

ETHICON LLC,
ETHICON ENDO-SURGERY, INC., and
ETHICON US, LLC.

Plaintiffs,

v.

INTUITIVE SURGICAL, INC., INTUITIVE
SURGICAL OPERATIONS, INC., and
INTUITIVE SURGICAL HOLDINGS, LLC

Defendants.

)
)
)
) C.A. No. 1-17-cv-871 (LPS) (CJB)
)
) **JURY TRIAL DEMANDED**
)
)
)
)
)
)

Plaintiffs Ethicon LLC, Ethicon Endo-Surgery, Inc., and Ethicon US, LLC (“Ethicon”) submit this desk reference book to accompany the interactive technology tutorial that is being submitted concurrently. The images, text, and slide numbers in this desk reference book correspond to the presentation in the interactive technology tutorial.

Jack B. Blumenfeld (#1014)
 Brian P. Egan (#6227)
 1201 North Market Street
 P.O. Box 1347 Wilmington, DE 19899
 (302) 658-9200 jblumenfeld@mnat.com
 began@mnat.com

Attorneys for Ethicon LLC, Ethicon Endo-Surgery, Inc. and Ethicon US, LLC


Diane P. Sullivan
WEIL GOTSHAL & MANGES, LLP
17 Hulfish Street Suite 201
Princeton, NJ 08542
(609) 986-1120

Christopher T. Marando
Christopher M. Pepe
Matthew D. Sieger
WEIL GOTSHAL & MANGES, LLP
2001 M Street, N.W.
Suite 600
Washington, D.C. 20005
(202) 682-7000


June 28, 2018

Ethicon Technology Tutorial


Instructions




This tutorial is accompanied with a narrative audio track. Please make sure that the speakers on your computer are turned ON and your volume is turned UP appropriately.




You may advance to the next slide at any time by pressing the next arrow (or the right arrow key).




You may go to a previous slide at any time by pressing the back arrow (or the left arrow key).




You may jump to any slide by entering the slide number in the field and pressing the enter key.



You may jump to any section in the tutorial by using the chapter menu.



When it is time to advance the slide, you will be prompted by a blinking next arrow.



⏪ back

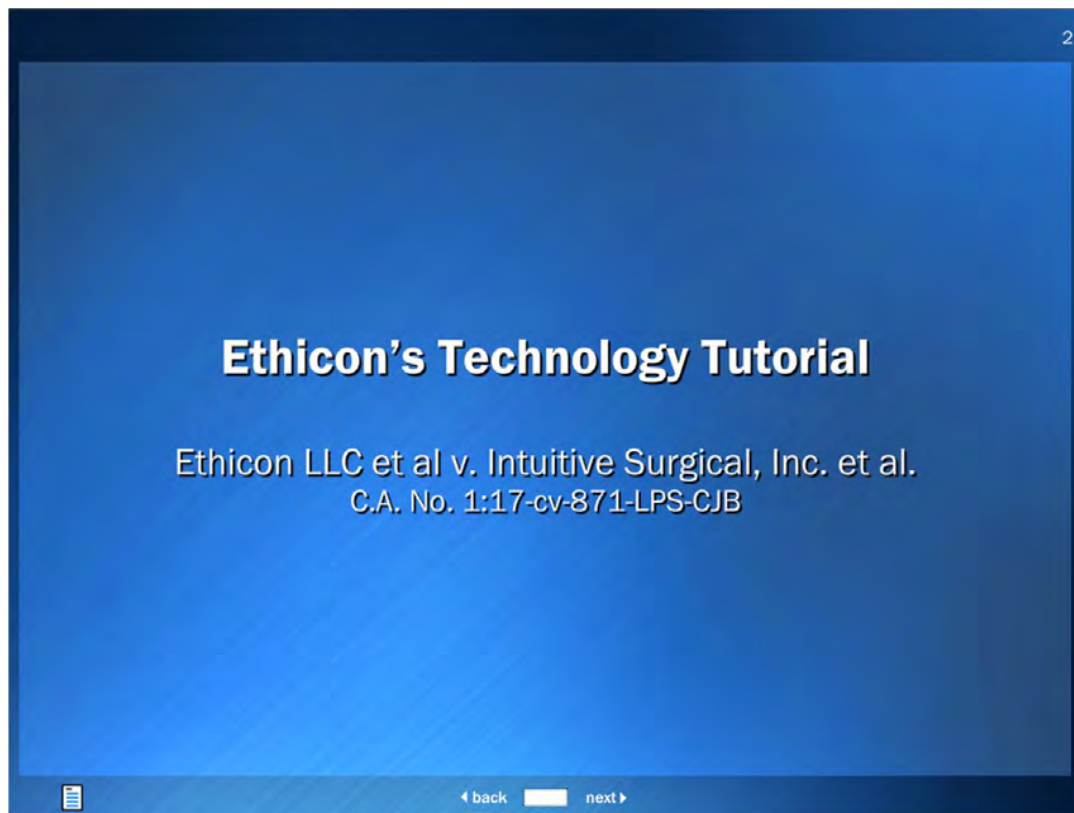
next ⏩

Slide 1

This tutorial is accompanied with a narrative audio track. Please make sure that the speakers on your computer are turned ON and your volume is turned UP appropriately. You may advance to the next slide at any time by pressing the next arrow (or the right arrow key). You may go to a previous slide at any time by pressing the back arrow (or the left arrow key). You may jump to any slide by entering the slide number in the field and pressing the enter key. You may jump to any section in the tutorial by using the chapter menu. When it is time to advance the slide, you will be prompted by a blinking next arrow.

