Evaluations: Surgical Sutures, Focusing on Medtronic Sutures and Needles

Biosyn, Caprosyn, Chromic Gut, Maxon, Monosof, Novafil, Plain Gut, Polysorb, Sofsilk, Surgilon, Surgipro II, Ti-Cron, P-12 Reverse Cutting Needles, V-20 Taper Point Needles

A Report Excerpted from *Health Devices*
November 2017

Also Includes Ratings and Purchasing Advice for:

Ethicon Sutures and Needles: Chromic Gut, Ethibond Excel, Ethilon, Monocryl, Nurolon, PDS II, Perma-Hand Silk, Plain Gut, Prolene, Pronova, Vicryl, PS-2 Reverse Cutting Needles, SH Taper Point Needles

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Evaluations: Surgical Sutures, Focusing on Medtronic Sutures and Needles

A Report Excerpted from *Health Devices*
November 2017

This report focuses on our Evaluations of Medtronic sutures. For perspective, it also includes a summary of our findings for the Ethicon sutures we also evaluated. That summary information is presented below and on the next four pages. Our detailed Evaluation results for the Medtronic products begin on page 8.

General note: We focused our testing on performance and workflow. We did not specifically evaluate the products in our other customary categories—safety, patient experience, interoperability, and user experience. Those topics are either not relevant to our testing or are covered elsewhere.

RATINGS: ETHICON

Product Line	Rating	Performance	Workflow
Chromic Gut	★★★★☆	Excellent	Good
Ethibond Excel	★★☆☆☆	Poor	Good
Ethilon	★★★☆☆	Good	Good
Monocryl	★★★☆☆	Good	Good
Nurolon	★★★☆☆	Good	Good
PDS II	★★★☆☆	Good	Good
Perma-Hand Silk	★★★☆☆	Good	Good
Plain Gut	★★★☆☆	Good	Good
Prolene	★★★☆☆	Good	Good
Pronova	★★★☆☆	Good	Good
Vicryl	★★★☆☆	Good	Good
PS-2 Reverse Cutting Needle	★★★★☆	Excellent	Good
SH Taper Point Needle	★★★☆☆	Good	Good

RATINGS: MEDTRONIC

Product Line	Rating	Performance	Workflow
Biosyn	★★★☆☆	Good	Good
Caprosyn	★★★☆☆	Good	Good
Chromic Gut	★★★☆☆	Good	Good
Maxon	★★★★☆	Excellent	Good
Monosof	★★★☆☆	Good	Good
Novafil	★★★☆☆	Good	Good
Plain Gut	★★★☆☆	Good	Good
Polysorb	★★★★☆	Excellent	Good
Sofsilk	★★★☆☆	Good	Good
Surgilon	★★☆☆☆	Poor	Good
Surgipro II	★★★☆☆	Good	Good
Ti-Cron	★★★☆☆	Good	Good
P-12 Reverse Cutting Needle	★★★☆☆	Good	Good
V-20 Taper Point Needle	★★★☆☆	Good	Good

Summary of Findings: Surgical Sutures

Ethicon Chromic Gut and Plain Gut—Short/Mid-Term Absorbable, Natural, Monofilament Sutures

Chromic Gut

Plain Gut

Performance

- **Chromic Gut—Excellent.** Chromic Gut sutures have been evaluated against ECRI Institute's performance criteria and found to meet all requirements, with a major advantage in tensile breaking force.
- **Plain Gut—Good.** Plain Gut sutures have been evaluated against ECRI Institute's performance criteria and found to meet all requirements.

Workflow—Good. Chromic Gut and Plain Gut sutures have been evaluated against ECRI Institute's workflow criteria and found to meet all requirements.

Ethicon Ethibond Excel and Nurolon—Nonabsorbable, Synthetic, Braided Sutures

Ethibond Excel

Nurolon

Performance

- **Ethibond Excel—Poor.** Ethibond Excel sutures have been evaluated against ECRI Institute's performance criteria and found to meet most requirements; however, they failed our knot security test.
- **Nurolon—Good.** Nurolon sutures have been evaluated against ECRI Institute's performance criteria and found to meet all requirements.

Workflow—Good. Both Ethibond Excel and Nurolon sutures met all standard packaging requirements and received a minor advantage for demonstrating minimal out-of-package memory.

Ethicon Ethilon, Prolene, and Pronova—Nonabsorbable, Synthetic, Monofilament Sutures

Ethilon

Prolene

Pronova

Performance—Good. Ethilon, Prolene, and Pronova sutures have been evaluated against ECRI Institute's performance criteria and found to meet all requirements.

Workflow—Good. Likewise, the sutures have been evaluated against ECRI Institute's workflow criteria and found to meet all requirements.

Ethicon Monocryl—Short-Term Absorbable, Synthetic, Monofilament Sutures

Performance—Good. Monocryl sutures have been evaluated against ECRI Institute's performance criteria and found to meet all requirements.

Workflow—Good. These sutures have been evaluated against ECRI Institute's workflow criteria and found to meet

all requirements, with a minor advantage for demonstrating minimal out-of-package memory.

Ethicon PDS II—Long-Term Absorbable, Synthetic, Monofilament Sutures

Performance—Good. PDS II sutures have been evaluated against ECRI Institute's performance criteria and found to meet all requirements.

Workflow—Good. PDS II sutures met all standard packaging requirements and received a minor advantage for demonstrating minimal out-of-package memory.

Ethicon Perma-Hand Silk—Nonabsorbable, Natural, Braided Sutures

Performance—Good. Perma-Hand Silk sutures have been evaluated against ECRI Institute's performance criteria and found to meet all requirements.

Workflow—Good. Perma-Hand Silk sutures met all standard packaging requirements and received a minor advantage for demonstrating minimal out-of-package memory.

Ethicon PS-2 Prime Reverse Cutting and SH Taper Point Suture Needles

PS-2 Prime Reverse Cutting

SH Taper Point

Performance

- **PS-2 Prime Reverse Cutting—Excellent**. Ethicon's prime reverse cutting needle has been evaluated against ECRI Institute's performance criteria and found to meet all requirements, with a major advantage in needle sharpness.
- **SH Taper Point—Good.** Ethicon's taper point needle has been evaluated against ECRI Institute's performance criteria and found to meet all requirements.

Workflow—Good. Ethicon's prime reverse cutting and taper point suture needles have been evaluated against ECRI Institute's workflow criteria and found to meet all requirements regarding proper package labeling, which allows easy identification of the package contents.

Ethicon Vicryl—Mid-Term Absorbable, Synthetic, Braided Sutures

Performance—Good. Vicryl sutures have been evaluated against ECRI Institute's performance criteria and found to meet all requirements.

Workflow—Good. Vicryl sutures met all standard packaging requirements and received a minor advantage for demonstrating minimal out-of-package memory.

Ethicon PS-2 Prime Reverse Cutting and SH Taper Point Suture Needles

PS-2 Prime Reverse Cutting

SH Taper Point

Performance

- **PS-2 Prime Reverse Cutting—Excellent.** Ethicon's prime reverse cutting needle has been evaluated against ECRI Institute's performance criteria and found to meet all requirements, with a major advantage in needle sharpness.

- **SH Taper Point—Good.** Ethicon's taper point needle has been evaluated against ECRI Institute's performance criteria and found to meet all requirements.

