

GST縫合釘介紹

壯生醫療器材



MEDICAL COMPANIES

The Function of Surgical Stapling

- Primary Objective: Hemostasis and leak prevention
- Cause of Leak and Hemorrhage
 - Wrong staple height selection (cartridge or reload)



Tissue Dynamics

Two physical states of living tissue must be considered: the fluid phase (extra cellular water is present in the tissue prior to compression); and the solid phase (after fluid evacuation, the tissue behaves much like a solid)

BIPHASIC NATURE

活體組織具備兩種自然型態
充滿組織液時 & 組織液釋出之後接近固態。

HYSTERESIS

滯後作用, 遲滯現象

There is a time lag between when pressure is applied to tissue and when the tissue's elastic forces can achieve balance with this pressure

VISCOELASTICITY

黏著與彈性

TISSUE CREEP

慢慢移動

例如長型的氣球, 再給予適當繼續不斷的壓力, 氣球會向兩端延展開來。

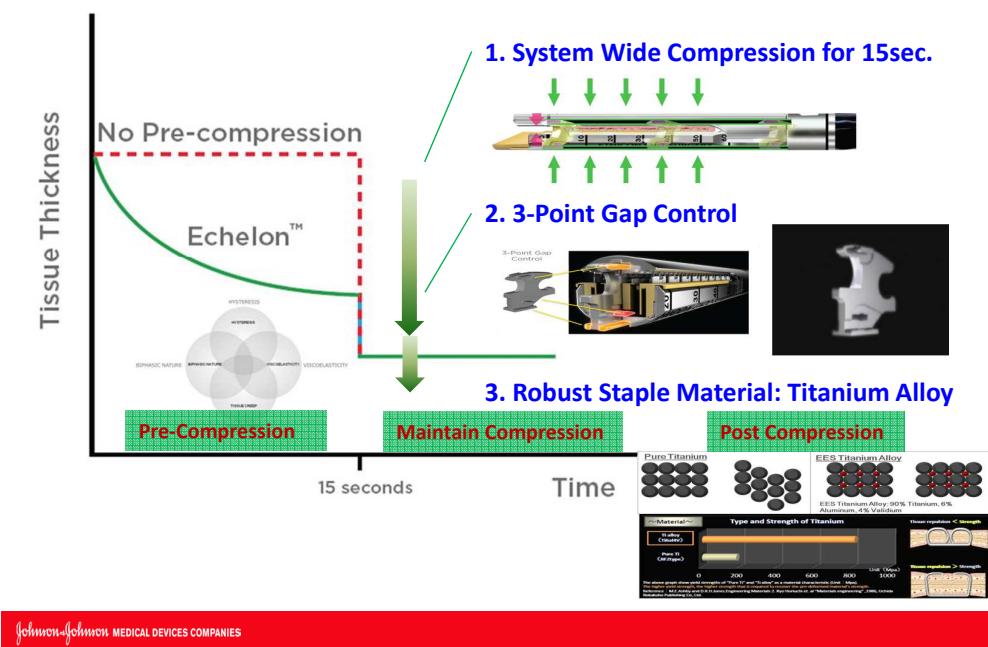
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What Tissue like?



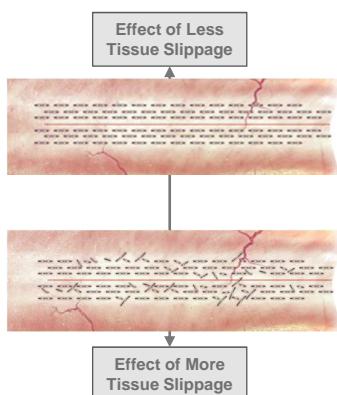
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EES Approach-Compression