6/28/2018

Ethicon Technology Tutorial

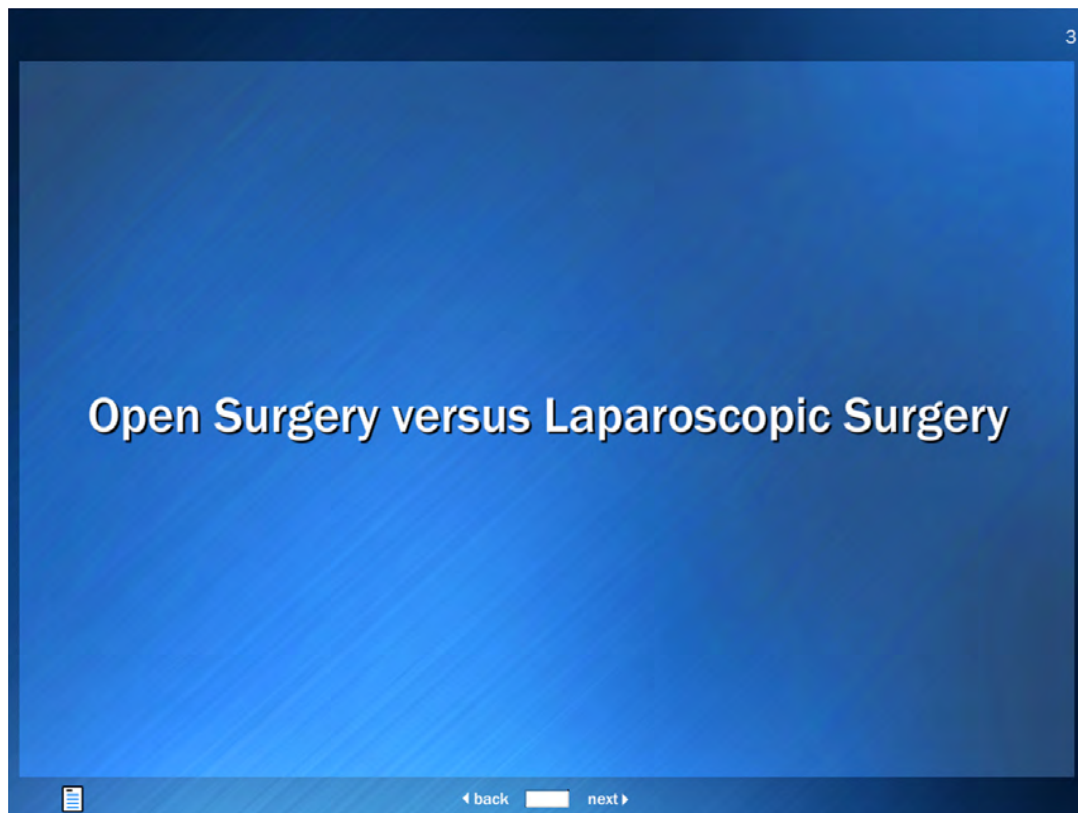


Slide 2

This is Ethicon's technology tutorial in the matter of *Ethicon LLC et al. v. Intuitive Surgical, Inc. et al.*, Civil Action No. 1:17-cv-871-LPS-CJB. There are seven patents asserted in this case. Each patent concerns surgical tools for use in laparoscopic surgical procedures. My name is Elizabeth Weiswasser, and I am an attorney representing Ethicon. I will be addressing some background concepts to provide context for the patented technology. My colleague Anish Desai will then discuss the asserted patents in more detail.

