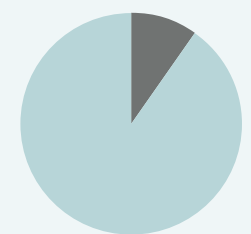


Peer-reviewed evidence

Stapler choice matters in reducing complications in thoracic surgery

Clinical and financial burden

Bleeding-related complications



Between **2-10%** of lobectomies^{1,2}

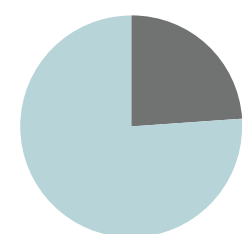


2.7x higher risk of in-hospital mortality²



\$16K incremental hospital costs²

Post-operative air leaks



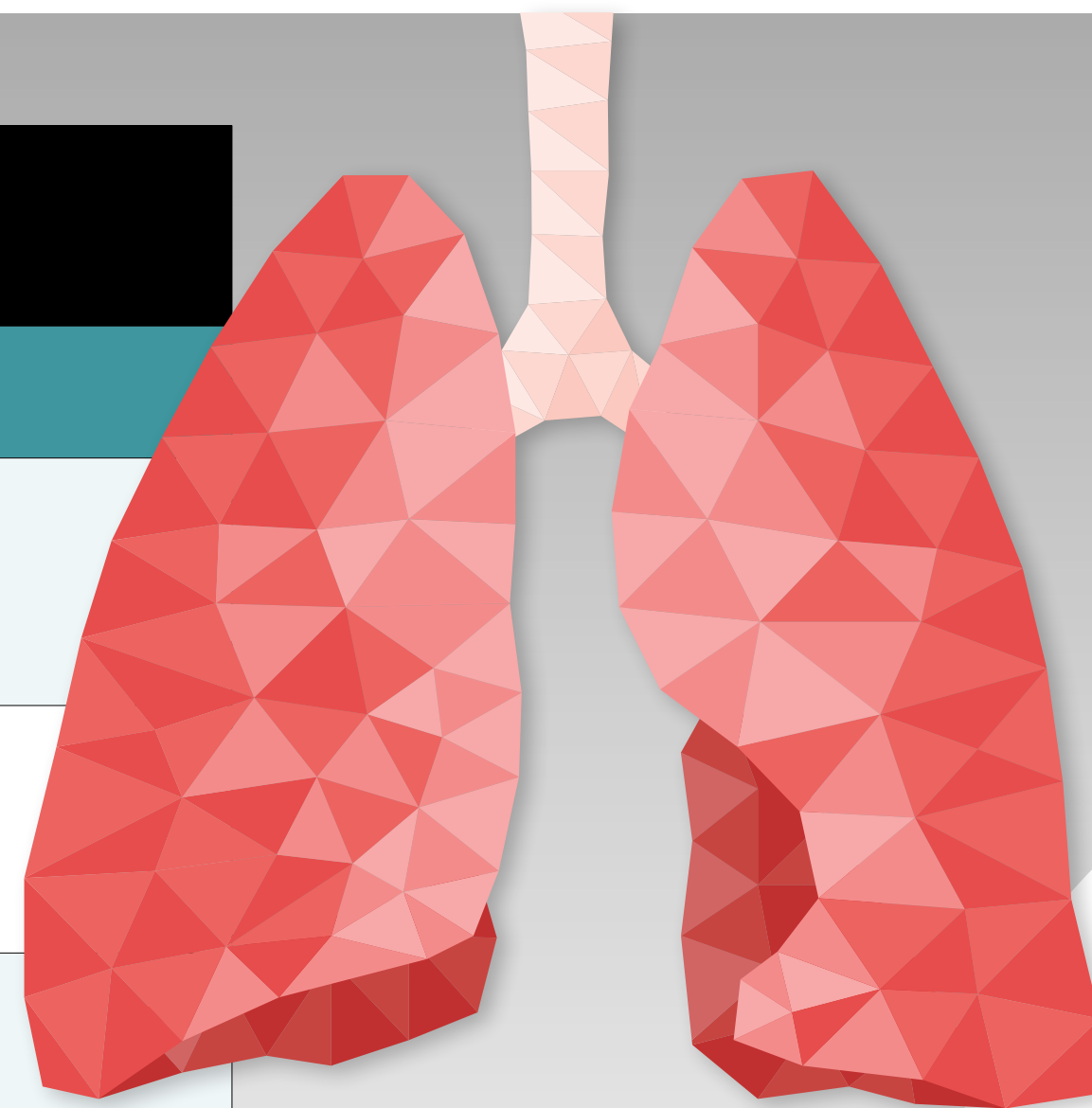
24% of lobectomies³



1.9x higher risk of in-hospital mortality³



\$6.5K incremental hospital costs³



Use of **ECHELON FLEX™ Powered Staplers** has been associated with improved clinical and economic outcomes in thoracic surgery^{4,5}



ECHELON FLEX™ PVS*

*PVS=Powered Vascular Stapler



ECHELON FLEX™ GST† System

†GST=Gripping Surface Technology

1. Kent M, et al. Open, video-assisted thoracic surgery, and robotic lobectomy; review of a national database. *Ann Thorac Surg.* 2014;97:236-444. **2.** Based on Ethicon (2016) internal analysis of data from 26,955 lobectomy procedures captured in Premier Perspective database for the period of 2008-2014. **3.** Yoo A, et al. Burden of air leak complications in thoracic surgery estimated using a national hospital billing database. *ClinicoEconomics Outcomes Res.* 2017;9:373-383. **4.** Ethicon retrospective analysis of clinical outcomes between Echelon Powered vs Medtronic non-powered endoscopic surgical staplers among patients undergoing video-assisted thoracoscopic surgery lobectomy. Review of 3,006 cases between 2012 and 2015 from the Premier Perspective® Hospital Database (8.2% vs 13.9%; $p=0.0218$). **5.** Staple line air leaks in porcine lungs using a physiologically-based ex-vivo lung chamber model. ECHELON FLEX™ GST System vs Endo GIA™ with Tri-Staple™ Technology. 20% vs 44%. GST 45 Blue & Green reloads vs Tri-Staple™ 45 Purple & Black, (n=110). Based on similar design features between ECHELON GST45 & GST60, no significant difference in performance is expected.

