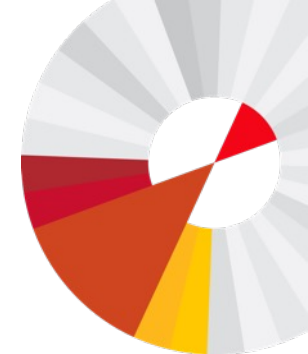




Stapling

The Science of Tissue Management





What is Tissue Management?

- Understanding the scientific properties of living tissue, and the relationship / interaction between living tissue and surgical instruments is the **foundation upon which we develop our devices.**
- We take full consideration of the impact surgical procedures have on tissue in the design and engineering of our devices in order to **improve patient outcomes and advance healing.**



Our Science of Tissue Management (SoTM) Philosophy



The principles for gently treating living tissue were established more than 100 years ago by Dr. William Halsted. Those principles haven't changed. However, with the evolution of surgery, techniques of interacting with tissue have become more complex.

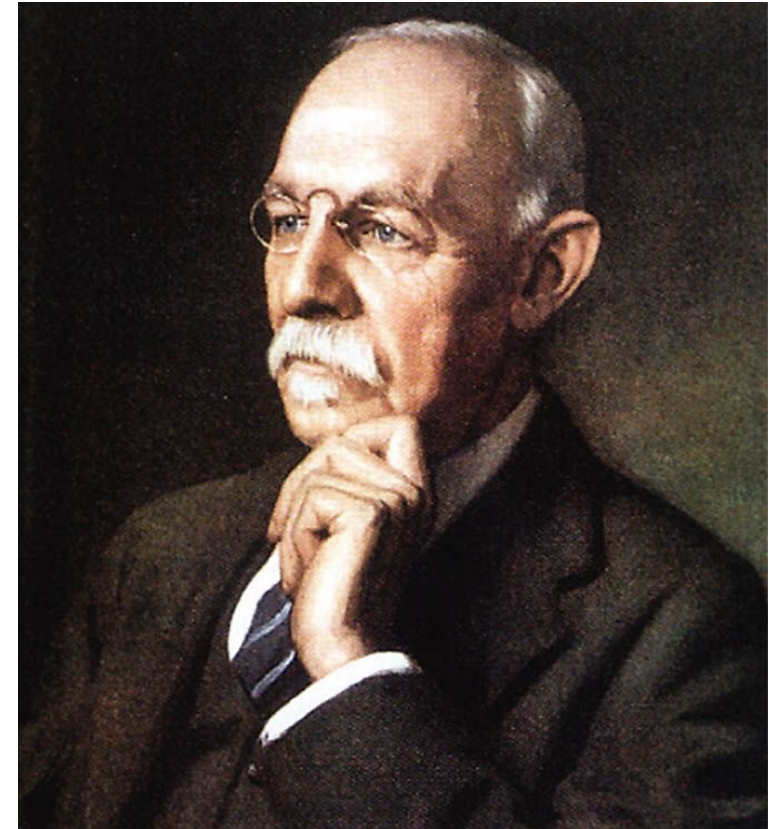
For these reasons, we at Ethicon Endo–Surgery are constantly working to deepen the understanding of living tissue dynamics, and to design our devices to help surgeons reduce trauma associated with their use.

Respect for living tissue lives at the heart of what we do.



Anastomotic Principles

- No tissue tension
- Leak–proof anastomosis
- Good hemostasis
- Adequate blood supply
- Adequate lumen



William S. Halsted, M.D.