6/28/2018

Ethicon Exhibit 2001.004
Intuitive v. Ethicon
IPR2018-01247

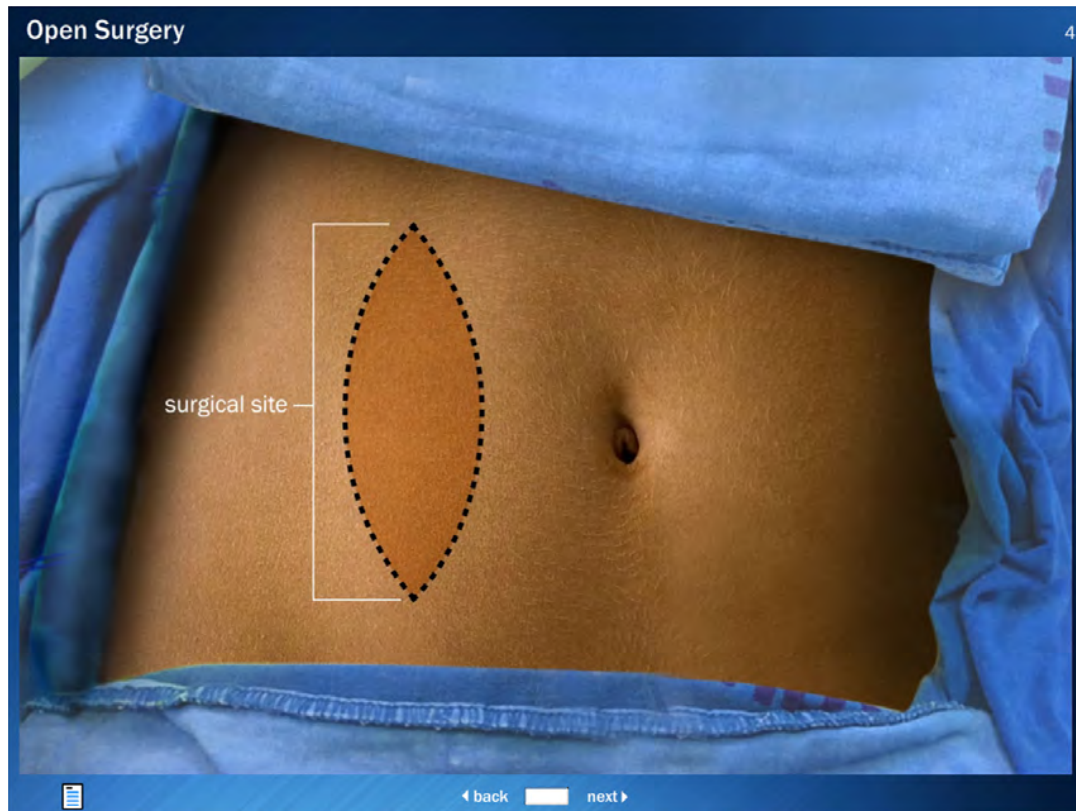


Slide 3

The first topic we will discuss is the difference between open surgery and laparoscopic surgery.

6/28/2018

Ethicon Technology Tutorial

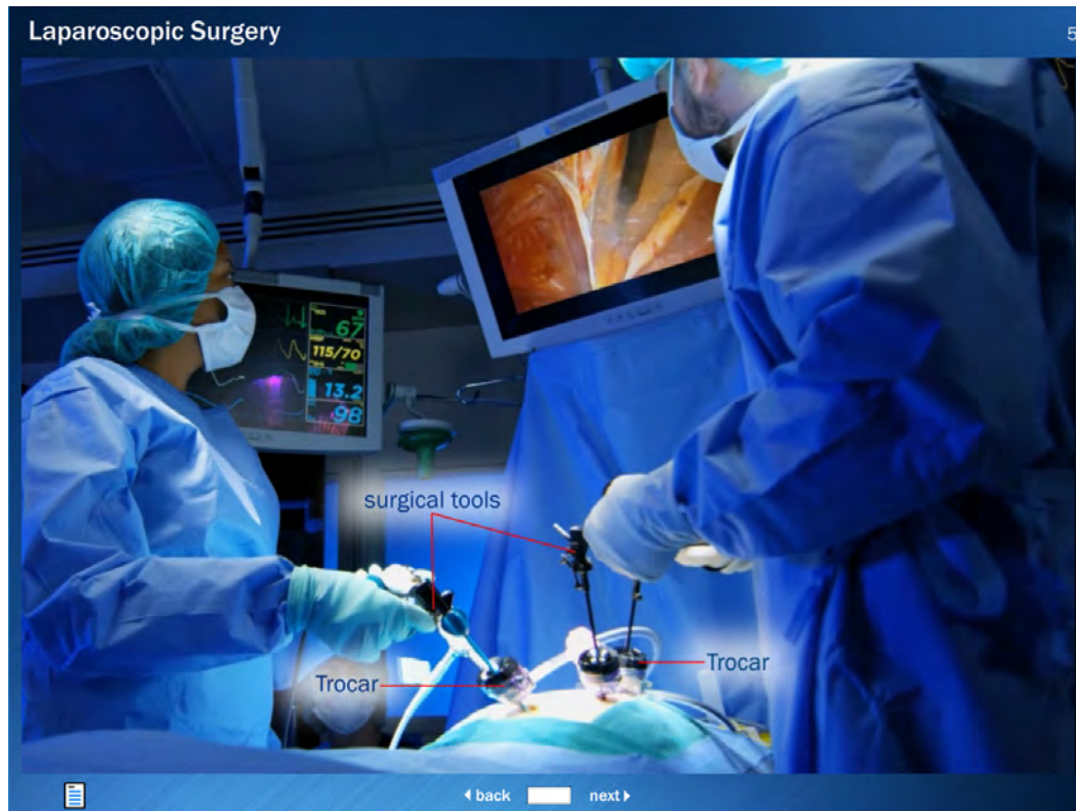


Slide 4

Traditional surgery is commonly referred to as open surgery. In open surgery, incisions are made that are large enough to allow the surgeon to view the surgical site. Because the surgeon has direct access to the surgical site, the surgeon can use tools of varying sizes and geometries. The benefit of direct access to the surgical site comes at the cost of a relatively long recovery time and increased pain for the patient.

6/28/2018

Ethicon Technology Tutorial



Slide 5

Laparoscopic surgery is an alternative to open surgery. Laparoscopic surgery replaces one large incision with several smaller incisions. The terms “laparoscopic” and “minimally invasive” are commonly used interchangeably. We’ll use the term laparoscopic for convenience. In a laparoscopic procedure, a small camera is inserted through one of the incisions, and the surgical site is displayed on a monitor. Devices called trocars are inserted through the incisions, and surgical tools are inserted through the trocars. The smaller incisions in laparoscopic surgery offer the potential benefits of reduced recovery time and pain, but they come at the cost of reduced access to the surgical site.

