

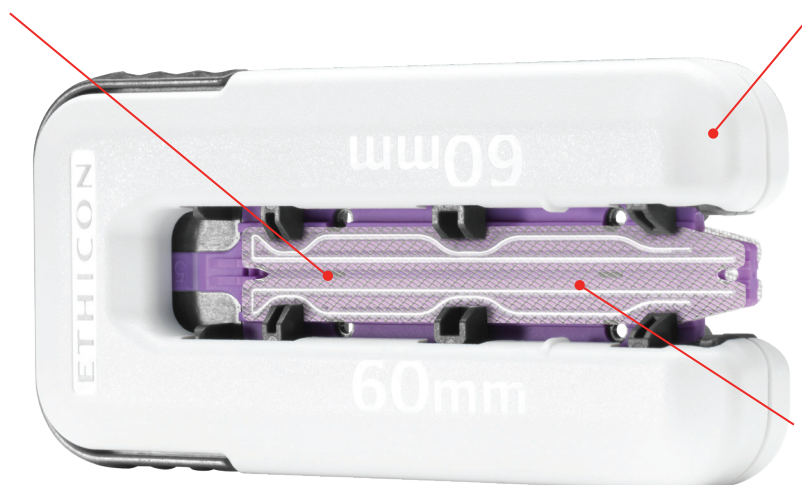
ECHELON ENDOPATH™ Staple Line Reinforcement

Fact Sheet

Experience the difference.

Same trusted materials
used in VICRYL™ & PDS™ sutures

Simple click-and-go applicator
for fast, easy buttress application*



Buttress Attachment
Material (BAM) to affix
buttress across the entire
anvil & cartridge

ECHELON ENDOPATH™ Staple Line Reinforcement
allowed a seamless buttress experience from start to
finish.^{2-4#}

- ✓ Seamless application^{1*}
- ✓ Seamless tissue manipulation^{2-5#}
- ✓ Seamless performance^{6-8†}

Greater strength^{9,10‡}

- 3x greater reinforcement compared to GORE® SEAMGUARD® Staple Line Reinforcement^{9,10‡}
- Demonstrated no significant difference in hemostasis when compared with GORE® SEAMGUARD® Staple Line Reinforcement with 45% less material left behind^{11,12¥}



* In a design validation with 17 nurses, 100% agreed that ECHELON ENDOPATH™ Staple Line Reinforcement is easy to load onto the endocutter. # In a benchtop test, ECHELON ENDOPATH™ Reinforcement covered all staple legs in (40/40) applications after tissue manipulation on porcine tissue during simulated surgical use, p<0.05. Based on benchtop testing and clinical effect is unknown. † Evaluation of ECHELON ENDOPATH™ Staple Line Reinforcement. A prospective, single-center of 48 lobectomy cases: Intraoperative staple line air leaks [3(6.3%)], median time of indwelling chest drainage [2 days], median length of hospital stay [10 days]. A prospective, multi-center study of 131 thoracic cases: no prolonged air leaks or empyema were deemed related to the device as determined by the surgeon. A prospective, multi-center study of 109 gastric cases: no bleeding, leaks or strictures were deemed related to the device as determined by the surgeon. ‡ Reinforcement measured via in vitro staple pull-through force at the time of initial implantation. ECHELON ENDOPATH™ Reinforcement (mean=22.02N, n=30) vs. GORE® SEAMGUARD® Reinforcement (mean=7.33N, n=30), p<0.001. Pre-clinical test data/results may not necessarily be indicative of human clinical performance. ¥ ECHELON ENDOPATH™ Staple Line Reinforcement vs. GORE® SEAMGUARD® Staple Line Reinforcement (with Endopath Echelon GST60G Reload) evaluated via gross observations of firings requiring intervention in 1.38mm to 2.32mm thick porcine ileum and jejunum tissues, evaluated via a 5-point Likert scale resulting in statistically no difference in Likert scores. Based on pre-clinical testing on animal models and clinical effect is unknown. Material: based on average total surface area measurements (26.97cm² vs. 49.21cm²).