Workflow—Good. Ethicon's prime reverse cutting and taper point suture needles have been evaluated against ECRI Institute's workflow criteria and found to meet all requirements regarding proper package labeling, which allows easy identification of the package contents.

Medtronic Biosyn and Caprosyn—Short/Mid-Term Absorbable, Synthetic, Monofilament Sutures

Biosyn

Caprosyn

Performance—Good. Biosyn and Caprosyn sutures have been evaluated against ECRI Institute's performance criteria and found to meet all requirements.

Workflow—Good. Biosyn and Caprosyn sutures have been evaluated against ECRI Institute's workflow criteria and found to meet all requirements.

Medtronic Chromic Gut and Plain Gut—Short/Mid-Term Absorbable, Natural, Monofilament Sutures

Chromic Gut

Plain Gut

Performance—Good. Chromic Gut and Plain Gut sutures have been evaluated against ECRI Institute's performance criteria and found to meet all requirements.

Workflow—Good. Chromic Gut and Plain Gut sutures have been evaluated against ECRI Institute's workflow criteria and found to meet all requirements.

Medtronic Maxon—Long-Term Absorbable, Synthetic, Monofilament Sutures

Performance—Excellent. Maxon sutures have been evaluated against ECRI Institute's performance criteria and found to meet all requirements, with a major advantage in tensile breaking force.

Workflow—Good. Maxon sutures have been evaluated against ECRI Institute's workflow criteria and found to meet all requirements.

Medtronic Monosof, Novafil, and Surgipro II—Nonabsorbable, Synthetic, Monofilament Sutures

Monosof

Novafil

Surgipro II

Performance—Good. Monosof, Novafil, and Surgipro II sutures have been evaluated against ECRI Institute's performance criteria and found to meet all requirements. Companion product lines Dermalon, Surgipro, and Vascufil should be expected to perform similarly.

Workflow—Good. Monosof, Novafil, and Surgipro II sutures have been evaluated against ECRI Institute's workflow criteria and found to meet all requirements. Companion product lines

Dermalon, Surgipro, and Vascufil should be expected to perform similarly.

Medtronic Polysorb—Mid-Term Absorbable, Synthetic, Braided Sutures

Performance—Excellent. Polysorb sutures have been evaluated against ECRI Institute's performance criteria and found to meet all requirements, with a major advantage in tensile breaking force.

Workflow—Good. Polysorb sutures have been evaluated against ECRI Institute's workflow criteria and found to meet all requirements.

Medtronic Sofsilk—Nonabsorbable, Natural, Braided Sutures

Performance—Good. Sofsilk sutures have been evaluated against ECRI Institute's performance criteria and found to meet all requirements.

Workflow—Good. Sofsilk sutures met all standard packaging requirements and received a minor advantage for demonstrating minimal out-of-package memory.

Medtronic Surgilon and Ti-Cron—Nonabsorbable, Synthetic, Braided Sutures

Surgilon

Ti-Cron

Performance

- **Surgilon—Poor.** Surgilon sutures have been evaluated against ECRI Institute's performance criteria and found to meet most requirements; however, they failed our knot security test.
- **Ti-Cron—Good.** Ti-Cron sutures have been evaluated against ECRI Institute's performance criteria and found to meet all requirements.

Workflow—Good. Both Surgilon and Ti-Cron sutures met all standard packaging requirements and received a minor advantage for demonstrating minimal out-of-package memory.

Medtronic P-12 Premium Reverse Cutting and V-20 Taper Point Suture Needles

P-12 Premium Reverse Cutting

V-20 Taper Point

Performance—Good. Medtronic's premium reverse cutting and taper point needles have been evaluated against ECRI Institute's performance criteria and found to meet all requirements.

Workflow—Good. Medtronic's premium reverse cutting and taper point suture needles have been evaluated against ECRI Institute's workflow criteria and found to meet all requirements regarding proper package labeling, which allows easy identification of the package contents.

Medtronic Biosyn and Caprosyn—Short/Mid-Term Absorbable, Synthetic, Monofilament Sutures

Ratings

BIOSYN

CAPROSYN

Product Details

- Name: Biosyn and Caprosyn
- Characteristics:
  - Biosyn: Absorbable (short/mid-term) monofilament, glycomer 631
  - Caprosyn: Absorbable (short/mid-term) monofilament, Polyglytone
- Date evaluated: July 2017
- Manufacturer: Medtronic Inc. [101809]

Product Description

1. These sutures are used to join together the opposing edges of a wound or incision. Typical uses:
   a) Biosyn—mid-term
      (1) Plastic surgery
      (2) Subcuticular skin closure
      (3) Ophthalmic surgery
   b) Caprosyn—short-term
      (1) Plastic surgery
      (2) Subcuticular skin closure
      (3) OB-GYN
      (4) Urology
      (5) Ear, nose, and throat
2. Major product components:
   a) Synthetic thread of varying lengths and diameters that holds wound or incision edges together for healing purposes.
   b) A suture needle to penetrate tissue and lay the suture material in its wake. The needle also facilitates knot-tying.
3. These products are typically used in the following locations:
   a) Operating rooms
   b) Emergency/trauma departments
   c) Doctors' offices

See the Evaluation Background on surgical sutures for a list of applicable specialties.

Significant Findings

We performed a variety of tests on this product, including physical testing, a review of product literature/specifications, and asking users about their experience with the device. We focused our testing on performance and workflow. We did not specifically evaluate the sutures in our other customary categories—safety, patient experience, interoperability, or user experience. Those topics either were not relevant to our testing or were covered elsewhere. For example, safety-related characteristics such as strength, knot retention, and breaking strength retention (BSR) were addressed in our performance testing.

Note: Our in vitro test method was designed to assess the BSR of the absorbable suture product lines, compared to their out-of-package knotted breaking force. We comment on how our results correlate to the manufacturer's BSR claims in the product's instructions for use, which (1) are based on in vivo models and (2) in some cases are reported in comparison to

USP minimums instead of measured initial breaking force. An in vivo model may offer more clinically relevant performance in terms of pH maintenance (i.e., some absorbable sutures tend to release acid as they degrade—this would be neutralized in vivo, but in vitro requires regular buffer pH testing and exchange), as well as any contributions to suture degradation via enzymatic interaction and mechanical tension from the patient as he or she moves. Therefore, because of the differences between the manufacturers' in vivo models and our methods, their claims may not be directly comparable to our results.

For more details on our testing, see the ECRI Institute's Testing section of our Evaluation Background on this technology.

PERFORMANCE—GOOD

Biosyn and Caprosyn sutures have been evaluated against ECRI Institute's performance criteria and found to meet all requirements.

WORKFLOW—GOOD

Biosyn and Caprosyn sutures have been evaluated against ECRI Institute's workflow criteria and found to meet all requirements.