6/28/2018

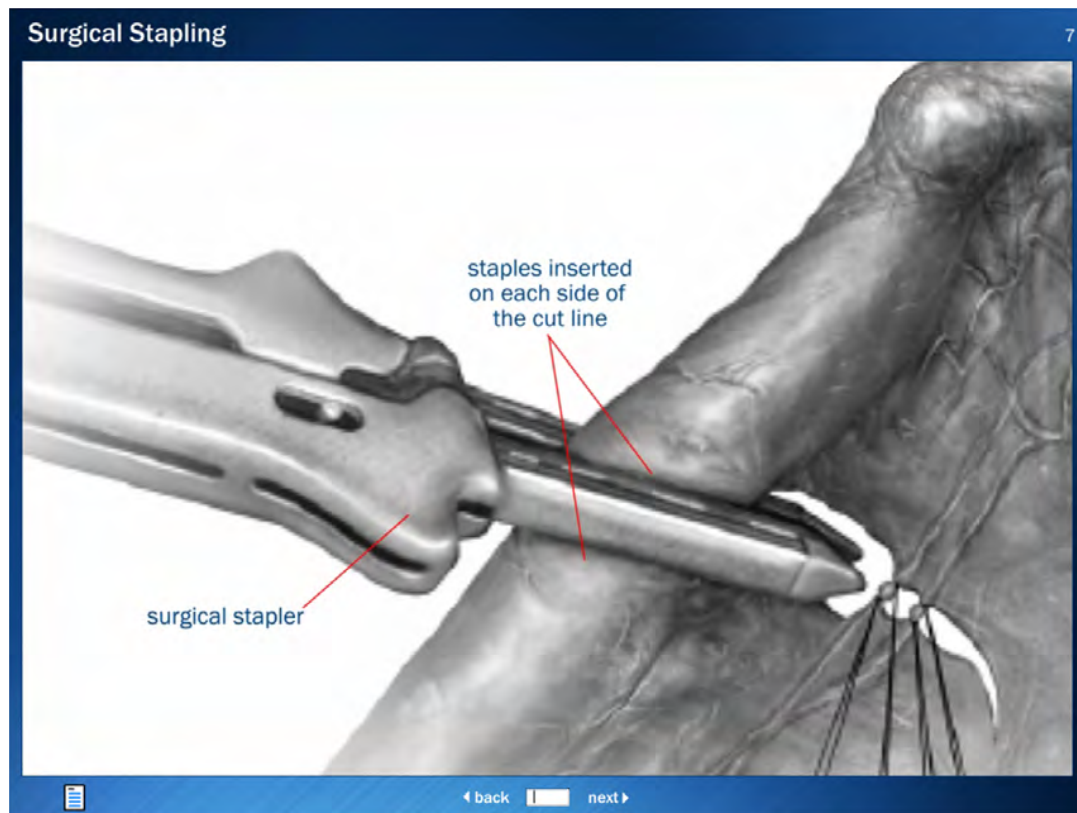


Slide 6

We will next describe some background concepts concerning surgical stapling.

6/28/2018

Ethicon Technology Tutorial

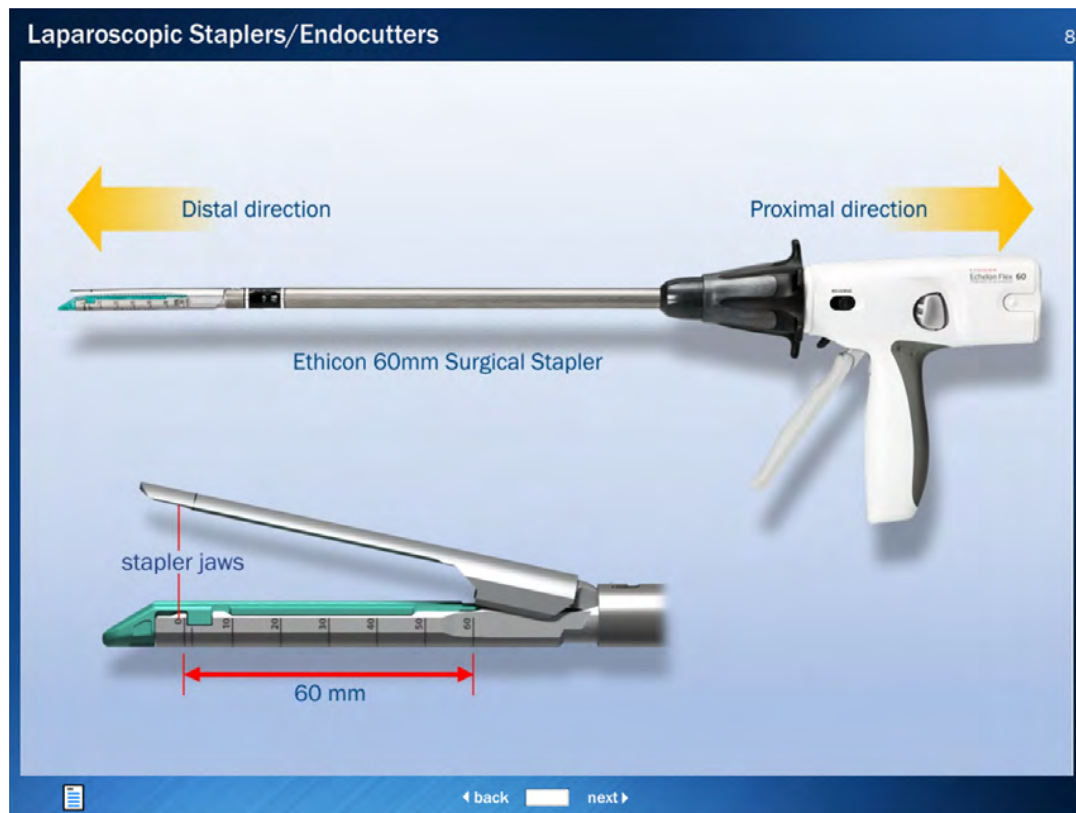


Slide 7

The surgical staplers at issue in this case cut tissue and simultaneously staple the tissue on each side of the cut line. This type of surgical stapler can be used to remove tissue from the body, such as a tumor, a piece of the intestine, or a piece of the stomach. A surgical stapler for use in open surgery is shown here.

