

Hemospray® FAQs



What is Hemospray?

Hemospray is an inert powder developed for endoscopic hemostasis. The powder is delivered by use of a carbon dioxide powered delivery system and through a catheter inserted through the working channel of an endoscope which provides access to the site of the bleed. It contains no human or animal proteins or botanicals and has no known allergens.

How does it work?

When Hemospray comes in contact with an actively bleeding site, the powder absorbs water, then acts both cohesively and adhesively, forming a mechanical barrier over the bleeding site.

What are the anticipated advantages over other therapies?

Hemospray, unlike traditional therapies, is a nonthermal, nontraumatic, noncontact modality that doesn't require the precise targeting of other endoscopic devices.

That means:

Nonthermal: No tissue changes occur as sometimes experienced with thermal modalities.

Nontraumatic: Since no force is applied at the treatment site, the powder minimizes the risk of tissue trauma as experienced with other modalities.

Noncontact: Aerosol delivery system eliminates the need for direct mechanical or contact forces with the treatment site.

Nonspecific targeting: Powder is sprayed toward the source of the bleed, so it does not require the en face approach and accuracy needed for conventional modalities.

Is Hemospray effective on anticoagulated patients?

Cook does not currently have sufficient data to make claims on the efficacy of Hemospray on anticoagulated patients. Preliminary results have been promising in this patient population, especially in cases where contact and thermal modalities pose additional challenges.

Does the powder need to be removed after use?

Hemospray is not absorbed by the body and does not require removal as it passes through the lower GI tract within 72 hours. Clinical experience indicates that the powder passes through the lower GI tract without occlusion.

Is the powder absorbed systemically?

To date, we have seen no clinical sign or symptoms of Hemospray being absorbed systemically. Furthermore, similar materials have been orally ingested over the years.

Can Hemospray be used on nonbleeding visible vessels?

Hemospray has not yet been evaluated for its effectiveness on nonbleeding sites.

Have powders previously been used as hemostatic agents?

Yes. Various granular hemostats have a long history of use for traumatic external injuries.

How can I tell when enough Hemospray has been deployed and hemostasis is achieved?

Continue applying Hemospray in short 1-2 second bursts until the bleeding site is completely covered with powder and no active bleeding is visualized.

Is there a limit to the amount of Hemospray that can be applied?

Hemostasis may not be immediate and multiple applications may be required; however no more than three Hemospray devices should be applied per patient.

Are there any special storage requirements for this device?

Similar to current devices, store in a dry location, away from temperature extremes.

What are the known long-term effects of Hemospray?

Similar materials of this family have been ingested for years with no complications. Hemospray is an inorganic powder and contains no human or animal proteins or botanicals.

Are there any postprocedural recommendations when using Hemospray?

Follow normal pre- and postprocedure standards of care.

How do I dispose of the device after use?

Depressurize completely by rotating base of handle counterclockwise. Dispose per institutional guidelines for biohazardous medical waste.

How do I prevent the catheter from becoming occluded?

Avoid direct contact with bodily fluids. This can be accomplished by flushing accessory channel with air prior to introducing catheter, eliminating mucosal or vessel contact with the catheter tip, not applying suction while catheter is in the endoscope channel, and not submerging the catheter tip in pooled blood. Additionally, when deploying powder, ensure the trigger button is pressed for at least 1-2 seconds. This ensures no residual powder is left in the catheter.

What experience is there in the treatment of severe bleeds?

Hemostasis was achieved in arterial bleeds that were created surgically in an anticoagulated porcine model. Additionally, postmarket registry clinical data suggests Hemospray is effective for achieving hemostasis in numerous types of arterial bleeds such as peptic ulcers, postendoscopic mucosal resection or dissection bleeds, Mallory-Weiss tears, upper GI postpolypectomy bleeds, and other hemorrhagic upper GI conditions including GAVE and Dieulafoy lesions.

Will combination therapies still be required with Hemospray?

Additional studies are being conducted to compare Hemospray with the current standard of care.

Has there been evidence of embolization?

No. In early animal work, neither localized nor distant (brain, liver or lung) vessel embolization was evident on necropsy and pathology examination.

What impact does Hemospray have on the clotting cascade?

Hemospray's primary mechanism of action is to form a mechanical barrier over the bleeding site, which immobilizes the blood. The immobilized blood then clots.

Is Hemospray a nanopowder?

No, the particle size of Hemospray is larger than that of a nanoparticle.

What is the difference between TC-325 and Hemospray?

TC-325 was simply the early preclinical descriptor used before the brand name Hemospray was developed.

What do I do if I get Hemospray on my skin, in my eyes, or if it is inhaled?

Hemospray is inert and nontoxic. As a granular material, Hemospray may cause potential irritation to the skin, eyes, and lungs. The Emergency First Aid measures to be considered for unintended exposure to Hemospray powder are as follows:

Skin: Wash with soap and water until clean.

Eyes: Flush with water until irritation ceases.

Inhalation: Move to area free from powder. If symptoms of irritation persist, contact physician. Inhalation may aggravate existing respiratory illness.

What data/publications are currently available for Hemospray?

- Mourad FH, Leong RW. Role of hemostatic powders in the management of lower gastrointestinal bleeding: A review. *Journal of Gastroenterology and Hepatology*. E-published 22 March 2018.
- Barkun AN, Adam V, Lu Y, et al. Using Hemospray Improves Cost-effectiveness Ratio in Management of Upper Gastrointestinal Nonvariceal Bleeding. *Journal of Clinical Gastroenterology*. 2018 Jan; 52(1): 36-44.
- Chen Y, Barkun A. Hemostatic Powders in Gastrointestinal Bleeding: A Systematic Review. *Gastrointestinal Endoscopy Clinics of North America*. 2015 July; 25(3): 535-552.
- Changela K, Papfragkakis H, Ofori E, et al. Hemostatic powder spray: a new method for managing gastrointestinal bleeding. *Therapeutic Advances in Gastroenterology*. 2015 May; 8(3): 125-135.
- Sulz MC, Frei R, Meyenberger C, Bauerfeind P, Semadeni GM, Gubler C. Routine use of Hemospray for gastrointestinal bleeding: prospective two-center experience in Switzerland. *Endoscopy*. 2014 Jul;46(7):619-24.
- Yau A, Ou G, Galoport C, et al. Safety and efficacy of Hemospray in upper gastrointestinal bleeding. *Canadian Journal of Gastroenterology and Hepatology*. 2014 Feb; 28(2): 72-76.
- Morris AJ, Smith LA, Stanley A, et al. Hemospray for non-variceal upper gastrointestinal bleeding: Results of the Seal Dataset (survey to evaluate the application of Hemospray in the luminal tract). *Journal of Clinical Gastroenterology*. E-published December 2013.

For more information on Hemospray, visit: hemospray.cookmedical.com

Summary of Clinical Data: Clinical data summary information that was, in part, the basis for granting the de novo can be found on the Cook Medical website at CookMedical.com/HemosprayData



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Not available in all markets. Consult with your local Cook representative or customer service center for details.