FINDINGS: MEDTRONIC BIOSYN AND CAPROSYN—SHORT/MID-TERM ABSORBABLE, SYNTHETIC, MONOFILAMENT SUTURES

	Biosyn			Caprosyn		
Size	3/0	4/0	5/0	3/0	4/0	5/0
Performance						
Mean breaking force (N)	28.2	15.3	9.0	24.9	14.1	8.4
Standard deviation	2.0	2.4	1.0	2.3	0.9	0.6
Compared to Ethicon	NSD	NSD	NSD	NSD	-8%	-13%
Mean diameter (mm)	NM	0.222	0.173	NM	0.233	0.168
Standard deviation	NM	0.006	0.003	NM	0.002	0.003
Mean area (mm^2)	NM	0.039	0.024	NM	0.043	0.022
Compared to Ethicon*	NM	-3%	+2%	NM	+1%	-1%
No. of knots slipped before breaking (out of 10)	0	0	0	0	0	0
Mean peak force before breaking or slipping (N)	23.2	16.5	10.1	33.1	19.2	10.2
Standard deviation	5.7	2.9	2.9	4.7	2.1	0.9
Compared to Ethicon	NSD	NSD	NSD	+33%	NSD	NSD
BSR: breaking force @ 3 days (N)	NA	NA	NA	19.9	12.3	6.8
Standard deviation	NA	NA	NA	2.2	0.4	0.4
% Original breaking force	NA	NA	NA	79.6%	87.5%	81.3%
Compared to Ethicon*	NA	NA	NA	-14%	-2%	+3%
BSR: breaking force @ 7 days (N)	21.7	10.6	7.0	17.4	7.9	3.4
Standard deviation	1.8	1.9	1.2	0.8	0.7	0.4
% Original breaking force	77.2%	69.6%	78.7%	69.8%	56.4%	40.1%
Compared to Ethicon*	+89%	+26%	+46%	+51%	-6%	-29%
BSR: breaking force @ 14 days (N)	11.0	4.7	3.6	NA	NA	NA
Standard deviation	1.1	0.8	1.2	NA	NA	NA
% Original breaking force	39.0%	30.0%	40.5%	NA	NA	NA
Compared to Ethicon*	NA	NA	NA	NA	NA	NA
BSR: breaking force @ 21 days (N)	7.1	2.1	2.0	NA	NA	NA
Standard deviation	0.4	0.2	0.2	NA	NA	NA
% Original breaking force	25.1%	13.5%	22.2%	NA	NA	NA
Compared to Ethicon*	NA	NA	NA	NA	NA	NA
Workflow						
Out-of-package memory**	44.7%			33.3%		
Standard deviation	2.5%			3.8%		

NSD—No statistical difference with competing product.
NM—Not measured, because either (1) no significant differences in breaking force were identified in competing products, in which case we did not assess suture diameter consistency, or (2) not enough product was provided to us.
BSR—Breaking strength retention.
NA—Not applicable.
* Statistical significance was not calculated due to sample size.
** Higher numbers are considered better: A suture with zero memory would unfold completely and thus have a result of 100%.

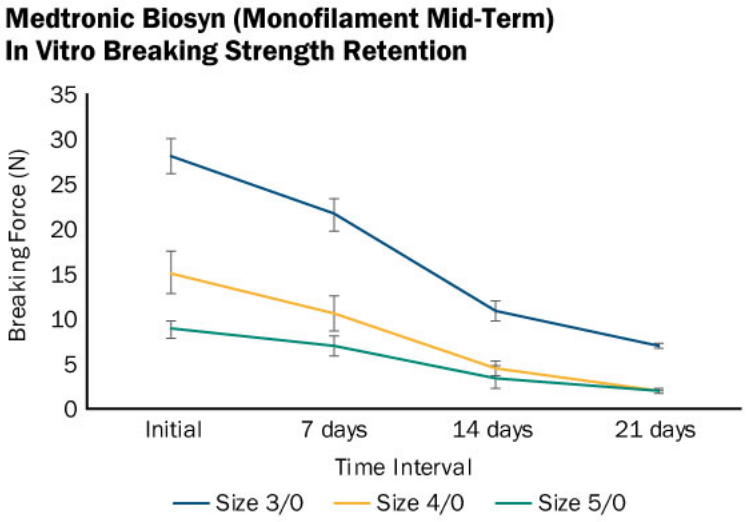

Figure 1. Medtronic Biosyn's tensile breaking force performance in sizes 3/0, 4/0, and 5/0 over a three-week absorption period.

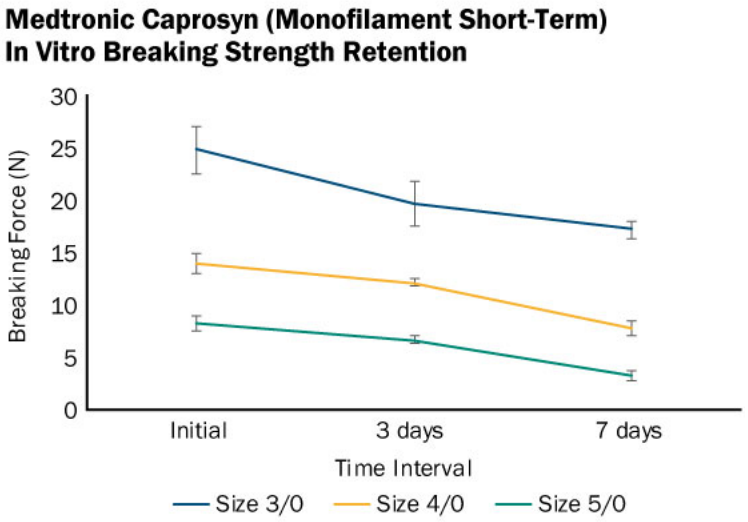

Figure 2. Medtronic Caprosyn's tensile breaking force performance in sizes 3/0, 4/0, and 5/0 over a one-week absorption period.

PURCHASE COST FOR MEDTRONIC BIOSYN AND CAPROSYN SUTURES

ECRI Institute analyzed detailed spend data for our member hospitals to determine (1) the average total number of sutures purchased annually by hospitals in each size cohort (based on number of beds) and (2) the percentage of total suture spend represented by this suture category. These figures were used to estimate an average spend for this product line.

Hospital Size (No. of Beds)	Average Annual Sutures Purchased, Total	Absorbable Short/Mid-Term Synthetic Monofilament Sutures as a Percentage of Total Sutures Purchased	Estimated Annual Spend
Small (<100)	500	10%	$3,100
Medium (100-600)	2,500	9%	$10,000
Large (>600)	10,000	9%	$51,000

DISCUSSION OF KEY MANUFACTURER CLAIMS

Medtronic Claim	Category	ECRI Institute Perspective
Biosyn		
Excellent strength out of package for maximum wound support over the critical wound healing period.	Performance	**ECRI Institute agrees.** Biosyn tensile breaking force is above the thresholds set by USP and is comparable to Ethicon's competing product.
Excellent knot security for wound closure.	Performance	**ECRI Institute agrees.** No Biosyn knots failed by slip.
Minimal memory for ease of handling.	Performance	**ECRI Institute does not agree.** Biosyn demonstrated only 45% total length when removed from package and would require clinicians to "remove memory" before use. It does have less out-of-package memory than Caprosyn, which demonstrates 33% total length when removed.
In vivo, demonstrates 75% USP minimum breaking force at 14 days and 40% at 21 days.	Performance	**ECRI Institute cannot confirm.** Our in vitro results somewhat align with Medtronic's in vivo absorption data. However, because of variations between our testing and how Medtronic derives its data, we cannot directly compare our findings with theirs.* As a synthetic absorbable suture, the strand degrades via a hydrolysis reaction. Our in vitro results indicate that at 14 and 21 days the strand's breaking strength retention is at approximately 56% and 31%, respectively. This is similar to the Medtronic data. As noted, however, the differences between our testing and Medtronic's mean the results can be highly variable.
Caprosyn		
Excellent pliability for ease of handling and tying.	Performance	**Unknown.** We have no data or information to support an opinion. ECRI Institute did not quantify strand pliability; however, Caprosyn was not difficult to manipulate for knot-tying purposes.
Structure maintains integrity after multiple passes.	Performance	**Unknown.** We have no data or information to support an opinion. Strand fray resistance was not part of ECRI Institute's Evaluation.
In vivo, demonstrates 50-60% USP minimum breaking force at 5 days and 20-30% at 10 days.	Performance	**ECRI Institute cannot confirm.** As noted in our comments on Biosyn, because of variations between our testing and how Medtronic derives its data, we cannot directly compare our findings with theirs.* As a synthetic absorbable suture, the strand degrades via a hydrolysis reaction. Our in vitro results indicate that at three and seven days the strand's breaking strength retention compared to USP minimum breaking force is at approximately 116% and 79%, respectively. This trend does not align with the Medtronic data, but the differences between our testing and Medtronic's mean the results can be highly variable.

