Drug Therapy Protocols: Human fibrinogen (RiaSTAP®)

Policy code	DTP_FIB_0924
Date	September, 2024
Purpose	To ensure a consistent procedural approach to human fibrinogen (RiaSTAP®) administration.
Scope	Applies to Queensland Ambulance Service (QAS) clinical staff.
Health care setting	Pre-hospital assessment and treatment.
Population	Applies to all ages unless stated otherwise.
Source of funding	Internal – 100%
Author	Clinical Quality & Patient Safety Unit, QAS
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Human fibrinogen (RiaSTAP®)

September, 2024

Drug class

Blood product derivative[1]

Pharmacology

Fibrinogen is a protein that in the presence of thrombin, Factor III and calcium ions, is converted into a stable and elastic three-dimensional fibrin haemostatic clot. The administration of human fibrinogen provides an increase in plasma fibrinogen level and can temporarily correct the coagulation defect of patients with fibrinogen deficiency. Fibrinogen is one of the first clotting factors depleted in traumatic injury and hypofibrinoginaemia is associated with increased mortality.[1–3]

Metabolism

Coagulation cascade activation by thrombin and subsequent fibrinolysis.

Indications[1–3]

- **Suspected traumatic haemorrhage**
  (requiring pre-hospital blood product transfusion AND
  (a point of care INR ≥ 1.3 OR a modified FibAT ≥ 4))

Contraindications

- Allergy AND/OR Adverse Drug Reaction
- Non-consenting conscious patient
  (e.g. Jehovah Witness)
- Patients less than 16 years of age

Precautions

- Nil in this setting

Side effects

- Fever
- Headache
- Thromboembolic episodes
- Allergy

Presentation

- Vials (powder and solvent): 1 g *human fibrinogen* (RiaSTAP®); 50 mL *Water for injection (WFI)*

Onset	Duration	Half-life
20 minutes	N/A	78 hours

Schedule

- Unscheduled.

Route of administration

Intravenous infusion (IV INF) ECCP

Special notes

- Ambulance officers must only administer medications for the listed indications and dosing range. Any consideration for treatment outside the listed scope of practice requires mandatory approval via the *QAS Clinical Consultation and Advice Line*.
- All cannulae and IV lines must be flushed thoroughly with sodium chloride 0.9% following each medication administration.
- All parenteral medications must be prepared in an aseptic manner. The rubber stopper of all vials must be disinfected with an appropriate antimicrobial swab and allowed to dry prior to piercing.
- The use of human fibrInogen in trauma is only beneficial to patients with confirmed low fibrinogen levels.
- Approximately 75% of patients will have correction of coagulopathy and bleeding after a single 50 mg/kg dose.[3]
- The lot numbers of all human fibrinogen vials administered to the patient must be documented on the patient's eARF.

Special notes *(cont.)*

- The QAS modified Fibrinogen on Admission in Trauma (FibAT) score is a validated and easy-to-use clinical prediction score used to identify trauma patients with a plasma fibrinogen concentration of 1.5 g or less. A score is calculated based on five patient characteristics. Those patients with a score equal to, or greater than four, are indicated for human fibrinogen.
- Complete the table by scoring 1 for yes and 0 for no.

modified FibAT variable	Score
Age < 33 years	
Out of hospital heart rate > 100 bpm	
Out of hospital SBP < 100 mmHg	
Temperature < 36°C	
Free intra-abdominal fluid on FAST	

- Informed consent for administration of blood products means a dialogue has occurred between the patient and the clinician. The significant risks, benefits and alternatives to transfusion, including the patient's right to refuse blood products, will have been discussed. As a result of the discussion the patient should:
  - Understand what medical action is recommended
  - Be aware of the risks and benefits associated with the blood products
  - Appreciate the risks, and possible consequences of not receiving the recommended therapy

Special notes *(cont.)*

- Be given an opportunity to ask questions
- Freely give consent for the administration of blood products.

- Medications administered intermittently rather than continuously may be administered via the same IV line, using the following procedure:
  1. STOP the transfusion.
  2. Flush the line via the injection port using sodium chloride 0.9% to clear blood from the IV port and tubing.
  3. Administer the medication.
  4. Flush the line with sodium chloride 0.9% before restarting the transfusion.

Adult dosages[1–3]

Suspected traumatic haemorrhage (requiring pre-hospital blood product transfusion AND (a point of care INR ≥ 1.3 OR a modified FibAT ≥ 4))

ECCP

IV INF

QAS Clinical Consultation and Advice Line approval required in all situations.

Weight	Dose	Volume
up to 50 kg	1 g	50 mL
> 50 – 75 kg	2 g	100 mL
> 75 kg	3 g	150 mL

In critical bleeding situations administer via slow push over 2–4 mins/g (50 mL).
Total maximum dose 3 g.