6/28/2018

Ethicon Technology Tutorial

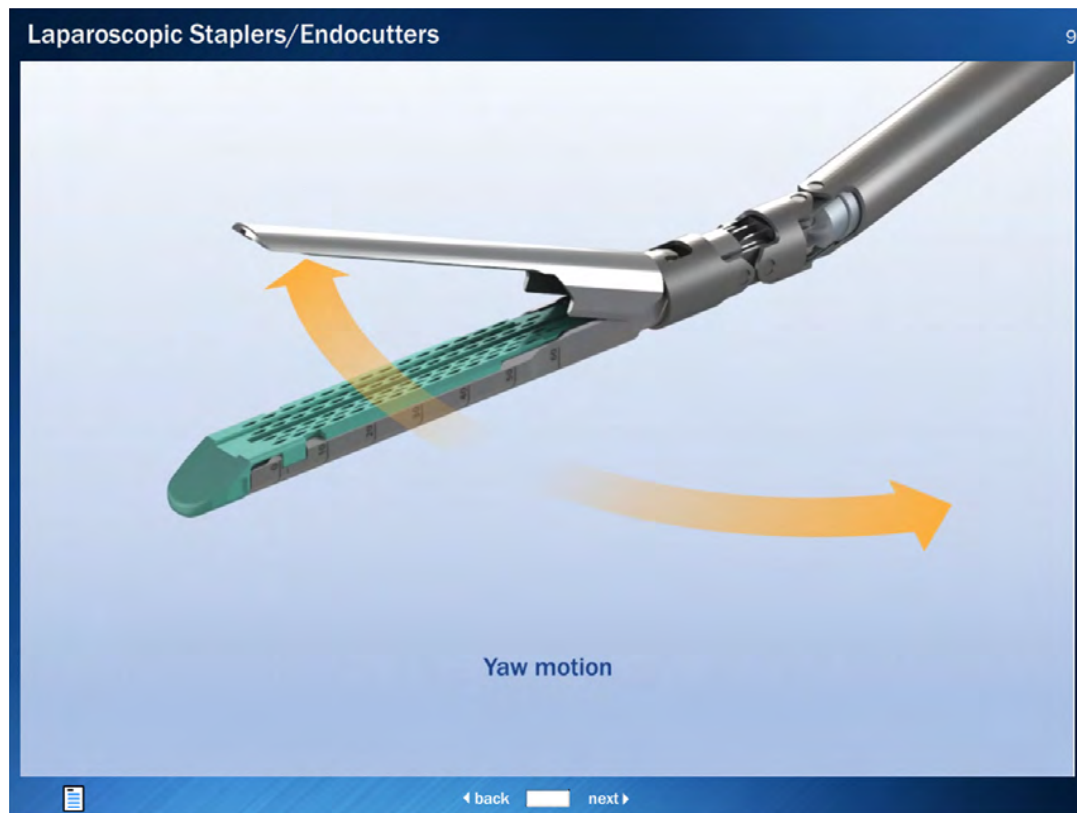


Slide 8

A laparoscopic surgical stapler is also called an endocutter. We will use the terms “stapler” and “endocutter” interchangeably in this tutorial to refer to this type of device. Unlike an open instrument, an endocutter must be inserted through a trocar. This requires a shaft that fits within the trocar and runs from the handle of the endocutter to the stapler jaws. The direction pointed toward the stapler jaws is called the “distal” direction and the opposite direction is called the “proximal” direction. An Ethicon 60mm endocutter is shown here. Endocutters are commonly referred to by the length of the staple line they produce. For example, it is common for endocutters to be referred to as 35mm endocutters, 45mm endocutters, or 60mm endocutters. We will next describe the basics of surgical stapling in more detail.