* Our in vitro test method was designed to assess the breaking strength retention (BSR) of the absorbable suture product lines, compared to their out-of-package knotted breaking force. We comment on how our results correlate to the manufacturer's BSR claims in the product's instructions for use, which (1) are based on in vivo models and (2) in some cases are reported in comparison to USP minimums instead of measured initial breaking force. An in vivo model may offer more clinically relevant performance in terms of pH maintenance (i.e., some absorbable sutures tend to release acid as they degrade—this would be neutralized in vivo, but in vitro requires regular buffer pH testing and exchange), as well as any contributions to suture degradation via enzymatic interaction and mechanical tension from the patient as he or she moves.

RECALLS AND HAZARDS

The following data is based on *Health Devices Alerts* records from January 2010 through May 2017.

HDA Record	Priority	Date of Last Update	Category
A28533: Medtronic—Various Suture Products: Inner Packaging May Have an Incomplete Seal, Potentially leading to Premature Degradation of Suture Material	Normal	May 11, 2017	Sterility

Medtronic Chromic Gut and Plain Gut—Short/Mid-Term Absorbable, Natural, Monofilament Sutures

Ratings

CHROMIC GUT

PLAIN GUT

Product Details

- Name: Chromic Gut and Plain Gut
- Characteristics: Absorbable (short/mid-term) monofilament, collagen
- Date evaluated: July 2017
- Manufacturer: Medtronic Inc. [101809]

Product Description

1. These sutures are used to join together the opposing edges of a wound or incision. Typical uses:
   a) Chromic Gut (Note: "Chromic Gut" implies that the collagen strands are processed with a chromium-salt solution in order to provide a greater resistance to absorption, yielding higher tensile strength for a longer period of time):
      (1) General surgery
      (2) OB-GYN
      (3) Ophthalmology
   b) Plain Gut
      (1) Skin closure, subcuticular skin closure
      (2) Ophthalmic surgery
2. Major product components:
   a) Natural thread of varying lengths and diameters that join wound or incision edges together for healing purposes.
      (1) For the purposes of this Evaluation, a gut suture is considered as "monofilament"; however, it is manufactured as twisted strands of collagen. The final product appears more similar to typical monofilament sutures than to braided.
      (2) Natural absorbable sutures degrade as a result of the patient's immune system response, while synthetic absorbable sutures degrade as a result of hydrolysis. As such, ECRI Institute could only replicate an absorption environment for synthetic absorbable sutures and cannot comment on the tensile strength over time for a natural absorbable suture.
   b) A suture needle to penetrate tissue and lay the suture material in its wake. The needle also facilitates knot-tying.
3. These products are typically used in the following locations:
   a) Operating rooms
   b) Emergency/trauma departments
   c) Doctors' offices

See the Evaluation Background on surgical sutures for a list of applicable specialties.

Significant Findings

We performed a variety of tests on this product, including physical testing, a review of product literature/specifications, and asking users for feedback on statistically significant findings. We focused our testing on performance and workflow. We did not specifically evaluate the sutures in our other customary categories—safety, patient experience, interoperability, or user experience. Those topics either were not relevant to our testing

or were covered elsewhere. For example, safety-related characteristics such as strength and knot retention were addressed in our performance testing.

For more details, see the ECRI Institute's Testing section of our Evaluation Background on this technology.

PERFORMANCE—GOOD

Chromic Gut and Plain Gut sutures have been evaluated against ECRI Institute's performance criteria and found to meet all requirements.

WORKFLOW—GOOD

Chromic Gut and Plain Gut sutures have been evaluated against ECRI Institute's workflow criteria and found to meet all requirements.

Recalls and Hazards

A search of ECRI Institute's *Health Devices Alerts* database for Medtronic's "Plain Gut" or "Chromic Gut" from January 2010 through May 2017 found no relevant records.

FINDINGS: MEDTRONIC CHROMIC GUT AND PLAIN GUT—SHORT/MID-TERM ABSORBABLE, NATURAL, MONOFILAMENT SUTURES

	Chromic Gut			Plain Gut	
Size	2/0	3/0	4/0	3/0	5/0*
Performance					
Mean breaking force (N)	22.8	14.2	8.3	15.0	3.7
Standard deviation	1.8	1.7	0.6	1.5	0.8
Compared to Ethicon	-16%	-22%	-25%	-18%	NSD
Mean diameter (mm)	0.396	0.318	0.243	0.320	NM
Standard deviation	0.004	0.003	0.004	0.004	NM
Mean area (mm^2)	0.123	0.079	0.046	0.080	NM
Compared to Ethicon**	+1%	+1%	-2%	+2%	NM
No. of knots slipped before breaking (out of 10)	0	0	0	0	0
Mean peak force before breaking or slipping (N)	23.9	15.3	8.4	15.0	3.9
Standard deviation	2.3	1.1	0.7	1.4	0.6
Compared to Ethicon	NSD	NSD	-11%	NSD	+30%
Workflow					
Out-of-package memory***	44.1%			36.4%	
Standard deviation	2.2%			1.7%	

Note: We were not able to test the breaking strength retention of natural absorbable sutures. Synthetic absorbable sutures are absorbed by hydrolysis, which we can simulate in lab testing. Natural absorbable suture are absorbed by an enzymatic process, which we can't simulate in the lab.
NSD—No statistical difference with competing product.
NM—Not measured, because either (1) no significant differences in breaking force were identified in competing products, in which case we did not assess suture diameter consistency, or (2) not enough product was provided to us.
* Medtronic Plain Gut was compared to Ethicon "Fast Absorbing Plain Gut" for this size.
** Statistical significance was not calculated due to sample size.
*** Higher numbers are considered better: A suture with zero memory would unfold completely and thus have a result of 100%.

PURCHASE COST FOR MEDTRONIC CHROMIC GUT AND PLAIN GUT SUTURES

ECRI Institute analyzed detailed spend data for our member hospitals to determine (1) the average total number of sutures purchased annually by hospitals in each size cohort (based on number of beds) and (2) the percentage of total suture spend represented by this suture category. These figures were used to estimate an average spend for this product line.

