NEXPOWDER™* ENDOSCOPIC HEMOSTASIS SYSTEM CLINICAL SUMMARY

ONE CASE EVERY THOUSAND PERSONS AND 20,000 DEATHS EVERY YEAR DUE TO GI BLEEDING CONDITIONS[1,2]

OVER 1 MILLION ENDOSCOPIC HEMOSTASIS PROCEDURES PERFORMED EVERY YEAR IN US AND EUROPE[1,2]

DELAYED BLEEDING IS THE MOST COMMON COMPLICATION OF ENDOSCOPIC RESECTION[3]

UP TO 9.7% INCIDENCE RATE PROCEDURES OF DELAYED BLEEDING AFTER RESECTION OF COLORECTAL LESIONS ≥2 CM[4]

HEMOSTATIC SPRAYS TREAT A WIDER SURFACE AREA AND DON'T REQUIRE PRECISE TARGETING[5]

BACKGROUND

- Gastrointestinal (GI) bleeding is a common condition worldwide accounting a significant proportion of hospital admissions and a major cause of morbidity and mortality.[6]
- Annual bleeding incidence is approximately 80 to 150 per 100,000 population for upper GI bleeding[2] and 20 to 30 per 100,000 for lower GI bleeding.[2]

DISEASE MANAGEMENT

- In most cases, the standard of care for the diagnostic evaluation of suspected GI bleeding is urgent (within 24 hours) upper endoscopy or colonoscopy.[7]
- Endoscopic hemostasis is frequently the first line treatment and are typically performed during upper or lower endoscopy using different devices available to the physician (clips, injection of agents, argon plasma coagulation, hemostasis graspers, sprays, bipolar probes, etc). Physicians frequently use more than one endoscopic device to achieve hemostasis.[7]
- The European Society of Gastrointestinal Endoscopy (ESGE) recommends the use of topical hemostatic sprays as a salvage therapy in instances where hemostasis is not initially achieved, or there is recurrent re-bleeding following a second attempt at endoscopic hemostasis for treatment of active nonvariceal upper gastrointestinal hemorrhage (NVUGIH).[5]
- The evidence relating to lower gastrointestinal bleeding (LGIB) is small scale and limited[8], making it difficult to make any recommendations around the use of topical sprays currently. Although, it seems likely from upper GI experience that, in instances where epinephrine is used for haemostasis, there could be a role for hemostatic sprays as a secondary modality[9].

UNMET NEED

Existing techniques are not always effective and are considered technically challenging.[7]

Endoscopic sprays (powders) have been introduced to the market to provide non-contact hemostasis to manage bleedings endoscopically without the need for precise targeting. They facilitate access to difficult anatomical locations and can cover larger bleeding sites than other hemostasis techniques.[7]

The endoscopic hemostasis spray may also be used to prevent post-procedural bleeds after therapeutic procedures such as polypectomy, endoscopic mucosal resection (EMR), and endoscopic submucosal dissection (ESD).[7]

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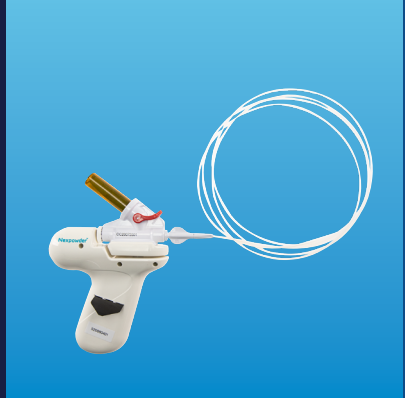
Further, Together

NEXPOWDER™* ENDOSCOPIC HEMOSTASIS SYSTEM CLINICAL SUMMARY



94% immediate hemostasis rate[1,2]

NOW YOU'RE IN CONTROL

NexPowder™* hemostatic spray has the same general advantages of noncontact catheter spray delivery systems: ease of use, no need for precise targeting, easier access to lesions in difficult locations, and ability to treat a wider surface area. But its unique delivery system does not impair visualization, has less catheter clogging and it can be used in the absence of active bleeding.

NexPowder™* hemostatic spray can be easily sprayed in the GI tract to manage bleeding conditions. It's intuitive, easy to use delivery device requires minimal training for physicians and staff. Because it reacts to moisture it can be used in a variety of clinical applications:

- Current hemostatic techniques are not always effective and are considered technically challenging. NexPowder™* is an innovative technology that can address this unmet need
- The unique product design minimizes catheter clogging and allows for more precise application
- The product does not require an active bleeding site and can be used in a variety of clinical applications
- It has an intuitive delivery system that does not use CO_2 and does not require additional air compressors like competitive technologies in the market
- Because it does not use CO_2 for the delivery, the product does not impair endoscopic visualization when it's applied

CLINICAL EVIDENCE

The NexPowder™* hemostatic spray has been evaluated in 2 clinical studies:

A prospective study assessed the feasibility of NexPowder™* application in refractory upper gastrointestinal bleeding. (17 patients) and has shown:

- Successful application in all patients.
- Initial hemostasis in 16 out of 17 patients: 94%.
- Rebleeding within 30 days was seen in 3 out of 16 patients (19%)
- Remnants of the gel was evident in 11 out of 16 patients (69%) at the second examination after 24 hours[10]

In a retrospective study in Korea monotherapy with NexPowder™* was administered to 56 patients with active bleeding. Immediate haemostasis was achieved in 96.4% (54/56) with a re-bleeding rate of 3.7% (2/54) and no adverse events.[11]

A prospective, multi-center, single blind randomized controlled trial is currently ongoing to further evaluate safety and efficacy of NexPowder™*. In this study standard-of-care hemostatic therapy is compared to standard-of-care hemostatic therapy plus adjunctive therapy with NexPowder™* hemostatic spray in patients with upper gastrointestinal bleeding from ulcers with high-risk stigmata (Forrest classification Ia, Ib, or IIa).[11]

This RCT will enroll 350 patients from institutions in Korea and potentially 1 site in Europe. Interim results are expected to be presented at UEGW, 2020.[11]

ORDER INFORMATION	NexPowder™ article code: **NHS03**

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