Medtronic

Discover how intelligent stapling has come full circle.

Frequently asked questions (FAQ)

Device basics

What components make up the Signia™ circular stapler?

The device, the full name of which is the Signia™ circular stapler with Tri-Staple™ technology, consists of the core elements of the Signia™ stapling system (i.e., power handle and power shell) supplemented by Signia™ circular adapters and Tri-Staple™ 2.0 circular reloads.

What are the intended applications of the Signia™ circular stapler?

The Signia™ stapler, when used with the Signia™ circular adapter and Tri-Staple™ 2.0 circular single-use reloads, has applications throughout the alimentary tract for the creation of end-to-end, end-to-side, and side-to-side anastomoses in both open and laparoscopic surgeries. The intended purpose of the device is creation of anastomosis.

What are the CFN or SKU codes?

The SKUs specific to the Signia™ circular stapler are:

SIGCIRSTND	Signia™ circular adapter (standard length)
SIGCIRXL	Signia™ circular adapter (XL length)
SIGCIR28MT	Circular reload with Tri-Staple™ technology, 28 mm reload, medium/thick
SIGCIR28XT	Circular reload with Tri-Staple™ technology, 28 mm reload, extra thick
SIGCIR31MT	Circular reload with Tri-Staple™ technology, 31 mm reload, medium/thick
SIGCIR31XT	Circular reload with Tri-Staple™ technology, 31 mm reload, extra thick
SIGCIR33MT	Circular reload with Tri-Staple™ technology, 33 mm reload, medium/thick
SIGCIR33XT	Circular reload with Tri-Staple™ technology, 33 mm reload, extra thick

CFN SKU decoder:

- SIG designates the item as part of the Signia™ stapling system.
- CIR indicates the component is part of the Signia™ circular stapler.
- The STND or XL code indicates a Signia™ circular adapter that is of standard or XL length.
- A two-digit number (28, 31, or 33) indicates the lumen size of a circular reload in millimeters.
- A two-letter code (MT or XT) indicates the tissue thickness in which the circular reload is designed to staple, medium/thick or extra thick.

Will this device require a software update?

Yes, your Signia™ power handle will need to be updated to the software 40.x series. One benefit of the Signia™ system is its upgradeable software, which provides you with the latest versions as we make continuous improvements – without the need to purchase new hardware.

Key features

How does Adaptive Compression™ technology work?

Adaptive Compression™ technology is designed to give you the feedback you want throughout clamping and firing.[1,2] It works in conjunction with the Signia™ stapling system to:

- Determine the compression profile (i.e., proper speed and pressure) based on tissue properties and thickness[3]
- Use tissue-sensing technology to measure[1,2] and adapt[2,4] the amount of applied pressure
- Notify you when tissue relaxation occurs,[5] when the staple line is complete,[2] and when the knife blade engages[2]

With this built-in intelligence to control compression,[3] you may avoid overcompressing the tissue[†,‡,2,4,6] and prevent damage to the anastomosis.[‡,7]

Does the Signia™ circular stapler have a fixed anvil or a tilting anvil?

The Signia™ circular stapler uses a Tilt-Top™ anvil, which tilts to facilitate easier removal from the anastomotic site.[§,8,9]

Can this device be reprocessed like the Signia™ linear stapler?

Yes, the Signia™ circular adapter is reusable for 50 procedures – but note that it does have its own unique, specific cleaning and sterilization instructions. Refer to the instructions for use (IFU) or our cleaning and sterilization guide for more details.

What's the purpose of the irrigation channel?