Components of Tissue Management

Tissue Dynamics

Composition and biomechanics of living tissue

Technology

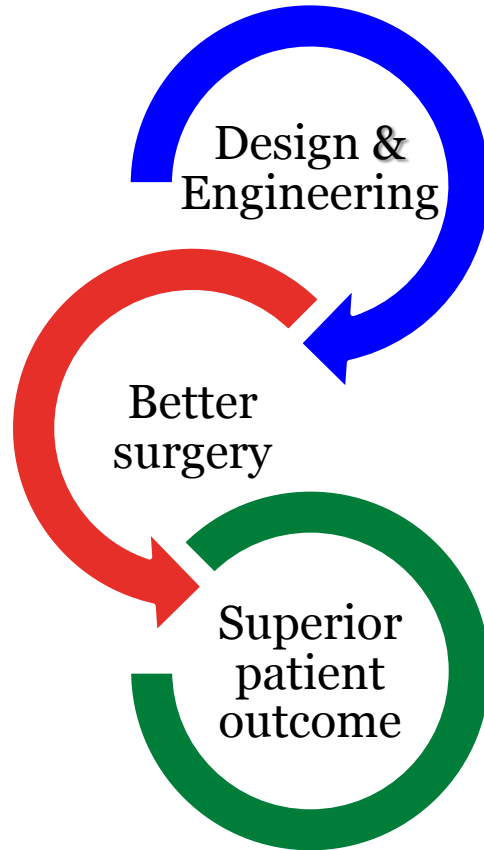
Device-tissue dynamic

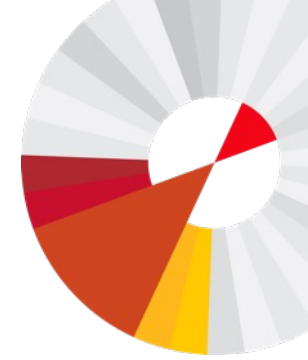
Human Factors

Human and device interactions

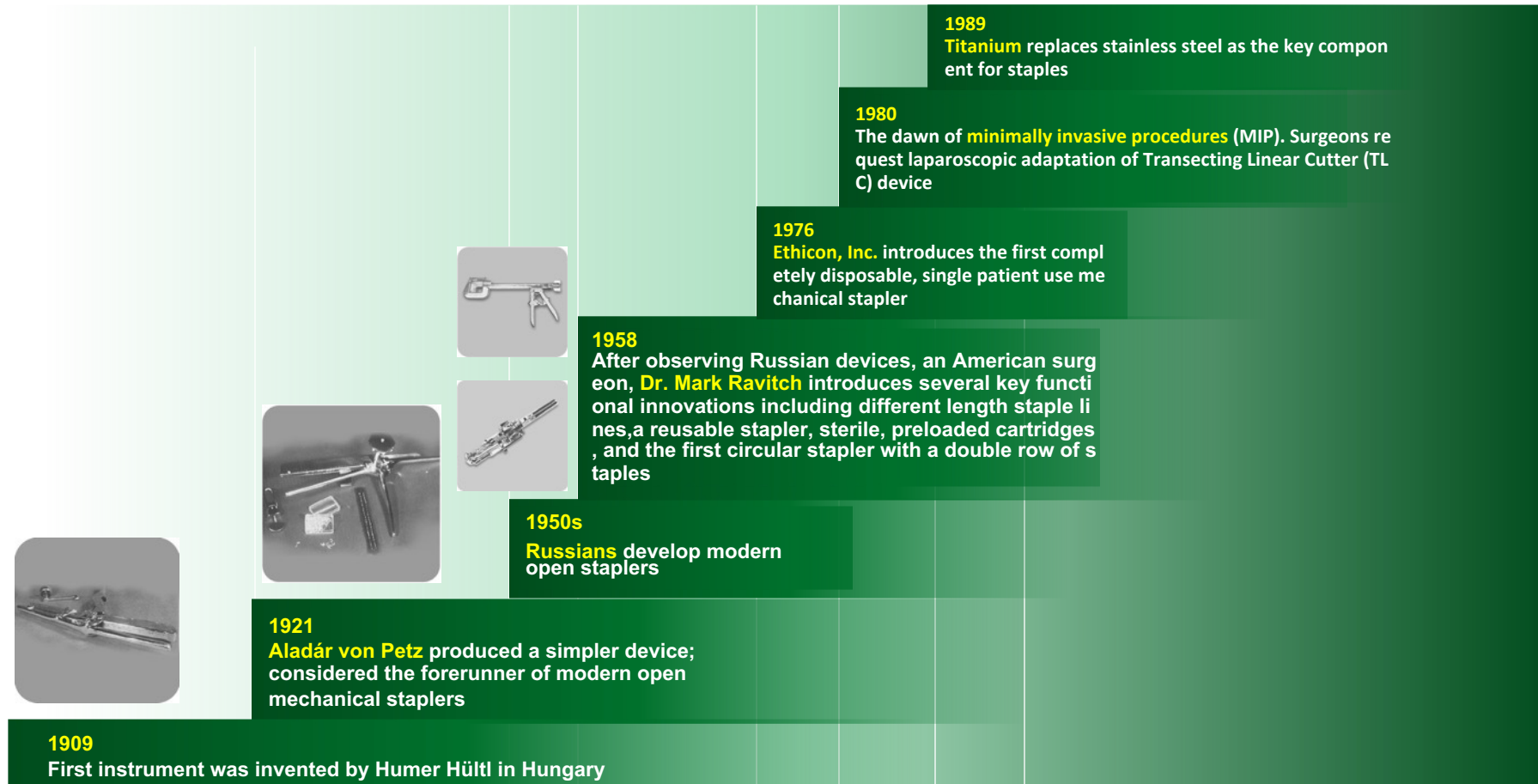


The Ethicon Approach





The Evolution of Surgical Stapling^{1,2,3,4}



1. Baker RS, et al. *Obes Surg.* 2004;14:1290-1298.
2. Hardy KJ. *Aust N Z J Surg.* 1990;60(8):625-633
3. Astafiev GV. *Surgical Staplers (Chirurgicheskiey Shivayushiye Apparaty).* 1967;7 [translated from the Russian].
4. Baker RS, et al. *Obes Surg.* 2004;14:1290-1298.



The Function of Surgical Stapling¹



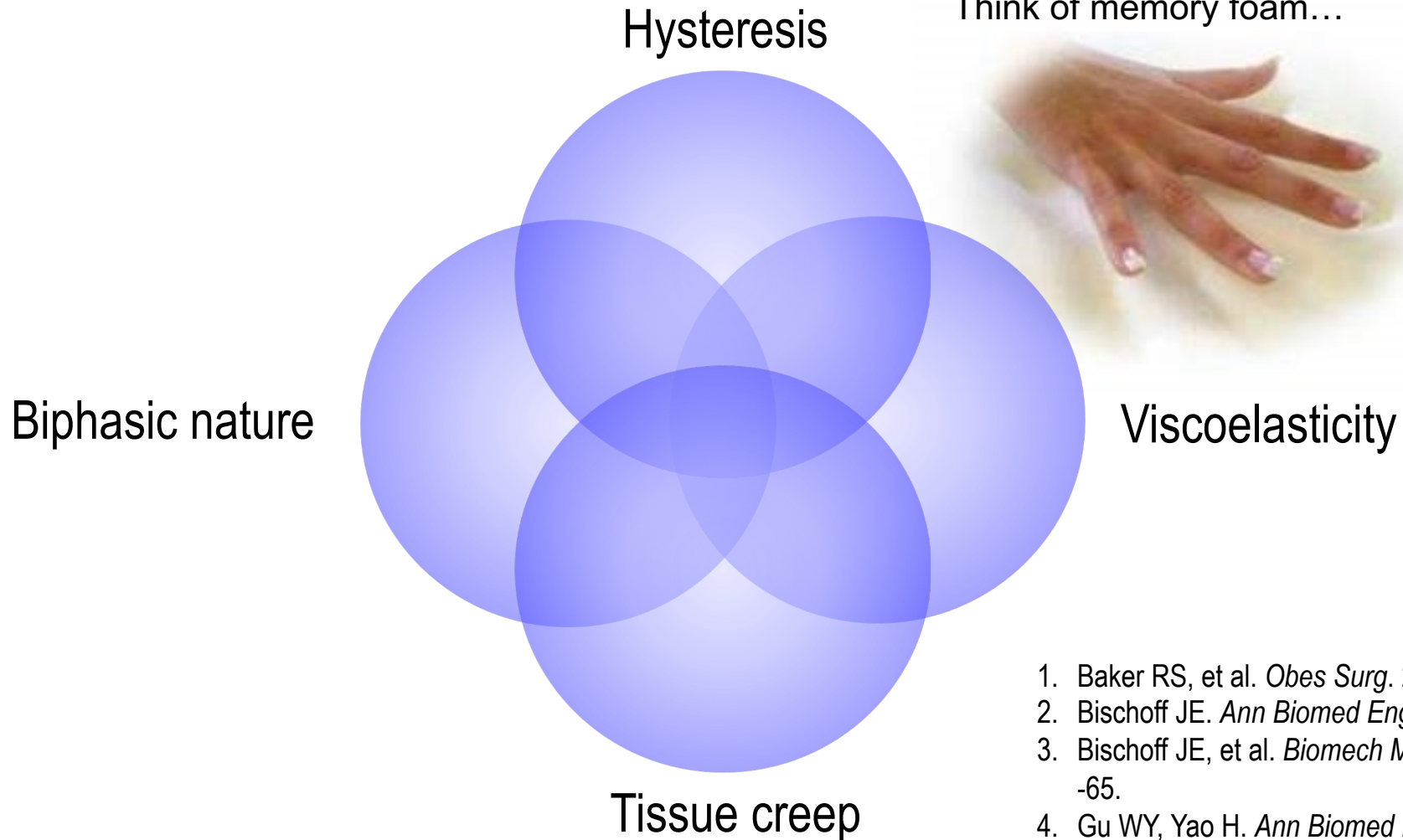
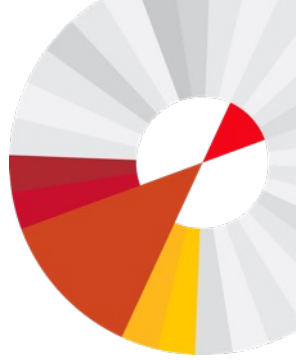
Primary Objective: Hemostasis and leak prevention with optimal compression applied

