FESILTY
human fibrinogen

RECONSTITUTION GUIDE

GRIFOLS

Please see Important Safety Information on the back and refer to accompanying full Prescribing Information for FESILTY.

A PREPARE VIALS

Product can be stored at room temperature (not above 30 °C/86 °F) and should not be frozen. If stored at room temperature, reconstitution can begin immediately.[1]

- **Remove the caps** from the vials, **cleanse each vial stopper** with an alcohol swab, and allow them to dry.

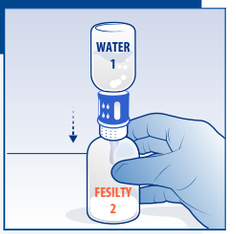
B CONNECT TRANSFER SYSTEM TO WATER VIAL

- Remove the paper seal from the blister.
- Place the **water vial (1) on a flat surface**.
- Place the **blue part** of the transfer system within the blister **straight onto the upright water vial** until it snaps into place.
- Do not twist the transfer system.

C INVERT

- Remove the blister from the transfer system, and **place the FESTILTY vial (2) on a flat surface.**

D CONNECT FESILTY VIAL

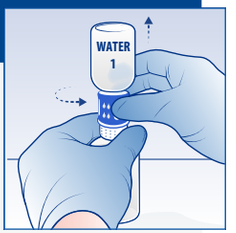


- **Turn the transfer system** with the water vial **upside down**.
- **Push the spike of the white end** of the transfer system **straight down** through the product stopper **until it snaps into place**.
- **After water transfer is complete,** gently **sway** to dissolve the powder **(do not shake)**.

The powder should be dissolved completely within approximately 3 minutes.[1]

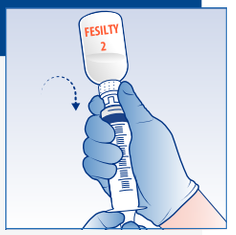
Discard the product if the powder is not fully dissolved within 30 minutes. After reconstitution the solution should be clear or slightly opalescent.

E DETACH TRANSFER SYSTEM



- **Unscrew** the blue part of the transfer system together with the empty water vial counterclockwise.
- **Discard the water vial** with the blue part of the transfer system attached.
- To maintain sterility, **do not touch** the luer-lock connector.
- Keep the solution at room temperature and **use within 4 hours** after dissolving.
- Do not use solutions that are cloudy or contain visible particles.

F DRAW SOLUTION



- **Screw a syringe** onto the luer-lock connector of the **white part of the transfer system** and **invert** it to easily **draw the solution into the syringe**.

PREPARATION AND RECONSTITUTION REMARKS:

- Inspect the carton kit before opening. Discard the kit if the package is damaged or if the seal on the carton shows signs of tampering.
- Do not use FESILTY after the expiration date on the vial label and carton.
- If stored refrigerated, allow the unopened vials of water (1) and product (2) to come to room temperature.
- Use aseptic technique (clean and sanitized) and a flat surface during reconstitution of FESILTY.

These are shortened instructions. Full instructions in the package insert must be read before use.

Please see Important Safety Information on the back and refer to accompanying full Prescribing Information for FESILTY.

FPO

SCAN TO VIEW THE RECONSTITUTION VIDEO

FESILTY
human fibrinogen

WHEN EVERY MINUTE COUNTS, COUNT ON FESILTY

FESILTY
human fibrinogen

ALL IN THE BOX

Each carton contains **everything you need** for simple and rapid reconstitution.

SHORTENED INSTRUCTIONS available inside the carton flap

IMMEDIATE AVAILABILITY

Can be stored at **room temperature (≤ 30 °C/86 °F)** and at the point of care.[1]

RAPID RECONSTITUTION IN ~3 MINUTES[1]

The **fastest reconstitution time among fibrinogen concentrates**.[1-3]

References: 1. FESILTY [package insert]. Grifols, S.A. **2.** FIBRYGA [package insert]. Octapharma USA, Inc. **3.** RiaSTAP. Summary of Product Characteristics. CSL Behring. 2023.

IMPORTANT SAFETY INFORMATION

Indications and Usage

FESILTY (fibrinogen, human-chmt) is a human blood coagulation factor indicated for the treatment of acute bleeding episodes in pediatric and adult patients with congenital fibrinogen deficiency, including hypo- or afibrinogenemia.

Limitations of Use:

FESILTY is not indicated for dysfibrinogenemia.

Contraindications

FESILTY is contraindicated in patients who have severe hypersensitivity reactions, including anaphylaxis, to FESILTY or its components (arginine hydrochloride, polysorbate 80, sodium citrate dihydrate, trehalose dihydrate).

Warnings and Precautions

Hypersensitivity reactions have occurred in patients receiving FESILTY. Should symptoms occur, discontinue FESILTY and administer appropriate treatment.

Thrombotic events have occurred in patients receiving FESILTY. Weigh the benefits of administration versus the risks of thrombosis.

FESILTY is made from pooled human plasma and may carry the risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Adverse Reactions

The most serious adverse reactions observed with FESILTY were thrombotic events, including portal vein thrombosis, deep vein thrombosis, and pain in extremity with clinically suspected thrombosis. One patient had an episode of epilepsy and died due to extradural hematoma 4 weeks after administration of FESILTY.

In a clinical study, the most common adverse reactions that occurred in >2% of patients receiving FESILTY were pain in extremity, back pain, hypersensitivity reactions, pyrexia, thrombosis, fibrin D dimer increased, headache, and vomiting.

Please see full Prescribing Information for FESILTY.

To report SUSPECTED ADVERSE REACTIONS, contact Grifols Therapeutics LLC at 1-800-520-2807 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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