Syringe preparation: *Gently withdraw the reconstituted human fibrinogen (refer to next page for human fibrinogen preparation details) from the vial using a 50 mL syringe to achieve a final concentration of 1 g/50 mL.*

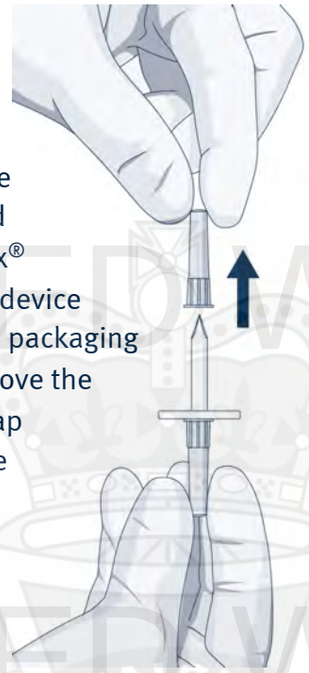
Paediatric dosages

Note: QAS officers are **NOT** authorised to administer human fibrinogen to patients less than 16 years of age.

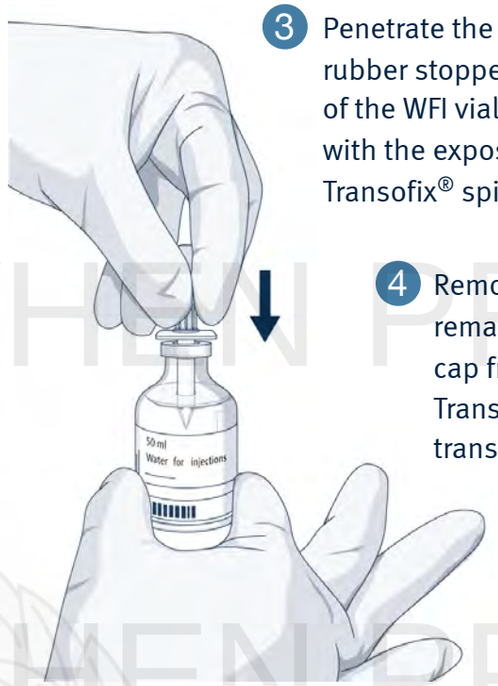
Human fibrinogen (RiaSTAP®) preparation

1 Place the supplied RiaSTAP® powder and Water for Injection (WFI) vials on a firm, flat surface. Remove caps and disinfect the rubber stoppers with a 2% chlorhexidine/ 70% isopropyl alcohol swab and allow to dry.

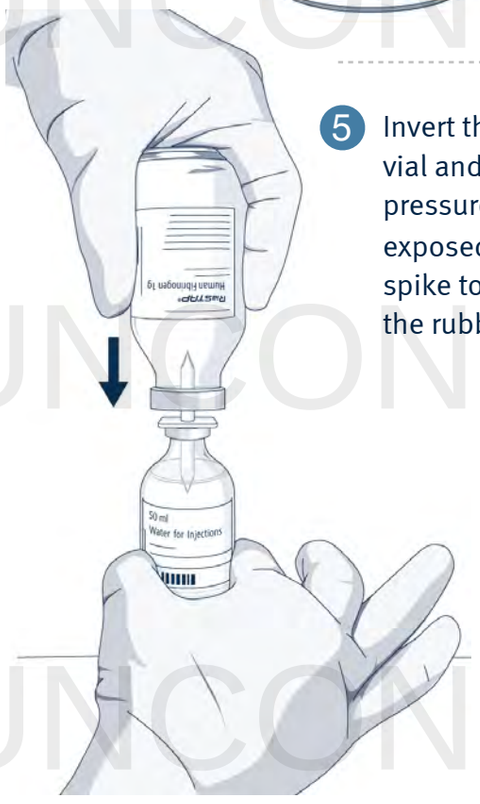
2 Open the supplied Transofix® transfer device from the packaging and remove the safety cap from one end.