Causes of potential leaks/hemorrhage from surgical stapling:

- Mechanical/tissue
 - Secondary to staple line failure
 - Most common cause of leaks
 - Usually within 2 days post-op
- Ischemic
 - Usually 5-7 days post-op
 - Rare

1. Baker RS, et al. *Obes Surg.* 2004;14:1290-1298.

Tissue Characteristics¹⁻⁴



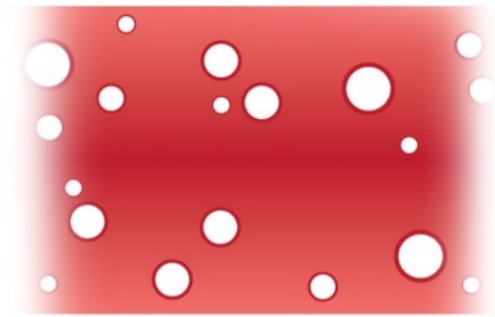
1. Baker RS, et al. *Obes Surg.* 2004;14:1290-1298.
2. Bischoff JE. *Ann Biomed Eng.* 2006;34(7):1164-1172.
3. Bischoff JE, et al. *Biomech Model Mechanobiol.* 2004;3(1):56-65.
4. Gu WY, Yao H. *Ann Biomed Eng.* 2003;31(10):1162-1170

Properties of Tissue

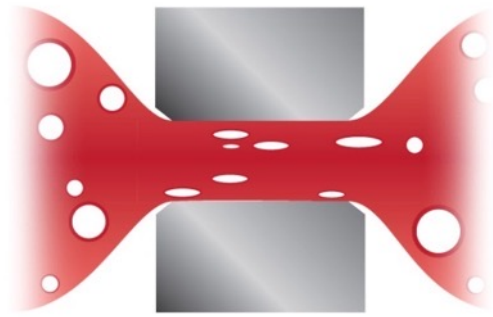
- Living tissue mainly consists of solid and fluid (biphasic nature)
- Tissue thickness changes when external force is applied, then tissue also has properties to return to the original shape over time (viscoelastic nature)
- Based on biphasic and viscoelastic nature, we have to consider... when using staplers
 - Thickness
 - Compressibility
 - Property variability



Tissue Dynamics in Action: Stapling Tissue



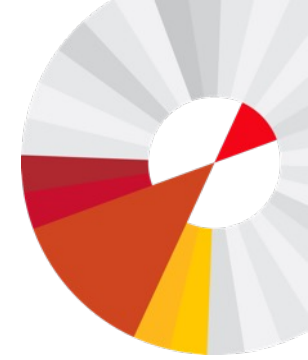
Living tissue before compression



Living tissue compressed to adequate thickness for stapling.

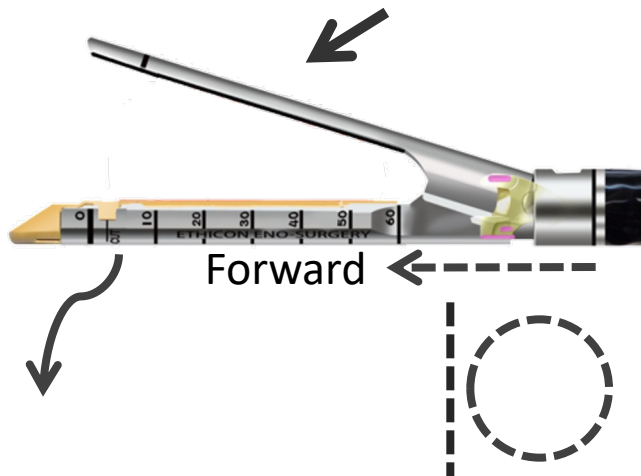


Energy is stored in the staple as compression is maintained



Two types of compression

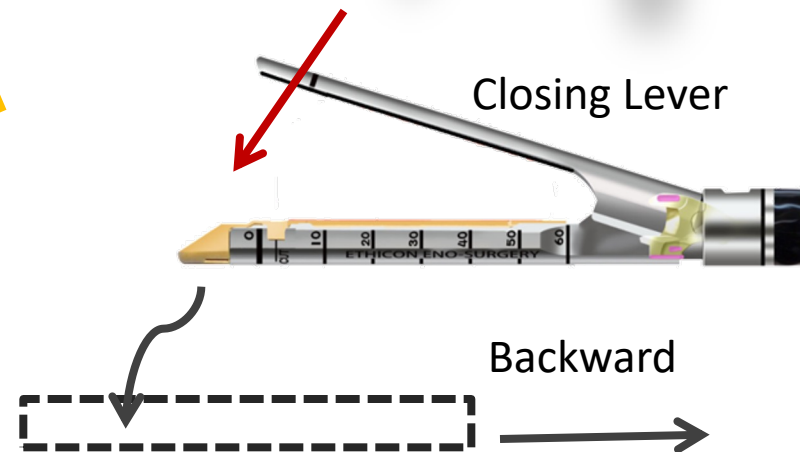
Focal Compression (V-shape)



**25%
Stronger**

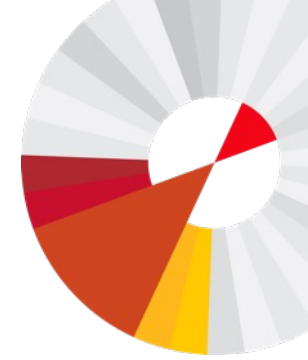


Cam Tube Compression (Parallel)