Real-world evidence

Fewer hemostasis-related complications in VATS lobectomy¹

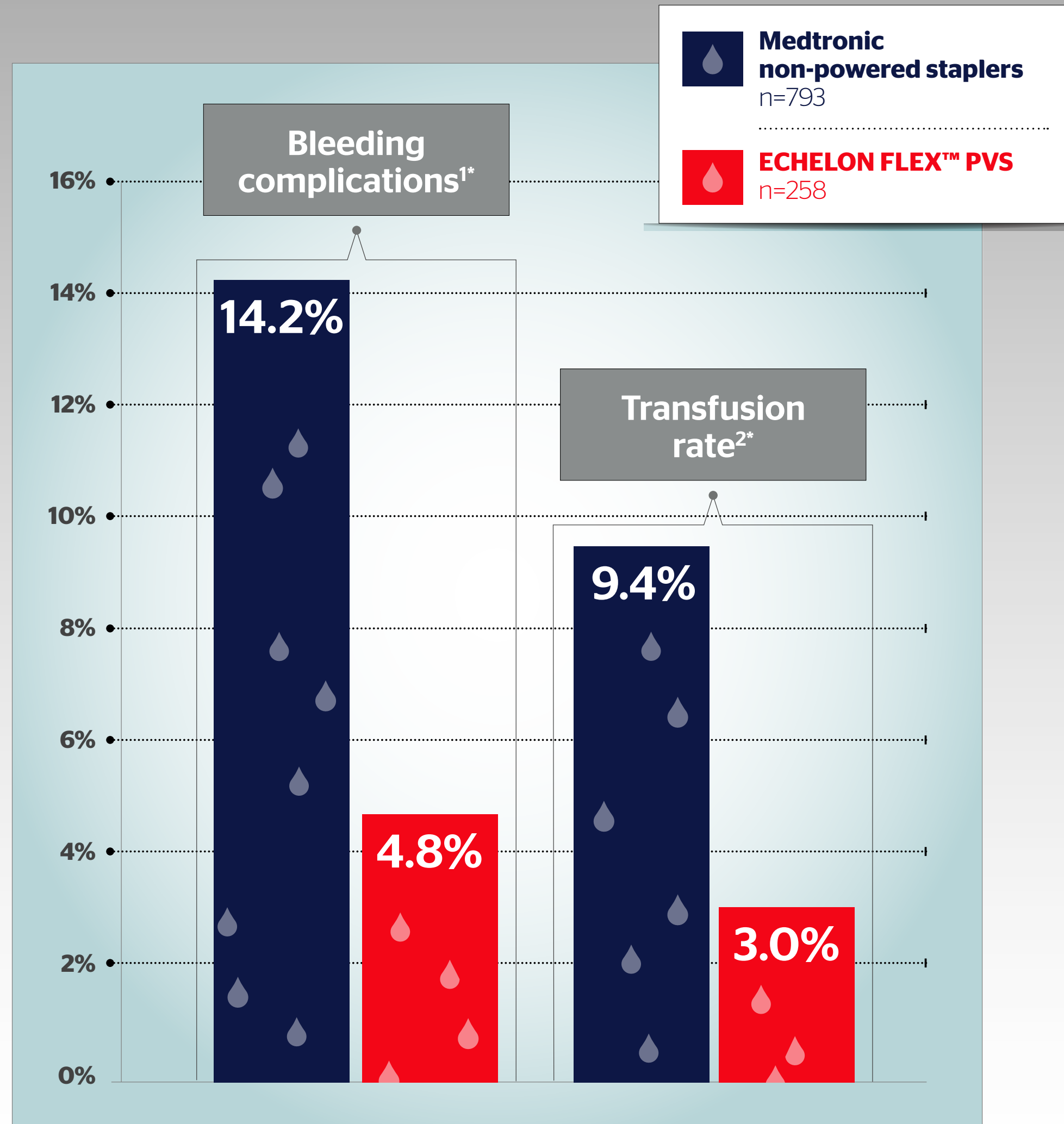


PEER-REVIEWED PUBLICATION REPORTS

Use of **ECHELON FLEX™ PVS*** has been associated with a reduction in hemostasis-related complications¹

3x lower

Source: *Advances in Therapy*



*In cases with ECHELON FLEX™ PVS used in combination with another ECHELON FLEX™ Powered Stapler

Why ECHELON FLEX™ PVS?

Designed for thoracic surgery

- Enables **improved access** and **more precise placement** on fragile vessels^{3†}
 - Narrower anvil⁴
 - Increased articulation⁵
 - Smaller shaft diameter⁶

- **Reduced tension on vessels by 60%^{7†}**



†vs Medtronic Endo GIA™ staplers

1. Ethicon retrospective analysis of clinical outcomes between Echelon Powered vs Medtronic non-powered endoscopic surgical staplers among patients undergoing video-assisted thoracoscopic surgery lobectomy. Review of 1,051 cases between 2012 and 2015 from the Premier Perspective® Hospital Database (4.8% vs 14.2%; $p=0.0098$). 2. Ethicon retrospective analysis of clinical outcomes between Echelon Powered vs Medtronic non-powered endoscopic surgical staplers among patients undergoing video-assisted thoracoscopic surgery lobectomy. Review of 1,051 cases between 2012 and 2015 from the Premier Perspective® Hospital Database (3.0% vs 9.4%; $p=0.023$). 3. Compared to the Endo GIA™ Curved Tip Reload with Tri-Staple™ technology. PVE35A, EGIA30CTAVM, and PSE45A articulation data from IFUs of each device. 4. Versus leading staplers on the market as of October 2017. 5. Based on articulation data from IFUs of each device. 6. Approach angles assessed in a virtual CAD environment in the 5th intercostal space. 7. Net tension applied to pulmonary vessel during stapler placement, clamp, fire, and release in ex vivo porcine model. ECHELON FLEX™ Powered Vascular Stapler (5.55 kPa-s, n=18) vs Endo GIA™ with Tri-Staple™ Technology (14.01 kPa-s, n=17) ($p=0.008$).