3 Penetrate the rubber stopper of the WFI vial with the exposed Transofix® spike.

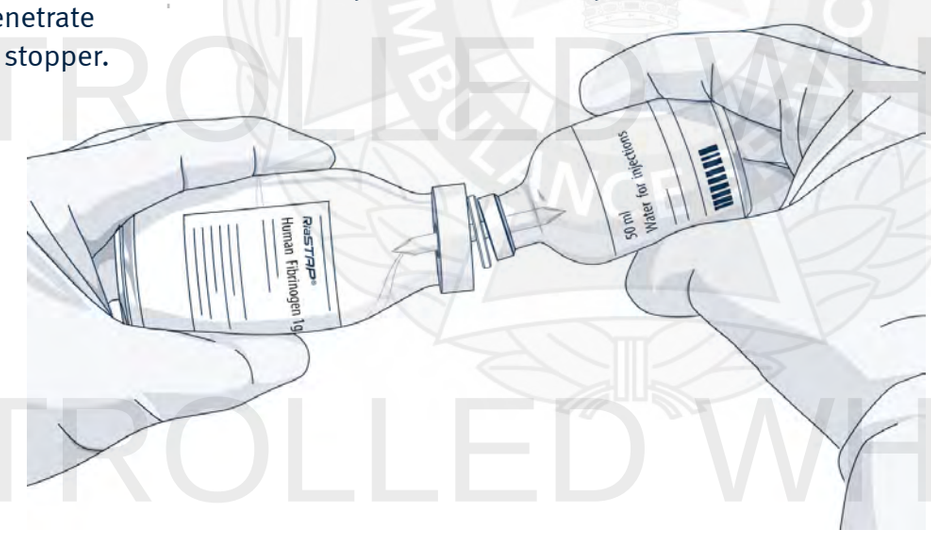


4 Remove the remaining safety cap from the Transofix® transfer device.



5 Invert the RiaSTAP® vial and with gentle pressure allow the exposed Transofix® spike to penetrate the rubber stopper.

6 Gently angle the interconnected vials to encourage the WFI to run slowly into the uppermost part of the RiaSTAP® vial – **DO NOT allow the WFI to pour directly on the RiaSTAP® powder.**

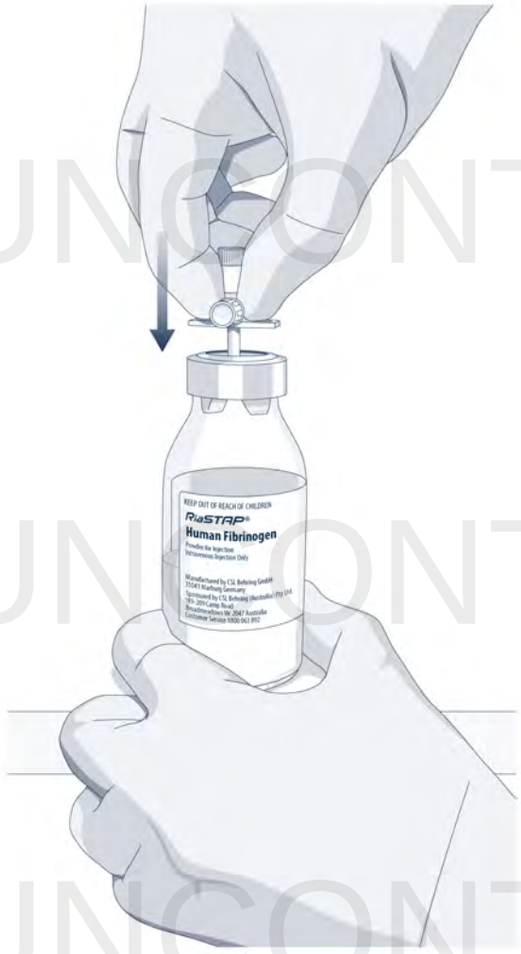


7 When all of the WFI contents are transferred disconnect the empty WFI vial and Transofix® transfer device from the RiaSTAP® vial.

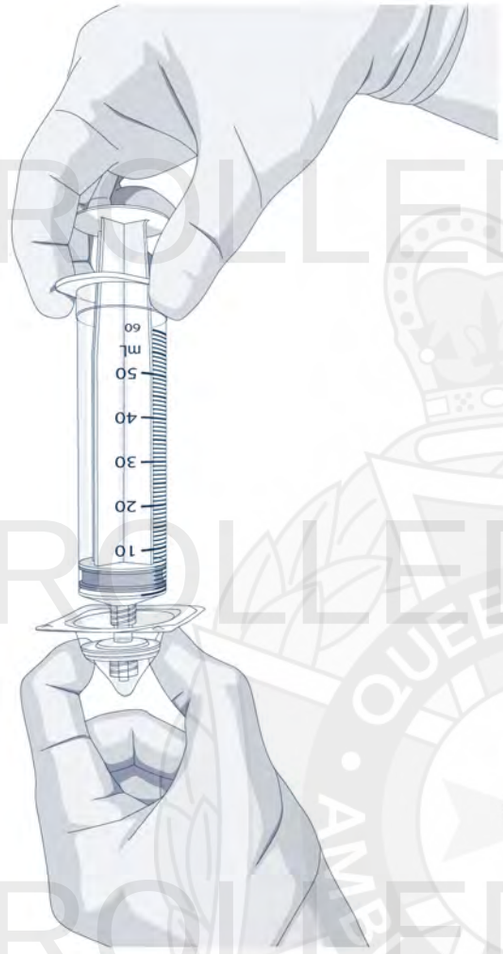
Gently swirl the RiaSTAP® vial to fully reconstitute the contents (may take 5–10 minutes) – **under NO circumstances is the vial to be shaken.**