Hospital Size (No. of Beds)	Average Annual Sutures Purchased, Total	Absorbable Natural Monofilament Sutures as a Percentage of Total Sutures Purchased	Estimated Annual Spend
Small (<100)	500	5%	$1,700
Medium (100-600)	2,500	6%	$13,000
Large (>600)	10,000	5%	$41,000

DISCUSSION OF KEY MANUFACTURER CLAIMS

Medtronic Claim	Category	ECRI Institute Perspective
Chromic Gut		
Purity of collagen for optimal tensile strength and in-vivo performance.	Performance	**Unknown.** We have no data or information to support an opinion. ECRI Institute did not assess the purity of the collagen used to construct Chromic Gut sutures, nor did we assess in vivo performance of natural absorbable sutures. Chromic Gut tensile breaking force is above the thresholds set by USP.
Surface smoothness to facilitate knot run-down and knot strength.	Performance	**Unknown.** We have no data or information to support an opinion. While Chromic Gut met ECRI Institute's requirements for knot slip without failure, we cannot conclude that this is from the strand's smoother surface.
Predictable strength and uniform in-vivo absorption.	Performance	**Unknown.** We have no data or information to support an opinion. Chromic Gut tensile breaking force met the thresholds set by USP with standard deviation similar to Ethicon's competing product line; however, we did not assess in vivo performance of natural absorbable sutures.
Plain Gut		
Purity of collagen for optimal tensile strength and in-vivo performance.	Performance	**Unknown.** We have no data or information to support an opinion. ECRI Institute did not assess the purity of the collagen used to construct Plain Gut sutures, nor did we assess in vivo performance of natural absorbable sutures. Plain Gut tensile breaking force is above the thresholds set by USP.
Surface smoothness to facilitate knot run-down and knot strength.	Performance	**Unknown.** We have no data or information to support an opinion. While Plain Gut met ECRI Institute's requirements for knot slip without failure, we cannot conclude that this is from the strand's smoother surface.

Medtronic Maxon—Long-Term Absorbable, Synthetic, Monofilament Sutures

Rating

Product Details

- Name: Maxon
- Characteristics: Absorbable (long-term) monofilament, polyglyconate
- Date evaluated: July 2017
- Manufacturer: Medtronic Inc. [101809]

Product Description

1. These sutures are used to join together the opposing edges of a wound or incision. Typical uses:
    a) Abdominal wall closure
    b) Oncology
    c) OB-GYN
    d) Orthopedics
2. Major product components:
    a) Synthetic thread of varying lengths and diameters that joins wound or incision edges together for healing purposes.
    b) A suture needle to penetrate tissue and lay the suture material in its wake. The needle also facilitates knot-tying.
3. These products are typically used in the following locations:
    a) Operating rooms
    b) Emergency/trauma departments
    c) Doctors' offices

See the Evaluation Background on surgical sutures for a list of applicable specialties.

Significant Findings

We performed a variety of tests on this product, including physical testing, a review of product literature/specifications, and asking users about their experience with the device. We focused our testing on performance and workflow. We did not specifically evaluate the sutures in our other customary categories—safety, patient experience, interoperability, or user experience. Those topics either were not relevant to our testing or were covered elsewhere. For example, safety-related characteristics such as strength, knot retention, and breaking strength retention (BSR) were addressed in our performance testing.

Note: Our in vitro test method was designed to assess the BSR of the absorbable suture product lines, compared to their out-of-package knotted breaking force. We comment on how our results correlate to the manufacturer's BSR claims in the product's instructions for use, which (1) are based on in vivo models and (2) in some cases are reported in comparison to USP minimums instead of measured initial breaking force. An in vivo model may offer more clinically relevant performance in terms of pH maintenance (i.e., some absorbable sutures tend to release acid as they degrade—this would be neutralized in vivo, but in vitro requires regular buffer pH testing and exchange), as well as any contributions to suture degradation via enzymatic interaction and mechanical tension from the patient as he or she moves. Therefore, because of the differences between the manufacturers' in vivo models and our methods, their claims may not be directly comparable to our results.

For more details on our testing, see the ECRI Institute's Testing section of our Evaluation Background on this technology.

PERFORMANCE—EXCELLENT

Maxon sutures have been evaluated against ECRI Institute's performance criteria and found to meet all requirements, with a major advantage in tensile breaking force.

FINDINGS: MEDTRONIC MAXON—LONG-TERM ABSORBABLE, SYNTHETIC, MONOFILAMENT SUTURES

Size	1	0	3/0
Performance			
Mean breaking force (N)	84.8	77.2	31.4
Standard deviation	11.3	5.4	5.8
Compared to Ethicon	+49%	+76%	+32%
Mean diameter (mm)	0.543	0.466	0.304
Standard deviation	0.005	0.002	0.006
Mean area (mm^2)	0.232	0.171	0.073
Compared to Ethicon*	+2%	0%	-3%
No. of knots slipped before breaking (out of 10)	0	0	0
Mean peak force before breaking or slipping (N)	100.0	73.7	34.8
Standard deviation	19.1	14.7	9.5
Compared to Ethicon	+55%	+54%	+48%
BSR: breaking force @ 7 days (N)	84.4	72.8	25.8
Standard deviation	27.1	8.8	3.0
% Original breaking force	99.6%	94.3%	82.2%
Compared to Ethicon*	+52%	+73%	+6%
BSR: breaking force @ 14 days (N)	90.4	71.5	23.8
Standard deviation	8.3	5.3	4.1
% Original breaking force	106.6%	92.7%	75.8%
Compared to Ethicon*	+52%	+75%	+1%
BSR: breaking force @ 21 days (N)	63.0	67.1	18.2
Standard deviation	3.2	3.5	1.8
% Original breaking force	74.2%	87.0%	58.0%
Compared to Ethicon*	+12%	+66%	-20%
BSR: breaking force @ 28 days (N)	47.7	45.0	12.6
Standard deviation	4.9	1.2	1.8
% Original breaking force	56.2%	58.3%	40.3%
Compared to Ethicon*	-8%	+18%	-44%
BSR: breaking force @ 35 days (N)	31.6	23.7	7.1
Standard deviation	1.2	1.2	0.8
% Original breaking force	37.2%	30.7%	22.7%
Compared to Ethicon*	-35%	-26%	-65%
BSR: breaking force @ 42 days (N)	14.4	16.5	5.1
Standard deviation	0.9	1.2	0.5
% Original breaking force	17.0%	21.4%	16.2%
Compared to Ethicon*	-63%	-38%	-72%
Workflow			
Out-of-package memory**	40.0%		
Standard deviation	2.5%		

BSR—Breaking strength retention.
* Statistical significance was not calculated due to sample size.
** Higher numbers are considered better: A suture with zero memory would unfold completely and thus have a result of 100%.

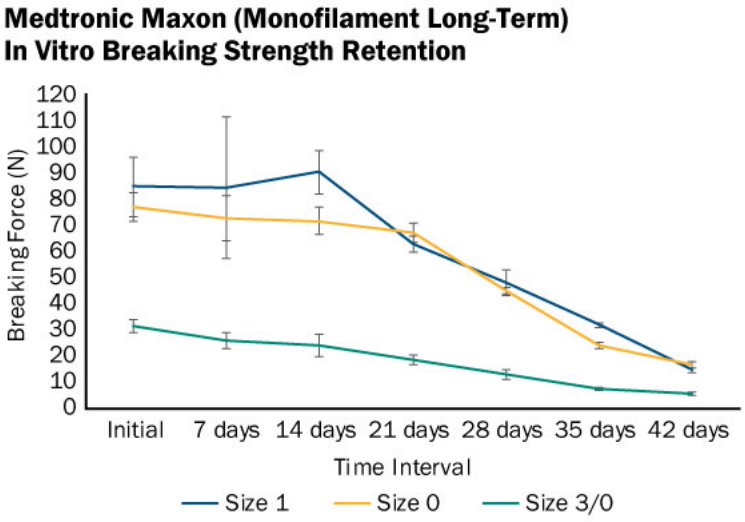

Figure 3. Medtronic Maxon's tensile breaking force performance in sizes 1, 0, and 3/0 over a six-week absorption period.