The irrigation channel allows for integrated leak testing of the staple line.[10]

Dare to compare

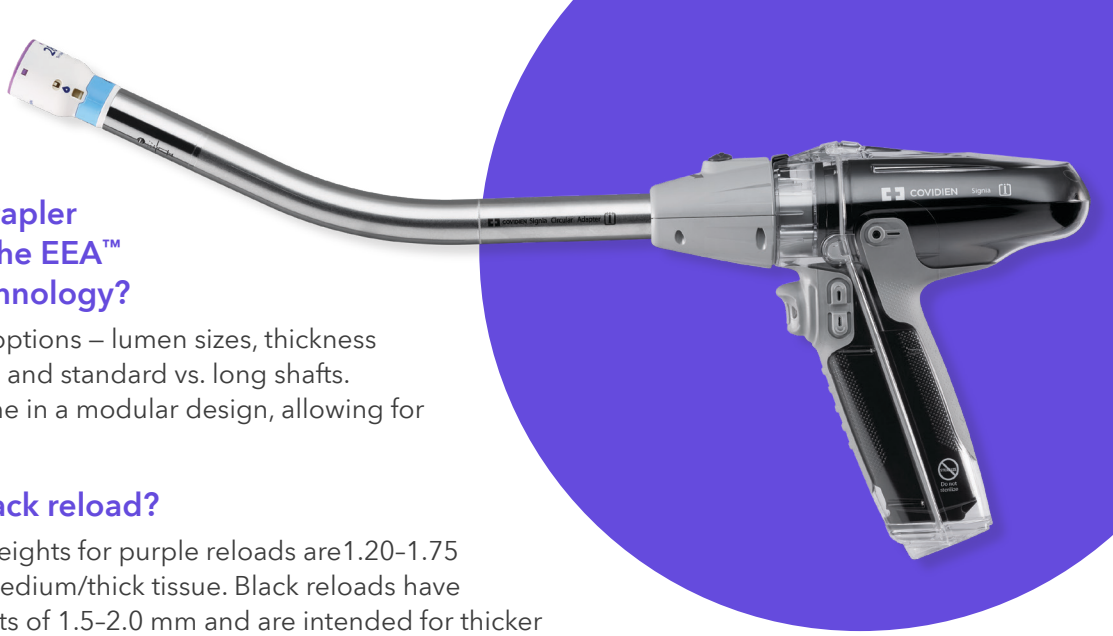
How is the Signia™ circular stapler different from the competition?

The Signia™ circular stapling system provides several functionalities you won't find with any other circular stapler.

- It's the **only** circular stapler with powered and intelligent clamping to control compression.[◊,4,11]
- It's the **only** circular stapler that allows the user to leak-test the staple line without removing the instrument from the lumen.[◊,¶,10]
- It's the **only** circular stapler that separates staple and cut functions,[◊,4,11] confirming staple line formation before engaging the knife.[4]

Plus, the system allows you to select from an array of device components to meet your needs, from reusable circular adapters to multiple single-use reload sizes to procedure-specific options.

† Compared to manual clamping circular staplers, $p < 0.001$, n = 5 for SIGCIR, n = 9 for TriEEA.
‡ Bench test results may not necessarily be indicative of clinical performance.
§ Compared to a circular stapler with a fixed anvil. Preclinical results may not correlate with clinical performance in humans. Based on removal force testing in an ex vivo canine model (n=14, $p = 0.000$).
◊ As of January 2024.
¶ For 28, 31, and 33 mm sizes only.



Does the Signia™ circular stapler provide the same sizes as the EEA™ stapler with Tri-Staple™ technology?

Yes, surgeons have all the same options – lumen sizes, thickness indications (i.e., purple vs. black), and standard vs. long shafts. However, these options now come in a modular design, allowing for SKU reduction.

Should I use a purple or black reload?

The approximate closed staple heights for purple reloads are1.20–1.75 mm, and they are intended for medium/thick tissue. Black reloads have approximate closed staple heights of 1.5–2.0 mm and are intended for thicker tissue. You should always use clinical judgement when selecting a reload.

Why does this device use Tri-Staple™ technology as opposed to 3-D staples or adjustable height staples?

Because of its proven benefits. More than 10 years of clinical data demonstrate that Tri-Staple™ technology allows greater perfusion,[†,12] provides superior performance in variable thicknesses,[‡,13-17] and generates less stress on tissue.[†,§,16,18] Reloads with Tri-Staple™ technology have sloped cartridge faces that apply a "gradual compression" profile as the Signia™ circular stapler monitors and adjusts pressure using Adaptive Compression™ technology.[2,4] By comparison, the Echelon Circular™* powered stapler has a manual clamp, so the user cannot control clamping forces any better than with a manual device.

