culture, then remove and quantify all urine from SUB(s) port, infuse 75% of that volume under ultrasound guidance to fill the kidney, catheters and bladder (not more than 6-10 mL total). Do this under sedation if not compliant (usually sedation not needed) so that the patient can be in dorsal recumbency and immobile for 20-30 minutes. Remove litter box for 1-2 hours. Do not repeat same day.

WEEK 18:

Day 120-122: Renal panel, urinalysis, cytology and culture, then remove and quantify all urine from SUB(s) port, infuse 75% of that volume under ultrasound guidance to fill the kidney, catheters and bladder (not more than 6-10 mL total). Do this under sedation if not compliant (usually sedation not needed) so that the patient can be in dorsal recumbency and immobile for 20-30 minutes. Remove litter box for 1-2 hours. Do not repeat same day.

WEEK 30:

Day 204-206: CBC/CHEM, urinalysis, cytology and culture, then remove and quantify all urine from SUB(s) port, infuse 75% of that volume under ultrasound guidance to fill the kidney, catheters and bladder (not more than 6-10 mL total). Do this under sedation if not compliant (usually sedation not needed) so that the patient can be in dorsal recumbency and immobile for 20-30 minutes. Remove litter box for 1-2 hours. Do not repeat same day.

REPEAT EVERY 3-months thereafter unless infection recurs and then modify schedule.

For Technical Information, please contact:

Allyson Berent, DVM, DACVIM at allyson.berent@gmail.com

and /or

Chick Weisse, VMD, DACVS at chick.weisse@gmail.com

T-FloLoc™ INFECTION Protocol CHART

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T-FloLoc™ For Infection

T-FloLoc™ - Infection	Day	1	2	3	4	5	8-10	15-17	22-24	29-31	36-38	50-65	78-80	120-122	204-206

Day 1	Day 2	Day 3	Day 4	Day 5	Day 8-10	Day 15-17
☐Focused UT US ☐CBC/Chem ☐Urine cytology ☐UA ☐UCS ☐Infusion 1 ☐Infusion 2	☐Urine cytology ☐UA ☐Infusion 1 ☐Infusion 2	☐Urine cytology ☐UA ☐UCS ☐Infusion 1 ☐Infusion 2	☐Urine cytology ☐UA ☐Infusion 1 ☐Infusion 2	☐Renal panel ☐Urine cytology ☐UA ☐UCS ☐Infusion 1 ☐Infusion 2	☐Renal panel ☐Urine cytology ☐UA ☐UCS ☐Infusion	☐Renal panel ☐Urine cytology ☐UA ☐UCS ☐Infusion
Day 22-24	**Day 29-31**	**Day 36-38**	**Day 50-65**	**Day 78-80**	**Day 120-122**	**Day 204-206**
☐Renal panel ☐Urine cytology ☐UA ☐UCS ☐Infusion ☐**Stop abx 1-3 days prior to next tx**	☐Renal panel ☐Urine cytology ☐UA ☐UCS ☐Infusion	☐Renal panel ☐Urine cytology ☐UA ☐UCS ☐Infusion	☐Renal panel ☐Urine cytology ☐UA ☐UCS ☐Infusion	☐CBC/Chem ☐Urine cytology ☐UA ☐UCS ☐Infusion	☐Renal panel ☐Urine cytology ☐UA ☐UCS ☐Infusion	☐CBC/Chem ☐Urine cytology ☐UA ☐UCS ☐Infusion

Every 3 mo after
☐Renal panel ☐Urine cytology ☐UA ☐UCS ☐Infusion

Infusion procedure:

1) Remove and quantify all urine from SUB(s) through port.
2) Infuse up to 75% of that volume under ultrasound guidance to fill the kidney, catheters, and bladder **OR** until the pelvis is getting some dilation (not more than 6-10 mL total). This may be done under sedation if patient is not compliant so that the patient remains in dorsal recumbency and is immobile for 20-30 minutes (sedation is usually not needed). DO NOT LET PELVIS ENLARGE. IF IT DOES, STOP UNTIL IT DECOMPRESSES DOWN THE SUB, AND THEN GIVE ANOTHER PULSE.
3) If patient is compliant, keep bladder small so that they do not urinate for 1-2 hours, and remove the litter box from the cage for 1-2 hours.
4) The second infusion should be done 2-4 hours after the first infusion.

T-FloLoc™ INFECTION Protocol CHART

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Individual T-FloLoc™ Infection Protocol Chart

Name: **MR#:**

Date:				
	Day 1	Day 2	Day 3	Day 4
Culture				
UA Sediment				
UA pH				
UA Bacteria				
UA WBC				
Cytology				
Volume Removed				
Volume Infused				
% EDTA Infused				
Times Per Day				
Dwell Time				
Sedation				
Date:				
	Day 5	Day 8-10	Day 15-17	
Culture				
UA Sediment				
UA pH				
UA Bacteria				
UA WBC				
Cytology				
Volume Removed				
Volume Infused				
% EDTA Infused				
Times Per Day				
Dwell Time				
Sedation				

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Individual T-FloLock™ Infection Protocol Chart

Name: **MR#:**

Date:				
	Day 22-24	Day 29-31	Day 36-38	Day 50-65
Culture				
UA Sediment				
UA pH				
UA Bacteria				
UA WBC				
Cytology				
Volume Removed				
Volume Infused				
% EDTA Infused				
Times Per Day				
Dwell Time				
Sedation				
Date:				
	Day 78-80	Day 120-122	Day 204-206	
Culture				
UA Sediment				
UA pH				
UA Bacteria				
UA WBC				
Cytology				
Volume Removed				
Volume Infused				
% EDTA Infused				
Times Per Day				
Dwell Time				
Sedation				

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T-FloLoc™ MINERALIZATION Protocol

Note: This protocol is based on initial clinical experience presented at the Veterinary Interventional Radiology and Endoscopy (VIRIES) conference in 2017. Successful demineralization of a SUB device was accomplished in 8/10 devices and successful eradication of recurrent urinary tract infections was successful in 3/4 patients. The protocols recommended is what has been deemed to be safe and effective in this small groups of feline patients in the authors experience.

