CAREPATHrx™
Specialty Pharmacy & Infusion Solutions

Home Infusion & Specialty Pharmacy
CHARTWELL
PENNSYLVANIA, LP

ADMINISTRATION OF CATHFLO® ACTIVASE®

Section: Nursing
Compliance: ACHC Infusion Pharmacy
INS STANDARDS: 8, 10, 11, 12, 13, 16, 17, 18, 20, 21, 41, 49, 59
ACHC STANDARDS: DRX5-1D, DRX5-5E, DRX7-21A
TJC STANDARDS: IC.02.01.01, MM.05.01.07, MM.06.01.01, NPSG.01.01.01, PC.02.01.01, PC.02.01.03, PC.02.03.01
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Approved by, Title and Date Approved: Kathleen Patrick, President, 1/1/21, 5/1/21, 2/7/23, 9/1/23, 5/7/24

I. POLICY SCOPE

To assess catheter function and prevent complications, the Central Venous Access Device (CVAD) is routinely flushed to assess patency. A catheter occlusion is suspected if there is resistance or the inability to flush a catheter lumen or inability to withdraw blood, sluggish blood return, resistance, frequent occlusion alarms on electronic infusion pump, swelling or leaking at infusion site. Catheter salvage is preferred over removal or replacement of existing CVAD. Cathflo® Activase® (alteplase) is a thrombolytic indicated for the restoration of function to CVAD, when occlusion is caused by fibrin formation.

II. NURSING OVERVIEW

Assess CVAD patency by flushing each lumen according to provider orders and *Nursing* policy on *Flushing and Locking Catheters*. Nursing to further assess patency by aspirating for blood return and then flushing lumen. For preventative measures refer to *Nursing* policy on *Flushing and Locking Catheters.* Patient/caregiver flushing technique to be reviewed by nurse clinician.

Mechanical causes of an occlusion (e.g., kinked or clamped catheter, pinch-off syndrome, catheter - associated deep vein thrombus (CA-DVT), implanted vascular access port failure, patient position, migration of catheter, obstructed needleless end connector) should be eliminated prior to administration of Cathflo® Activase®.

Radiographic and other studies (i.e., dye studies) may be implemented to confirm catheter tip location, evaluate catheter function.

Cathflo® Activase® is indicated for all catheter lumens with partial, withdraw or complete occlusions. Prolonged fibrin formation is a risk factor for catheter-associated bloodstream infections (CABSI). Do not leave an occluded lumen untreated, regardless of another lumen being available for intravenous administration.

Cathflo® Activase® must be administered by a trained home care nurse.

Signs and symptoms of CVAD occlusion:

1. Inability to withdraw blood (withdraw occlusion)
2. Sluggish blood return (partial occlusion)
3. Sluggish flow or resistance when flushing (partial occlusion)
4. Inability to flush lumen (total occlusion)
5. Frequent occlusion alarms on infusion pump (partial occlusion)
6. Swelling and/or leaking at the site

Use of Cathflo® Activase® to restore patency to midline peripheral catheters is off-label and should be used with caution and only after careful assessment of continued need for vascular access, and to rule out catheter malfunction. Additional studies are required to establish safety.

III. PROCEDURES

A. Supplies:

1. Cathflo® Activase® 2mg vial
2. Vial of preservative-free Sterile Water for injection, USP. **Do not use Bacteriostatic Water**
3. Stopcock (withdraw or complete occlusion)
4. (1) 10 mL syringe (withdraw or complete occlusion)
5. (1) 10 mL syringe with 20g. 1" safety needle
6. Prefilled 0.9% sodium chloride syringe(s)
7. Antiseptic cleanser
8. Non-sterile gloves

B. Identify patient using at least 2 patient identifiers.

C. Review prescriber's order or standard protocol. Verify the medication matches the medication label. Compare medication or solution to prescriber's order or pharmacy protocol (if applicable, Appendix A) and medication label to ensure right patient, right dose, right route of administration, rate of administration, and total volume to infuse.