Product overview

Seamless application^{1*}

- Simple click-and-go applicator with no anvil or cartridge side for fast, easy buttress application.^{1*}
- Designed for OR efficiency. 4 steps to attach compared to 12 steps to attach with GORE® SEAMGUARD® Staple Line Reinforcement and 16 steps with PERI-STRIPS DRY with VERITAS Collagen Matrix Staple Line Reinforcement.^{13#}



Seamless tissue manipulation^{2-5†}

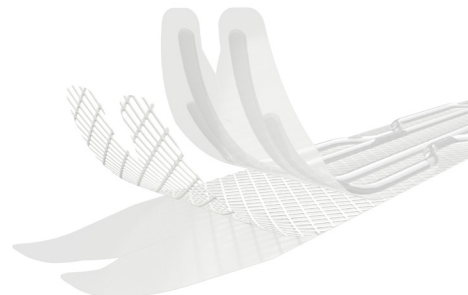
- Proprietary buttress attachment material (BAM) affixed buttress across the entire anvil and cartridge face for no slipping, twisting, sliding or bunching.^{2-5†}
- Delivered exceptional coverage. 100% of ECHELON ENDOPATH™ Staple Line Reinforcement applications covered all staples with buttress vs 28% of GORE® SEAMGUARD® Staple Line Reinforcement applications[‡] and 0% of Endo GIA™ Reinforced Reload with Tri-Staple™ Technology applications[¥] after tissue manipulation.^{2-4,14}



Seamless performance^{6-8§}

The use of ECHELON ENDOPATH™ Staple Line Reinforcement has been associated with low complication rates and positive patient outcomes in thoracic and bariatric studies.^{6-8§}

- The use of SLR was associated with zero bleeding, leaks and strictures in bariatric procedures.^{6†}
- The use of SLR was associated with zero prolonged air leaks or empyema.^{7‡}
- SLR had fewer intraoperative air leaks at the staple line, shorter time of indwelling chest drainage and length of hospital stay in lobectomy procedures compared to conventional stapling^{8§}



^{*} In a design validation with 17 nurses, 100% agreed that ECHELON ENDOPATH™ Staple Line Reinforcement is easy to load onto the endocutter. [#] Based on loading steps per IFUs prior to tissue manipulation 4 steps to attach ECHELON ENDOPATH™ Staple Line Reinforcement compared to 12 steps to attach GORE® SEAMGUARD® Staple Line Reinforcement and 16 steps to attach PERI-STRIPS DRY with VERITAS Collagen Matrix Staple Line Reinforcement. [†] In a benchtop test, ECHELON ENDOPATH™ Reinforcement covered all staple legs in (40/40) applications after tissue manipulation on porcine tissue during simulated surgical use, p<0.05. Based on benchtop testing and clinical effect is unknown. [‡] In a benchtop test, ECHELON ENDOPATH™ Staple Line Reinforcement covered all staple legs in (40/40) applications compared to GORE® SEAMGUARD® (11/40) after tissue manipulation on porcine tissue during simulated surgical use, p<0.05. Based on benchtop testing and clinical effect is unknown. [§] Evaluation of ECHELON ENDOPATH™ Staple Line Reinforcement. A prospective, single-center of 48 lobectomy cases: Intraoperative staple line air leaks [3(6.3%)], median time of indwelling chest drainage [2 days], median length of hospital stay [10 days]. A prospective, multi-center study of 131 thoracic cases: no prolonged air leaks or empyema were deemed related to the device as determined by the surgeon. A prospective, multicenter study of 109 gastric cases: no bleeding, leaks or strictures were deemed related to the device as determined by the surgeon. [¶] Review of 109 gastric cases, in which ECHELON ENDOPATH™ Staple Line was used at least in 1 firing, showed no surgeon identified device-related adverse events through a 70-day post-procedure follow-up visit as determined by the surgeon. [Ⓚ] 131 thoracic cases, in which ECHELON ENDOPATH™ Staple Line Reinforcement was used at least 1 firing, were analyzed and no adverse related events were deemed related to the device as determined by the surgeon. [§] A prospective, single-center evaluation of ECHELON ENDOPATH™ Staple Line Reinforcement in 48 lobectomy cases compared against a historical control group of 200 cases using conventional products without Staple Line Reinforcement. Intraoperative staple line air leaks [3(6.3%) vs 57 (28.5%), p<.001], median time of indwelling chest drainage [2 days vs 2.5 days, p=.049], median length of hospital stay [10 days vs 12 days, p<.001]

Ordering information

ECHELON ENDOPATH™ Staple Line Reinforcement

Code	Description	Qty per sales unit	
ECH60R	ECHELON ENDOPATH™ Staple Line Reinforcement	6	

