



**SIMPLYCONVERT
STUDIOS**

Danger in the Operating Room:

Surgical Stapler Litigation and Case Criteria



Today's Agenda

- **Introductions** | JESSIE HOERMAN
- **Surgical Stapler Litigation Overview** | BRENDA FULMER
- **Case Criteria Overview** | JESSIE HOERMAN



Today's Presenters



JESSIE HOERMAN
FOUNDER / CEO



BRENDA FULMER
SHAREHOLDER



FDA Classification

- Entered the market as Class I medical devices
- Other examples of Class I devices:
 - Bandages
 - Non-electric wheelchairs
- “Low Risk” versus “Medium Risk”
- May 30, 2019: Unanimous agreement that surgical staplers should be reclassified as Class II devices with special controls



Examples of Class I
Medical Devices



*One of these things is
not like the others...*



ECRI Institute: Top 10 list of health technology hazards

“An independent health safety group identified misuse of surgical staplers as a top health technology concern. The ECRI Institute, a nonprofit that maintains a database of hospital-reported adverse events, released its Top 10 Technology Hazards report.”

MedCityNews

DAILY, HEALTH IT, MEDICAL DEVICES

Surgical stapler misuse tops list of health technology hazards

Misuse of surgical staplers led the ECRI Institute's Top 10 Technology Hazards report for 2020. Earlier this year, the FDA revealed 11,181 serious injuries related to stapler incidents had been reported in the last decade.

By ELISE REUTER

Post a comment / Dec 11, 2019 at 7:05 PM



An independent health safety group identified misuse of surgical staplers as a top health technology concern. The [ECRI Institute](#), a nonprofit that maintains a database of hospital-reported adverse events, released its [Top 10 Technology Hazards](#) report.

The report is intended to predict what issues will be important in the coming year and make practical recommendations to hospitals to prevent them, said Robert Schluth, senior project officer of health devices for ECRI.



Use of Surgical Staplers

- Suturing
- Resection
- Transection
- Anastomosis

Purported Benefits of Use

- Increased speed
- Diminished tissue reaction
- Lessened infection risk



CartoonStock.