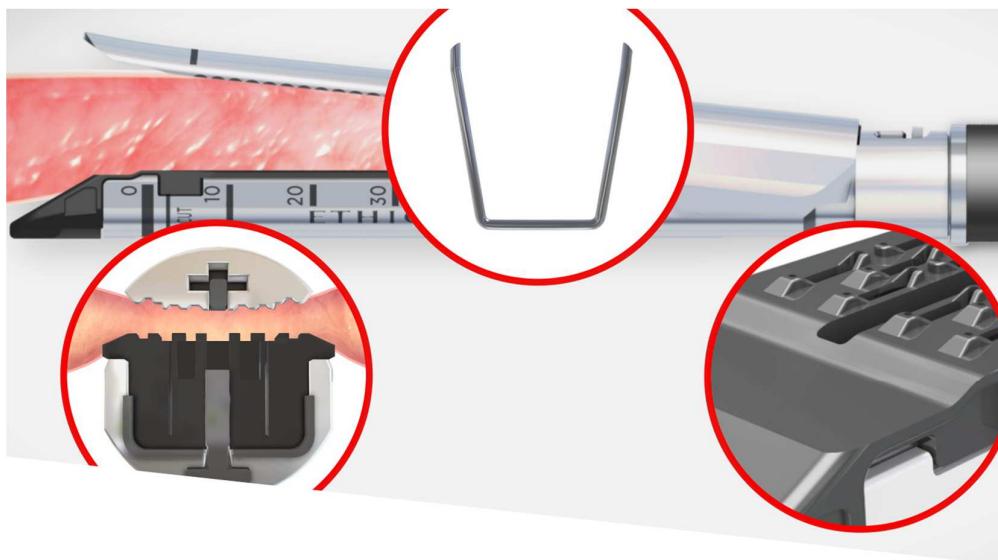
Unmet Need in Stapling: Tissue Slippage

Staple Formation



Tissue Slippage

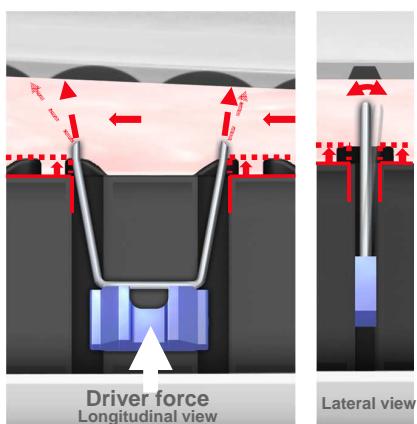




GST System design enhancements

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Gripping Surface Technology



Improved staple trajectory to the pocket by:

- ▶ Reducing the impact of tissue flow
- ▶ Support staple legs for a longer distance
- ▶ Improved longitudinal and lateral alignment

Asymmetric, bent tips

improve the tip trajectory to the pockets



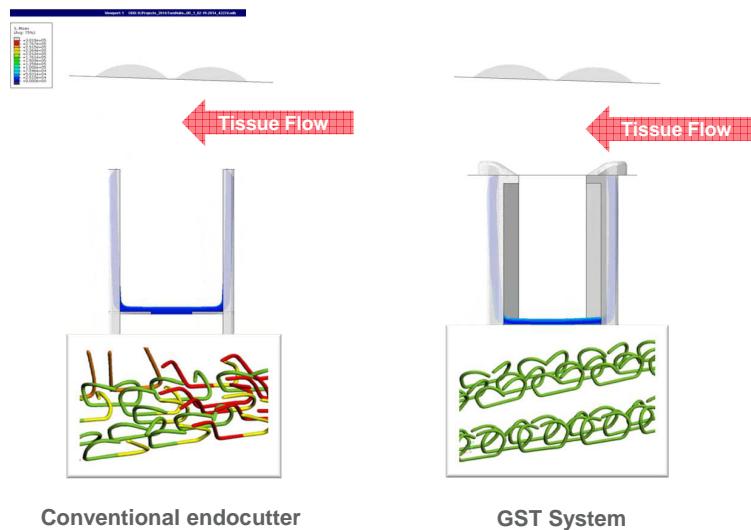
ETHICON

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

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Tissue slippage effect on staple formation