Major Advantage

1. Superior initial tensile breaking force:

   a) The mean knotted tensile breaking force of all three Maxon sizes tested was at least 20% higher than the competing Ethicon product line, PDS II. The cross-sectional area of these two products is fairly comparable—ECRI Institute believes it is worthwhile to mention the diameter, although other contributing factors could include suture material and manufacturing process. Note that the breaking force of Maxon size 1 has a very wide standard deviation compared to other sizes and product lines tested.

   b) Sutures must maintain suitable strength for the required wound or incision closure. A stronger suture can withstand higher forces that may be encountered during the healing process without failure.

WORKFLOW—GOOD

Maxon sutures have been evaluated against ECRI Institute's workflow criteria and found to meet all requirements.

PURCHASE COST FOR MEDTRONIC MAXON SUTURES

ECRI Institute analyzed detailed spend data for our member hospitals to determine (1) the average total number of sutures purchased annually by hospitals in each size cohort (based on number of beds) and (2) the percentage of total suture spend represented by this suture category. These figures were used to estimate an average spend for this product line.

Hospital Size (No. of Beds)	Average Annual Sutures Purchased, Total	Absorbable Synthetic Monofilament Sutures as a Percentage of Total Sutures Purchased	Estimated Annual Spend
Small (<100)	500	5%	$3,100
Medium (100-600)	2,500	7%	$19,000
Large (>600)	10,000	7%	$73,000

DISCUSSION OF KEY MANUFACTURER CLAIMS

Medtronic Claim	Category	ECRI Institute Perspective
Excellent strength out of package for maximum wound support over the critical wound healing period.	Performance	**ECRI Institute agrees; we consider this a significant benefit.** Maxon has excellent strength out of package. Maxon has a major advantage in offering at least 20% higher tensile strength than its competing product line in all sizes tested.
Excellent knot security for secure wound closure.	Performance	**ECRI Institute agrees.** Maxon met our required criteria for knot security in that no samples yielded a slipped knot. Maxon's breaking force in our knot slip test was also approximately 52% higher than that of the competing product.
Six week in vivo tensile strength for long-term wound support—80% at one week, 75% at two weeks, 65% at three weeks, 50% at four weeks, and 25% at six weeks.	Performance	**ECRI Institute cannot confirm.** Our in vitro results somewhat align with Ethicon's in vivo absorption data. However, because of variations between our testing and how Ethicon derives its data, we cannot directly compare our findings with theirs.* As a synthetic absorbable suture, the Maxon degrades via a hydrolysis reaction. Our in vitro results indicate the following breaking strength retention profile for Maxon sutures: 92% original strength at one week, 92% at two weeks, 73% at three weeks, 52% at four weeks, and 18% at six weeks. This is similar to the Medtronic data. As noted, however, the differences between our testing and Medtronic's mean the results can be highly variable.
Minimal memory for ease of handling.	Performance	**ECRI Institute does not agree.** Maxon demonstrated only 45% total length when removed from package and would require clinicians to "remove memory" before use.

* Our in vitro test method was designed to assess the breaking strength retention (BSR) of the absorbable suture product lines, compared to their out-of-package knotted breaking force. We comment on how our results correlate to the manufacturer's BSR claims in the product's instructions for use, which (1) are based on in vivo models and (2) in some cases are reported in comparison to USP minimums instead of measured initial breaking force. An in vivo model may offer more clinically relevant performance in terms of pH maintenance (i.e., some absorbable sutures tend to release acid as they degrade—this would be neutralized in vivo, but in vitro requires regular buffer pH testing and exchange), as well as any contributions to suture degradation via enzymatic interaction and mechanical tension from the patient as he or she moves.

RECALLS AND HAZARDS

The following data is based on *Health Devices Alerts* records from January 2010 through May 2017.

HDA Record	Priority	Date of Last Update	Category
A28533: Medtronic—Various Suture Products: Inner Packaging May Have an Incomplete Seal, Potentially Leading to Premature Degradation of Suture Material	Normal	May 11, 2017	Sterility

Medtronic Monosof, Novafil, and Surgipro II—Nonabsorbable, Synthetic, Monofilament Sutures

Ratings

MONOSOF

NOVAFIL

SURGIPRO II

Product Details

- Name: Monosof, Novafil, and Surgipro
- Characteristics:
  - Monosof: Nonabsorbable monofilament, nylon
  - Novafil: Nonabsorbable monofilament, polybutester
  - Surgipro: Nonabsorbable monofilament, polypropylene
- Date evaluated: July 2017
- Manufacturer: Medtronic Inc. [101809]

Product Description

1. These sutures are used to join together the opposing edges of a wound or incision. Typical uses:
   a) Monosof (Note: Medtronic considers Monosof and Dermalon as the same product available in different colors. As such, ECRI Institute tested only Monosof, which had a higher usage among Medtronic customers.)
      (1) Skin closure
      (2) Ophthalmology
   b) Novafil (Note: Medtronic offers another polybutester suture product line called Vascufil, which is similar to Novafil but with a Plytribolate coating to minimize tissue drag in certain procedures. As such, ECRI Institute tested only Novafil, which had a higher usage among Medtronic customers.)
      (1) Skin closure
      (2) Plastic surgery
      (3) General surgery
      (4) Cardiovascular surgery
      (5) Ophthalmology
   c) Surgipro II (Note: Medtronic considers Surgipro and Surgipro II as the same product available in different sizes, with Surgipro being available in larger sizes and Surgipro II available in smaller sizes. As such, ECRI Instituted tested only Surgipro II, which had a higher usage among Medtronic customers.)
      (1) Skin closure
      (2) Cardiovascular surgery
2. Major product components:
   a) Synthetic thread of varying lengths and diameters that joins wound or incision edges together for healing purposes.
   b) A suture needle to penetrate tissue and lay the suture material in its wake. The needle also facilitates knot-tying.
3. These products are typically used in the following locations:
   a) Operating rooms
   b) Emergency/trauma departments
   c) Doctors' offices

See the Evaluation Background on surgical sutures for a list of applicable specialties.

Significant Findings

We performed a variety of tests on this product, including physical testing, a review of product literature/specifications, and asking users for feedback on statistically significant findings. We focused our testing on performance and workflow. We did not specifically evaluate the sutures in our other customary categories—safety, patient experience, interoperability, or user experience. Those topics either were not relevant to our testing or were covered elsewhere. For example, safety-related characteristics such as strength and knot retention were addressed in our performance testing.

For more details, see the ECRI Institute's Testing section of our Evaluation Background on this technology.

PERFORMANCE—GOOD

Monosof, Novafil, and Surgipro II sutures have been evaluated against ECRI Institute's performance criteria and found to meet all requirements. Companion product lines Dermalon, Surgipro, and Vascufil should be expected to perform similarly.

