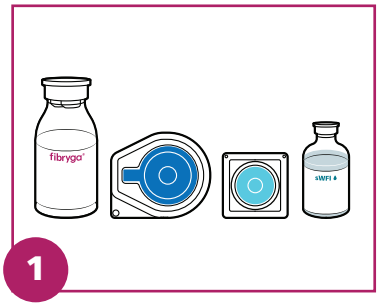
fibryga®

Fibrinogen Concentrate (Human) Powder
for Solution for Injection / Infusion, 1 g/vial

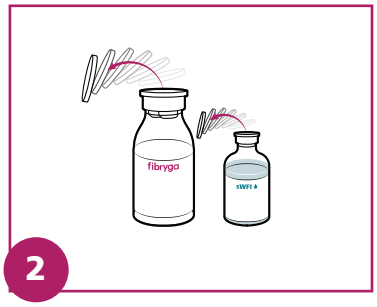
Reconstitution Instructions

Ensure the Fibryga® vial and the water for injection are at room temperature



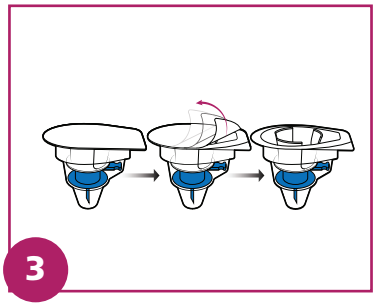
1

Lay out the Fibryga® kit contents on a clean flat surface. You will need a 50 mL syringe.



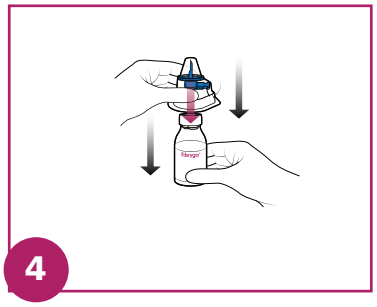
2

Remove the plastic caps and discard. Clean the rubber stoppers with an alcohol swab and allow them to dry.



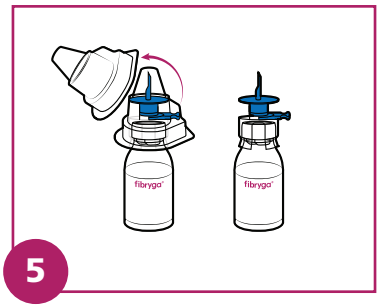
3

Peel away the paper cover of the outer package of the Octajet® transfer device.



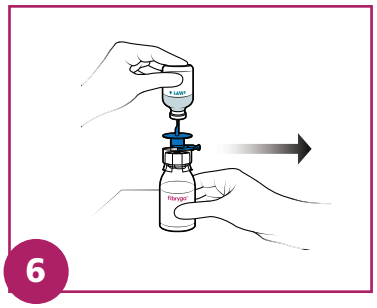
4

Maintain the transfer device in its outer package. Place the Octajet® device onto the Fibryga® vial and spike. Ensure the plastic clips of the Octajet® device securely lock to the Fibryga® vial.



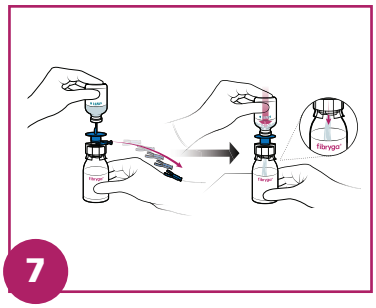
5

While holding onto the powder vial, remove the outer package from the Octajet® device. Do not touch the blue water spike.



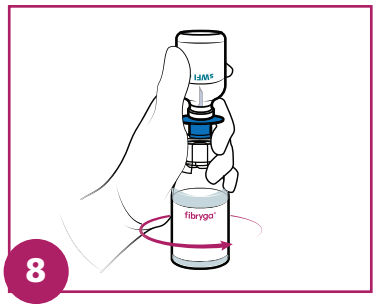
6

Hold the Fibryga® vial on a flat surface. Invert the water vial and place it over the blue water spike. Push spike of the Octajet® through the rubber stopper of the water vial in one smooth motion.
Ensure the water vial fully covers both holes of the blue water spike to avoid vacuum loss.



