Article published online: 2026-02-16

Failure of release of the Hot AXIOS distal flange: "handle springing" as a rescue technique

The adoption of lumen-apposing metal stents (LAMSs) with endoscopic ultrasound (EUS) guidance has expanded therapeutic options across multiple clinical settings [1, 2]. These devices enable sequential all-in-one electrocautery-enhanced penetration of two adjacent organs, with immediate fistula protection through the release of a dumbbell-shaped fully covered metal stent. Under normal conditions, following manufacturer's instructions, stent deployment consists of four steps controlled by handle manipulation. After the catheter tip has been advanced into the target organ (Step 1), the safety clip is removed and the stent lock released. In Step 2, retraction of the stent deployment hub to the first predefined position (number 2 arrow) withdraws the outer sheath at the tip of the catheter, allowing exposure and release of the distal (first) flange. Step 3 involves catheter retraction, leading to apposition of the distal flange against the organ wall. Finally, in Step 4, further retraction of the deployment hub to the final position (number 4) completes sheath withdrawal and releases the proximal (second) flange.

Despite standardized deployment and growing operator experience, there have been an increasing number of reports of distal flange release failure with the Hot AXIOS stent and electrocautery-enhanced delivery system (Boston Scientific, Marlborough, Massachusetts, USA), even in the absence of technical errors or detectable device damage. Failure to deploy the distal flange may result in overt perforation and peritoneal contamination, especially in the setting of biliary/gallbladder drainage or gastrointestinal anastomoses. Recently, the manufacturer recalled three sizes of this device (6 × 8, 8 × 8, and 20 × 10 mm) owing to safety concerns [3]. This measure highlights a critical safety issue, particularly in the context of limited and incomplete literature on stent deployment malfunctions.

Here, we report the incidence of this issue from a prospective series and describe a rescue technique.

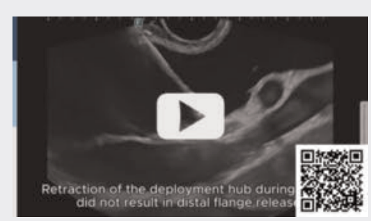
Within our tertiary referral academic center, we systematically enrolled all consecutive procedures performed using the Hot AXIOS stent between December 2020 and March 2025 in our Prospective Registry of Therapeutic EUS (PROTECT). During this interval, among 478 EUS-guided placements of this device, failure or impairment of distal flange release was prospectively registered in 12 cases (see **Tab. 1s**).

In these procedures, standard handle manipulation did not result in complete distal flange deployment, despite appropriate intraluminal catheter positioning, absence of extreme scope angulation, and adequate operative space for LAMS release. In all affected cases, despite the handle being in the position of complete distal flange release after Step 2 (**Fig. 1s a**), the EUS image (**Fig. 1s b**) suggested that the distal flange remained only partially released, apparently constrained by the outer sheath (**Fig. 1s c**). This event occurred during four EUS-guided choledochoduodenostomies and eight EUS-guided anastomoses, involving 6 × 8-mm LAMSs and 20 × 10-mm LAMSs respectively, with the first occurrence being in mid-2023.

Various intuitive corrective maneuvers, including waiting inside the target lumen, gentle to-and-fro catheter adjustments, and releasing the elevator to facilitate flange release proved ineffective. During one early case, the catheter with the unreleased flange was withdrawn to assess its integrity. Outside the patient, we continued standard deployment by further retracting the deployment hub to complete Step 4. Notably, the system showed sequential release of the distal flange first, followed by the proximal flange. This observation was informative: it suggested that the distal flange was not "defective" in its ability to expand, but rather remained partially constrained by the sheath at the end of Step 2, and was only fully liberated once the sheath was retracted beyond its nominal Step 2 position.

This observation led to the deliberate adoption of what we termed "handle springing" as a rescue technique (see ▶ **Video 1**), though not endorsed by the manufacturer. After Step 2 is completed, the stent lock is unlocked as if preparing to proceed to Step 4; however, instead of continuous linear retraction of the deployment hub, rhythmic, minimal amplitude traction movements are applied to the deployment hub (**Fig. 2s**). These millimetric oscillations produce repeated microretractions of the sheath at the catheter tip, which appears to be sufficient to disengage the distal flange. Importantly, once distal flange release is achieved, the deployment hub still remains in its intermediate position, with the proximal flange still constrained until being intentionally deployed, and the operator can then proceed normally with Step 3 (apposition) and Step 4 (proximal flange release).