Hearing your concerns

The Signia™ circular stapler seems more complicated than my current circular stapler.

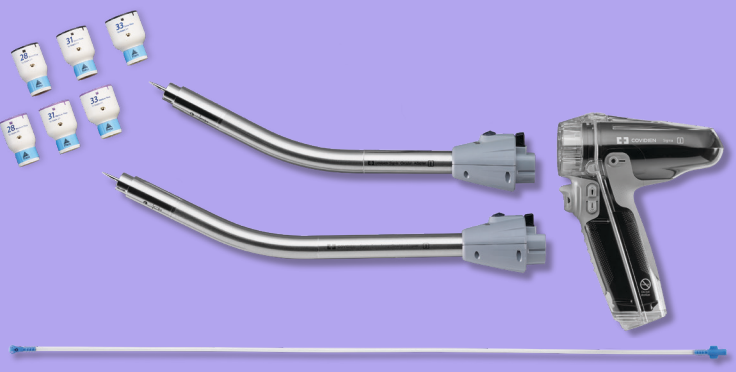
The design of the Signia™ circular stapler is intended to provide empowered anastomotic performance with features that actually simplify its use. The Signia™ stapler is an intelligent powered stapling platform,[19,20] and a key feature is the easy-to-read[◊,21] OLED display screen on the back of the power handle. This screen provides user-guided feedback to simplify set up and use[¶,21] of a versatile, modular design with a universal handle to address your stapling challenges. Whether you need a standard or XL shaft, or a medium or extra-thick tissue reload, all can be utilized on one platform. Also, the Signia™ power handle can be used for your linear stapling needs.

The Signia™ circular stapler seems more expensive. What is its economic value?

The Signia™ circular stapler's Adaptive Compression™ technology automatically measures[1,2] and adapts[2,4] the amount of applied pressure and speed during clamping based on tissue properties and thickness.[3] These features partner with Tri-Staple™ technology to provide more confidence in your staple lines[#,22,23] and greater leak reduction.[Δ,24] Reducing these postoperative complications can result in long-term cost savings – procedures where no anastomotic leaks occur are associated with a shorter length of stay and lower costs compared to procedures with leaks.[25] The Signia™ circular stapler also produces 88% less waste than the Echelon Circular™* powered stapler.[∞,26]

† Compared to flat-faced cartridges with single-height staples.
‡ Preclinical results may not correlate with clinical performance in humans. Bench test results may not necessarily be indicative of clinical performance. Compared to Ethicon Echelon Flex™*.
§ Compared to Echelon Flex™* green reloads analysis comparing different stapler designs, performance, and impact on tissues under compression using 2-D finite element analysis.
◊ 23 out of 23 surgeons surveyed agreed.
¶ 38 out of 38 surgeons surveyed agreed.
# Based on survey results from trained surgeons comparing CDH31P to SIGCIR31XT (n = 15, p = 0.008). Based on survey results from trained surgeons using Signia™ circular stapler. 16 out of 16 surgeons agreed.
Δ Preclinical results may not correlate with clinical performance in humans. Based on leak testing in an in vivo canine model comparing to Ethicon Circular™* powered stapler. (SIGCIR28MT: n = 18; CDH29P: n = 14; p = 0.028).
∞ Total waste based on device component weights and expected circulation ratio of each component on a per-procedure basis comparing CDH31P to the Signia™ circular stapler with a 31 mm Tri-Staple™ reload (n = 3, p < 0.001).

I can't get all the EEA™ staplers with Tri-Staple™ technology at my hospital. Do you have a full portfolio for the Signia™ circular stapler, and how do you supply it?



We offer two adapter length options and two Tri-Staple™ reload thickness options (medium/thick and extra thick) which come in three lumen sizes (28, 31, and 33 mm).

We manufacture the Signia™ circular stapler on a dedicated production line separate from the lines that manufacture EEA™ staplers with Tri-Staple™ technology. While there are shared elements between the two products (such as Tri-Staple™ technology), many of the necessary components are different, and the team plans to ensure enough capacity and available product before the release of units for sale.

What if something goes wrong during a procedure?

