



What is Hemospray?

Hemospray is an inert (bentonite) powder developed for endoscopic haemostasis. 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 direct force is applied at the treatment site, the powder minimises 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. Clinical experience indicates that the powder passes through the lower GI tract without occlusion.¹

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.

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 immobilises the blood. The immobilised blood then clots.

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 haemostatic agents?

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

How can I tell when enough Hemospray has been deployed and haemostasis 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 visualised.

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

Each device contains 20 g of Hemospray powder. No more than three Hemospray devices should be applied per patient.

How do I prevent the catheter from becoming occluded?

Avoid direct contact with bodily fluids. This can be accomplished by flushing the accessory channel with air prior to introducing the catheter. To eliminate fluid from entering the working channel, temporarily occlude the catheter by placing a thumb over the red catheter hub while advancing the catheter down the accessory channel. Eliminate mucosal or vessel contact with the catheter tip, avoid applying suction while the catheter is in the endoscope channel, and do not submerge 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.

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 and has no known allergens.



Are there any post-procedural recommendations when using Hemospray?

Follow normal pre- and post-procedure standards of care.

How do I dispose of the device after use?

Depressurise completely by rotating the activation knob until CO² cartridge depressurises completely. Dispose per institutional guidelines for biohazardous medical waste.

What experience is there in the treatment of severe bleeds?

Haemostasis was achieved in arterial bleeds that were created surgically in an anticoagulated porcine model.² Additionally, post-market registry clinical data suggests Hemospray is effective for achieving haemostasis in numerous types of arterial bleeds, such as peptic ulcers, postendoscopic mucosal resection or endoscopic submucosal dissection.³

Will combination therapies still be required with Hemospray?

Studies have shown Hemospray to be effective when used as a monotherapy.^{3,4} Use of multiple modalities is at the discretion of the attending physician, as with any other haemostasis procedure.

Has there been evidence of embolisation?

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

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 publications are currently available for Hemospray?

- Hookey L, Barkun A, Sultanian R, et al. Successful hemostasis of active lower GI bleeding using a hemostatic powder as monotherapy, combination therapy or rescue therapy. *Gastrointest Endosc.* 2019;89(4):865-871.
- Hussein M, Alzoubaidi D, Weaver M, et al. Use of Hemospray in the treatment of lower gastrointestinal bleeds: outcomes from the international multicenter Hemospray registry. DDW. 2020:SU1039
- Hussein M, Alzoubaidi D, O'Donnell M, et. al. Hemostatic powder TC-325 treatment of malignancy related upper gastrointestinal bleeds: international registry outcomes. J Gastroenterol Hepatol. 2021;36(11):3027-3032.
- Mourad FH, Leong RW. Role of hemostatic powders in the management of lower gastrointestinal bleeding: a review. *J Gastroenterol Hepatol.* 2018;33(8):1445-1453.
- Barkun AN, Adam V, Lu Y, et al. Using Hemospray improves the cost-effectiveness ratio in management of upper gastrointestinal nonvariceal bleeding. *J Clin Gastroenterol*. 2018;52(1):36-44.
- Chen Y, Barkun A. Hemostatic powders in gastrointestinal bleeding: a systematic review. *Gastrointest Endosc Clin N Am.* 2015;25(3):535-552.
- Changela K, Papafragkakis H, Ofori E, et al. Hemostatic powder spray: a new method for managing gastrointestinal bleeding. *Therap Adv Gastroenterol.* 2015;8(3):125-135.
- Sulz MC, Frei R, Meyenberger C, et al. Routine use of Hemospray for gastrointestinal bleeding: prospective two-center experience in Switzerland. *Endoscopy*. 2014;46(7):619-624.
- Yau A, Ou G, Galoport C, et al. Safety and efficacy of Hemospray in upper gastrointestinal bleeding. *Can J Gastroenterol Hepatol.* 2014;28(2):72-76.
- Morris AJ, Smith LA, Stanley A, et al. Hemospray for nonvariceal upper gastrointestinal bleeding: results of the Seal Dataset (survey to evaluate the application of Hemospray in the luminal tract). *J Clin Gastroenterol*. E-published December 2013.

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

¹Bustamante-Balén M, Plumé G. Role of hemostatic powders in the endoscopic management of gastrointestinal bleeding. *World J Gastrointest Pathophysiol.* 2014;5(3):284-292. doi:10.4291/wjgp.v5.i3.284.

²Giday SA, Kim Y, Krishnamurty DM, et al. Long-term randomized controlled trial of a novel nanopowder hemostatic agent (TC-325) for control of severe arterial upper gastrointestinal bleeding in a porcine model. *Endoscopy*. 2011;43(4):296-299. doi:10.1055/s-0030-1256125.

³Alzoubaidi D, Hussein M, Rusu R, et. al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. *Dig Endosc.* 2020;32(1):96-105.

⁴Lau JYW, Pittayanon R, Kwek A, et al. Comparison of a hemostatic powder and standard treatment in the control of active bleeding from upper nonvariceal lesions: a multicenter, noninferiority, randomized trial. *Ann Intern Med.* 2022;175(2):171-178.



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