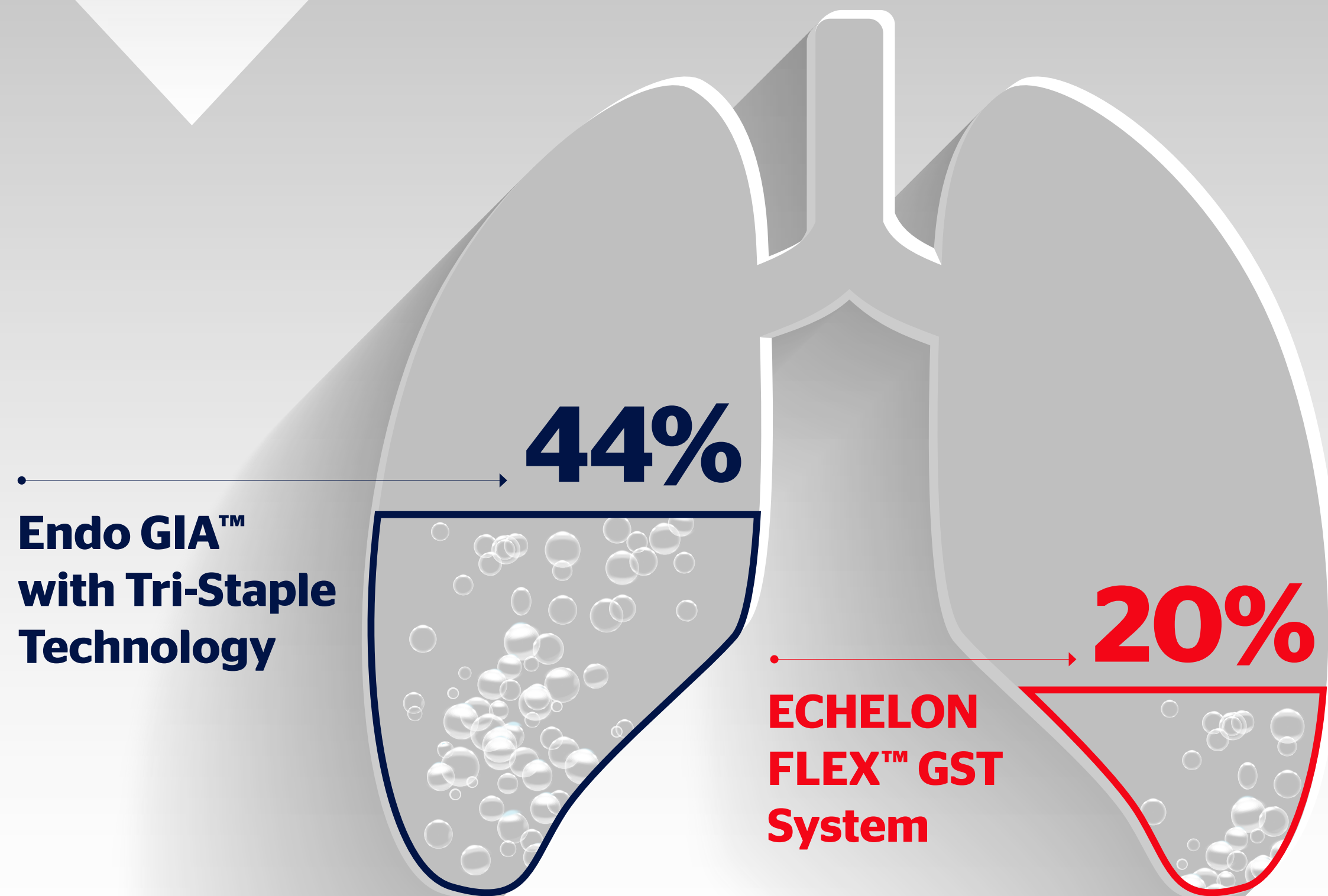
Evidence through innovation

Physiologic Lung Model reveals fewer air leaks¹



IN THE ONLY VENTILATION MODEL SIMULATING PHYSIOLOGIC BREATHING

2x fewer staple-line air leaks
with ECHELON FLEX™ GST System¹



Why ECHELON FLEX™ GST System?