D. Before use, allow medication or solution to reach room temperature according to instructions.

E. Educate patient/caregiver on:

1. Indication for use
2. Procedure
3. Potential adverse reactions, signs, and symptoms of adverse reactions
4. The appropriate provider of treatment (the prescriber OR the pharmacist; BOTH the prescriber and the pharmacist) to contact during business hours, the availability of an answering system to receive calls during evenings, nights, weekends and holidays and the accessibility of a Pharmacist, Nurse, and Dietician 24 hours a day, 7 days a week. Notify pharmacy by calling the

number listed at the top of the medication label; (Refer to CarepathRx NOTIFICATION OF PHARMACIST AND PROVIDER ALGORITHM).

F. Perform hand hygiene (refer to CarepathRx (Hand Hygiene policy).

G. Clean and disinfect work area using an appropriate disinfectant.

H. Gather supplies on a clean, disinfected, aseptic field.

I. Inspect equipment and supplies for product integrity and function before use; inspect packaging for damage; inspect vials for cracks, particulate matter, and clarity of medication. Verify expiration date.

J. Immediately prior to equipment assembly, hand hygiene is repeated, and non-sterile gloves are donned.

K. Prepare Cathflo® for instillation according to medication label or package insert. Reconstitution of Solution:

1. Remove protective caps from medication vials
2. Scrub the rubber stopper of the vials with antiseptic swab for 30 seconds, allow to dry completely for at least 60 seconds.
3. Aseptically attach needle to syringe. Pull back the plunger of the syringe until the amount of air equals the amount of Sterile Water for Injection, USP to be withdrawn. Insert syringe with needle attached into the vial of preservative-free Sterile Water for Injection, USP.
4. Slowly inject air into the vial.
5. Invert vial and aseptically withdraw 2.2 mL of Sterile Water for Injection, USP. **Do not use Bacteriostatic Water for Injection.**
6. Remove syringe from the vial.
7. Hold the syringe with the plunger side down and tap the side of the syringe to move air to the top of the liquid. Carefully expel air.
8. Inject the 2.2 mL of Sterile Water for Injection, USP, into the Cathflo Activase vial. Slight foaming is not unusual; let the vial stand undisturbed to allow large bubbles to dissipate.
9. Mix by gently swirling until the contents are completely dissolved. DO NOT SHAKE. The reconstituted preparation results in a colorless to pale yellow transparent solution containing 1 mg/mL Cathflo Activase.
10. Cathflo Activase contains no antibacterial preservatives and should be reconstituted immediately
before use.
11. Inspect the reconstituted vial for foreign matter and discoloration.

L. Procedure for instillation for **partial** occlusion:

1. Aseptically withdraw required volume of solution in Appendix A, Home *Cathflo® Activase® Protocol*.
2. Clamp catheter. Before attaching syringe to hub of the catheter, scrub the hub vigorously for 30 seconds and allow to dry for 60 seconds. Remove needle from syringe and attach syringe to hub.

3. Open clamp. Instill Cathflo® Activase® into the occluded catheter and clamp catheter.
4. After 30 minutes of dwell time, unclamp the catheter and assess catheter function by attempting to aspirate blood. If the catheter is functional with blood return restored, go to Step 7. If the catheter is not functional, clamp the catheter and go to Step 5.
5. After 120 minutes of dwell time, assess catheter function by unclamping catheter and attempting to aspirate blood and catheter contents. If the catheter is functional, go to Step 7. If the catheter is not functional, clamp the catheter and go to Step 6.
6. If catheter function is not restored after one dose of Cathflo® Activase®, a second dose of equal amount may be instilled. Repeat the procedure beginning with Step 1 under Reconstitution of Solution.
7. If catheter function has been restored, aspirate 4–5 mL of blood to remove Cathflo® Activase® and residual clot and flush the catheter with 0.9% Sodium Chloride Injection using a pulsatile technique. Clamp catheter.
8. If catheter patency is not restored after 2 doses, notify physician of occluded catheter.

