# Grifols launches FESILTY™ (fibrinogen, human-chmt) in the US

- **The new fibrinogen concentrate, FESILTY™ (fibrinogen, human-chmt), approved in the US for acute bleeding episodes in pediatric and adult patients with congenital fibrinogen deficiency (CFD), is now available in the US.**

- **FESILTY complements Grifols' bleeding management portfolio, expanding therapeutic options for patients.**

FESILTY, the new fibrinogen concentrate from Grifols, is now available in the US. Approved by the US Food and Drug Administration in December 2025, FESILTY is indicated to treat acute bleeding episodes in pediatric and adult patients with congenital fibrinogen deficiency (CFD), including hypo- or afibrinogenemia. FESILTY is not indicated for dysfibrinogenemia.

FESILTY provides healthcare professionals and patients a new treatment option for acute bleeding in patients with CFD, a rare inherited condition caused by genetic mutations that impair the production or function of fibrinogen. Produced in the liver, fibrinogen is a plasma protein essential for blood clotting and wound healing. When fibrinogen levels are insufficient, the body's ability to effectively control bleeding is compromised, particularly during acute bleeding episodes.

A highly purified product with a precisely defined amount of fibrinogen, FESILTY enables rapid and predictable restoration of fibrinogen levels – which is critical in bleeding events. In contrast, alternate treatment options such as cryoprecipitate and fresh frozen plasma include additional proteins, often require infusions of large volumes to achieve adequate fibrinogen levels, and take longer to prepare and administer.[1]

FESILTY can be stored at room temperature at the point of care and is supplied as a complete kit, allowing for rapid reconstitution in approximately 3 minutes.

Grifols, a global healthcare company and leading producer of plasma-derived medicines, today announced the US launch of its new fibrinogen concentrate. The launch of FESILTY enhances Grifols' bleeding management offering and further expands its portfolio of plasma-derived medicines to benefit patients and healthcare professionals.

### Clinical evidence supporting approval

FDA approval of FESILTY was based on evidence from the clinical study "A Prospective, Open-label, Phase I/III Study Investigating Pharmacokinetic Properties of BT524 and Efficacy and Safety of BT524 in the Treatment and Prophylaxis of Bleeding in Patients With Congenital Fibrinogen Deficiency" (NCT02065882).

Two medical journals recently published results from this study. The findings, published in *Thrombosis and Haemostasis* (October 2025) and *Thrombosis Research* (March 2026) confirmed the therapy's pharmacokinetics, hemostatic efficacy, and safety for treatment of acute bleeding episodes in both adults and children with CFD.[2,3]

**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.**

**References: 1.** FESILTY™ Prescribing Information. Durham, NC: Grifols USA, LLC. 2025**. 2.** Djambas Khayat C, El-Beshlawy A, Meddeb B, et al. Pharmacokinetics, hemostatic efficacy, and safety of a new human fibrinogen concentrate in adult and pediatric patients with congenital fibrinogen deficiency. *Thromb Haemost*. 2025. October. doi: 10.1055/a-2715-2994. **3**. Khayat CD, El-Beshlawy A, Omar N, et al. Efficacy and safety of prophylaxis and treatment of bleeding events with a novel fibrinogen concentrate from human plasma in patients with congenital fibrinogen deficiency. *Thromb Res*. 2026 March. doi:10.1016/j.thromres.2026.109616.

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