The Signia™ circular stapler has been designed with multiple safety features to minimize the risk of failure. In the rare event of a complication, the Signia™ system stores memory in both the handle and the circular adapter. If for some reason the handle experiences an error, a new handle can be attached to the adapter to continue with the procedure.

Why don't you offer a 29 mm lumen size?

We offer a selection of lumen sizes and adapter shaft lengths to provide you with the flexibility to address your clinical needs. A measurement of internal lumen diameter shows there is a difference of less than a millimeter between our 28 mm size and the Echelon Circular™* powered stapler's 29 mm size.

Risk statement: Potential complications may include but are not limited to unspecified infection, hypersensitivity/allergic reaction, fistula, failure to anastomose, hemorrhage/blood loss/bleeding, peritonitis, sepsis, hemothorax, bowel burn, ischemia, stenosis, foreign body in patient, perforation, bowel perforation, environmental contamination, gastro-intestinal obstruction/occlusion, tissue breakdown.

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3. Based on internal test report #RE00258180, Memo – Signia™ power EEA™ clamping. Oct 2023.
4. Based on report #RE00052291 rev R, Gen II Power Pack EEA™ stapler application software design document. Nov 2023.
5. Based on internal test report #RE00174815 rev 1, Software settings for monitoring tissue relaxation. Oct 2021.
6. Based on internal test report #RE00185349 rev.1, Tissue clamp benchmark vs. manual instruments (Tulip, DST™, & Ethicon™*). Nov 2023.
7. Kim JS, Park SH, Kim NS, et al. Compression automation of circular stapler for preventing compression injury on gastrointestinal anastomosis. *Int J Med Robot.* 2022;18(3):e2374.
8. Based on internal report #R2128-014-0, Anvil removal force. January 2011.
9. Based on internal memo RE00482367, PEEA/Tri-Staple™ EEA™ anvil equivalence memo. October 2023.
10. Based on internal report #RE00124842 rev C, Signia™ circular stapling system (PEEA) summative usability. Sept 2019.
11. Based on the Echelon Circular™* powered stapler 510(k) summary, no. K163523. April 18, 2017.
12. Based on internal test report #2128-002-2, Final analysis of staple-line vascularity using MicroCT. July 2015.
13. Based on internal test report #PCG-001, Tyvek pull-apart test comparing Echelon™* and Tri-Staple™ technology. March 2011.
14. Based on internal test report #PCG-004, Undercrimp comparisons in increasing pads of foam between Echelon™* and Tri-Staple™ technology. January 2012.
15. Based on internal test report #PCG-006, Staple formation comparison between Medtronic EGIA60AXT and Ethicon ECR60G in an ex-vivo tissue model. January 2012.
16. Based on internal test report #PCG-018, 2-D FEA of linear staplers. November 2012.
17. Based on internal test report #PCG-019, Comparative test of Endo GIA™ stapler using black reloads with Tri-Staple™ technology and Ethicon Echelon Flex™* black reloads. June 2014.
18. Based on internal test report #PCG-007 rev 1, Perfusion into Clamped Media. Sept. 2, 2011.
19. Based on internal report # RE00026887, Signia™ stapling system 510(k) report. 2016.
20. Based on internal test report #R2146-173-0, ASA verification testing with slow speed force limit evaluation. 2015.
21. Based on internal test report #RE00024826 rev D, Signia™ stapling system summative usability report. September 2016.
22. Based on internal test report #RE00394109 rev. 0, Distal tip motion and user feedback for circular staplers: EEA™ with Tri-Staple™, Signia™ circular with Tri-Staple™, and Ethicon™* Echelon™* circular powered stapler. October 2023.
23. Based on internal report #RE00480654, PEEA post-summative lab user questionnaire. October 2023.
24. Based on internal test report #RE00550119 rev.0, Comparative in vivo leak testing. January 2025.
25. Lee SW, Gregory D, Cool CL. Clinical and economic burden of colorectal and bariatric anastomotic leaks. *Surg Endosc.* 2020;34(10):4374–4381.
26. Based on internal test report #RE00421208 rev. 0, PCG-055: Per procedure waste. January 4, 2023.

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