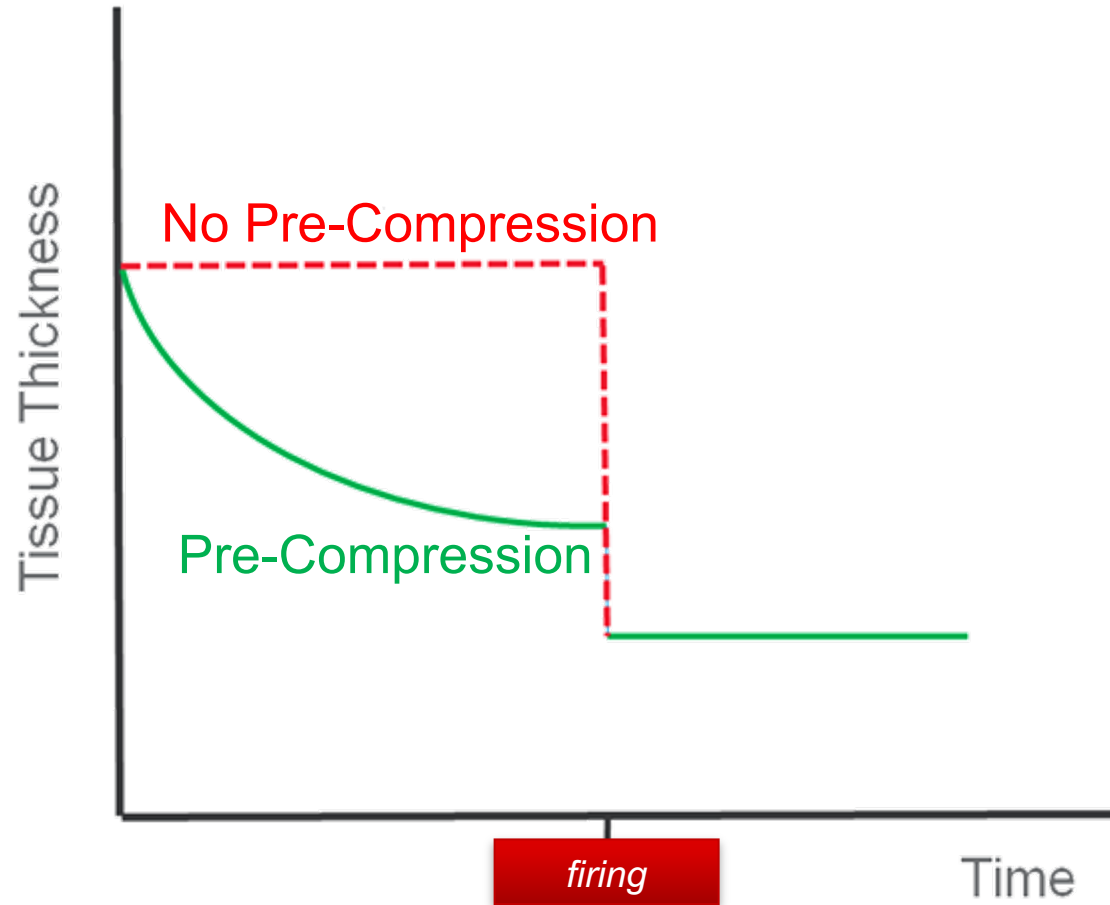




Pre-Compression

Pre-compression is necessary for a good staple formation

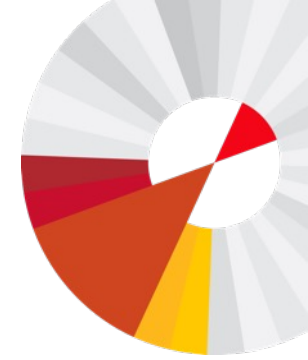




Holding compression before firing:

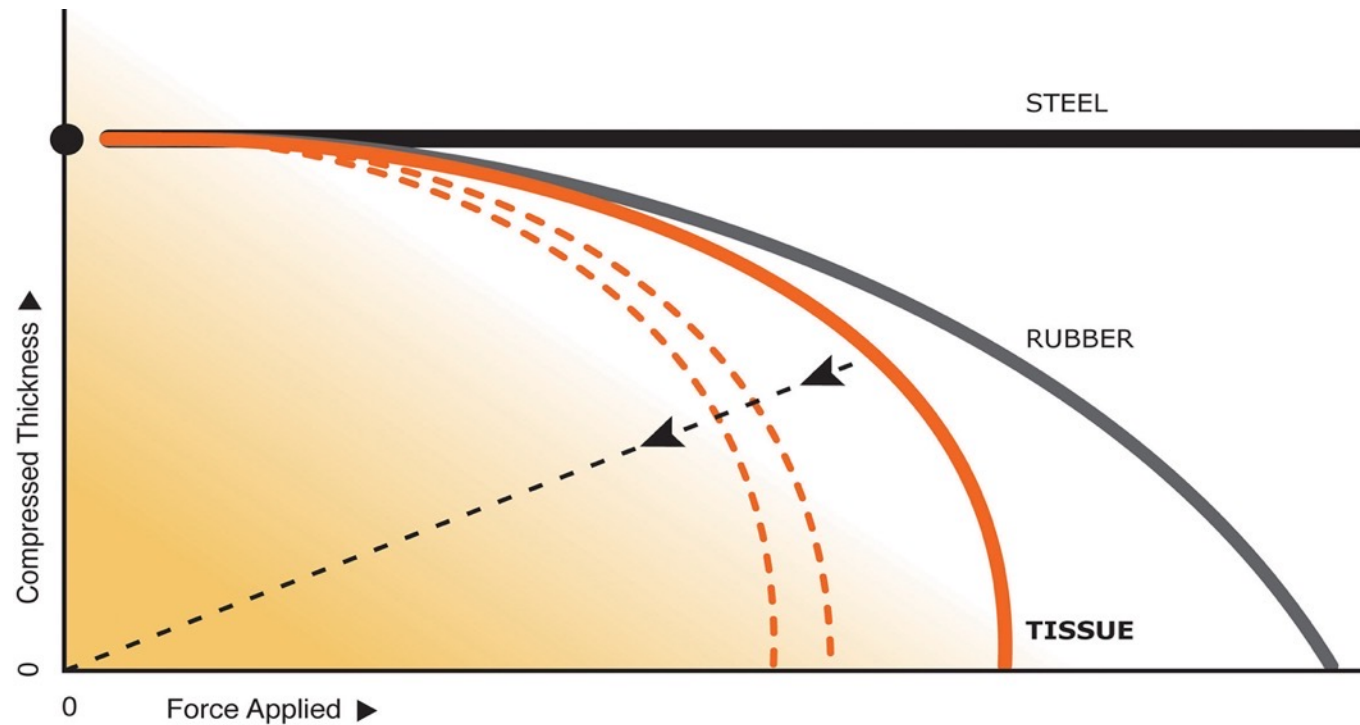
- Prepares the tissue to be fired upon
- Reduces stress on the tissue prior to firing
- Minimizes tissue flow
- Optimizes staple formation

Graph for illustrative purposes only where tissue thickness is greater than the closed staple height

