Class: Manufactured blood product (human)	Alternate Product Name: • Fibrinogen Concentrate (Human), FCH	Company/Supplier: CSL Behring Canada, Inc.

Routes	Intravenous			Other		
	Direct IV	Intermittent IV Infusion	Continuous Infusion	SC	IM	Other
Acceptable routes	Yes	Yes * see administration	No	No	No	N/A

Description	• RiaSTAP® (Fibrinogen concentrate (Human), FCH) is a pasteurised, preservative free, lyophilised human fibrinogen concentrate. It is derived from human plasma and presented as a white powder for reconstitution with sterile water for injection.
Availability	• **Vial sizes/dosages:** • 1 gram per vial reconstituted with 50 mL sterile water for diluent. • Supplied by Canadian Blood Services (CBS). • **Contact <u>your</u> local laboratory/transfusion laboratory service regarding in house stock availability at your site.**
Indications	• Treatment of acute bleeding episodes and bleeding prophylaxis in adult and pediatric patients with congenital afibrinogenemia and hypofibrinogenemia. • Treatment of uncontrolled bleeding due to acquired fibrinogen deficiency in the setting of surgical interventions – *off label*. • Treatment of uncontrolled bleeding due to acquired fibrinogen deficiency in the setting of post-partum hemorrhage or consumptive coagulopathy (ex., disseminated intravascular coagulation, acute presentation of acute promyelocytic leukemia) – *off-label.*
Contraindications	• Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. • For a complete listing, see the contraindications section of product monograph. <u>http://labeling.cslbehring.ca/PM/CA/RiaSTAP/EN/RiaSTAP-Product-Monograph.pdf.</u>
Warnings	• Hypersensitivity reactions, including anaphylaxis, are possible. Should symptoms occur, discontinue treatment and follow adverse event protocol. See <u>Nursing Policy and Procedure Blood Components and Plasma Protein Product – Administration of #1141.</u> • Products made from human plasma may contain infectious agents, such as viruses and, theoretically, the variant Creutzfeldt-Jakob disease (vCJD) agent that can cause disease. The risk that such products will transmit an infectious agent has been reduced by plasma donor screening, testing for the presence of certain current viruses, and by viral inactivation/removal steps. There is also the possibility that unknown infectious agents may be present in such products. • There is a risk of thrombosis in patients with congenital or acquired fibrinogen deficiency receiving human fibrinogen concentrate, particularly with high doses or repeated dosing. Exercise caution when administering this product to patients with a history of deep vein thrombosis, pulmonary embolism, arterial thrombosis, or liver disease as there is a theoretical

	increase in thrombosis risk. Patients receiving RiaSTAP® should be monitored for signs and symptoms of thrombosis (See WARNINGS AND PRECAUTIONS AND ADVERSE EVENTS in product monograph).

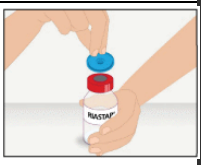
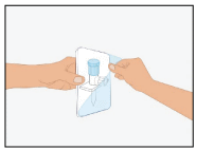
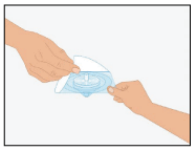
Dosage	• **Dosage should be determined by a physician experienced in the care of patients with hypofibrinogenemia.**
	• Fibrinogen Concentrate administration should be considered in bleeding patients with acquired hypofibrinogenemia and the following serum fibrinogen levels:
	  • Non-pregnant patient - 1.5 g/L or less.
	  • Pregnant or post-partum patient - 2 g/L or less.
	• The recommended initial dose of Fibrinogen Concentrate in the setting of acquired fibrinogen deficiency is 4 g IV for adults (50 kg or greater) and 30-60 mg/kg (to a maximum 4 g dose) for children.
	  • Fibrinogen Concentrate 4 grams ≈ fibrinogen in 10 units Cryoprecipitate.
	• Individual dosing in the setting of congenital fibrinogen deficiency may vary based on the body weight, laboratory values, and the patient's clinical condition. **Consultation with a Hematologist familiar with factor dosing in the setting of congenital bleeding disorders is strongly recommended.**
	• For further information about dosage please review the product monograph.
	• **Consult with the Transfusion Medicine Physician on-call for safe dosing recommendations, available through switchboard at (306) 655-1000.**