ECHELON™ 3000 Stapler

Code	Description	Jaw length	Shaft length	Qty per sales unit	
ECH60C	ECHELON™ 3000 60mm Compact	60mm	280mm	3	
ECH60S	ECHELON™ 3000 60mm Standard	60mm	340mm	3	
ECH60L	ECHELON™ 3000 60mm Long	60mm	440mm	3	

ECHELON ENDOPATH™ Reloads

Code	Color	Description		Open staple height	Closed staple height	Qty per sales unit
GST60W	White	White reload intended for use in thin tissue		2.6mm	1.0mm	12
GST60B	Blue	Blue reload intended for use in regular tissue		3.6mm	1.5mm	12
GST60D	Gold	Gold reload intended for use in regular/thick tissue		3.8mm	1.8mm	12
GST60G	Green	Green reload intended for use in thick tissue		4.1mm	2.0mm	12
GST60T	Black	Black reload intended for use in very thick tissue		4.2mm	2.3mm	12

1. Ethicon Project Zeppelin Nurse Design Validation Completion Report, A.1. 06/15/2020. Windchill Document #PRC089156 (EM_ETH_STAP.302229.1)

2. Ethicon Project Zeppelin Coverage after Manipulation Comparison Completion Report, A.1. 01/28/2019. Windchill Document #PRC086040 (EM_ETH_STAP.301624, EM_ETH_STAP.301548, EM_ETH_STAP.387960)

3. Ethicon, Zeppelin Echelon Buttress Test Methods, P.4. 09/27/2022. Windchill Document #SCN042153 (EM_ETH_STAP.301624, EM_ETH_STAP.301548, EM_ETH_STAP.387960)

4. Ethicon Zeppelin Claim Testing Memo, A.1. 03/19/2019. Windchill Document #SCN063382 (EM_ETH_STAP.301624, EM_ETH_STAP.301548, EM_ETH_STAP.387960)

5. Ethicon, Final Report: Evaluation of the Tissue Healing Response Following Use of the EB3 Zeppelin Echelon Reinforcement Material Device for Laparoscopic Gastric, D.3 Windchill Document #PSP006552 (EM_ETH_STAP.301548)

6. Wheeler A, Schram J, Gersin K, et al. Safety and Usability of the Echelon Endopath Staple Line Reinforcement in Gastric Resections. J Surg. 2023; 19(2). DOI: 10.37421/1584-9341.2023.19.85 (EM_ETH_STAP.389017, EM_ETH_STAP.107246.1)

7. Kesler KA, Zeltsman D, Martin LW, et al. Safety and usability of an endo staple line reinforcement device for pulmonary resections. J Thorac Dis. 2023;15(11):6151-6159. (EM_ETH_STAP.389017, EM_ETH_STAP.107248.1)

8. Mitsui S, Tanaka Y, Nishikubo M, et al. Safety and efficacy of new staple-line reinforcement in lung resection: a prospective study of 48 patients. Surg Today. 2024;54(7):779-786. (EM_ETH_STAP.389017, EM_ETH_STAP.387962)

9. Ethicon Project Zeppelin In Vitro Staple Pull Through Comparison Testing Completion Report, B.1. 04/02/2019. Windchill Document #PRC085697 (EM_ETH_STAP.302830)

10. Ethicon Zeppelin and Gore Staple Pull-Through Assessment, A.1. 04/25/2019. Windchill Document #PRC089936 (EM_ETH_STAP.302830)

11. Ethicon, Evaluation of Hemostasis Following Use of the EB3 Zeppelin Echelon Reinforcement Material Device in Swine - Acute, C.1. 01/19/2019. Windchill Document # PSB004768 (EM_ETH_STAP.387972.1)

12. Ethicon, Dimensional Measurements of GORE® SEAMGUARD® compared to ECHELON ENDOPATH™ Staple Line Reinforcement, B.1. 07/29/2019. Windchill Document #SCN066699(EM_ETH_STAP.387972.1)

13. (EM_ETH_STAP.387775)

14. Ethicon, Buttress Securement Assessment of Competitor Devices, A.1. 09/12/2019 Windchill Document #PRC091367 (EM_ETH_STAP.387960)

Please refer always to the Instructions for Use / Package Insert that come with the device for the most current and complete instructions.

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