6/28/2018

Ethicon Technology Tutorial

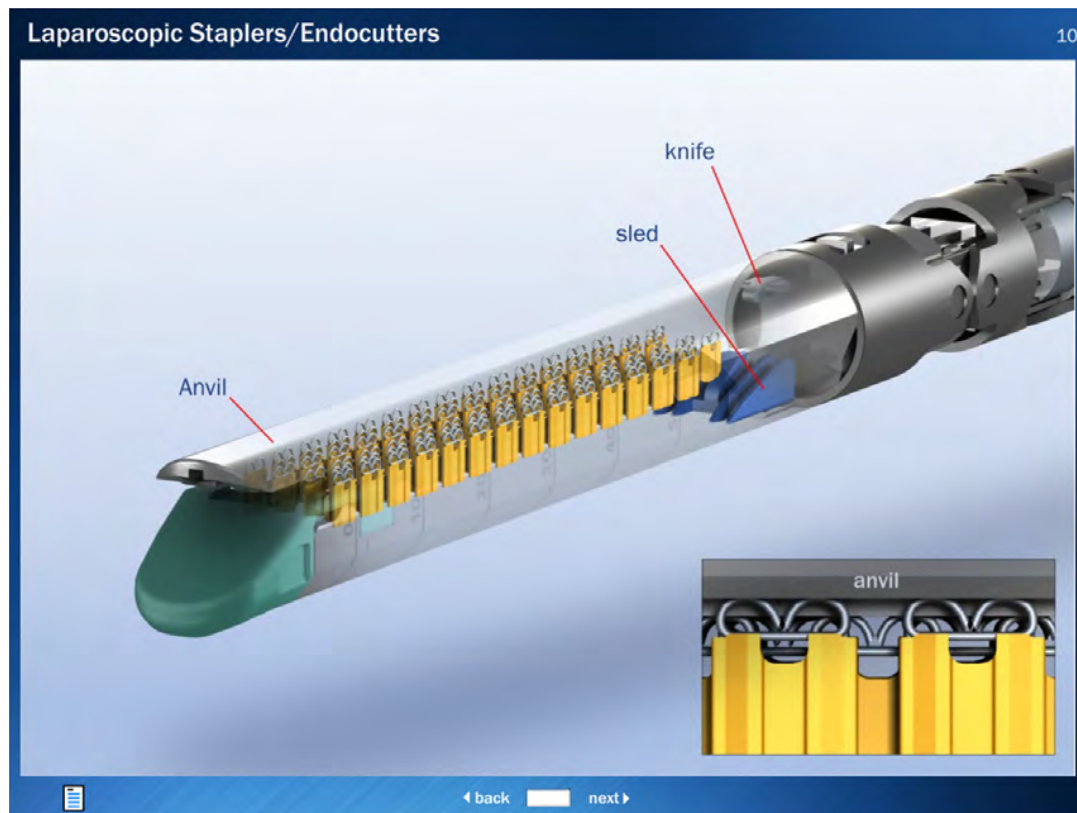


Slide 9

This is a depiction of the shaft and stapler jaws of an endocutter. The stapler has two jaws, which can also be referred to as the end effector. Because endocutters are operated through trocars and in tight spaces, they typically include controls that allow the surgeon to position the stapler jaws without moving the handle. For example, the endocutters will include controls that spin the shaft and stapler jaws. This is also called “roll” motion. The endocutters also include controls to articulate the stapler jaws. By articulate, we mean rotating the jaws side to side, which is called “yaw” motion, and up and down, which is called “pitch” motion.

6/28/2018

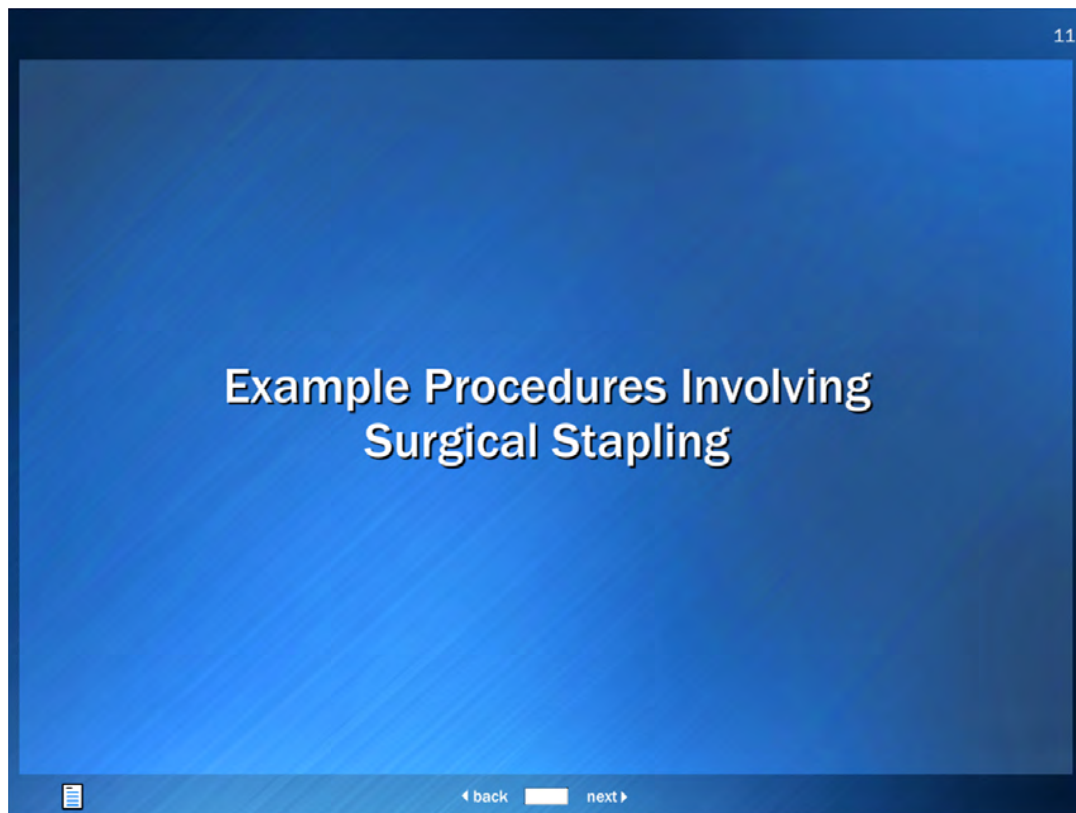
Ethicon Technology Tutorial



Slide 10

We will now describe how an endocutter clamps, cuts, and staples tissue. Prior to use, a stapler reload cartridge is inserted into a pocket in one of the stapler jaws. The surgeon then positions the jaws and clamps them around tissue. The surgeon is now ready to cut and staple. This is also referred to as “firing” the endocutter. When the surgeon fires, a knife connected to a sled advances forward in the cartridge toward the end of the jaws. The knife cuts the tissue, and the sled pushes staples upwardly on both sides of the knife into the opposite jaw. This jaw is referred to as the anvil. When the staples strike the anvil, the staples are bent inwardly to form a “B” shaped staple around the tissue. In this way, tissue on either side of the cut line is stapled.