Pre-administration Testing Requirements	• Determination of the patient's fibrinogen level using an appropriate method (e.g., Clauss fibrinogen assay) or pattern consistent with hypofibrinogenemia demonstrated by thromboelastography (TEG) is recommended before and during the treatment with RiaSTAP® in order to avoid overdosing. • **Link to the Test Catalogue for Fibrinogen level specimen requirements.** https://www.saskatoonhealthregion.ca/locations_services/Services/Pathology-Laboratory-Med/healthpractitioners/Pages/Test%20catalogue/fib.aspx • As directed by most responsible health practitioner (MRHP).
Ordering	• Specify type of coagulation concentrate and dosage required. • To request product from the Transfusion Medicine Laboratory, use the Plasma Protein Product Request Form #103221.
Forms Required	• Informed Consent for Blood Components and/ or Plasma Protein Products #101479. • Plasma Protein Product Request Form #103221. • Transfusion/Infusion Administration and Assessment Record #101059. • Saskatchewan Transfusion Adverse Event Report Form #103695 (only needed if adverse event occurs). • Notification of Administration of Blood and/or Blood Products Form #103854. • **Forms can be located in the Lab Services Manual or Forms on Demand.** **https://www.saskatoonhealthregion.ca/locations_services/Services/Pathology-Laboratory-Med/healthpractitioners/Pages/requisitions.aspx**

Supplies Required	• The product package contains:
	  • One single-use RiaSTAP® vial (with hanger attached).
	  • One single-use sterile water for Injection vial 50 mL.
	  • Mini-spike dispensing pin and filter set *(**NEW** – supplied by the manufacturer and issued from the TML with product).*
	• Additional supplies needed:
	  • One butterfly infusion set (can use if patient does not have an IV in place).
	  • One transfer needle.
	  • One luer lock syringe (appropriate size based on volume) for administration.
	  • Sterile alcohol swab (for cleaning the tops of the vials).
	  • Labels (to affix onto infusion syringe).

Administration	• **Blood consent**: **Is required** due to human plasma component. • **Pre-infusion:** Ensure recent patient weight is on file and pertinent laboratory results are available. • Perform all other appropriate pre-administration checks per protocol, detailed in the Nursing Policy and Procedure Blood Components and Plasma Protein Product – Administration of #1141. • **Administration:** ***Congenital fibrinogen deficiency*: Administer the entire dose at a maximum rate of 5 mL per minute (approximately 100 mg per minute; 1 reconstituted vial over 10 minutes).*** **** Syringe pump: Microbore tubing required. Not to exceed 5 mL per minute (~100 mg/min).*** ***Acquired fibrinogen deficiency (off-label): Administer the entire dose at a maximum rate of 20 mL per minute (approximately 400 mg per minute; 1 reconstituted vial over 2.5 minutes).*** **** Syringe pump: Microbore tubing required. Not to exceed 20 mL per minute (~400 mg/min).*** • **SMART pump:** select 'blood fibrinogen concent.' • **Minibag:** NOT recommended. • **Access:** Can be given via CVC, PICC, Port-a-Cath®, or peripheral IV. • **Compatible Solutions:** Can flush line with 0.9% normal saline pre and post administration of RiaSTAP®. No other drugs/solutions (including normal saline) can be co-administered in the same line while RiaSTAP® is being infused. • **Preparation and Reconstitution** **NOTE:** Reconstitute only immediately before administration. Administer within 3 hours after reconstitution. DO NOT refrigerate after reconstitution. DO NOT further dilute in any IV solutions. DO NOT mix with other drugs or IV solutions.

Use aseptic technique (clean and germ free) when preparing and reconstituting RiaSTAP®.