Differences in design principles

Endo GIA™ with Tri-Staple™ Technology

ECHELON FLEX™ GST System

GRADUATED STAPLE HEIGHT



- All leaks originated from outer row of staples¹
- Third-party study found that outer row of graduated staples may not compress lung parenchyma enough to seal correctly²

UNIFORM STAPLE HEIGHT



- Exceptional staple line integrity across the broadest range of tissue thicknesses³
- More reload choices to meet specific tissue needs

SINGLE-STAGE COMPRESSION



- Higher force exerted on tissue during firing

MULTI-STAGE COMPRESSION



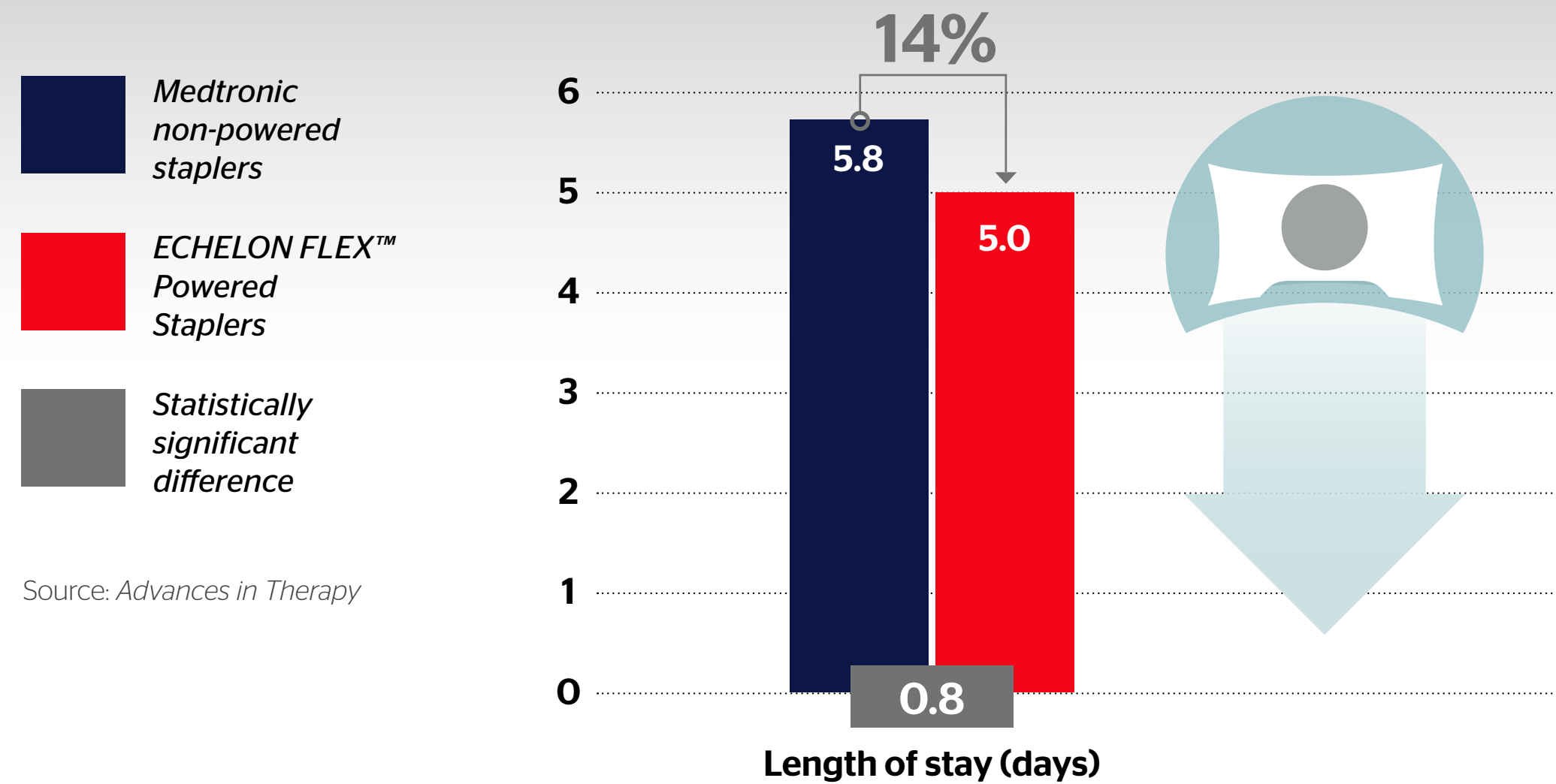
- Designed to reduce the forces exerted on tissue during firing