6/28/2018

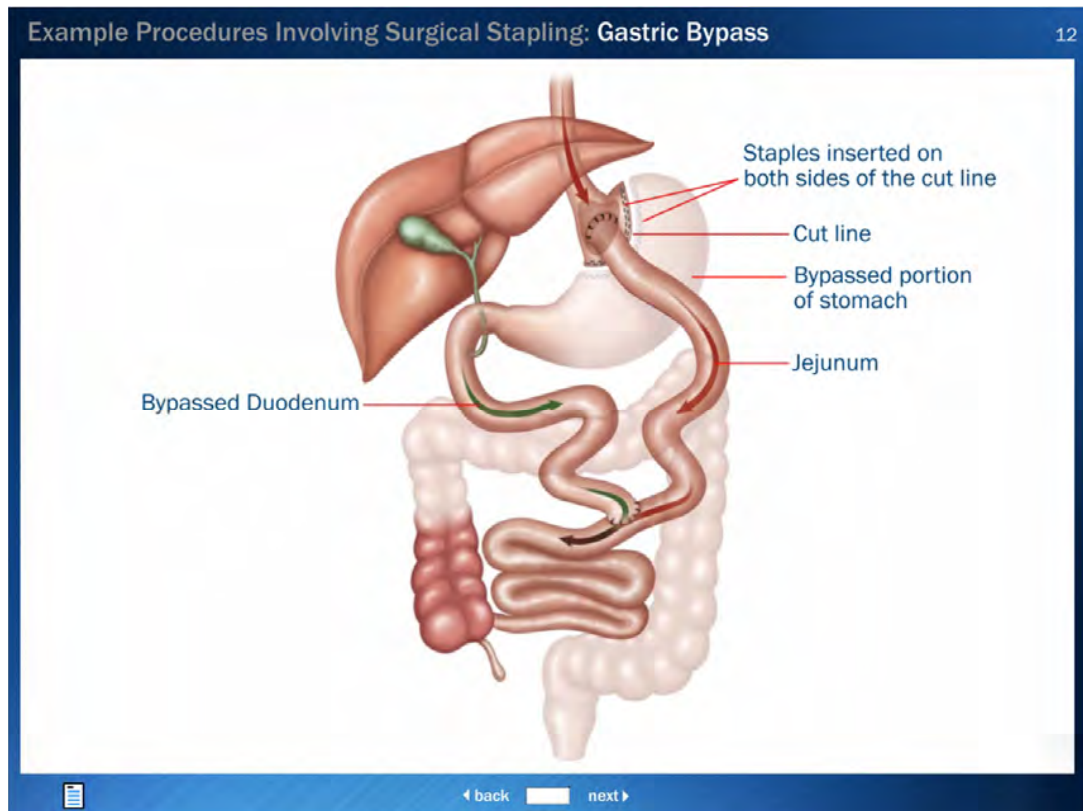


Slide 11

We'll now discuss some example procedures involving surgical stapling.

6/28/2018

Ethicon Technology Tutorial

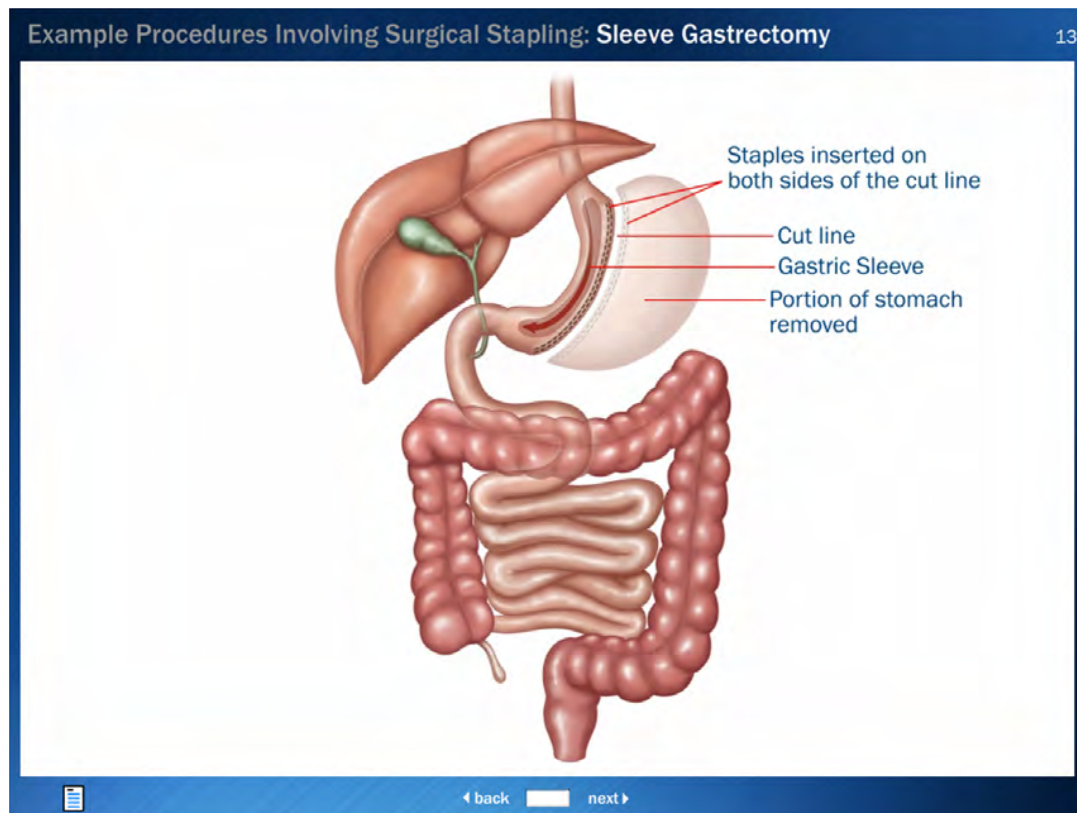


Slide 12

Bariatric surgery is an example procedure that involves cutting and stapling tissue in the body. Specific types of bariatric surgery include gastric bypass and gastric sleeve surgery. In the illustrated gastric bypass procedure, an endocutter is used to simultaneously cut stomach tissue and staple on both sides of the cut line, sealing the tissue after the cut.

