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Memorandum

To: MDSS, Ludger Moeller
CC: CMP #01-2026
From: Hagit Ephrath
Date: Jan 26, 2026
Re: Rationale Supporting the Decision Not to Issue a Field Safety Notice

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Objective

This NTF documents the rationale for not issuing a formal Field Safety Notice (FSN) within the scope of complaint CMP #01-2026.

Description of the Issue

During a focused European product launch conducted on January 9, 2026, at Gemelli Hospital (Rome, Italy), two commercial EndoZip procedures experienced a failure of the suture wire cutting function. Both events occurred on the same day in two different patients.

In both cases, suturing, tightening, and clipping actions were completed successfully; however, the suture wire was not cut at the end of the suturing sequence. This prevented withdrawal of the system until an alternative cutting method was used. No patient harm or adverse clinical outcome was reported.

As a precautionary measure following the observed technical failure, the EndoZip systems shall be returned from the logistics center. Although the events did not result in patient harm, the company elected to implement corrective improvements prior to any further commercial use.

Under CMP #01-2026, a Field Safety Corrective Action (FSCA) was initiated to return the remaining EndoZip systems held at the importer warehouse (Kalms). The logistics center was

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notified, and device shipment is currently in process.

An FSN was not issued because, at the time of the events, the EndoZip systems used during the procedures at the involved site were the only site available for clinical use. No additional systems remained at the site, and no systems had been distributed to or were in use at any other external sites or users.

Accordingly, there was no broader field population requiring notification, and all necessary actions were adequately addressed through the FSCA measures already implemented.

Hagit Ephrath

VP QA, Regulatory and Clinical Affairs & PPRC