3. EXCLUSIONS

Alteplase 2mg vials must not be used:

- In patients with known hypersensitivity to Alteplase
- In patients with known hypersensitivity to Gentamicin
- For occlusions in any device not accessing a vein.
- For myocardial infarction, pulmonary embolism or ischaemic stroke.
  The 2 mg presentation of alteplase is not indicated for use in myocardial infarction, acute pulmonary embolism or acute ischaemic stroke (due to risk of massive under dosing). Only 10, 20 or 50 mg presentations are indicated for use in those indications.

4. CAUTIONS

3.1 General:

- The co-administration of heparin with alteplase has not been shown to improve the rates of catheter function restoration and is not recommended. If heparin is considered necessary to prevent re-occlusion this should be administered separately after catheter function has been restored.
- Because of the risk of damage to the vascular wall or collapse of soft-walled catheters, vigorous suction should not be applied during attempts to determine catheter occlusion. Excessive pressure should be avoided when alteplase is instilled into the catheter. Such force could cause rupture of the catheter or expulsion of the clot into the circulation.

3.2 Bleeding:

- Caution should be exercised with patients who have active internal bleeding or who have had any of the following within 48 hours: surgery, obstetrical delivery, percutaneous biopsy of viscera or deep tissues, or puncture of non-compressible vessels.
- Caution should be exercised with patients who have thrombocytopenia, other haemostatic defects (including those secondary to severe hepatic or renal disease), or any condition for which bleeding constitutes a significant hazard or would be particularly difficult to manage because of its location, or who are at high risk for embolic complications (e.g., venous thrombosis in the region of the catheter. Should serious bleeding in a critical location (e.g., intracranial, gastrointestinal, retroperitoneal, pericardial) occur, treatment with alteplase should be stopped and the drug should be withdrawn from the catheter.

3.3 Infection:

- Using alteplase in patients whose catheters are occluded by infected thrombi may release microorganisms into the systemic circulation leading to sepsis. As with all catheterisation procedures, care should be taken to maintain aseptic technique and appropriate antibiotic treatment used as necessary.

3.4 Interaction with other medicinal products

- Drugs affecting coagulation/platelet function: The risk of haemorrhage is increased if coumarin derivatives, oral anticoagulants, platelet aggregation inhibitors, unfractionated heparin or LMWH or other agents inhibiting coagulation are administered (before, during or within the first 24 hours after treatment with alteplase.
- ACE inhibitors: Concomitant treatment with ACE inhibitors may enhance the risk of suffering a hypersensitivity reaction.

5. REFERENCES

1. Summary of product characteristics. Actilyse Cathflo 2 mg powder for solution for injection and infusion. Boehringer Ingelheim Limited. Last updated 09 Nov 2018

Brighton and Sussex University Hospitals NHS Trust

PHARMACY PROCEDURE:

USE OF ALTEPLASE (ACTILYSE CATHFLO®) FOR OCCLUDED CENTRAL VENOUS ACCESS DEVICES (CVAD)

1. INTRODUCTION

Alteplase 2mg vials (Actilyse Cathflo®) is indicated for the thrombolytic treatment of occluded CVAD.

A maximum dose of 2mg may be used on up to two occasions to restore function of ports, single and multiple lumen lines, including those used for haemodialysis, which became dysfunctional due to thrombotic occlusion.

2. PROCEDURE

In patients with a body weight of 30 kg or more, a total dose of 2 mg alteplase should be instilled into the dysfunctional central venous access device.

In patients with a body weight below 30 kg, the volume of reconstituted solution to be instilled into the dysfunctional central venous access devices should correspond to 110% of the internal lumen volume of the device. The total dose of alteplase should not exceed 2 mg

Patient weight 30kg+	Patient weight <30kg
1. Reconstitute a 2mg vial of Alteplase using 2.2mL of sterile water for injection. **This gives a concentration of 1mg/mL**	1. Reconstitute a 2mg vial of Alteplase using 2.2mL of sterile water for injection. **This gives a concentration of 1mg/mL**
2. If the occluded CVAD has an internal volume greater than 2mL, dilute the alteplase to the same volume as the CVAD internal volume using sterile sodium chloride 0.9%.	2. Draw up a volume equal to 110% of the internal lumen volume.
3. Instil the alteplase solution into the dysfunctional CVAD.	3. Instil the alteplase solution into the dysfunctional CVAD.
4. After 30 minutes of dwell time, assess catheter function by attempting to aspirate blood. If the catheter is functional, go to step 7. If the catheter is not functional, go to step 5.	4. After 30 minutes of dwell time, assess catheter function by attempting to aspirate blood. If the catheter is functional, go to step 7. If the catheter is not functional, go to step 5.
5. After 120 minutes of dwell time, assess catheter function by attempting to aspirate blood and catheter contents. If the catheter is functional, go to step 7. If the catheter is not functional, go to step 6.	5. After 120 minutes of dwell time, assess catheter function by attempting to aspirate blood and catheter contents. If the catheter is functional, go to step 7. If the catheter is not functional, go to step 6.
6. If catheter function is not restored after the first dose, a second dose of equal amount may be instilled. Repeat the procedure beginning with Step 1. If after a second dose of alteplase the device remains dysfunctional consider device replacement.	6. If catheter function is not restored after the first dose, a second dose of equal amount may be instilled. Repeat the procedure beginning with Step 1. If after a second dose of alteplase the device remains dysfunctional consider device replacement.
7. If catheter function has been restored, aspirate 4–5mL of blood to remove alteplase and residual clot, and gently irrigate the catheter with sterile sodium chloride 9 mg/ml (0.9 %) solution for injection.	7. If catheter function has been restored, aspirate 4–5mL of blood in patients weighing 10kg or more, or 3mL in patients with a body weight below 10kg to remove alteplase and residual clot, and gently irrigate the catheter with sterile sodium chloride 9 mg/ml (0.9 %) solution for injection.
Alteplase is a biological product. **Trade name and batch number must be recorded on the drug chart.**	