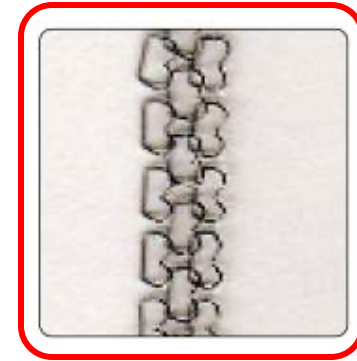
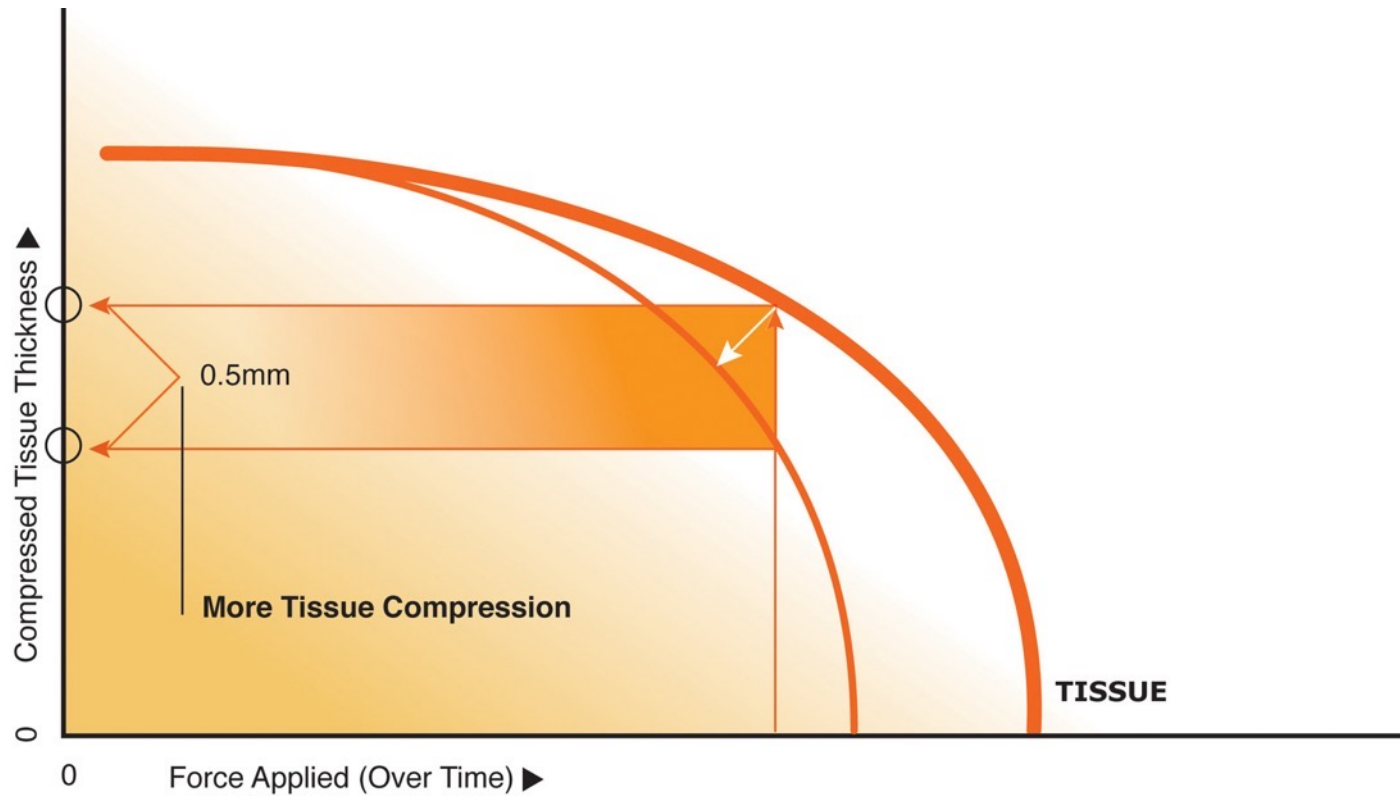


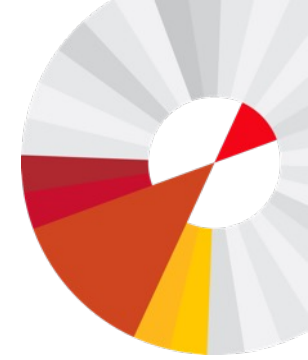
Compression Dynamics

Reaction of Different Materials Under Pressure: Tissue



Compression Dynamics

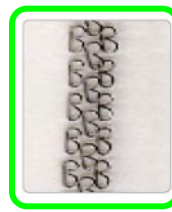
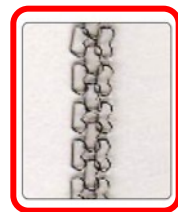
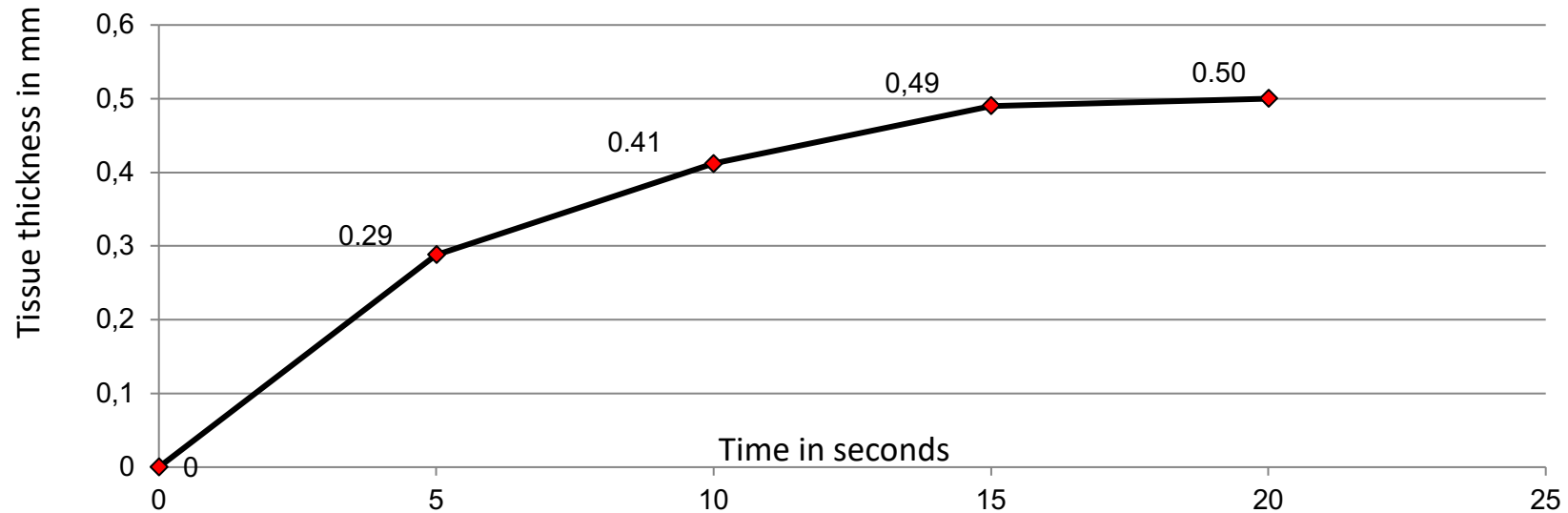




15 seconds gives an optimal thickness

Sample: Echelon 60mm

Tissue thickness reduction (mm) over time (s) after Echelon 60 jaw closure



Tissue thickness varies widely throughout the body from organ to organ.



