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

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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

1. Ryder M, Pulcini E, Parker A, Fisher S, James G. Evaluation of the effectiveness of 2% tetrasodium EDTA on six antibiotic resistant organisms in an in vitro vascular catheter model. poster #247 Society for Healthcare Epidemiology in America (SHEA) conference, St. Louis, Mo., Mar. 2017.
2. Kanaa M, et al. Cathasept line lock and microbial colonization of tunneled hemodialysis catheters: a multicenter randomized controlled trial. Am J Kidney Dis. 2015;66(6):1015-23.
3. Percival SL, et al. Tetrasodium EDTA as a novel central venous catheter lock solution against biofilm. Infect Control Hosp Epidemiol 2005;26:515-19.
4. Ryder M. Catheter–related infections: It's all about biofilm. Medscape: Topics in Advanced Nursing e-Journal. 2005. http://www.medscape.com/viewarticle/508109.
5. Kite P, Eastwood K, Sugden S, Percival SL. Use of in vitro-generated biofilms from hemodialysis catheters to test the efficacy of a novel antimicrobial catheter lock for biofilm eradication in vitro. J Clin Microbiol. 2004;42(7):3073-6.