M. Procedure for instillation for **withdraw or complete** occlusion: (Stopcock method using negative pressure and (1) 10 mL syringe)

1. Aseptically withdraw required volume of solution as outlined in Appendix A, Home *Cathflo® Activase® Protocol*.
2. Clamp catheter. Scrub the connection between the catheter lumen and the injection cap and/or extension tubing vigorously for 30 seconds and allow to dry for 60 seconds. Aseptically remove needleless end cap and/or extension tubing from catheter hub.
3. Attach the 3-way stopcock to the catheter hub with the stopcock in the off position to the patient.
4. Attach an empty 10 mL syringe to one of the ports on the stopcock.
5. Attach the syringe containing Cathflo® Activase® to the other port on the stopcock and turn stopcock off to the syringe containing Cathflo® Activase®.
6. Unclamp the catheter.
7. Aspirate catheter using empty syringe until the plunger is pulled back to the 8 ml mark on the syringe and while maintaining negative pressure, turn the stopcock off to the empty syringe. This will allow Cathflo® Activase® to be drawn into the central line.
8. Repeat the negative pressure technique with the Cathflo® Activase® syringe. Pull back on the plunger in the Cathflo® Activase® syringe until entire dose is drawn into the catheter by negative pressure (Note: You do not push the plunger to instill the fluid. It is being drawn into the catheter by negative pressure). This may require several aspiration attempts.
9. Reclamp the catheter and turn the stopcock off to the catheter.
10. After 30 minutes of dwell time, unclamp the catheter, turn the stopcock off to the Cathflo® Activase® syringe and assess catheter function by attempting to aspirate blood. If the catheter is functional, go to Step 13. If the catheter is not functional, clamp the catheter, turn the stopcock off to the catheter and go to Step 12.

11. After 120 minutes of dwell time, assess catheter function by unclamping catheter, turning the stopcock off to the Cathflo® Activase® syringe and attempting to aspirate blood and catheter contents. If the catheter is functional, go to Step 12. If the catheter is not functional, clamp the catheter, turn the stopcock off to the catheter and go to Step 13.
12. If catheter function has been restored, aspirate 4–5 mL of blood in patients ≥10 kg or 3 mL in patients <10 kg to remove Cathflo® Activase® and residual clot, and flush the catheter with 0.9% Sodium Chloride Injection using a pulsatile technique. Clamp catheter.
13. If catheter function is not restored after one dose of Cathflo® Activase®, a second dose of equal amount may be instilled. Repeat the procedure beginning with Step 1 under Reconstitution of Solution.
14. If catheter patency is not restored after 2 doses, notify physician of occluded catheter

N. Document:

1. Date and time of administration, route, VAD (VASCULAR ACCESS DEVICE) type and lumen
2. Product lot number and expiration date.
3. Indication for administration of Cathflo® Activase®
4. Dwell time of Cathflo® Activase®
5. Restoration of patency
6. Number of doses
7. Notification of physician if patency is not restored after administration of 2 doses.
8. Receipt of education provided (verbal or written)

O. Storage and handling

1. Cathflo® Activase® contains no antibacterial preservatives and should be reconstituted immediately before use. The solution may be used for intracatheter instillation within 4 hours following reconstitution when stored at 2−30° C (36−86° F).
2. Store lyophilized Cathflo® Activase® at refrigerated temperature (2−8° C/36−46° F). Do not use beyond the expiration date on the vial. Protect the lyophilized material during extended storage from excessive exposure to light.
3. There is no efficacy or safety information on dosing in excess of 2 mg per dose for this indication. Studies have not been performed with administration of total doses greater than 4 mg (two 2-mg doses).

IV. TRAINING

This policy will be posted on the Company shared drive.

V. REFERENCES

Nickel B, Gorski L, Kleidon T, et al. Infusion Therapy Standards of Practice, 9th Edition. *J Infus Nurs*. 2024;47(1S Suppl 1):S1-S285. doi:10.1097/NAN.0000000000000532

"Cathflo Activate (ALTEPLASE) Dosage & Administration." *Cathflo,* Cathflo® Activase® (alteplase) Dosage & Administration

Accreditation Commission for Health Care (7/21/2022). *ACHC Standards*

The Joint Commission. (2022). *Joint Commission Resources E-dition*

Cathflo Activase (Alteplase) [package insert]. South San Franciso, CA. Genentech, Inc.; 2019.

Appendix A

Home Cathflo® Activase® Protocol

Cathflo® Activase® (alteplase) is the drug of choice for catheter occlusions caused by fibrin. Alteplase is an enzyme that binds to fibrin in a thrombus and converts plasminogen to plasmin thereby initiating fibrinolysis.

Indications: restoration of function to central venous access devices as assessed by the ability to withdraw blood.