Even within each organ, tissue thickness ranges greatly.¹

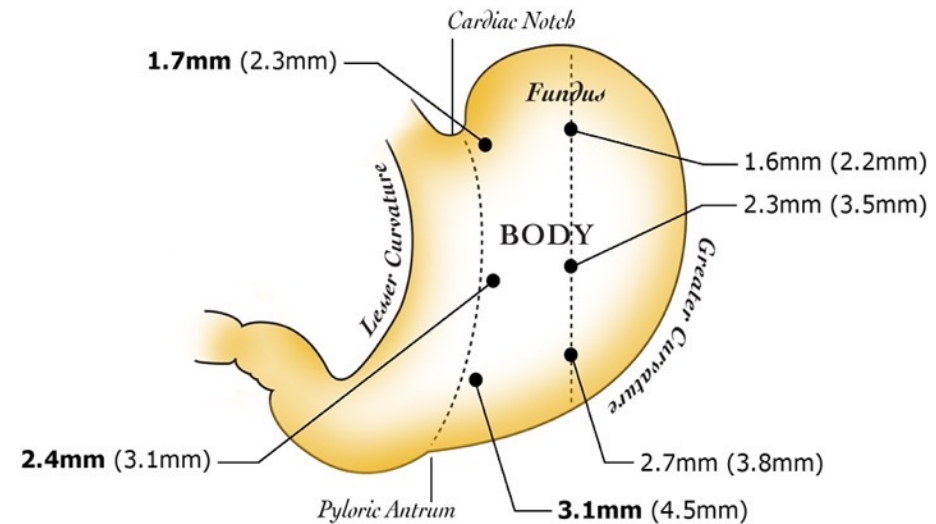


Diagram of the stomach indicating the locations of measurements* (n=50) measurements at each location

*Mean measurement (maximum measurement)

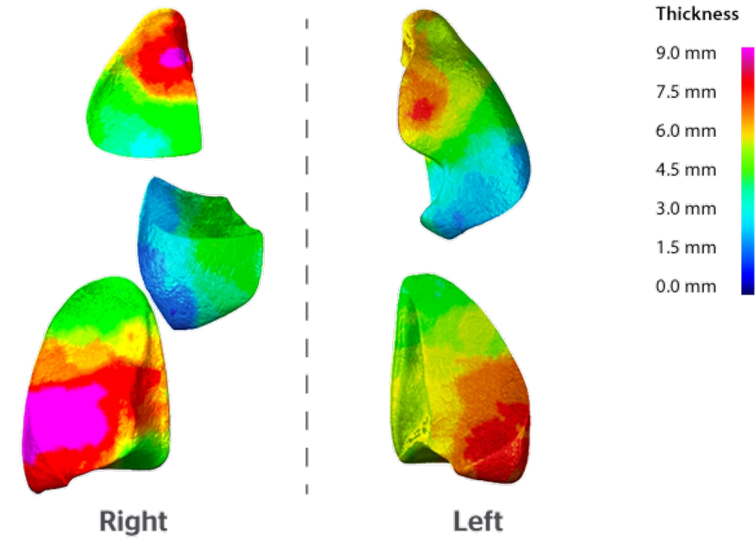
1. This illustration is intended solely as a quick reference guide for tissue thickness measured on excised gastric specimens of obese patients. For interpretation of the information above, please refer to the complete article: Elariny H, Gonzalez H, Wang B, Tissue thickness of human stomach measured on excised gastric specimens of obese patients. *Surg Technol Int.* XIV (2005); 14:119-124.



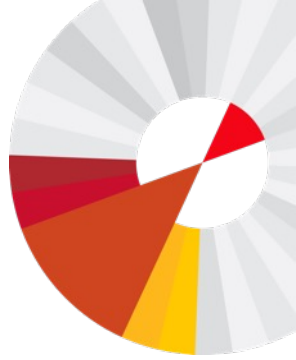
Tissue thickness varies organ by organ



Tissue thickness in a given organ varies location by location ¹

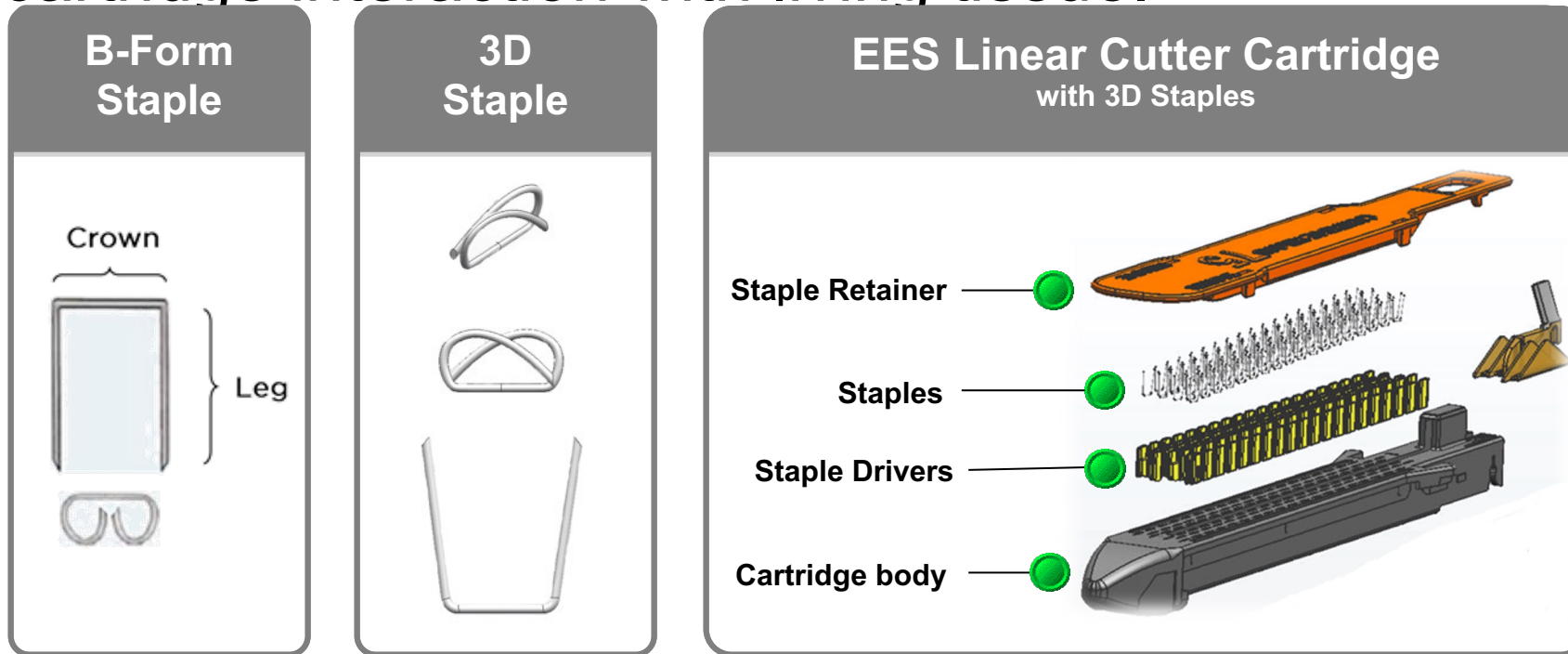


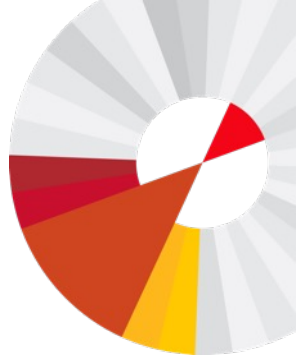
1. This illustration is intended solely as a quick reference guide for tissue thickness measured on excised human lung specimens. The thickness map has been derived by interpolating values between singular points of measurement and is for illustrative purposes only (n=12). As measured in A-P direction at 8g/mm² at 15 seconds, thickness may vary with different (surgical) approaches.