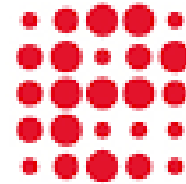


Product Identification

Johnson & Johnson – Ethicon
Covidien / Medtronic



COVIDIEN



**Ethicon
Endo-Surgery**

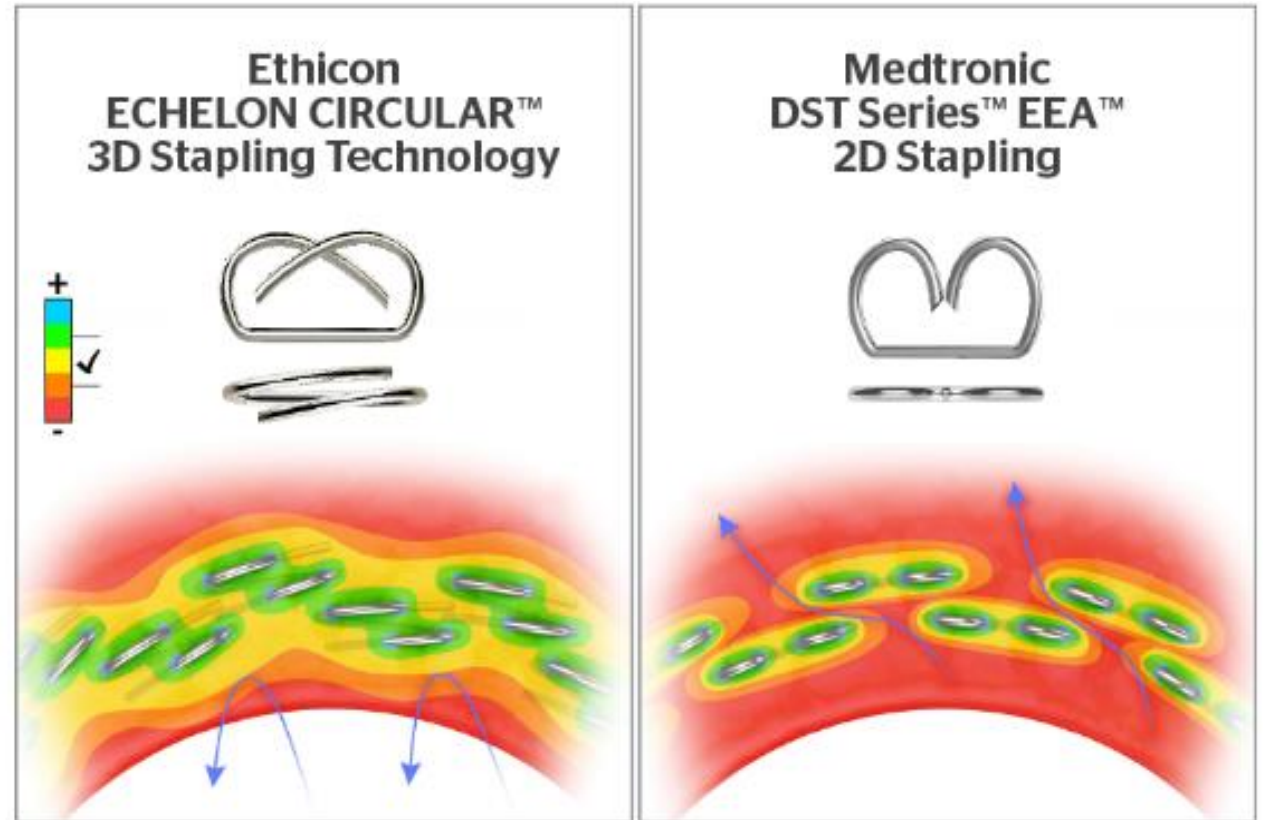
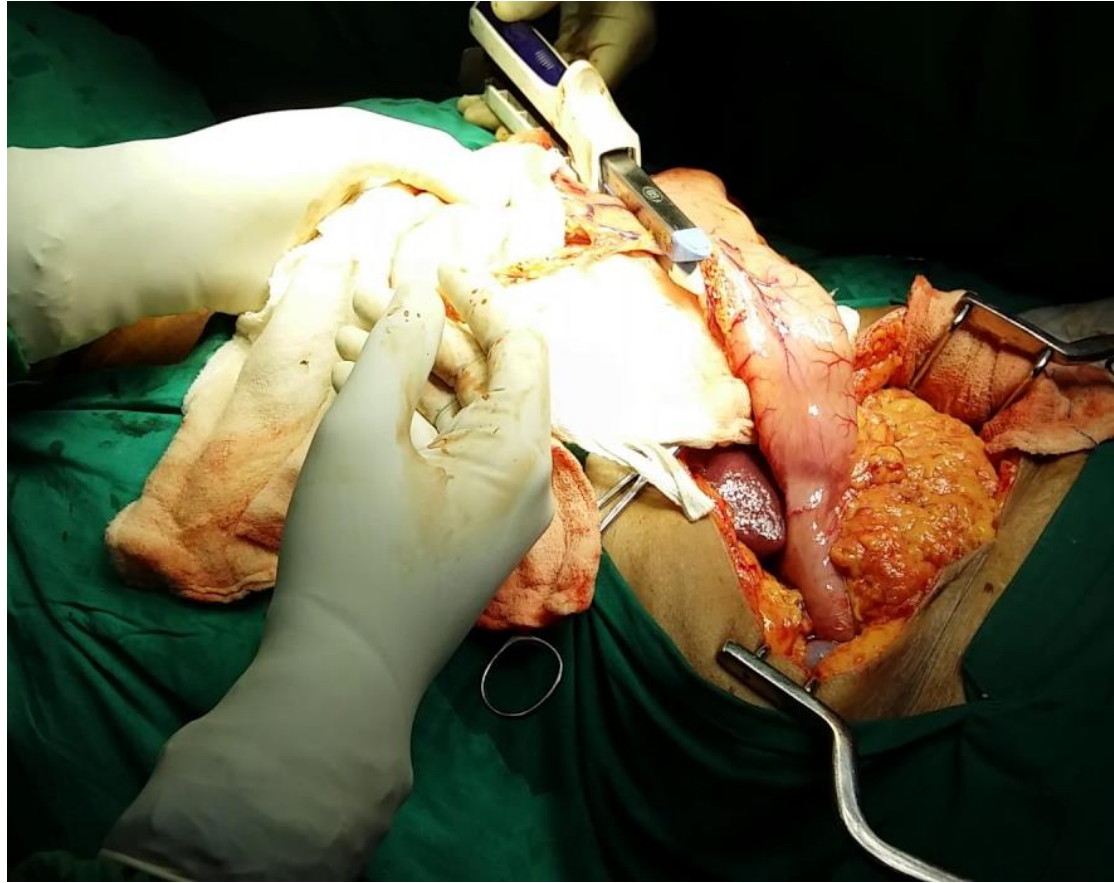
PART OF THE *JOHNSON & JOHNSON* FAMILY OF COMPANIES