After reconstitution, the RiaSTAP® should be colourless and clear to slightly opalescent. Inspect visually for particulate matter and discolouration prior to administration. **Do NOT use if the solution is cloudy or contains particulates.**

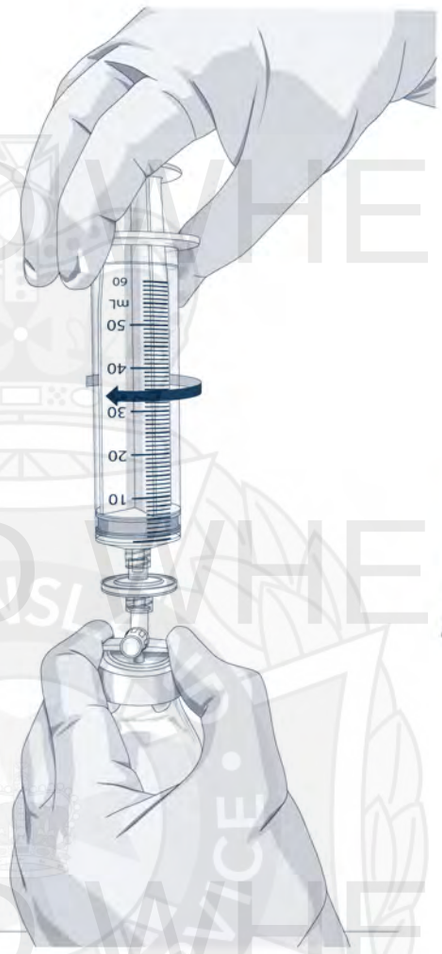
Human fibrinogen (RiaSTAP®) preparation



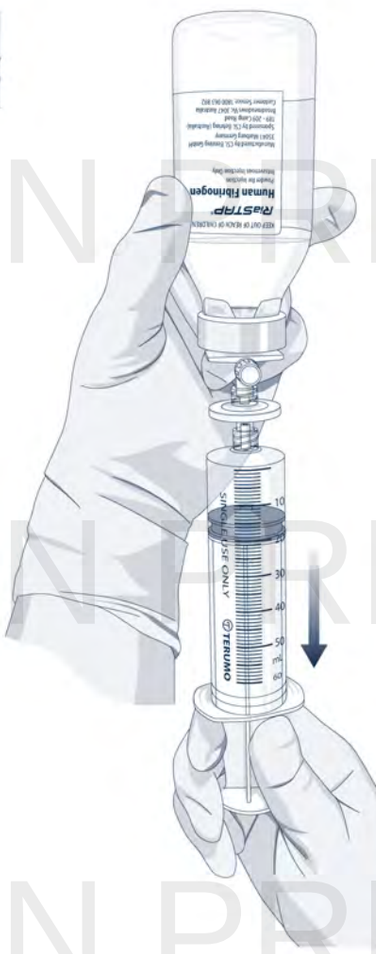
8 Place the reconstituted RiaSTAP® vial on a firm flat surface. Penetrate the vial's rubber stopper with the supplied Mini-Spike® dispensing pin.



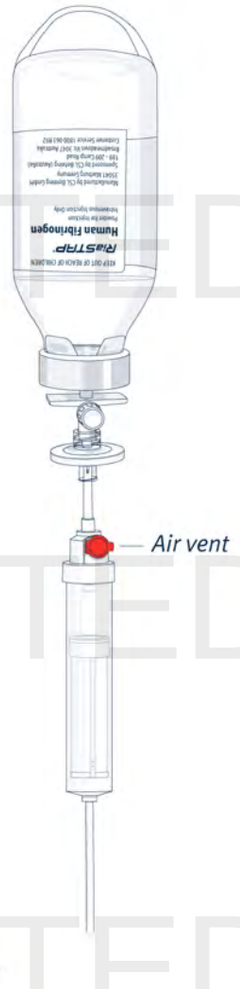
9 Attach a 50 mL Luer-Lok™ syringe to the PALL® Medical syringe filter.



10 Gently screw the filter and syringe onto the dispensing pin.



11 OPTION 1:
Withdraw the reconstituted RiaSTAP® into the syringe.



OPTION 2:
Attach a giving set;
Prime chamber and line;
Attach to IV bung;
Open air vent to enable flow.

QAS blood/blood products storage