The Staple & Cartridge Configuration

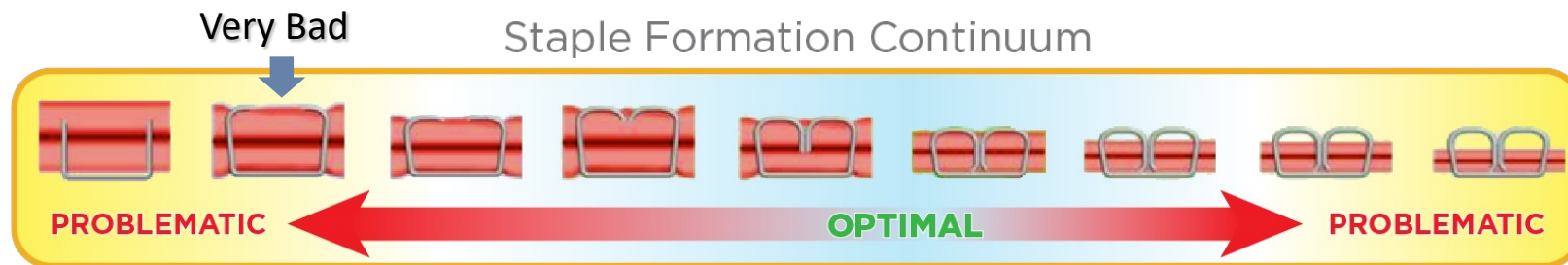
Appropriate staple formation is a combination of the instrument and cartridge interaction with living tissue.





The Function of Surgical Stapling

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

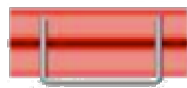


The Staple Formation Continuum

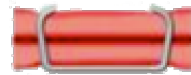
Proper staple formation is necessary to achieve a leak-proof and hemostatic staple line. A staple is considered malformed when the legs of the staple do not close properly after deployment. When staples are malformed or not secure, surgical outcomes may be compromised.



Staple migration during firing



BAD



VERY BAD

Staple legs lie on top of tissue.