1. **Allow the vials of RiaSTAP® and diluent to reach room temperature before use.** The lyophilized protein is refrigerated, while the water diluent is stored at room temperature. Warming of the vials will ease with dissolving the powder and lessen patient discomfort in the vein when administering.	
2. Remove the caps from the product vial and the diluent vial to expose the central portion of the rubber stoppers.	
3. Clean the surface of both of the rubber stoppers with an alcohol swab for 15 seconds and allow it to dry.	
4. Using an appropriate sized syringe and transfer needle, aspirate the 50 mL of the sterile water for injection into the syringe.	
5. Place the RiaSTAP® concentrate vial on a flat and solid surface. Slowly depress the plunger on the syringe to inject all the diluent into the RiaSTAP® vial.	
6. Gently swirl the product vial to ensure the product is fully dissolved (generally 5 to 10 minutes). Do not shake the vial which causes formation of foam. **TIP:** Slowly injecting the sterile water along the insides of the glass will assist with less foaming.	
7. Open the plastic blister containing the mini-spike dispensing pin provided with RiaSTAP.	
8. Take the provided dispensing pin and insert it into the stopper of the vial with the reconstituted product.	
9. After the dispensing pin is inserted, remove the cap. After the cap is removed, do not touch the exposed surface.	
10. Open the blister with the “syringe filter” provided with RiaSTAP.	

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<tr><td></td><td>
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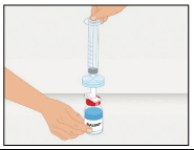
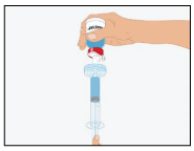
<tr><td>11. Screw the syringe onto the filter.</td><td>  </td></tr>
<tr><td>12. Screw the syringe with the mounted filter onto the dispensing pin.</td><td>  </td></tr>
<tr><td>13. Draw the reconstituted product into the syringe.</td><td>  </td></tr>
<tr><td>14. When completed, remove the filter, dispensing pin and empty vial from the syringe and dispose of properly.</td><td></td></tr>
<tr><td>15. Complete patient and product information on the labels provided by Transfusion Medicine and affix to the plastic syringe containing RiaSTAP®.</td><td></td></tr>
<tr><td>16. Clean the intended injection site with an alcohol swab and attach the luer lock syringe containing RiaSTAP ®. Administer product.</td><td></td></tr>
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For additional preparation/reconstitution and administration information see Administration section of the Product Monograph.
Lab testing post administration: Determination of the patient’s fibrinogen level is recommended before and during the treatment with RiaSTAP®. As directed by most responsible healthcare practitioner (MRHP).

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<tr><td>Nursing Implications</td><td>

Patient monitoring: Follow the Nursing Policy and Procedure Blood Components and Plasma Protein Product – Administration of #1141.
Documentation: Administration and vital signs shall be recorded on the Transfusion/Infusion Administration and Assessment Record #101059.

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<tr><td>Adverse Events</td><td>

See Warnings section.
Refer to Nursing Policy and Procedure Blood Components and Plasma Protein Product – Administration of #1141 for managing of allergic transfusion reaction and call MRHP.
Document adverse event on Saskatchewan Transfusion Adverse Event Report Form #103695, whether or not the transfusion was discontinued.

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<tr><td>Comments</td><td>

Can contact the Saskatchewan Bleeding Disorders Program at (306) 381–4185, Monday to Friday, 0800 – 1630 for education and administration assistance.

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<tr><td>References</td><td>

RiaSTAP® Product Monograph, approval date of May 27, 2020. Submission control #237751. http://labeling.cslbehring.ca/PM/CA/RiaSTAP/EN/RiaSTAP-Product-Monograph.pdf. Accessed on January 3, 2021.

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	• National Advisory Committee on Blood and Blood Products. NAC Statement on Fibrinogen Concentrate. [Updated April 9 2020] https://www.nacblood.ca/resources/guidelines/downloads/FC%20Statement%20Update%20Final2020.pdf Accessed November 2, 2020. • Saskatoon Health Region Policies and Procedures Nursing Policy and Procedure Blood Components and Plasma Protein Product – Administration of #1141. https://www.saskatoonhealthregion.ca/about/NursingManual/1141.pdf. Accessed December 2, 2020.