



FOR IMMEDIATE RELEASE

BAXTER LAUNCHES PERCLOT ABSORBABLE HEMOSTATIC POWDER

Marks first passive hemostat for Baxter in the U.S. market, broadening portfolio offering to include a full range of active and passive hemostatic products

DEERFIELD, Ill., July 24, 2023 – Baxter International Inc. (NYSE:BAX), a global leader in advancing surgical innovation, today announced the launch of **PERCLOT** Absorbable Hemostatic Powder in the U.S. **PERCLOT** is a passive, absorbable hemostatic powder that is ready to use and designed for patients with intact coagulation to address mild bleeding.¹

“**PERCLOT** is a strong complement to Baxter’s leading hemostat portfolio,” said Steve Wallace, president, Advanced Surgery at Baxter. “The launch of **PERCLOT** in the U.S. allows us to provide surgeons with a full range of active and passive hemostatic products for bleeding control, helping to optimize care for their patients.”

To coincide with the launch of **PERCLOT** in the U.S., Baxter is working closely with key customers representing multiple leading hospitals across the country to add **PERCLOT** to their standard of care for low level bleeds. **PERCLOT** granules have a molecular structure that rapidly absorbs water, forming a gelled adhesive matrix that provides a mechanical barrier against further bleeding and results in the accumulation of platelets, red blood cells, and coagulation proteins (thrombin, fibrinogen, etc.).

PERCLOT further enhances clinicians’ ability to optimize patient care by addressing a broader range of intraoperative bleeding. Addressing intraoperative bleeding is important in reducing blood transfusions and major complications for patients, as well as lowering the total cost of care.^{2,3} A blood management strategy that includes effective hemostasis is essential in today’s environment where there is a shortage of blood donations.

Baxter has successfully continued to expand the global commercial presence of **PERCLOT** since [acquiring the product in July 2021](#). To date, **PERCLOT** has sales in more than 35 countries worldwide.

For more information on **PERCLOT**, visit <https://advancedsurgery.baxter.com/perclot> .

About PERCLOT

PERCLOT is a passive, absorbable hemostatic powder that is ready to use and designed for patients with intact coagulation to address mild bleeding.¹ **PERCLOT** is composed of absorbable polysaccharide granules. These granules are derived from purified plant starch, biocompatible, non-pyrogenic, and do not contain any human or animal components. **PERCLOT** granules have a molecular structure that rapidly absorbs water, forming a gelled adhesive matrix that provides a mechanical barrier against further bleeding and results in the accumulation of platelets, red blood cells, and coagulation proteins (thrombin, fibrinogen, etc.).⁴ It is used as an adjunctive hemostatic device to control bleeding during open and laparoscopic surgical procedures, including gynecologic, general, cardiovascular, and urology.

About Baxter

Every day, millions of patients, caregivers and healthcare providers rely on Baxter's leading portfolio of diagnostic, critical care, kidney care, nutrition, hospital and surgical products used across patient homes, hospitals, physician offices and other sites of care. For more than 90 years, we've been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers who make it happen. With products, digital health solutions and therapies available in more than 100 countries, Baxter's employees worldwide are now building upon the company's rich heritage of medical breakthroughs to advance the next generation of transformative healthcare innovations. To learn more, visit www.baxter.com and follow us on [Twitter](#), [LinkedIn](#) and [Facebook](#).

INDICATIONS

- **PERCLOT** Absorbable Hemostatic Powder is indicated in surgical procedures (except neurological and ophthalmic) as an adjunctive hemostatic device to assist when control of suture line bleeding or capillary, venous, and arteriolar bleeding by pressure, ligature, and other conventional procedures are ineffective or impractical.

IMPORTANT RISK INFORMATION

- Do not inject or place **PERCLOT** into blood vessels such as artery or vein as potential for embolization and death may exist.
- Do not use **PERCLOT** for treatment of severe or extreme bleeding.
- Do not inject into bladder or ureteral lumen.
- Single use only. Do not re-use. Do not re-sterilize. Re-use or reprocessing of a single use device may lead to contamination and compromised device function or structural integrity.
- Safety and efficacy of **PERCLOT** have not been clinically evaluated in children (less than 21 years old) and pregnant or lactating women.
- **PERCLOT** should be used with caution in the presence of infection or in contaminated areas of the body. If signs of infection or abscess develop where **PERCLOT** has been applied, re-operation may be necessary in order to allow drainage.
- Safety and efficacy of **PERCLOT** in neurological and ophthalmic procedures have not been established.

- Safety and efficacy of **PERCLOT** have not been clinically evaluated for use in controlling post-partum bleeding or menorrhagia.
- Once hemostasis is achieved, excess **PERCLOT** should be removed from the site of application by irrigation and aspiration particularly when used in the pericardial cavity and around foramina of bone, areas of bony confine, the spinal cord, and/or the optic nerve and chiasm. **PERCLOT** achieves its maximum swelling within 10 minutes when exposed to blood or other fluids. Dry, white **PERCLOT** should be removed. The possibility of the product interfering with normal function and/or causing compression of surrounding tissues due to swelling is reduced by removal of excess dry material.
- The effect of this product on patients with known sensitivity to starch or starch-derived materials has not been studied.
- The efficacy of **PERCLOT** in achieving hemostasis in cortical bone and spinal bleeding has not been studied in randomized clinical trials.
- Blood vessels, suture line gaps, and large needle holes with a diameter of ≥ 2 mm must be ligated prior to **PERCLOT** application.
- Do not apply more than 50g of **PERCLOT** in diabetic patients as it has been calculated that amounts in excess of 50g could affect the glucose load.
- As with other hemostatic agents, do not apply **PERCLOT** to sites where there is negative peripheral venous pressure as material may be drawn into the vascular system potentially resulting in life-threatening thromboembolic events.

Rx Only. For safe and proper use please refer to full device Instructions for Use for Contraindications, Warnings, and Precautions.

Forward-Looking Statements

*This release includes forward-looking statements concerning potential benefits associated with **PERCLOT**. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: demand for and market acceptance for new and existing products; product development risks; inability to create additional production capacity in a timely manner or the occurrence of other manufacturing or supply difficulties (including as a result of natural disasters, public health crises and epidemics/pandemics, regulatory actions or otherwise); satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; product quality, manufacturing or supply, or patient safety issues; changes in law and regulations; and other risks identified in Baxter's most recent filing on Form 10-K and Form 10-Q and other SEC filings, all of which are available on Baxter's website. Baxter does not undertake to update its forward-looking statements.*

PERCLOT is a registered trademark of CryoLife, Inc.
Baxter is a registered trademark of Baxter International Inc.

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¹Assessment of the hemostatic efficacy of PERCLOT, Surgicel Powder, and Arista in a Porcine Liver Abrasion Model. December 2021. Baxter Date on File. REF-36820.

² Stokes et al.: Impact of bleeding-related complications and/or blood product transfusions on hospital costs in inpatient surgical patients. BMC Health Services Research 2011 11:135.

³ David A. Iannitti, Chong Kim, Diane Ito & Josh Epstein (2021) Impact of an active hemostatic product treatment approach on bleeding related complications and hospital costs among inpatient surgeries in the United States, Journal of Medical Economics, 21:1,514-523, DOI: 10.1080/13696998.2021.

⁴ PERCLOT IFU