WORKFLOW—GOOD

Monosof, Novafil, and Surgipro II sutures have been evaluated against ECRI Institute's workflow criteria and found to meet all requirements. Companion product lines Dermalon, Surgipro, and Vascufil should be expected to perform similarly.

Recalls and Hazards

A search of ECRI Institute's *Health Devices Alerts* database for "Monosof," "Dermalon," "Novafil," Surgipro," and "Vascufil" from January 2010 through May 2017 found no relevant records.

FINDINGS: MEDTRONIC MONOSOF, NOVAFIL, AND SURGIPRO II—NONABSORBABLE, SYNTHETIC, MONOFILAMENT SUTURES

	Monosof			Novafil			Surgipro II		
Size	3/0	4/0	5/0	3/0	4/0	5/0	4/0	5/0	6/0
Performance									
Mean breaking force (N)	13.9	11.0	5.5	13.6	9.8	6.0	10.4	6.5	3.2
Standard deviation	1.2	0.6	0.5	1.4	0.9	0.5	0.7	0.7	0.3
Compared to Ethicon*	NSD	NSD	-19%	NECP	NECP	NECP	-19%	-11%	-11%
Mean diameter (mm)	NM	NM	0.155	NM	NM	NM	0.205	0.150	0.100
Standard deviation	NM	NM	0.005	NM	NM	NM	0.003	0.001	0.001
Mean area (mm^2)	NM	NM	0.019	NM	NM	NM	0.032	0.018	0.008
Compared to Ethicon*	NM	NM	+3%	NECP	NECP	NECP	+1%	-1%	-4%
No. of knots slipped before breaking (out of 10)	0	0	0	0	0	0	0	0	0
Mean peak force before breaking or slipping (N)	16.4	14.1	6.7	18.4	11.2	7.1	11.7	7.2	3.3
Standard deviation	1.9	1.3	0.5	1.6	1.5	0.6	0.6	0.2	0.2
Compared to Ethicon*	NSD	+18%	-13%	NECP	NECP	NECP	NSD	NSD	-8%
Workflow									
Out-of-package memory **	22.7%			39.2%			33.0%		
Standard deviation	1.0%			1.8%			2.9%		

NSD—No statistical difference with competing product.
NECP—No equivalent competitor product.
NM—Not measured, because either (1) no significant differences in breaking force were identified in competing products, in which case we did not assess suture diameter consistency, or (2) not enough product was provided to us.
* Statistical significance was not calculated due to sample size.
** Higher numbers are considered better: A suture with zero memory would unfold completely and thus have a result of 100%.

PURCHASE COST FOR MEDTRONIC MONOSOF, NOVAFIL, AND SURGIPRO II SUTURES

ECRI Institute analyzed detailed spend data for our member hospitals to determine (1) the average total number of sutures purchased annually by hospitals in each size cohort (based on number of beds) and (2) the percentage of total suture spend represented by this suture category. These figures were used to estimate an average spend for this product line.

Hospital Size (No. of Beds)	Average Annual Sutures Purchased, Total	Nonabsorbable Synthetic Monofilament Sutures as a Percentage of Total Sutures Purchased	Estimated Annual Spend
Small (<100)	500	30%	$23,000
Medium (100-600)	2,500	26%	$120,000
Large (>600)	10,000	23%	$440,000

DISCUSSION OF KEY MANUFACTURER CLAIMS

Medtronic Claim	Category	ECRI Institute Perspective
Monosof/Dermalon		
Enhanced tensile strength in fine sizes helps minimize strand breakage.	Performance	**ECRI Institute agrees, but the benefit is not likely significant.** Monosof tensile breaking force is above the thresholds set by USP for a synthetic monofilament suture; however, it was either comparable to or weaker than the competing Ethicon product line in the sizes tested (3/0, 4/0, 5/0).
Excellent security with snug and flattened knots and consistent knotting strength.	Performance	**ECRI Institute agrees.** No Monosof knots failed by slip, and knotted breaking strength had a fairly consistent standard deviation.
Minimal memory for ease of handling.	Performance	**ECRI Institute does not agree.** Although these products met our required criteria, they did not exhibit our preferred performance level. Our Out-of-Package Memory results can be found in the Findings table above.
Novafil/Vascufil		
Minimal memory for ease of handling.	Performance	**ECRI Institute does not agree.** See Out-of-Package Memory findings above. While this product exhibited less memory (i.e., a higher score) than Medtronic's other synthetic nonabsorbable monofilaments, it does not provide our preferred performance level of 75%.
Superior strength to polypropylene for secure and reliable closures.	Performance	**ECRI Institute does not agree.** In sizes 4/0 and 5/0, Medtronic's Surgipro II demonstrated a higher knotted tensile breaking force.
Superior pliability for easy handling and tying.	Performance	**Unknown.** We have no data or information to support an opinion. While we did not quantify pliability, during surgical knot-tying, Novafil was noticeably easier to tie than other nonabsorbable monofilament sutures.
Great knot security.	Performance	**ECRI Institute agrees.** No Novafil knots failed by slip, and knotted breaking strength had a fairly consistent standard deviation.
Polybutester construction offers a controlled elasticity that will accommodate swelling that occurs during the healing process.	Performance	**ECRI Institute agrees.** The Novafil force-extension curve gathered in breaking force testing showed that the polybutester material is more compliant than other nonabsorbable monofilament suture materials.
Vascufil sutures' Polytribolate coating provides the following advantages: 1. Provides smooth knot run down 2. Facilitates parachute technique 3. Reduces tissue drag	Performance	**Unknown.** We have no data or information to support an opinion. As Novafil accounts for a larger percentage of Medtronic's polybutester suture usage, ECRI Institute did not evaluate its associated Polytribolate-coated product line.
Surgipro II/Surgipro		
Maximum flexibility of strand.	Performance	**Unknown.** We have no data or information to support an opinion. ECRI Institute did not quantify strand pliability; however, Surgipro II was not difficult to manipulate for knot-tying purposes.
Excellent security with snug and flattened knots and consistent knotting strength.	Performance	**ECRI Institute agrees.** No Surgipro II knots failed by slip, and knotted breaking strength had a fairly consistent standard deviation.
Minimal memory for ease of handling.	Performance	**ECRI Institute does not agree.** See Out-of-Package Memory results above.

Medtronic Polysorb—Mid-Term Absorbable, Synthetic, Braided Sutures

Rating

Product Details

- Name: Polysorb
- Characteristics: Absorbable (mid-term) braided, polyglactin 910
- Date evaluated: July 2017
- Manufacturer: Medtronic Inc. [101809]

Product Description

1. These sutures are used to join together the opposing edges of a wound or incision.
2. Typical uses for this product line are:
    a) General surgery
    b) Plastic surgery
    c) OB-GYN
    d) Orthopedics
3. Major product components:
    a) Synthetic thread of varying lengths and diameters that holds wound or incision edges together for healing purposes.
    b) A suture needle to penetrate tissue and lay the suture material in its wake. The needle also facilitates knot-tying.
4. Typical location the device is used in:
    a) Operating rooms
    b) Emergency/trauma departments
    c) Doctors' offices

See the Evaluation Background on surgical sutures for a list of applicable specialties.