Following its initial success, this maneuver was systematically applied in all subsequent cases. In each case, distal flange deployment was achieved promptly after



Video 1 The handle springing technique to obtain distal flange release after endoscopic ultrasound-guided choledochoduodenostomy with a 6 × 8-mm Hot AXIOS stent is demonstrated. This technique is not endorsed by the manufacturer.

initiation of the maneuver, without the need for device exchange or procedural escalation, and no related post-procedural complications occurred (**Table 1s**).
While definitive conclusions require bench testing, several plausible mechanisms may explain why Step 2 retraction sometimes fails to fully uncover the distal flange. These might include: (i) minor batch-related variations in the relative positioning of the stent within the outer sheath, which may leave the flange partially covered at the end of Step 2 and require further sheath retraction (i. e. progression toward Step 4) for it to be sufficiently uncovered; (ii) incomplete transmission of handle motion to distal sheath retraction, particularly with more angulated scope positions, tortuous delivery system introduction, or a tightly closed elevator, conditions that may dissipate energy and create an apparent mismatch between the handle position and the actual sheath retraction; (iii) static friction at the interface between the outer sheath and the flange, exceeding kinetic friction, a phenomenon that could be more pronounced with larger flanges such as on 20-mm LAMSs, although this issue has also been observed with smaller stent sizes; (iv) operator-related factors, including subtle differences in handle grip, deployment speed, or applied force, which may influence distal flange mechanics.
In conclusion, the issue of distal flange release failure deserves further investigation to better characterize the mechanisms and prevention of this phenomenon. From a design perspective, these observations may inform future refinements aimed at reducing the sensitivity of distal flange disengagement to external variability.
Pending further technical evaluation, when failure to release occurs in currently marketed devices, handle springing may represent a simple and reproducible rescue technique that preserves procedural control and patient safety. As this issue can often be salvaged by experienced operators, structured training in the recognition and management of adverse events and technical challenges is critical to ensure procedural success, particularly when optimal deployment does not occur.

Contributors' Statement

Giuseppe Vanella: Conceptualization, Data curation, Writing - original draft. Giuseppe Marzocca: Data curation. Michiel Bronswijk: Validation, Writing - review & editing. Roy L. J. van Wanrooij: Validation, Writing - review & editing. Roberto Junior Ruggiero: Data curation. Schalk Willem Van der Merwe: Validation, Writing - review & editing. Paolo Giorgio Arcidiacono: Conceptualization, Writing - review & editing.

Conflict of Interest

G. Vanella has received lecture fees and consultancy fees from Boston Scientific and travel grants from Euromedical. M. Bronswijk has received grant support from Boston Scientific and consultancy fees from Ovesco Ag. R.L.J. van Wanrooij has received consultancy fees from Boston Scientific and Cook medical, and a speaker's fee from Olympus. S. van der Merwe holds the Cook chair in Interventional endoscopy, has received consultancy fees from Cook, Pentax, and Olympus, and co-chairs the Boston Scientific Chair in Therapeutic Biliopancreatic Endoscopy. G. Marzocca, R.J. Ruggero, and P.G. Arcidiacoono declare that they have no conflict of interest.

Clinical Trial

Trial Registration: ClinicalTrials.gov | Registration number (trial ID): NCT04813055 | Type of study: Prospective registry

The authors

Giuseppe Vanella[1,2], **Giuseppe Marzocca**[1,2], **Michiel Bronswijk**[3,4], **Roy L. J. van Wanrooij**[5], **Roberto Junior Ruggiero**[1,6], **Schalk Van der Merwe**[3], **Paolo Giorgio Arcidiacono**[1,2]

1 Pancreatobiliary Endoscopy and Endosonography Division, IRCCS Ospedale San Raffaele, Milan, Italy
2 Medicine and Surgery, Vita-Salute San Raffaele University, Milan, Italy
3 Gastroenterology and Hepatology, KU Leuven University Hospitals Leuven Gasthuisberg Campus, Leuven, Belgium
4 Gastroenterology and Hepatology, Imelda Hospital, Bonheiden, Belgium
5 Gastroenterology and Hepatology, Amsterdam UMC Location VUmc, Amsterdam, Netherlands
6 Universita degli Studi della Campania Luigi Vanvitelli, Caserta, Italy

Corresponding author

Giuseppe Vanella, MD, PhD
Pancreatobiliary Endoscopy & Endosonography Division, Pancreas Translational & Clinical Research Center, IRCCS San Raffaele Scientific Institute, Vita-Salute San Raffaele University, Via Olgettina 60, 20132 Milan, Italy
vanella.giuseppe@hsr.it

Supplementary Material

Supplementary Material is available at https://doi.org/10.1055/a-2800-4292

References

[1] Vanella G, Dell'Anna G, Bronswijk M et al. Endoscopic ultrasound-guided biliary drainage and gastrointestinal anastomoses: the journey from promising innovations to standard of care. Ann Gastroenterol 2022; 35: 441–451 doi:10.20524/aog.2022.0736
[2] van der Merwe SW, van Wanrooij RLJ, Bronswijk M et al. Therapeutic endoscopic ultrasound: European Society of Gastrointestinal Endoscopy (ESGE) Guideline. Endoscopy 2022; 54: 185–205 doi:10.1055/a-1717-139134937098
[3] Government of Canada HC. Hot AXIOSTM Stent And Electrocautery-Enhanced Delivery System – Recalls, advisories and safety alerts – Canada.ca. 2025.https://recalls-rappels.canada.ca/en/alert-recall/hot-axiostm-stent-and-electrocautery-enhanced-delivery-system-0

Bibliography

Endoscopy 2026; 58: 421–422
DOI 10.1055/a-2800-4292
ISSN 0013-726X
published online 16.2.2026

Georg Thieme Verlag KG, Oswald-Hesse-Str. 50, 70469 Stuttgart, Germany