A different approach to hemostasis.





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



Images courtesy of Dr. John Morris, Glasgow Royal Infirmary, Glasgow Scotland.

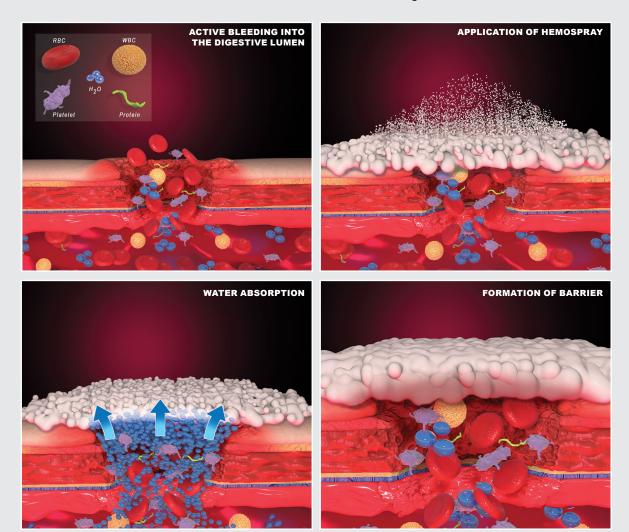
A different modality

What is Hemospray?

Hemospray is an inert mineral powder developed for endoscopic hemostasis that contains no human or animal proteins or botanicals and has no known allergens.

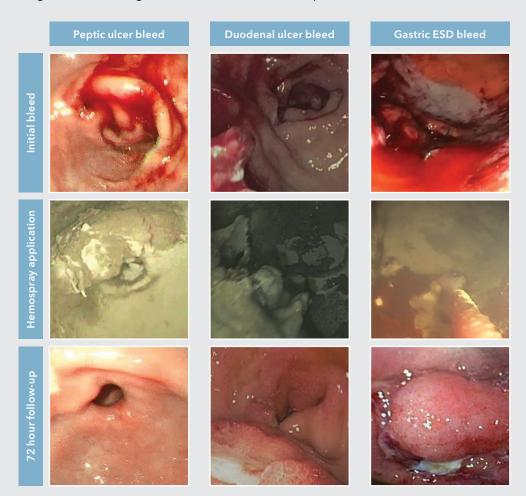
How does it work?

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



When to use Hemospray?

Hemospray is a different endoscopic modality that has demonstrated results in a wide range of nonvariceal gastrointestinal (GI) hemostasis procedures.



Hemospray has also demonstrated successful results with these additional nonvariceal bleed types:

Gastritis Mallory-Weiss tears Esophagitis Gl neoplasms Dieulafoy lesions GAVE/watermelon stomach Gastric angiodysplasia Post endoscopic mucosal resection (EMR)

Peptic ulcer bleed images courtesy of Prof. Joseph Sung, Chinese University of Hong Kong, Hong Kong, China. Duodenal ulcer bleed images courtesy of Dr. Lars Karlsen, Stavanger University Hospital, Stavanger, Norway. Gastric ESD bleed images courtesy of Dr. David Serra, Hospital da Luz, Lisbon, Portugal.

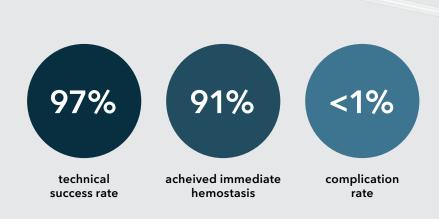
A different approach to hemostasis

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

- Nonthermal: The procedure causes no tissue changes, unlike some thermal modalities.
- Atraumatic: Since no force is applied at the treatment site, the powder minimizes the risk of tissue trauma that may result from other modalities.
- **Noncontact:** The aerosol delivery system eliminates the need for direct mechanical or contact forces with the treatment site by the delivery system.
- **Nonspecific targeting:** Powder is sprayed toward the source of the bleed, so it does not require the en face approach and the precise targeting of other modalities.

Simplifying hemostasis for you and your patient

Mechanical, injectable, and thermal therapies are used alone or in combination to manage GI bleeding. Hemospray is an easy to use, safe, and effective alternative to these traditional therapies. A systematic review of 20 studies¹ shows that Hemospray has a technical success rate of 97% when used to manage non-variceal upper GI bleeding, with increasing success by publication year. Immediate hemostasis was achieved in 91% of patients. Immediate hemostasis, recurrent bleeding, and mortality were similar in studies comparing Hemospray to alternative methods. Complications were reported in <1% of patients.



COON

1. Aziz M, Weissman S, Mehta TI, et al. Efficacy of Hemospray in non-variceal upper gastrointestinal bleeding: a systematic review with meta-analysis. *Ann Gastroenterol.* 2020;33(2):145-154.

Activate, open, and deploy

In three steps you can deploy Hemospray to treat nonvariceal GI bleeds. Activate the $\rm CO_2$ cartridge, open the valve, and spray toward the source of bleeding.



Hemospray reference articles

CLINICAL

Alzoubaidi 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.

Yen-I C, Wyse J, Lu Y, et al. TC-325 hemostatic powder versus current standard of care in managing malignant GI bleeding: a pilot randomized clinical trial. *Gastrointest Endosc*. 2020;91(2):321.e1-328.e1.

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.

Haddara S, Jacques J, Lecleire S, et al. A novel hemostatic powder for upper gastrointestinal bleeding: a multicenter study (the "GRAPHE" registry). *Endoscopy*. 2016;48(12):1084-1095.

Chen YI, Barkun AN. 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.