1. Staple line air leaks in porcine lungs using a physiologically-based ex-vivo lung chamber model. ECHELON FLEX™ GST System vs Endo GIA™ with Tri-Staple™ Technology. 20% vs 44%, GST 45 Blue & Green reloads vs Tri-Staple™ 45 Purple & Black. (n=110). Based on similar design features between ECHELON GST45 & GST60, no significant difference in performance is expected. 2. Imhoff DJ, Monnet E. Inflation pressures for ex vivo lung biopsies after application of graduated compression staples. *Vet Surg.* 2016;45:79-82. 3. The ECHELON FLEX™ GST System was designed and tested to meet rigorous design requirements for staple line integrity. The GST System accommodates a tissue thickness range of 1.0 mm to 4.0 mm (measured at 8g/mm², tissue comfortably compressed to closed staple height during firing per IFU) while the Medtronic Tri-Staple™ portfolio is intended for a tissue thickness range of 0.75 mm to 3.0 mm (per IFU and materials downloaded from Medtronic website on Nov 16, 2016).

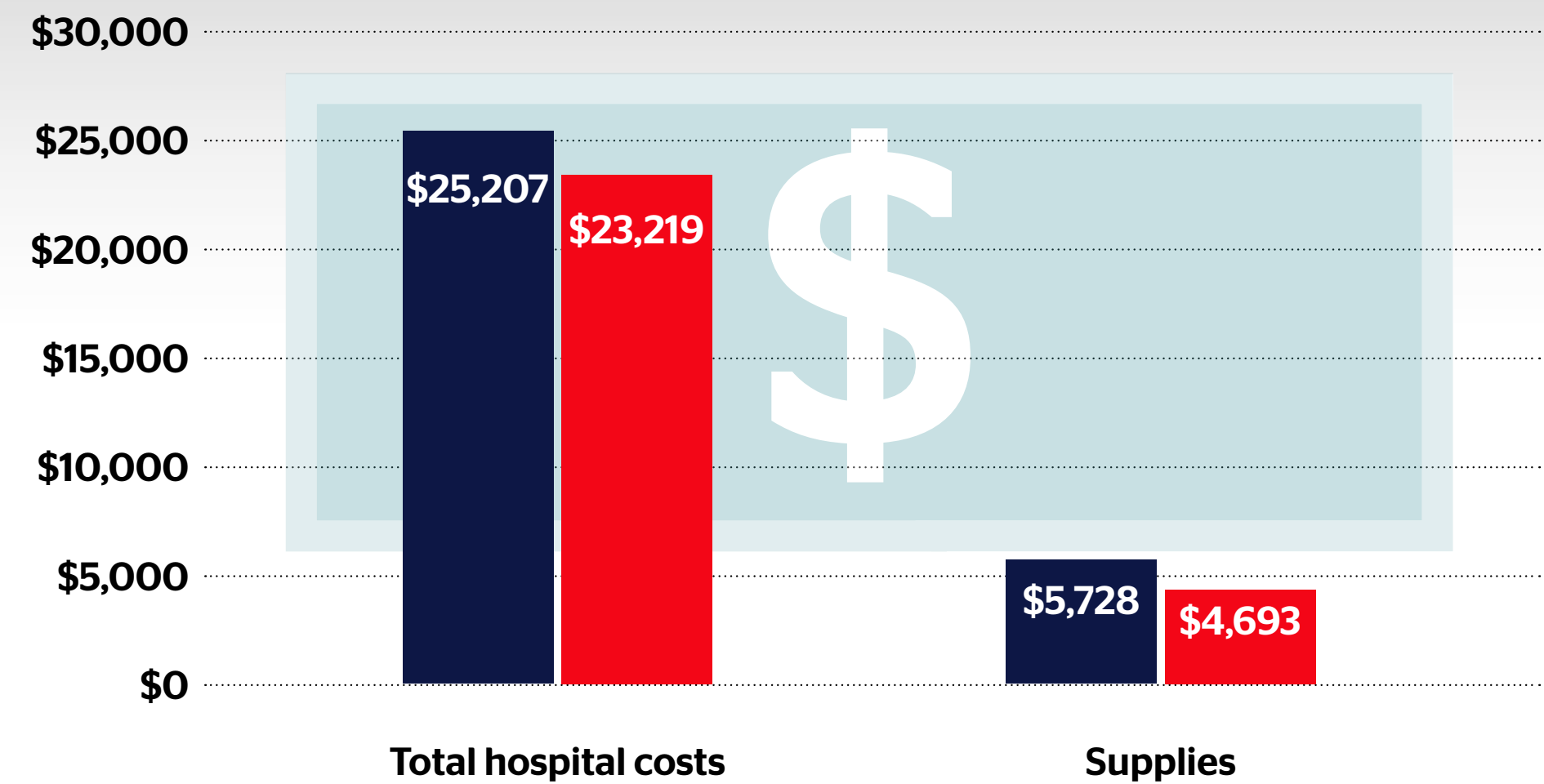
Economic evidence

Improved **economic value** in VATS lobectomy

Improved hemostasis outcomes were associated with use of ECHELON FLEX™ PVS *plus* another ECHELON FLEX™ Powered Stapler—**without increasing costs**¹



Source: *Advances in Therapy*



ECHELON FLEX™ Powered Staplers

Tissue-specific devices designed to improve precision in thoracic surgery



ECHELON FLEX™ PVS enables more precise placement on fragile vessels²

ECHELON FLEX™ GST System enables you to transect as you intend, even on challenging tissue



¹. Ethicon retrospective analysis of outcomes between Echelon Powered vs Medtronic non-powered endoscopic surgical staplers among patients undergoing video-assisted thoracoscopic surgery lobectomy. Review of 1,051 cases between 2012 and 2015 from the Premier Perspective® Hospital Database. Hemostasis-related complications: 4.8% vs 14.2%; $p=0.010$. Transfusion: 3.0% vs 9.4%; $p=0.023$. Total hospital costs: \$23,219 vs \$25,207; $p=0.242$. ². Compared to the Endo GIA™ Curved Tip Reload with Tri-Staple™ technology, PVE35A, EGIA30CTAVM, and PSE45A articulation data from IFUs of each device.