Providing alignment for staple legs to hit the anvil pockets

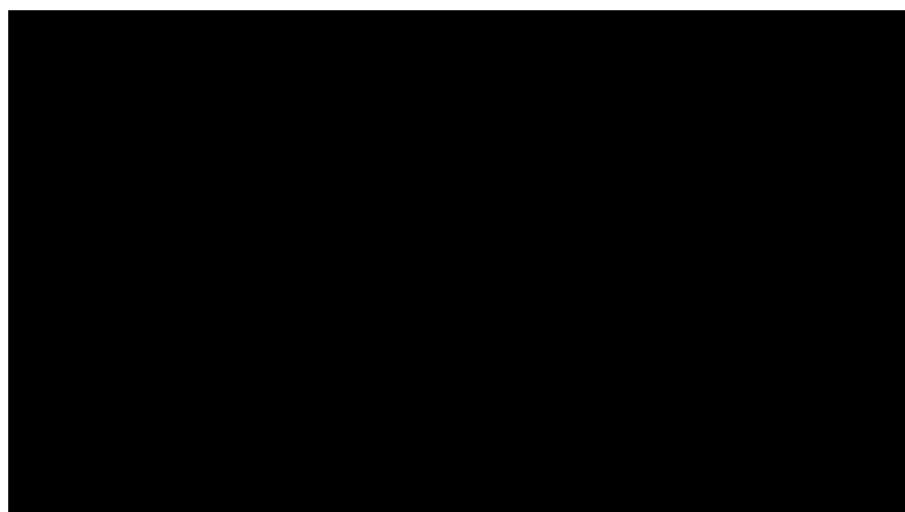


Tissue flow demonstration during firing with gold reload at tissue thickness of 3.2mm

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Less Tissue Slippage for More Targeted Transections

Less tissue milking to potentially eliminate reloads[‡]

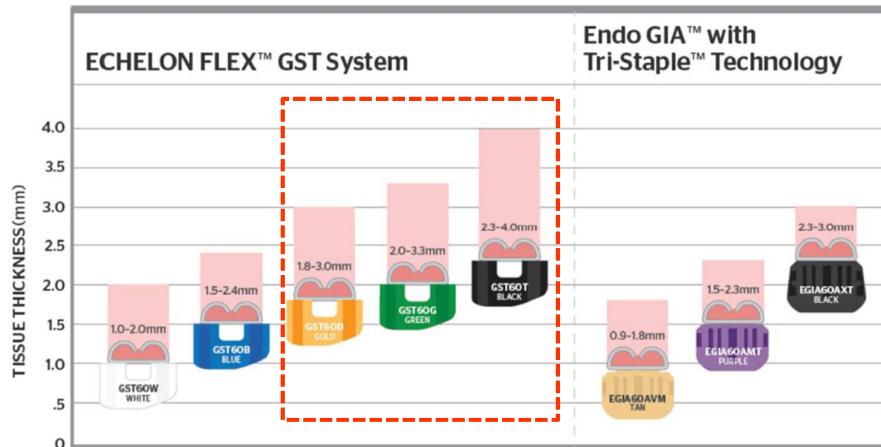


distance between dots is 8mm



020267-140820

縫合釘適用之組織厚度



金、綠、黑色的GST釘
適用於厚或非常厚的組織

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小結

- System-wide compression 讓組織顯現真實高度
- 透過改良釘夾設計提供bend tip及Gripping surfaces, 適用於不同高度的組織及厚組織, 形成三排一致釘高的完美B形成釘, 避免術後爆釘及組織滑動, 減少要多打一釘
- 使用Stainless steel 42000鋼材, 能提供最佳的切割效果

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健保給付狀態

- 104年11月共同擬定會議決議，切割刀片不論在縫合器或縫合釘上，在體內均可達到相同目的，**列屬同功能類別特材，核價方式已將縫合器加上縫合釘併同考量訂定相同支付點數。**

特材代碼	中英文品名	單位	支付點數	生效日期	事前審查 生效日期
SAU08ECFLEET	”愛惜康”愛喜龍弗雷克斯安德派思可彎式縫合器” ECHELON” Flex Endopath Stapler Articulating Endoscopic Linear Cutter	支	9000	107/07/01	105/04/01
SAU08EEC45ET	”愛惜康”愛喜龍 45 安德派思縫合器” ETHICON”Echelon 45 Endopath Endoscopic Linear Cutters and Reloads	支	9000	107/07/01	105/04/01
SAU08EEC60ET	”愛惜康”愛喜龍安德派思縫合器(60)”ETHICON” Echelon 60 Endopath Stapler	支	9000	107/07/01	105/04/01
SAU08ETS45ET	”愛惜康”安德派思切割縫合器” ETHICON” Endopath Endoscopic Linear Cutter Reloading Unit	支	9000	107/07/01	105/04/01
SAU07ECR45ET	”愛惜康”愛喜龍45安德派思縫合釘” Ethicon” Echelon 45 Endopath Endoscopic Linear Cutters and Reloads-Staple	支	4843	105/04/01	098/07/01
SAU07TR45BET	”愛惜康”安德派思切割縫合釘” ETHICON” Endopath Endoscopic Linear Cutter Reloading Unit- Staple	支	4843	105/04/01	097/10/01
SAU07ECR60ET	”愛惜康”愛喜龍安德派思縫合釘” ETHICON” Echelon 60 Endopath Stapler- Staple	支	5891	105/04/01	096/01/01