Contraindications: Cathflo® Activase® should not be administered to patients with known hypersensitivity to alteplase or any component of the formulation.

Population: Cathflo® Activase® will be dispensed for any patient whenever specifically ordered by a prescriber per pharmacy protocol. Cathflo® Activase® must be administered by a trained home care nurse.

Dosing:

Adult Patients (>30 kg)	Pediatric Patients (10-30 kg)	Pediatric Patients (<10 kg)
2 mL (2 mg) per occluded lumen, may repeat x1.	1 mL (1 mg) per occluded lumen, may repeat x1.	110% of catheter fill volume per occluded lumen, may repeat x1. See Appendix B in "Administration of Cathflo® Activase®" nursing policy for catheter fill volume by device.

How Supplied:

1. Cathflo® Activase® 2 mg vial(s)
2. Preservative-free sterile Water for Injection vial(s)
3. Stopcock
4. 10 mL syringe
5. 10 mL syringe with 20 g 1" safety needle
6. Prefilled 0.9% sodium chloride syringe(s)
7. Antiseptic cleanser
8. Non-sterile gloves

Procedure: administer in accordance with "Administration of Cathflo® Activase®" nursing policy.

Patient Prescriber Date

References:

1. Cathflo Activase (alteplase) [package insert]. South San Francisco: Genentech, Inc; 2019.
2. Anderson DM, Pesaturo KA, Casavant J, Ramsey EZ. Alteplase for the Treatment of Catheter Occlusion in Pediatric Patients. *Annals of Pharmacotherapy*. 2013;47(3):405-410.
3. UPMC Children's Hospital of Pittsburgh. *Central Venous Catheter Clearance Using Alteplase or Hydrochloric Acid (PTCMDIV802).* Practice Council, 2022

APPENDIX B

Each volume listed is the total amount to be administered.
This includes catheter fill volume *PLUS* 0.1mL needleless connector fill volume *(except implanted ports)*

Cook Spectrum® (Antimicrobial) Hyperalimentation System Catheter (HAS – long-term cuffed)				
French Size	Description	Small Lumen #1 Volume (mL)	Small Lumen #2 Volume (mL)	Large Lumen Volume (mL)
4.0	Cook Spectrum® Hyperalimentation System Catheter 25cm.	0.2		
5.0	Cook Spectrum® Hyperalimentation System Catheter 25cm.	0.3		
7.0 D	Cook Spectrum® Hyperalimentation System Catheter 20cm. & 25 cm.	0.2		0.2
9.0 D	Cook Spectrum® Hyperalimentation System Catheter 25cm.	1.1		1.2
8.0 T	Cook Spectrum® Hyperalimentation System Catheter 25cm.	(Red) 1.0	(Blue) 1.0	(Yellow) 1.2
Cook™ Central Venous TPN Catheters *Catheter Discontinued but may still be in patient population (Tunneled and Cuffed)				
French Size	Description	Small Lumen #1 Volume (mL)	Small Lumen #2 Volume (mL)	Large Lumen Volume (mL)
3.0	TPN Single Lumen Catheter*	0.5		
4.0	TPN Single Lumen Catheter*	0.6		
5.0	TPN Single Lumen Catheter*	0.8		
5.0 D	Double Lumen TPN Catheter	0.6		0.6
6.0 D	Double Lumen TPN Catheter	0.7		0.8
6.5	TPN Single Lumen Catheter*	1.2		
7.0 D	Double Lumen TPN Catheter	0.8		1.0
9.5	TPN Single Lumen Catheter*	2.3		
9.0 D	Double Lumen TPN Catheter*	1.7		2.2

10.0 D	Double Lumen TPN Catheter*	1.8		1.8
12.0 D	Double Lumen TPN Catheter*	2.1		2.8
8.0 T	Triple Lumen TPN Catheter*	1.3	1.3	1.9