Product ID Clues

- Named in Operative Report
- Billing Records
- Purchasing Agreements
- Type of Procedure
- Color of Reload
- Size of Reload
- Length of Stapler Arm
- Length of Closed Staple

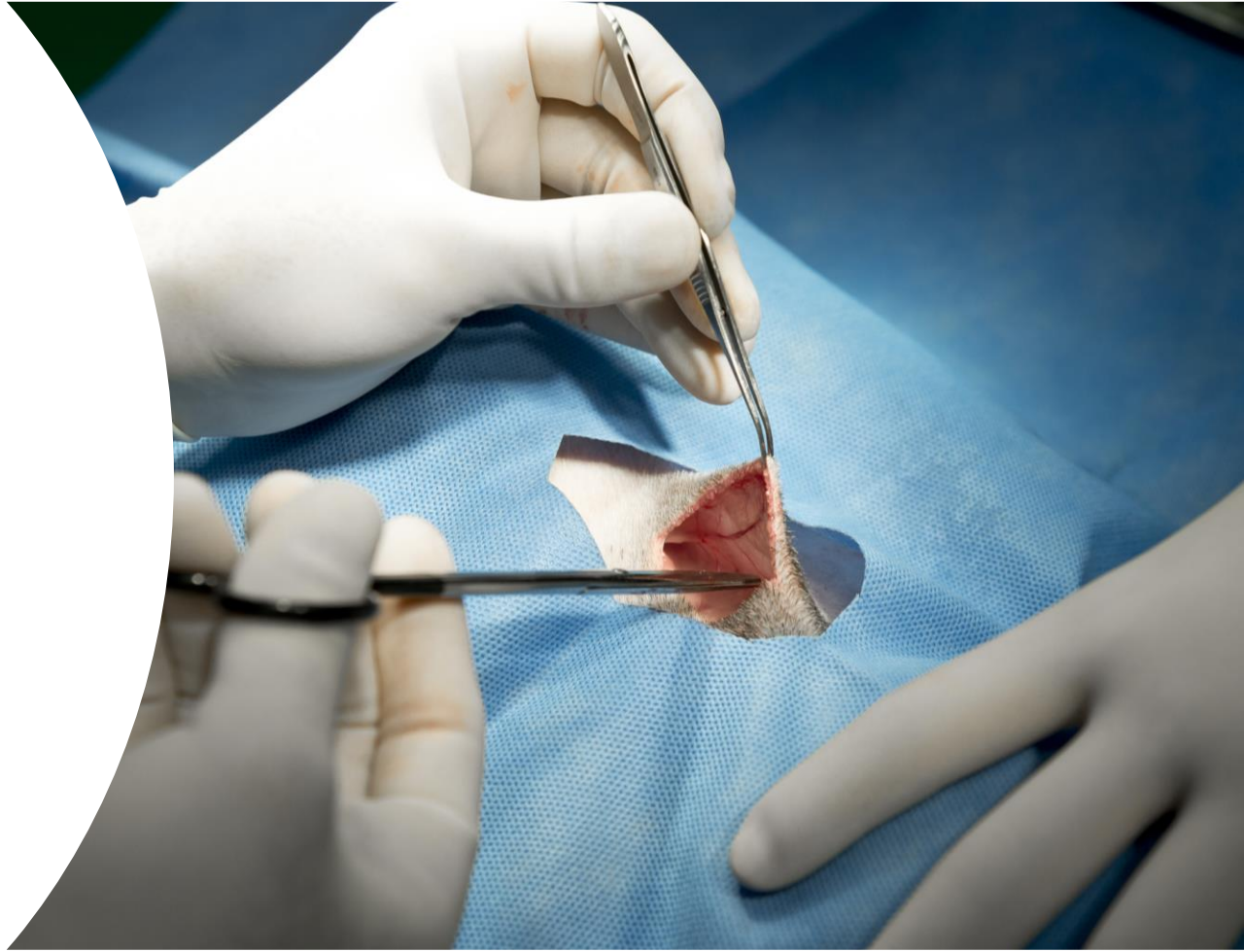




Conceptual comparison demonstrating potential effects of tissue compression during firing. Results can vary based on tissue characteristics, device design, techniques and other factors.

Types of Surgical Stapler Failures

- Stapler Misfires
- Staple Misapplication
- Staple Malformation
- Not A Case:
 - Misplacement of Stapler or Staples
 - Anastomosis Too Tight



FDA Recommendations for Health Care Providers

Safe Use of Surgical Staplers and Staples – Letter to Health Care Providers

Following issuance of the letter to health care providers, the FDA has taken [additional actions](#). The FDA will continue to monitor this issue and will keep the public informed if significant new information becomes available.