T-FloLoc™ (Tetra-EDTA) Protocol for MINERALIZATION

Provided by Drs. Allyson Berent and Chick Weisse

Precautions:

1. **Clip the port site and scrub using aseptic technique as usual when accessing the SUB™.**
2. **Follow instructions on SUB Flushing in *THE SUB™ FLUSH KIT or T-FloLoc™ IFUs.***
3. **This should only be used if there is some flush occurring into all catheters. If there is no flush, then the T-FloLoc™ will likely not work to demineralize.**
4. **If the pelvis is dilated and the SUB™ is occluded (partially=flushing some), doing 3 serial days (BID) of infusions is recommended. If the SUB is occluded (partially) but the ureter is patent so there is no pelvis dilation, then doing 2x in first week (once daily), then weekly, then every other week, then monthly, then every 3 months is recommended.**

Week 1

Day 1: Standard urinary tract ultrasound and SUB flush. Drain the system as much as possible to empty bladder and renal pelvis. This may not be possible if occluded. Sometimes you cannot drain as much as you can flush. If this is the case, be careful not to overfill pelvis since you cannot drain it. Initially drain the system and submit urine for UA, cytology and culture at start of the demineralization protocol (Day 1). The, flush with 0.5 mL sterile saline to see bubbles in bladder and kidney. Drain the saline. Do not ever add more fluid in than you were able to remove. Once the saline is removed, infuse 1.0-1.5 mL of 2% EDTA to see bubbles in kidney and bladder and leave it to dwell. Do this one time. Infuse slowly in pulses to see the bubbles, but avoid overfilling the renal pelvis. Allow the pelvis to passively drain between pulses.

Day 2, 3, 4, and/or 5: Same as Day 1 but a repeat culture is not necessary. By the end of this week, the SUB should be flushing well.

Week 2

Day 8: Standard urinary tract ultrasound and SUB flush. Drain the system as much as possible to empty bladder and renal pelvis. Flush with 0.5 mL sterile saline to see bubbles in bladder and kidney. Drain the saline. Then infuse 1.5 mL of 2% EDTA to see bubbles in kidney and bladder and leave it to dwell. Do this one time.

Week 4

Day 22-24: Standard urinary tract ultrasound and SUB flush. Drain the system as much as possible to ideally empty bladder and renal pelvis. Flush wilth 0.5 mL sterile saline to see bubbles in bladder and kidney. Drain the saline. Then infuse 1.5 mL of 2% EDTA to see bubbles in kidney and bladder and leave it to dwell. Do this one time.

Week 8

Day 50-52: Standard urinary tract ultrasound and SUB flush and urine culture. Standard urinary tract ultrasound and SUB flush. Drain the system as much as possible to ideally empty bladder and renal pelvis. Flush with 0.5 mL sterile saline to see bubbles in bladder and kidney. Drain the saline. Then infuse 1.5 mL of 2% EDTA to see bubbles in kidney and bladder and leave it to dwell. Do this one time.

Week 14

Day 92-94: Renal panel, UA, UCS, Urine cytology. Standard urinary tract ultrasound and SUB flush. Drain the system as much as possible to ideally empty bladder and renal pelvis. Flush with 0.5 mL sterile saline to see bubbles in bladder and kidney. Drain the saline. Then infuse 1.5 mL of 2% EDTA to see bubbles in kidney and bladder and leave it to dwell. Do this one time.

WEEK 26:

Day 176-178: Renal panel, UA, UCS, Urine cytology. Standard urinary tract ultrasound and SUB flush. Drain the system as much as possible to ideally empty bladder and renal pelvis. Flush with 0.5 mL sterile saline to see bubbles in bladder and kidney. Drain the saline. Then infuse 1.5 mL of 2% EDTA to see bubbles in kidney and bladder and leave it to dwell. Do this one time.

EVERY 3-months thereafter:

Renal panel (or CBC/CHEM every 6 months), UA, UCS, Urine cytology. Standard urinary tract ultrasound and SUB flush. Drain the system as much as possible to empty bladder and renal pelvis. Flush with 0.5 mL sterile saline to see bubbles in bladder and kidney. Drain the saline. Then infuse 1.5 mL of 2% EDTA to see bubbles in kidney and bladder and leave it to dwell. Do this one time.

For Technical Information, please contact:

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and /or

Chick Weisse, VMD, DACVS at chick.weisse@gmail.com

T-FloLoc™ MINERALIZATION Protocol CHART

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Individual T-FloLoc™ Mineralization Protocol Chart

Name: **MR#:**

Date:				
	Day 1	**Day 3-5**	**Day 8**	**Day 22-24**
Culture				
UA Sediment				
UA pH				
UA Bacteria				
UA WBC				
Cytology				
Volume Removed				
Volume Infused				
% EDTA Infused (typically 2%)				
Times Per Day				
Dwell Time				
Sedation (if needed)				
Date:				
	Day 50-52	**Day 92-94**	**Day 176-178**	
Culture				
UA Sediment				
UA pH				
UA Bacteria				
UA WBC				
Cytology				
Volume Removed				
Volume Infused				
% EDTA Infused				
Times Per Day				
Dwell Time				
Sedation (if needed)				

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