Impact of Powered and Tissue-Specific Endoscopic Stapling Technology on Clinical and Economic Outcomes of VATS Lobectomy Procedures

Daniel Miller, MD; Sanjoy Roy; Edmund Kassis, MD; Sashi Yadalam; Sushama Ramiseti; Stephen Johnston

Methodology

Data source: Premier Healthcare Database

- Over 6 million cases annually in wide range of surgical areas
- >700 contributing hospitals
- Represents 20% of HIPAA-compliant US inpatient discharges
- Used in 375+ peer-reviewed publications

Study design established prior to data collection

- Focused on a primary research question: ***Does stapler choice matter in VATS lobectomy?***
- Protocol-driven
- Data analyzed included hospital length of stay, operating time, hospital costs, complications, and readmissions
- Analysis included ICD-9 and ICD-10 codes related to hemorrhage, hematoma, acute post-hemorrhagic anemia, seroma, and transfusion

2-step control for confounding factors

1. Primary analysis multivariate statistical model included:

- Surgeon and hospital types (facility size, procedure volumes, teaching/non-teaching, etc.)
- Patient demographics (age, gender, payer type, etc.)
- Clinical characteristics (comorbidities, concomitant resections, etc.)

2. Confirmatory analysis matched patient cohorts by propensity scores

Meets rigorous publication standards

- Followed academic research guidelines
- Adhered to a results-agnostic publication policy
- Involved external clinical expert to ensure unbiased interpretation
- Underwent peer review with clinical scientific journal

Quantification of Air Leaks in a Physiologic Lung Model: Effects of Ventilation and Stapler Design

Chad E. Eckert, PhD; Jason L. Harris, PhD; Jordon Wong, BS; Suzanne Thompson, DVM; Edmund S. Kassis, MD; Masahiro Tsuboi, MD; Seth Force, MD

Methodology

The need for a new model

- Limited understanding of air leak causes
- Difficult to isolate stapler contribution to air leaks in clinical setting
- Existing models did not simulate physiologic breathing