March 8, 2019

Dear Health Care Provider,

The U.S. Food and Drug Administration (FDA) is aware of adverse events associated with surgical staplers and [additional recommendations for health care providers](#) to reduce the risk of adverse events associated with these devices. [Additional actions](#) we intend to take to help ensure the safe use of surgical staplers and staples.

Because surgical staplers and staples for internal use have been the subject of medical device reports submitted for both surgical staplers and staples, the FDA has a comprehensive picture of the safety profile for these devices. The FDA found that from January 1, 2011 to March 31, 2018, there were 366 deaths, over 9,000 serious injuries, and over 32,000 malfunctions.

- 366 deaths,
- over 9,000 serious injuries, and
- over 32,000 malfunctions.

The FDA believes that many of the problems identified are attributable to surgical staplers for internal use because their function is contingent on proper function and use of the stapler.

Some of the most commonly reported problems include:

- opening of the staple line or malformation of the staple line,
- misfiring,
- difficulty in firing,
- failure of the stapler to fire the staple, and

- misapplied staples (e.g., user applying staples to the wrong tissue or applying staples of the wrong size to the tissue).

Stapler and/or staple malfunctions or misuse may result in prolonged surgical procedures or unplanned, additional surgical interventions, which may lead to other complications, such as:

- bleeding,
- sepsis,
- fistula formation,
- tearing of internal tissues and organs,
- increased risk of cancer recurrence, and
- death.

RECOMMENDATIONS:

- Read and carefully follow the stapler manufacturer's instructions for use.
- Have a range of staple sizes available and select the appropriate size cartridge for the tissue type and thickness.
 - If you have difficulty squeezing the handle of the stapler, you may need to select a different size staple.
 - Avoid using the stapler on tissue that is too thick or too thin for the selected staple size, as this could result in staple malformation.
 - Be aware that different companies may use different color schemes on the cartridges to indicate different staple sizes.
- Consider other options if the patient's tissue is edematous (swollen with fluid), friable (tissue that readily tears, fragments, or bleeds when gently palpated or manipulated), or necrotic (death of tissue), as the staples may be less likely to securely approximate tissue.
- Be familiar with the structures around the intended staple site.
 - Check that unintended structures, such as urinary bladder, or foreign objects, such as clips, are not in the staple line.
- Avoid using on large blood vessels, such as the aorta.
- Avoid clamping the stapler on delicate tissue, as clamping can still cause injury even if no staples are fired.
- If a malfunction of the stapler occurs while applying staples across a blood vessel, then clamp or ligate the vessel before releasing the stapler, while the stapler is still closed on the tissue.



Injuries Resulting from Surgical Stapler Failures

- Excessive Bleeding
- Tissue and Organ Destruction
- Procedure Complications and Additional Surgeries
- Failure to Anastomose
- Infection, Sepsis, Fistula Formation
- Increased Risk of Cancer Recurrence
- Chronic Digestive Issues
- Diminished Quality of Life
- Long-Term Disability
- Death



Case Criteria

Available for download:
SimplyConvert.com > Resources >
Litigations and Practice Areas



SURGICAL STAPLER (July 2021)

Are you or a loved one concerned about an injury or complication that was caused by a stapler during surgery?

- Yes
- No

Please select the type of surgery that required the use of a stapler.

- Colon surgery (colectomy, colostomy, proctocolectomy)
- Rectal surgery (hemorrhoidectomy, internal sphincterotomy, rectopexy)
- Gastrointestinal surgery (gastric bypass, appendectomy, adrenalectomy, splenectomy)
- Gynecological surgery
- Thoracic surgery (heart, lung, artery)
- Other surgery
- No surgery

Please select any injuries you experienced as a result of staples being used during surgery.

- Anastomosis that fails to close
- Colostomy that fails to close
- Colostomy bag
- Fistula formation (abnormal connection between organs or other tissue in the body)
- Hernia
- Infection
- Organ damage
- Perforation of bowel or small intestine
- Other injury
- No Injuries

Was this a robot-assisted surgery?

- Yes
- No
- I do not know

What date was the surgery performed?

- MM/YYYY
- Surgery within the last 5 years
- Surgery more than 5 years ago

Qualified:
Contract sent instantly
(if auto contracts enabled)

Pending Review:
Reach out to client for
more information

Not Qualified:
Unqualified contact rejected instantly,
but saved for future marketing

Lead 1:
Priority lead

Lead 2:
Second priority lead

THANK YOU!

Questions?

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- Jessie Hoerman: jess@simplyconvert.com





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