SESLHDMG/125
Medicine Guideline
Fibrinogen Concentrate for management of severe fibrinogen deficiency in Cardiac Surgery

Areas where Protocol/Guideline applicable	SESLHD Cardiothoracic Operating Theatres and Cardiothoracic Intensive Care Unit
Authorised Prescribers:	Cardiothoracic Anaesthetists and Intensivists
Indication for use	Critical bleeding in cardiac surgery patients with severe fibrinogen deficiency
Clinical condition	Critical bleeding in cardiac surgery patients with severe fibrinogen deficiency, where the FIBTEM A5 on Rotational Thromboelastometry (ROTEM) testing is 6 or less as per Cardiac and Vascular ROTEM Transfusion Algorithm
Proposed Place in Therapy	First line, in cardiothoracic theatres and intensive care when FIBTEM A5 is 6 or less on ROTEM. This means administration of a single dose of fibrinogen concentrate (RiaSTAP®) as per Cardiac and Vascular ROTEM Transfusion Algorithm. Cryoprecipitate to be used in less severe fibrinogen deficiencies as demonstrated by ROTEM.
Adjunctive Therapy If part of combination therapy, list other drugs	For use in conjunction with other blood components and products, and drugs as part of the Cardiac and Vascular ROTEM Transfusion Algorithm and resuscitation. Blood components and products include RCC, FFP, Platelets, Cryoprecipitate and Beriplex. Intravenous fluids including sodium chloride 0.9% and Plasmalyte 148, and Albumin 5% may be used for resuscitation. Drugs include Desmopressin (DDAVP), tranexamic acid and protamine, Calcium Chloride 10%.
Contra-indications	Known anaphylactic or severe systemic reactions to human plasma-derived products.
Precautions	Monitor patients for early signs of anaphylaxis or hypersensitivity reactions, if necessary, discontinue administration and institute appropriate treatment. Thrombotic events have been reported. Weigh benefits of administration versus risks of thrombosis. As fibrinogen concentrate (RiaSTAP®) is made from human blood, it may carry a risk of transmitting infectious agents, such as viruses and variant Creutzfeldt-Jacob disease.

<table>
<tr><td>Important Drug Interactions</td><td>The interaction of fibrinogen concentrate (RiaSTAP®) with other drugs has not been established.</td></tr>
<tr><td>Dosage</td><td>
<table>
<tr><th>FIBTEM A5</th><th>Fibrinogen Concentrate (RiaSTAP®) (Dose if > 55kg)</th></tr>
<tr><td>6</td><td>4G</td></tr>
<tr><td>4-5</td><td>5G</td></tr>
<tr><td>0-3</td><td>6G</td></tr>
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In patients less than 55kg decrease the dose by 1G.

Cost of Fibrinogen is $1100 per vial</td></tr>
<tr><td>Duration of therapy</td><td>Single dose only.

Less severe deficiencies as demonstrated by ROTEM are managed by administration of cryoprecipitate.</td></tr>
<tr><td>Prescribing Instructions</td><td>To be prescribed and documented on the anaesthetic chart as an intraoperative medication if administered in operating theatres.

To be prescribed on eRIC if required in cardiothoracic intensive care.</td></tr>
<tr><td>Storage</td><td>Refrigerate at 2°C to 8°C. Protect from light.
Do not use after expiry date.
12G of RiaSTAP® is stored in the STG Anaesthetics ASB medication room and 6G of RiaSTAP® is stored in POWH CTICU for use in cardiac theatres and CTICU.</td></tr>
<tr><td>Preparation and Reconstitution</td><td>RiaSTAP® is presented as a vial containing 1G of human fibrinogen, and one vial of diluent containing 50mL of water for injection.

Use aseptic technique when reconstituting and administering fibrinogen concentrate.

Reconstitute fibrinogen concentrate (RiaSTAP®) at room temperature as follows:
Remove cap from the product vial and clean the surface of the rubber stopper with an antiseptic solution and allow to dry.
Inject 50mL of Sterile Water for injection into the product vial using the transfer set.
Gently swirl the product vial to ensure the product is fully dissolved, this usually takes 5-10 minutes. The solution should be colourless and clear to slightly opalescent. If particles are visible do not use. Do not shake the vial.
Insert the provided dispensing pin and syringe filter into the stopper of the reconstituted fibrinogen concentrate (RiaSTAP®) vial and draw the reconstituted fibrinogen concentrate (RiaSTAP®) into the syringe.
If the product is not used immediately after reconstitution, it should be stored</td></tr>
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	below 25 degrees and used within 6 hours. The reconstituted product should not be stored in a refrigerator.
Administration Instructions	Do not mix fibrinogen concentrate (RIASTAP®) with other medicinal products or intravenous solutions. Use aseptic technique when administering fibrinogen concentrate (RIASTAP®) Administer fibrinogen concentrate (RIASTAP®) via a dedicated intravenous line and clear the line with a sodium chloride 0.9% flush after administration. Administer by a slow intravenous push, at a rate not exceeding 5mL/min.
Adverse Reactions	The most serious adverse reactions after administration of fibrinogen concentrate are allergic- anaphylactic reactions and thromboembolic complications including myocardial infarction, pulmonary embolism, deep venous thrombosis, and arterial thrombosis. The most common adverse reactions are fever and headache.
Monitoring requirements	Monitor for early signs of anaphylaxis or hypersensitivity reactions. Monitor for symptoms and signs of thrombosis. Repeat ROTEM and administer cryoprecipitate as per Cardiac and Vascular ROTEM Transfusion Algorithm if required if the FIBTEM A5 is less than 12 and bleeding is ongoing.
Management of Complications	In the event of an anaphylactic or hypersensitivity reaction, discontinue administration and institute standard management for anaphylaxis or hypersensitivity reaction. Thromboembolic complications including myocardial infarction, pulmonary embolism, deep venous thrombosis, arterial thrombosis may occur. Standard management of these conditions should be implemented.
Basis of Protocol/Guideline:	1. Administration of fibrinogen concentrate (RiaSTAP®) Northern Sydney Local Health District 2. CSL, Product Information, fibrinogen concentrate (RIASTAP®) 2017 accessed April 2025 at https://www.cslbehring.com.au 3. Cardiac and Vascular ROTEM Transfusion Algorithm 2025 4. Fibrinogen Concentrate in the management of critical bleeding, Local operating procedure-clinical, The Royal Hospital for Women 2021 5. National Blood Authority, Patient Blood Management Guidelines for adults with critical bleeding 2023 (accessed March 2025)

Groups consulted in development of this guideline	Cardiothoracic anaesthetists, surgeons and intensivists. Intensive care nurses. Pharmacists. Haematologist.

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GOVERNANCE	
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