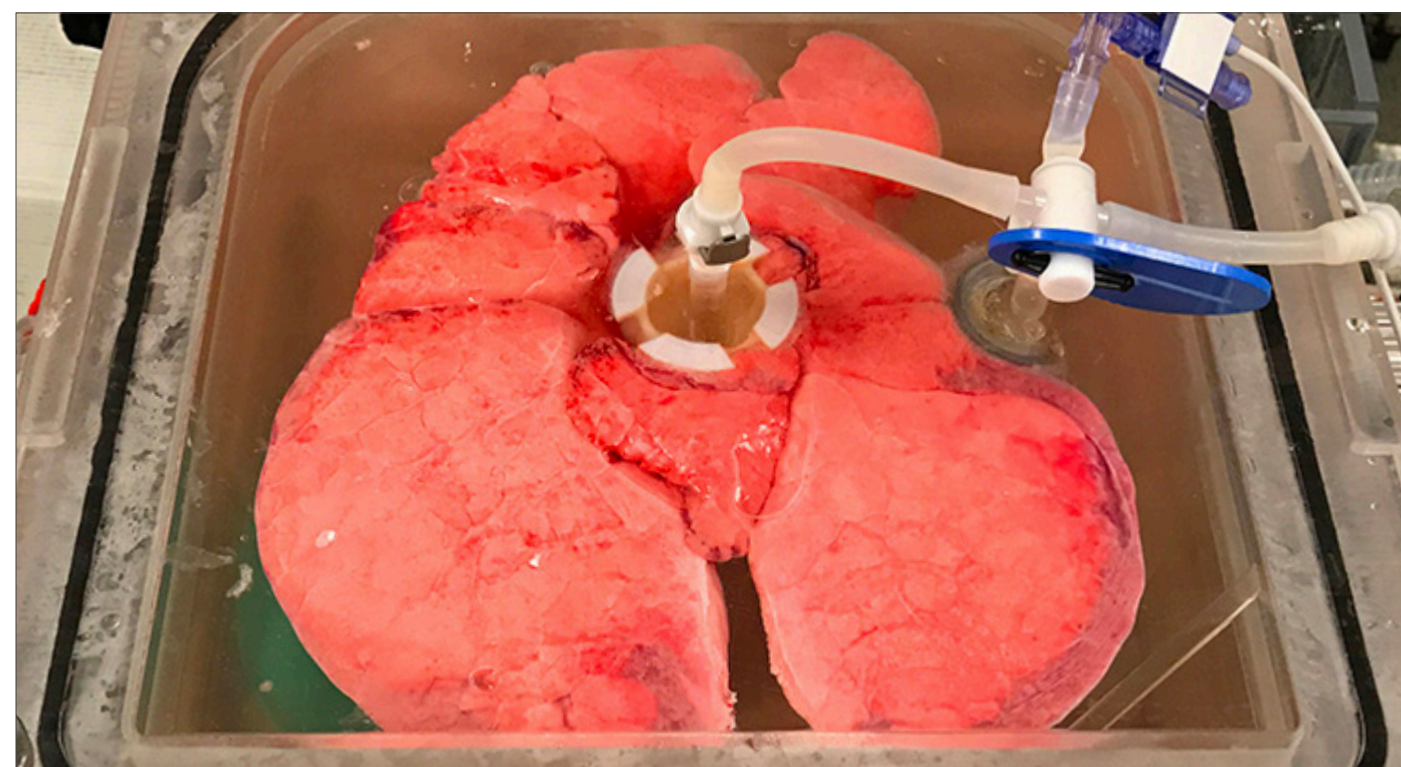
Physiologic Lung Model

- **First of its kind** to simulate natural breathing conditions
- Approximates clinical conditions by **simulating 2 breathing modalities** in ex vivo lung tissue
 - **Ventilated breathing** (intra-operative/positive pressure)
 - Cannulation port with mechanical compressor
 - **Physiologic breathing** (post-operative/negative pressure)
 - Piston simulates diaphragmatic motion
- Collects and measures air leaks by incidence and volume
- Published in *IEEE Transactions on Biomedical Engineering*

Testing method

ECHELON FLEX™ GST System vs Endo GIA™ with Tri-Staple™ Technology

- Wedge resection in porcine lung tissue
- *Study 1*: Thinner tissue (n=50); *Study 2*: Thicker tissue (n=60)
- Two crossing staple lines in each sample
- Clinically relevant chamber pressures (Ventilator: avg. 36 cm H₂O; Physiologic: avg. -14 cm H₂O)
- Leaks defined as bubbles originating from staple line, captured by the system



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