Cook™ Central Venous Catheters (Nontunneled and Noncuffed)				
French Size	Description	Distal Lumen Volume (mL)	Mid Lumen Volume (mL)	Proximal Lumen Volume (mL)
3.0	Polyurethane Central Venous Catheter (5cm & 8cm)	20G- 0.2		
4.0 D	Spectrum Polyurethane **Antimicrobial** Coated Catheter	20G - 0.3		22G - 0.3
4.0 D	Polyurethane Central Venous Catheter (5cm and 8cm)	20G - 0.3		23G - 0.3
5.0 D	Polyurethane Central Venous Catheter (5cm and 8cm)	20G - 0.3		20G - 0.3
5.0 T	Spectrum Polyurethane **Antimicrobial** Coated Catheter	18 G- 0.4	23 G- 0.3	23G- 0.3
5.0 T	Polyurethane Central Venous Catheter (12cm)	18G - 0.4	23G - 0.3	23G - 0.3
7.0 T	Spectrum Polyurethane **Antimicrobial** Coated Catheter	16 G- 0.6	18 G- 0.7	18 G- 0.7
7.0 T	Polyurethane Central Venous Catheter (15cm)	16G - 0.6	18G – 0.4	18G – 0.4

Cook™ Peripherally Inserted Central Catheters (PICCs)				
French Size	Description	Distal Lumen Volume (mL)	Mid Lumen Volume (mL)	Proximal Lumen Volume (mL)
3.0	Spectrum Polyurethane Turbo-Ject Antimicrobial Catheter	19G- 0.62		
4.0	Spectrum Polyurethane Turbo-Ject Antimicrobial Catheter	17 G- 0.86		
4.0 D	Spectrum Polyurethane	22G- 0.71		24G- 0.56

	Turbo-Ject Antimicrobial Catheter			
5.0	Spectrum Polyurethane Turbo-Ject Antimicrobial Catheter	17G- 1.1		
5 D	Spectrum Polyurethane Turbo-Ject Antimicrobial Catheter	18G- 0.82		18G- 0.82
6 T	Spectrum Polyurethane Turbo-Ject Antimicrobial Catheter	17G- 1.14	19G- 0.83	19G- 0.83

BARD ™ Central Venous Catheters (Tunneled and Cuffed)				
French Size	Description	White Lumen	Red Lumen	Blue Lumen
2.7	Broviac ™ Single Lumen Catheter (silicone)	0.3		
4.2	Broviac ™ Single Lumen Catheter (silicone)	0.4		
6.6	Broviac ™ Single Lumen Catheter (silicone)	0.8		
7.0 D	Hickman ™ Dual Lumen Catheter (silicone)	0.7	0.9	
9.0 D	Hickman ™ Dual Lumen Catheter (silicone)	0.7	1.2	
9.6	Hickman ™ Single Lumen Catheter (silicone)	1.9		
12.0 D	Hickman ™ Dual Lumen Catheter (silicone)	1.9	1.9	
10.0 T	Hickman ™ Triple Lumen Catheter (silicone)	1.5	0.9	0.9
12.5 T	Hickman ™ Triple Lumen Catheter (silicone)	1.7	0.8	0.8
10.0 D	Leonard ™ Dual Lumen Catheter (silicone)	1.4	1.4	
4.0	Hohn ™ Single Lumen Catheter (silicone)	0.3		
5.0	Hohn ™ Single Lumen Catheter (silicone)	0.4		
5.0	Hohn ™ Single Lumen Catheter with VitaCuff © Antimicrobial Cuff (silicone)	0.4		
7.0 D	Hohn ™ Dual Lumen Catheter (silicone)	0.3	0.4	
7.0 D	Hohn ™ Double Lumen Catheter with VitaCuff ™ Antimicrobial Cuff (silicone)	0.3	0.4	
BARD ™ PowerPICC				
French Size	Description	Lumen 1 (mL)	Lumen 2 (mL)	
3F	Provena Polyurethane Catheter Single Lumen	0.63		
3F	SV Polyurethane Catheter Single Lumen	0.47		
4F	Polyurethane Catheter Single Lumen	0.77		
4F D	Provena Polyurethane Catheter Dual Lumen	(18G) 0.62	(18G) 0.62	
4F D	SV Polyurethane Catheter Dual Lumen	(19G) 0.61	(21G) 0.48	
5F	Polyurethane Catheter Single Lumen	0.76		