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主動將GST縫合釘比照既有品項納入給付

- 考量全民福祉，雖GST縫合釘具有較佳的臨床成效，本公司亦比照既有品項納入健保給付

特材代碼	中英文品名	單位	支付點數	生效日期	事前審查 生效日期
SAU07GST45ET	”愛惜康”愛喜龍加強型可彎式電動腔鏡直線型切割縫合器-縫合釘”ETHICON” Echelon Flex Powered Plus Articulating Endoscopic Linear Cutter- Reload	支	4843	107/05/01	107/05/01
SAU07GST60ET	”愛惜康”愛喜龍加強型可彎式電動腔鏡直線型切割縫合器-縫合釘”ETHICON” Echelon Flex Powered Plus Articulating Endoscopic Linear Cutter- Reload	支	5891	106/03/01	106/03/01

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臨床證據1: GST釘有較佳臨床成效(較前一代的ECR好)

J Laparoendosc Adv Surg Tech A. 2017 May;27(5):489-494. doi: 10.1089/lap.2016.0513. Epub 2016 Dec 19.

Evaluation of a Powered Stapler System with Gripping Surface Technology on Surgical Interventions Required During Laparoscopic Sleeve Gastrectomy.

Fegelman E¹, Knippenberg S¹, Schwiers M¹, Stefanidis D², Gersin KS², Scott JD³, Fernandez AZ⁴.

研究目的：比較GST釘與ECR釘(前一代)在進行腹腔鏡胃袖切除術(LSG)時，在縫合處所需進行額外處置(staple line interventions; SLIs)的差異

研究樣本：111位病人(38位ECR釘；73位GST釘)

研究結果：**GST釘組所需進行額外處置的次數顯著較少**
(1.1 ± 1.45 vs 1.9 ± 1.29 , $p=0.036$)

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臨床證據2: 相同釘高較不易漏氣

Med Devices (Auckl). 2018 Dec 14;11:433-442. doi: 10.2147/MDER.S184851. eCollection 2018.

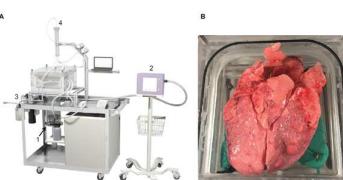
Preclinical quantification of air leaks in a physiologic lung model: effects of ventilation modality and staple design.

Eckert CE¹, Harris JL¹, Wong JB¹, Thompson S², Kassis ES³, Tsuboi M⁴, Ott HC⁵, Force S⁶.

研究目的：以豬肺測試staple line對於縫合後漏氣(leak)的影響，
以漏氣發生率，漏氣率及漏氣量評估

研究樣本：110付豬肺，分為不同釘高(Tri-staple)及相同釘高
(GST釘)2組，各55付

研究結果：**不同釘高較相同釘高的縫合釘易發生漏氣的情況**



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模擬術中(正壓)及術後(負壓)狀態之漏氣評估結果

Table 2 Summary leak data for PPV

Test group	Leak volume (mL)	Leak rate (mL/min)	P-value	Leak incidence rate (%)	P-value	Trachea pressure (cm H ₂ O)	P-value
GRD (thinner)	12.2 (45.1)	1.22 (4.51)	0.031 ^a	20	0.009 ^b	35.6 (1.04)	0.146 ^c
UNI (thinner)	0 (0)	0 (0)		0		35.7 (1.11)	
GRD (thicker)	41.9 (145)	4.19 (14.5)		30		36.8 (4.09)	
UNI (thicker)	6.26 (19.6)	0.626 (1.96)		17		34.9 (6.21)	
GRD (thinner + thicker)	28.4 (112)	2.84 (11.2)	0.012 ^a	25	0.012 ^b	36.3 (3.04)	0.261 ^d
UNI (thinner + thicker)	3.42 (14.7)	0.342 (1.47)		9		35.3 (4.47)	

Notes: ^aMann-Whitney test. ^bTwo-sample proportion test. ^cANOVA test. ^dt-test. Mean (SD) leak volume, leak rate, leak incidence rate, and trachea pressure for PPV testing. P-values from statistical tests are provided. Note: in eight of the datasets (four GRD, four UNI specimens), transducer calibration errors resulted in corrupt trachea pressures, so they were not included in the trachea pressure statistical testing.