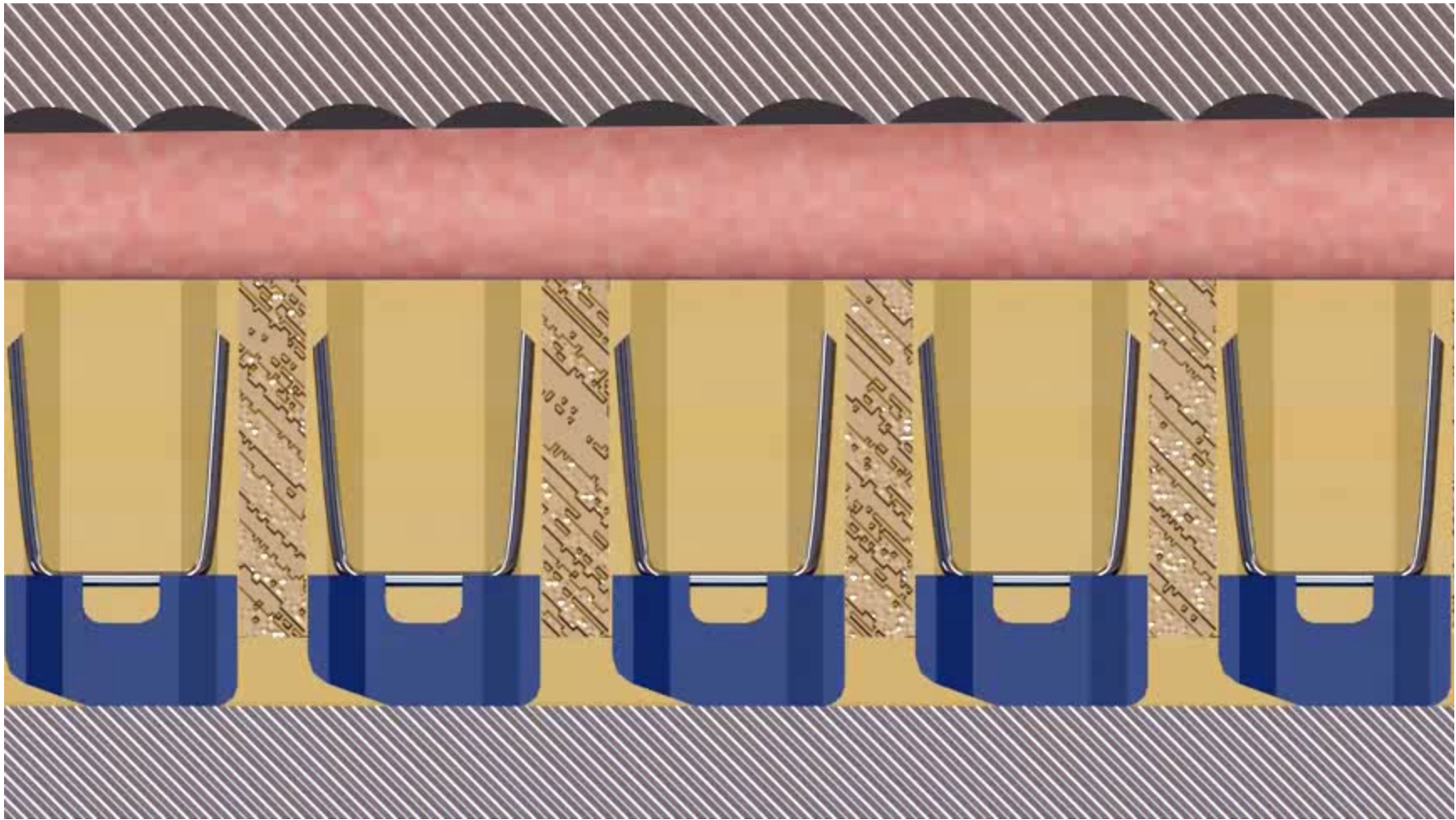
GOOD

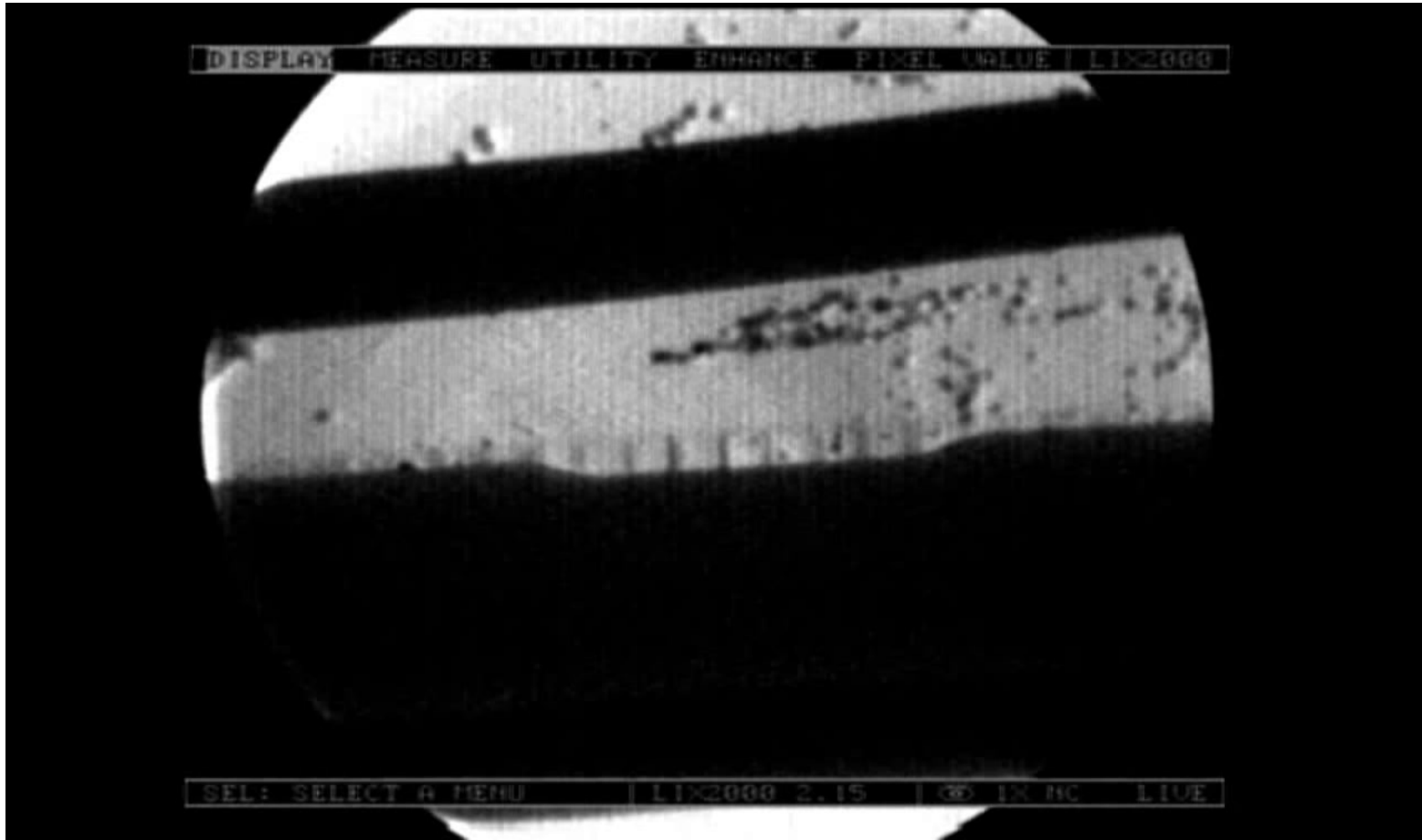
The tissues have been pierced three times. The legs are bent over and pierce the tissue. This staple line will hold.



GOOD

Tissue will tear before staple comes open.

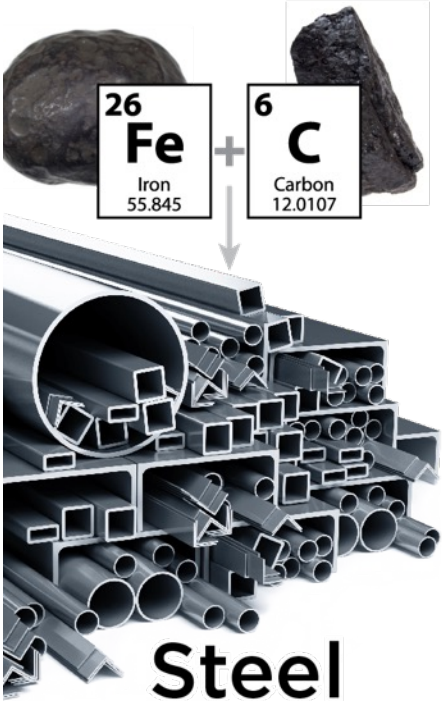




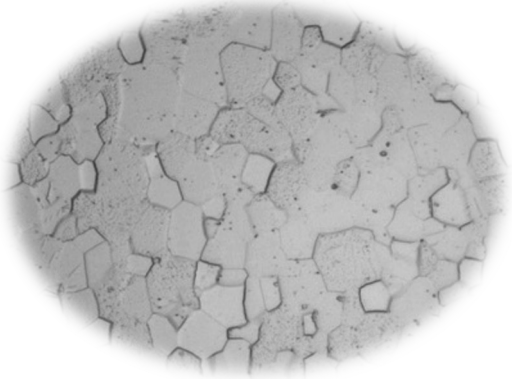


Structure of Unalloyed Titanium Compared to Titanium Alloy

Just as steel achieves its high-strength from combining iron and carbon...



Commercially Pure Titanium
Consists of a single phase that is relatively soft in the annealed state



Titanium Alloy*
Consists of two different phases that result in a higher strength in the annealed state



* Ethicon uses Ti 3 Al 2.5 V and Ti 6 Al 4 V for staples

Human Factors

■ Preoperative

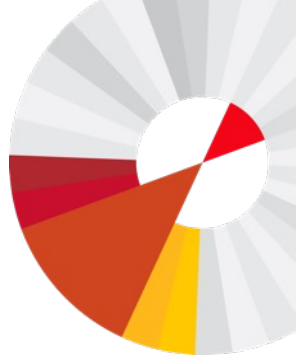
- Surgeon Training , comfort with devices used
- Patient Co-morbid Conditions
- Prior Treatment and Surgical Prep

■ Intraoperative - Anastomotic Principles

- No Tissue Tension
- Leak-Proof Anastomosis
- Good Hemostasis
- Adequate Blood Supply
- Adequate Lumen

■ Postoperative

- Pain Control – NSAIDs, Narcotics
- Inflammatory Response & Healing





End of modules: Thank You