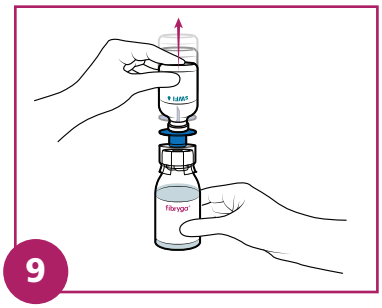
7

Remove the blue ring and press the water vial down using downward force in one motion (to start the vacuum) then let the water flow into the Fibryga® vial automatically.



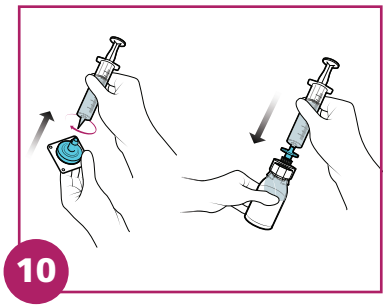
8

Gently swirl the powder vial until the powder is fully dissolved. Do not shake the vial – this will cause foam formation.



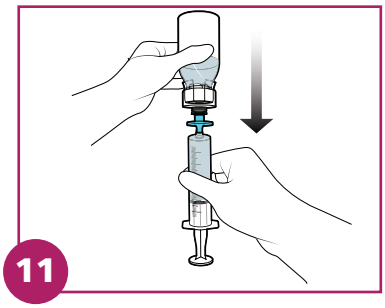
9

In one hand, hold the Fibryga® vial and secure the clear portion of the transfer device. In the other hand, hold the water vial and grip the blue disc of the transfer device.
In one motion, remove the water vial together with the blue spike/disc.
Do not remove the water vial alone as it will expose the spike.



10

Open filter package and attach 50 mL syringe.
Attach the filter and syringe to the Luer lock on the Fibryga® vial.



11

Withdraw the solution through the filter into the syringe.

octapharma®

Vial Size	Volume of WFI to be Added to Vial	Approximate Available Volume	Nominal Concentration per mL
1g	50 mL	50 mL	20mg

Administration Instructions	
Description	FIBRYGA® (Fibrinogen Concentrate (Human), 1 g/vial) is a sterile, freeze dried preparation of highly purified fibrinogen. FIBRYGA® is prepared from large pools of human plasma employing precipitations, filtrations and chromatographic steps. Pathogen inactivation/removal is accomplished by a solvent detergent (S/D) method and nanofiltration (20 nm).
Indications and Clinical Use	FIBRYGA® is indicated for the treatment of acute bleeding episodes and perioperative prophylaxis in adult and pediatric patients with congenital afibrinogenemia and hypofibrinogenemia.
Contraindications	FIBRYGA® is contraindicated in individuals who have manifested severe immediate hypersensitivity reactions, including anaphylaxis to FIBRYGA® or its components.
Storage	FIBRYGA® can be stored at +2°C to +25°C for up to 36 months from the date of manufacture. Do not use product after expiry date. Stability of the reconstituted solution has been demonstrated for up to 24 hours at + 25°C. Discard partially used vials. Do not freeze. Protect from exposure to light. Keep in a safe place out of the reach and sight of children.
Dosage **For detailed dosing instructions see the FIBRYGA® Product Monograph.**	The recommended target fibrinogen plasma level is 100 mg/dL for minor bleeding or minor surgery and 150 mg/dL for major bleeding or major surgery. **FIBRYGA® dose when baseline fibrinogen level is known** Dose should be individually calculated for each patient based on the target plasma fibrinogen level based on the type of bleeding, actual measured plasma fibrinogen level and body weight, using the following formula: $\text{Dose (mg/kg body weight)} = \frac{\text{[Target level (mg/dL) - measured level (mg/dL)]}}{\text{1.8 (mg/dL per mg/kg body weight)}}$ **FIBRYGA® dose when baseline fibrinogen level is not known** If the patient's fibrinogen level is not known, the recommended dose is 60 mg per kg of body weight administered intravenously. Monitoring of patient's fibrinogen level is recommended during treatment with FIBRYGA®.

Reference: 1. Fibryga® Product Monograph. Octapharma. August 10, 2018.