Abbreviations: GRD, graduated staple height; PPV, positive pressure ventilation; UNI, uniform staple height.

相同釘高組 表現較好

Table 3 Summary leak data for NPV

Test group	Leak volume (mL)	Leak rate (mL/min)	P-value	Leak incidence rate (%)	P-value	Chamber pressure (cm H ₂ O)	P-value
GRD (thinner)	57.1 (202)	5.71 (20.2)	0.014 ^a	44	0.015 ^b	-14.1 (3.63)	0.817 ^c
UNI (thinner)	2.02 (5.57)	0.202 (0.557)		16		-13.9 (2.79)	
GRD (thicker)	242 (711)	24.2 (71.1)		43		-14.7 (2.54)	
UNI (thicker)	32.7 (86.6)	3.27 (8.66)		23		-14.5 (2.50)	
GRD (thinner + thicker)	158 (546)	15.8 (54.6)	0.003 ^a	44	0.004 ^b	-14.3 (3.07)	0.858 ^d
UNI (thinner + thicker)	18.7 (65.4)	1.87 (6.54)		20		-14.3 (2.62)	

Notes: ^aMann-Whitney test. ^btwo-sample proportion test. ^cANOVA test. ^dt-test. Mean (SD) leak volume, leak rate, leak incidence rate, and chamber pressure for NPV testing. P-values from statistical tests are provided.

Abbreviations: GRD, graduated staple height; NPV, negative pressure ventilation; UNI, uniform staple height.

相同釘高組 表現較好

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臨床證據3：相同釘高較不易漏氣

Original Article - Research
Veterinary Surgery / Volume 45, Issue 1 First published: 23 November 2015

Inflation Pressures for Ex Vivo Lung Biopsies After Application of Graduated Compression Staples

Darren J. Imhoff, Eric Monnet

研究目的：比較相同釘高(Endo GIA 45-2.5;EG)及2種不同釘高(Tri-staple medium/thick;TST、Tri-staple vascular/medium;TSV)的縫合釘漏氣所需的壓力有何差異

研究樣本：18片狗肺葉，3種縫合釘，每種縫合6片肺葉

研究結果：不同釘高的縫合釘漏氣所需的壓力顯著較低

(TSV:29.2 cmH₂O; TST:26.0 cmH₂O
EG:38.0 cmH₂O)



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臨床證據4: GST釘有更好的黏膜抓持能力

Obes Surg. 2018 Nov;28(11):3446-3453. doi: 10.1007/s11695-018-3363-0.

Initial Assessment of Mucosal Capture and Leak Pressure After Gastrointestinal Stapling in a Porcine Model.

Thompson SE¹, Young MT¹, Lewis MT¹, Boronyak SM¹, Clymer JW², Fegelman EJ¹, Nagle DA¹.

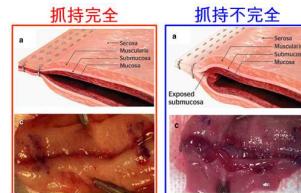
研究目的：評估不同縫合釘的黏膜抓持程度及所產生的影響

研究樣本：90個豬迴腸，3種縫合釘，每種縫合30個樣本

研究結果：1. 縫合部位漏氣(leak)，有78%是因黏膜抓持不完全

2. 抓持黏膜的程度越好，漏氣所需的壓力顯著越大，即越不易漏氣

3. GST藍釘、金釘和Tri-staple紫釘相較，漏氣所需的壓力分別高出39%($p<0.001$)及23%($p=0.022$)



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結語

- 考量民眾福祉，GST釘已於106年比照既有品項納入健保給付
- GST釘與Tri-staple從仿單登載的適應症而言，應屬同功能類別特材

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報告完畢 謝謝聆聽

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