A different approach to hemostasis.



NOW available in the USA.

Hemospray®

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



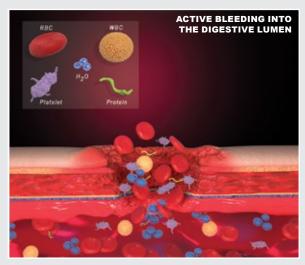
A different modality

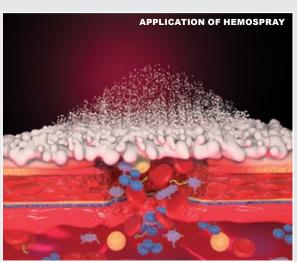
What is Hemospray?

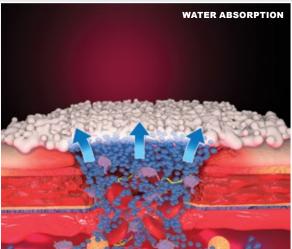
Hemospray is an inert mineral powder developed for endoscopic hemostasis which contains no human or animal proteins or botanicals and has no known allergens.

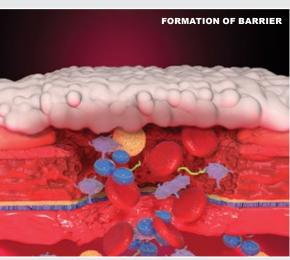
How does it work?

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.









When to use Hemospray?

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



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

Gastritis Dieulafoy Lesions

Mallory Weiss Tears GAVE/Watermelon Stomach Esophagitis Gastric Angiodysplasia

GI Neoplasms Post 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

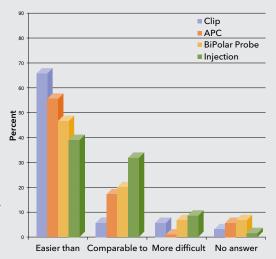
Hemospray unlike traditional therapies is a nonthermal, nontraumatic, noncontact modality that doesn't require the precise targeting of other modalities. That means:

- **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 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

An ease of use comparison was made for 79 patient treatments in a postmarket clinical registry and Hemospray was determined to be comparable to or easier than administration of other hemostasis treatment modalities.

Hemostasis was achieved in under 10 minutes in over 77% of cases with Hemospray. Hemospray was thought to save time in 59% of cases.¹



¹Morris 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.

Contributors SEAL post market evaluation:

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Activate, Open and Deploy

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



Hemospray Reference Articles

CLINICAL

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.

Haddara S, Jacques J, Lecleire S, et al. A Novel Hemostatic Powder for Upper Gastrointestinal Bleeding: A Multicenter Study (the "GRAPHE" registry). 2016 Dec; 48(12): 1084-1095.

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):125-35.

Szalai M, Kullmann T, Durcsán H, et al. Hemospray: a novel therapeutic option in the management of acute upper gastrointestinal bleeding. *Orvosi Hetilap*. 2015 Mar;156(13):528-31.

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 Feb;47(2)167-71.

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

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

Selvapatt N., Hoare J. A novel method of achieving haemostasis in transfusion-dependent small bowel malignancy-related bleeding. *BMJ Case Reports*. E-published 16 December 2014.

Zimmer, V., Lammert F. Retrograde transpyloric hemostatic powder intervention of a concealed prepyloric antral ulcer. *Gastrointestinal Endoscopy.* 2014 Dec; 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. *Scandinavian Journal of Gastroenterology*. 2014 Nov;49(11):1290-5.

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*. 2014 Nov; 48(10): E89-92.

Bustamante-Balén M, Plumé G.World J. Role of hemostatic powders in the endoscopic management of gastrointestinal bleeding. *Gastrointest Pathophysiol*. 2014 Aug 15;5(3):284-92.

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.

lacucci M. Hemostatic spray- a welcome addition to the armamentarium against gastrointestinal bleeding. *Canadian Journal of Gastroenterology and Hepatology*. 2014 Feb; 28(2): 71.

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.

Holster IL, Kuipers EJ, Tjwa ET. Hemospray in the treatment of upper gastrointestinal hemorrhage in patients on antithrombotic therapy. *Endoscopy.* 2013 Jan;45(1):63-6.

Dietrich, C., Hochdörffer, R., et al. Successful use of Hemospray to control refractory duodenal diverticular bleeding. *Endoscopy.* 2014. 46(S01): E605-E606.

Kratt T, LangeJ, Königsrainer A, et al. Successful Hemospray treatment for recurrent diclofenac-induced severe diffuse lower gastrointestinal bleeding avoiding the need for colectomy. *Endoscopy.* 2014; 46(S 01): E173-E174.

Tarantino, Barresi, Granata, et al. Hemospray for arterial hemorrhage following endoscopic ultrasound -guided pseudocyst drainage. *Endoscopy.* 2014;46(S01):E71.

Granata, Curcio, Azzopardi, Barresi, Tarantino, Traina. Hemostatic powder as rescue therapy in a patient with H1N1 influenza with uncontrolled colon bleeding. *Gastrointestinal Endoscopy.* 2013 Sept: 78(3): 451.

Babiuc RD, Purcarea M, Sadagurschi R, Negreanu L. Use of Hemospray in the treatment of patients with acute UGIB - short review. *Journal of Medicine and Life*. 2013 Jun; 6(2):117-119.

Moosavi S, Chen YI, Barkun AN. Topical hemostatic agents: a systematic review with particular emphasis on endoscopic application in GI bleeding. *Gastrointestinal Endoscopy*. 2013 May; 77(5):692-700.

Soulellis CA, Carpentier S, Chen YA, et al. Lower GI hemorrhage controlled with endoscopically applied TC-325. *Gastrointestinal Endoscopy.* 2013 Mar;77(3):504-507.

Holster IL, Kuipers EJ, Tjwa ET. Hemospray in the treatment of upper gastrointestinal hemorrhage in patients on antithrombotic therapy. *Endoscopy.* 2013 Jan;45(1):63-6.

Chen YI, Barkun AN, Soulellis C, et al. Use of the endoscopically applied hemostatic powder TC-325 in cancerrelated upper GI hemorrhage: preliminary experience. *Gastrointestinal Endoscopy.* 2012 Jun;75(6):1278-81.

Sung JJ, Luo D, Wu JC, et al. Early clinical experience of the safety and effectiveness in achieving hemostasis in patients with acute peptic ulcer bleeding. *Endoscopy*. 2011 Apr; 43(4):291-5.

NON-CLINICAL

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 Jan; 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. *Diseases of the Esophagus*. 2016 Aug; 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. *Digestive Disease Sci.* 2013 Dec; 58(12):3422-8.

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 Apr;43(4):296-9.

Product Specifications

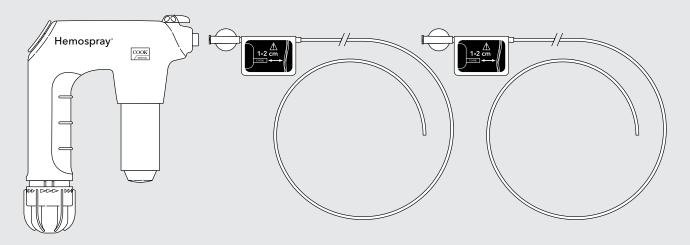
Used for hemostasis of nonvariceal gastrointestinal bleeding.

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

Order Number	Reference Part Number	Catheter French Size Fr	Catheter Length cm	Minimum Accessory Channel 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 Service for details.

Device comes preassembled and each package contains an extra catheter. No additional materials 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**

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