Szalai M, Kullmann T, Durcsán H, et al. Hemospray: a novel therapeutic option in the management of acute upper gastrointestinal bleeding. *Orv Hetil.* 2015;156(13):528-531.

Chen YI, Barkun AN, Nolan S. Hemostatic powder TC-325 in the management of upper and lower gastrointestinal bleeding: a two-year experience at a single institution. *Endoscopy.* 2015;47(2):167-171.

Appleby VJ, Hutchinson JM, Beckett CJ, et al. Use of the haemostatic agent TC-325 in the treatment of bleeding secondary to endoscopic retrograde cholangiopancreatography sphincterotomy. *QJM*. 2015;108(1):79-80.

Parsi MA, Jang S. Hemospray for diffuse anastomotic bleeding. *Gastrointest Endosc*. 2014;80(6):1170.

Selvapatt N, Hoare J. A novel method of achieving haemostasis in transfusion-dependent small bowel malignancy-related bleeding. *BMJ Case Rep.* 2014;2014:bcr2014208122.

Zimmer V, Lammert F. Retrograde transpyloric hemostatic powder intervention of a concealed prepyloric antral ulcer. *Gastrointest Endosc.* 2014;80(6):1207.

Masci E, Arena M, Morandi E, et al. Upper gastrointestinal active bleeding ulcers: review of literature on the results of endoscopic techniques and our experience with Hemospray. *Scand J Gastroenterol.* 2014;49(11):1290-1295.

Smith LA, Stanley AJ, Bergman JJ, 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*. 2014;48(10):e89-e92.

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

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. lacucci M. Hemostatic spray - a welcome addition to the armamentarium against gastrointestinal bleeding. *Can J Gastroenterol Hepatol.* 2014;28(2):71.

Yau AHL, Ou G, Galorport C, et al. Safety and efficacy of Hemospray in upper gastrointestinal bleeding. *Can J Gastroenterol Hepatol.* 2014;28(2):72-76.

Dietrich C, Hochdörffer R, Fuchs ES, et al. Successful use of Hemospray to control refractory duodenal diverticular bleeding. *Endoscopy*. 2014;46(suppl 1 UCTN):E605-E606.

Kratt T, Lange J, Königsrainer A, et al. Successful Hemospray treatment for recurrent diclofenac-induced severe diffuse lower gastrointestinal bleeding avoiding the need for colectomy. *Endoscopy*. 2014;46(suppl 1 UCTN):E173-E174.

Tarantino I, Barresi L, Granata A, et al. Hemospray for arterial hemorrhage following endoscopic ultrasound-guided pseudocyst drainage. *Endoscopy*. 2014;46(suppl 1 UCTN):E71.

Granata A, Curcio G, Azzopardi N, et al. Hemostatic powder as rescue therapy in a patient with H1N1 influenza with uncontrolled colon bleeding. *Gastrointest Endosc*. 2013;78(3):451.

Barkun AN, Moosavi S, Martel M. Topical hemostatic agents: a systematic review with particular emphasis on endoscopic application in GI bleeding. *Gastrointest Endosc.* 2013;77(5):692-700.

Holster IL, Kuipers EJ, Tjwa ETTL. Hemospray in the treatment of upper gastrointestinal hemorrhage in patients on antithrombotic therapy. *Endoscopy*. 2013;45(1):63-66.

Chen YI, Barkun AN, Soulellis C, et al. Use of the endoscopically applied hemostatic powder TC-325 in cancerrelated upper GI hemorrhage: preliminary experience (with video). *Gastrointest Endosc.* 2012;75(6):1278-1281.

Sung JJY, Luo D, Wu JCY, et al. Early clinical experience of the safety and effectiveness of Hemospray in achieving hemostasis in patients with acute peptic ulcer bleeding. *Endoscopy.* 2011;43(4):291-295.

NONCLINICAL

Barkun AN, Adam V, Lu Y, et al. Using Hemospray improves the cost-effectiveness ratio in the management of upper gastrointestinal nonvariceal bleeding. *J Clin Gastroenterol.* 2018;52(1):36-44.

Beye B, Barret M, Alatawi A, et al. Topical hemostatic powder promotes reepithelialization and reduces scar formation after extensive esophageal mucosal resection. *Dis Esophagus*. 2016;29(6):520-527.

Giday SA, Van Alstine WG, Van Vleet JF, et al. Safety analysis of a hemostatic powder in a porcine model of acute severe gastric bleeding. *Dig Dis Sci.* 2013;58(12):3422-3428.

Giday 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.

Product specifications

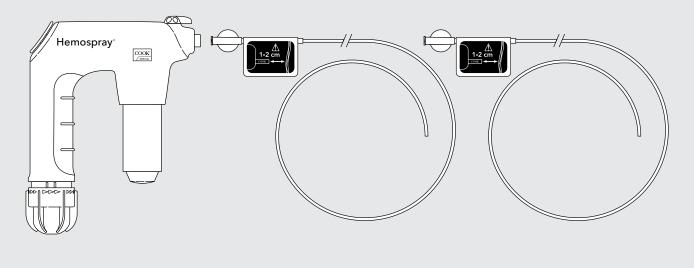
Used for hemostasis of nonvariceal gastrointestinal bleeding.

This device is supplied sterile and is disposable. It is intended for single use only.

Order Number	Reference Part Number	Catheter Diameter Fr	Catheter Length cm	Minimum Accessory Channel Diameter mm
G56572	HEMO-7	7	220	2.8
G21049	HEMO-10	10	220	3.7

Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Support & Delivery for details.

Device comes preassembled, and each package contains an extra catheter. No additional materials are required for usage. 3-year shelf life.



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**

Customer Service

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AI, ESC, IR, OHNS, PI, RH, SUR-A4