5F D	FT Polyurethane Catheter Dual Lumen	(18G) 0.66	(18G) 0.66	
5F D	Polyurethane Catheter Dual Lumen	(18G) 0.67	(18G) 0.67	
5F T	HF PowerPICC Polyurethane Catheter	(18G) 0.86	(19G) 0.54	(19G) 0.54
6F D	Polyurethane Catheter Dual Lumen	(18G) 0.72	(18G) 0.72	
6F T	Polyurethane Catheter Triple Lumen	(17G) 0.86	(19G) 0.57	(19G) 0.57
BARD ™ PowerPICC SOLO Catheter (polyurethane)				
French Size	Description	Lumen 1 (mL)	Lumen 2 (mL)	Lumen 3 (mL)
3Fr	PowerPICC Provena Catheter with SOLO Valve - Single Lumen	0.68 mL		
4Fr	PowerPICC SOLO Catheter - Single Lumen	0.83 mL		
4Fr	PowerPICC Provena Catheter with SOLO - Dual Lumen	0.66 mL	0.66 mL	
5Fr	PowerPICC SOLO Catheter - Triple Lumen	Red 0.81mL	Gray 0.57mL	White 0.57mL
Argon ™ Central Venous Catheters				
French Size	Description	Lumen 1 (mL)		
1.9	Single Lumen Silicone PICC Catheter	0.23		
MedCOMP ™ PICC				
French Size	Description	Lumen White 23G (mL)	Lumen Red 21G (mL)	
2.6 20cm	Vascu PICC silicone	0.27	0.27	
2.6 50cm	Vascu PICC silicone	0.28	0.32	
MedCOMP ™ Central Venous Catheters (Cuffed and Tunneled)				
French Size	Description	Lumen 1 (mL)	Lumen 2 (mL)	Lumen 3 (mL)
5F	Single Lumen MedCOMP CT CVC Polyurethane Proline Catheter	0.9		
5F D	Dual Lumen MedCOMP CT CVC Polyurethane Proline Catheter	0.7	0.7	
6F	Single Lumen MedCOMP CT CVC Polyurethane Proline Catheter	1.2		
6F D	Dual Lumen MedCOMP CT CVC Polyurethane Proline Catheter	0.8	0.8	

7F	Single Lumen MedCOMP CT CVC Polyurethane Proline Catheter	1.5		
7F D	Dual Lumen MedCOMP CT CVC Polyurethane Proline Catheter	0.9	0.9	

IMPLANTABLE PORTS

Must Utilize the following equation to determine the appropriate volume for implanted ports.

Volume to be administered = Catheter Length (cm) x Catheter Volume per cm + Port Volume (mL) + port needle priming amount (0.3mL) + Needleless Connector amount (0.1mL).

**Catheter lengths will need to be noted to ensure accurate volumes to instill.
**Catheter volume per cm in the tables below.
**Port volume is listed in the tables below.

** All implantable port needles have a 0.3mL priming volume

Bard PowerPorts®				
CATHETER VOLUMES PER CM				
Bard ®	**6Fr**	**8Fr**	**9.5Fr**	**9.6Fr**
	0.014mL/cm	0.02 mL/cm	0.02 mL/cm	0.02 mL/cm

Bard PowerPorts®	
Port Volumes (mL)	
Bard PowerPorts®	**Volume (mL)**
PowerPorts® ClearVUE isp implantable port	0.6
PowerPorts® ClearVUE Slim implantable port	0.4
PowerPorts® Isp MRI implantable port	0.6
PowerPorts® MRI implantable port	0.6
PowerPorts® Duo MRI Implantable port (dual lumen)	0.6 / 0.6
PowerPorts® Isp implantable port	0.6

PowerPorts® Slim implantable port	0.5
PowerPorts® Implantable Port	0.6
PowerPorts® VUE implantable Port	0.6
PowerPorts® VUE MRI implantable Port	0.5

MedCOMP ® Implantable Ports				
CATHETER VOLUMES PER CM				
MedCOMP®	**5Fr**	**6.6Fr**	**8Fr**	**9.6Fr**
	0.011 (mL/cm)	0.014 (mL/cm)	0.017 (mL/cm)	0.020 (mL/cm)
PORT VOLUMES (mL)				
MedCOMP®	**Titanium Mini Profile CT Port* (contains polyurethane)**	**Low Profile CT Port* (contains polyurethane)**	**Mid- size CT Port* (contains polyurethane)**	
	0.43 mL	0.43 mL	0.47 mL	