6/28/2018

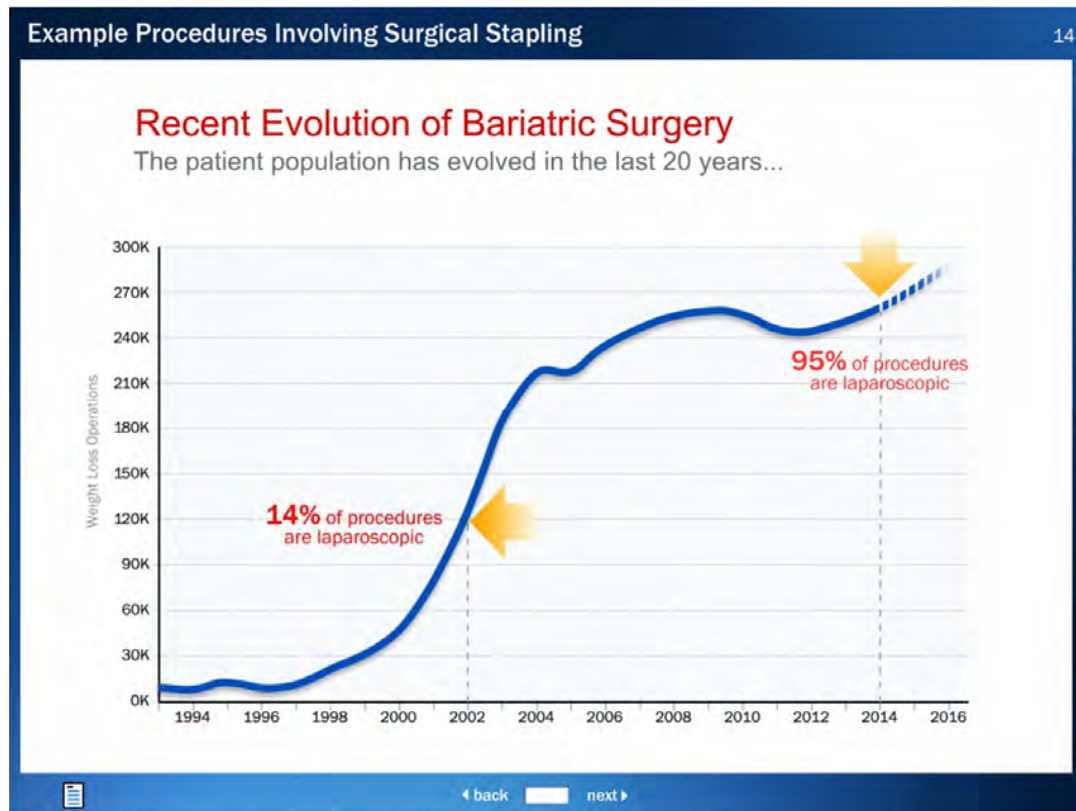
Ethicon Technology Tutorial



Slide 13

In a sleeve gastrectomy procedure illustrated here, portions of stomach tissue are cut using an endocutter, resulting in separate sealed sections after stapling on both sides of the cut. The narrow portion that is retained is called the gastric sleeve, and the remaining section is removed.

6/28/2018



Slide 14

With growing evidence of the positive health outcomes associated with bariatric surgeries, the procedure volume has grown substantially over the past 20 plus years. The procedures have also gone from being predominantly open procedures in the early 2000s to nearly entirely laparoscopic procedures as of 2014.

6/28/2018

Example Procedures Involving Surgical Stapling
15

25 years of leadership in MIP

Ethicon has evolved our portfolio to address changing surgical needs

As MIP surgery has developed and patient challenges have increased, we continue to focus our product innovation on **tissue-specific stapling that delivers superior outcomes.**

1991 - 2003	2005-2009	2011 - 2012	2014 - 2017
<p>EZ / ETS</p> 	<p>ECHELON</p> 	<p>ECHELON POWERED</p> 	
<p>Enabling minimally invasive approaches in thoracic, GYN and general surgery</p>	<p>Delivering enhanced compression in bariatric and colorectal surgery</p>	<p>Providing greater precision to address evolving bariatric, colorectal and thoracic procedures</p>	

◀ back
next ▶

Slide 15

Since the early 1990s, Ethicon has worked to develop numerous endocutters to address changing surgical needs, including surgical needs in bariatric procedures. In 2011, Ethicon introduced its first motor-powered endocutter — the ECHELON FLEX™ Powered ENDOPATH® Stapler. Ethicon's motor-powered endocutters dramatically reduce the force required to operate an endocutter, thereby minimizing unwanted movement of the device during procedures that could result in increased tissue trauma. In 2014, Ethicon introduced its ECHELON FLEX™ Stapler with Gripping Surface Technology (also known as GST), which greatly reduces tissue slippage while firing the stapler.

6/28/2018