Significant Findings

We performed a variety of tests on these products, including physical testing, a review of product literature/specifications, and asking users for feedback on statistically significant findings. We focused our testing on performance and workflow. We did not specifically evaluate the sutures in our other customary categories—safety, patient experience, interoperability, or user experience. Those topics either were not relevant to our testing or were covered elsewhere. For example, safety-related characteristics such as strength, knot retention, and breaking strength retention were addressed in our performance testing.

Note: Our in vitro test method was designed to assess the breaking strength retention (BSR) of the absorbable suture product lines, compared to their out-of-package knotted breaking force. We comment on how our results correlate to the manufacturer's BSR claims in the product's instructions for use, which (1) are based on in vivo models and (2) in some cases are reported in comparison to USP minimums instead of measured initial breaking force. An in vivo model may offer more clinically relevant performance in terms of pH maintenance (i.e., some absorbable sutures tend to release acid as they degrade—this would be neutralized in vivo, but in vitro requires regular buffer pH testing and exchange), as well as any contributions to suture degradation via enzymatic interaction and mechanical tension from the patient as he or she moves. Therefore, because of the differences between the manufacturers' in vivo models and our methods, their claims may not be directly comparable to our results.

For more details on our testing, see the ECRI Institute's Testing section of our Evaluation Background on this technology.

FINDINGS: MEDTRONIC POLYSORB—MID-TERM ABSORBABLE, SYNTHETIC, BRAIDED SUTURES			
Size	0	2/0	3/0
Performance			
Mean breaking force (N)	65.2	54.8	33.9
Standard deviation	2.9	1.4	0.3
Compared to Ethicon	+26%	+51%	+64%
Mean diameter (mm)	0.478	0.412	0.327
Standard deviation	0.026	0.031	0.026
Mean area (mm^2)	0.179	0.133	0.084
Compared to Ethicon*	+4%	+8%	+12%
No. of knots slipped before breaking (out of 10)	0	0	0
Mean peak force before breaking or slipping (N)	60.0	47.7	32.4
Standard deviation	4.4	2.9	1.4
Compared to Ethicon	+18%	+36%	+45%
BSR: breaking force @ 7 days (N)	48.4	42.1	23.7
Standard deviation	1.1	1.5	1.0
% Original breaking force	74.3%	76.8%	69.9%
Compared to Ethicon*	+8%	+35%	+27%
BSR: breaking force @ 14 days (N)	29.3	25.7	14.0
Standard deviation	1.8	1.0	0.9
% Original breaking force	45.0%	46.9%	41.4%
Compared to Ethicon*	-10%	+11%	+4%
BSR: breaking force @ 21 days (N)	7.4	8.6	3.4
Standard deviation	0.8	0.6	0.4
% Original breaking force	11.3%	15.7%	10.1%
Compared to Ethicon*	-52%	-41%	-50%
Workflow			
Out-of-package memory**	73.5%		
Standard deviation	3.3%		

BSR—Breaking strength retention.
* Statistical significance was not calculated due to sample size.
** Higher numbers are considered better: A suture with zero memory would unfold completely and thus have a result of 100%.

PERFORMANCE—EXCELLENT

Polysorb sutures have been evaluated against ECRI Institute's performance criteria and found to meet all requirements, with a major advantage in tensile breaking force.

Major Advantage

1. Superior initial tensile breaking force:

    a) The mean knotted tensile breaking force of all three Polysorb sizes tested was at least 20% higher than the competing Ethicon product line, Vicryl. Note, however, that Vicryl also meets USP tensile strength requirements and has a significantly smaller cross-sectional area (9%-24% smaller, depending on size). ECRI Institute believes it is worthwhile to point out the significant differences in the diameter of the two competing products; however, other factors could contribute to differences in tensile breaking force, including braid configuration and suture coating.

    b) Sutures must maintain suitable strength for the required wound or incision closure. A stronger suture can withstand higher forces that may be encountered during the procedure and the healing process without failure.

WORKFLOW—GOOD

Polysorb sutures have been evaluated against ECRI Institute's workflow criteria and found to meet all requirements.

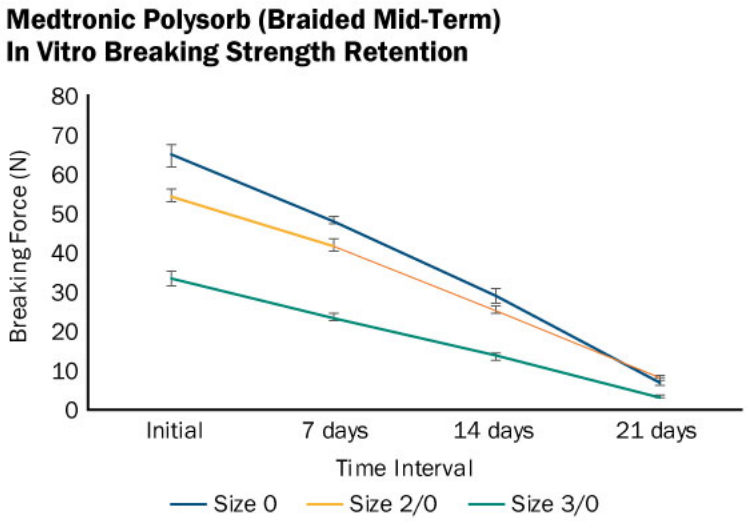

Figure 4. Medtronic Polysorb's tensile breaking force performance in sizes 0, 2/0, and 3/0 over a three-week absorption period.

PURCHASE COST FOR MEDTRONIC POLYSORB SUTURES

ECRI Institute analyzed detailed spend data for our member hospitals to determine (1) the average total number of sutures purchased annually by hospitals in each size cohort (based on number of beds) and (2) the percentage of total suture spend represented by this suture category. These figures were used to estimate an average spend for this product line.

Hospital Size (No. of Beds)	Average Annual Sutures Purchased, Total	Absorbable Mid-Term Synthetic Braided Sutures as a Percentage of Total Sutures Purchased	Estimated Annual Spend
Small (<100)	500	34%	$15,000
Medium (100-600)	2,500	35%	$100,000
Large (>600)	10,000	37%	$460,000

DISCUSSION OF KEY MANUFACTURER CLAIMS

Medtronic Claim	Category	ECRI Institute Perspective
Excellent strength out of package for maximum wound support over the critical wound healing period.	Performance	**ECRI Institute agrees; we consider this a significant benefit.** Polysorb received a major advantage for having at least 20% higher breaking force than its competing product line in all sizes tested. At around two weeks, Polysorb maintains approximately 44% of its original strength in support of wound healing, which is similar to the two-week strength retention of the competing product line.
Excellent knot security for secure wound closure.	Performance	**ECRI Institute agrees.** Polysorb met our required criteria for knot security in that no samples yielded a slipped knot. Knotted strength was also higher than the competing product.
Predictable in vivo absorption profile—80% of USP minimum breaking force at two weeks and 30% at three weeks.	Performance	**ECRI Institute cannot confirm.** Our in vitro results are similar to Medtronic's in vivo results. However, because of variations between our testing and how Medtronic derives its data, we cannot directly compare our findings with theirs.* As a synthetic absorbable suture, the Polysorb degrades via a hydrolysis reaction. Our in vitro results indicate that at two and three weeks the strand's breaking strength retention compared to USP minimum breaking force is approximately 85% and 24% averaged across all sizes tested.

* Our in vitro test method was designed to assess the breaking strength retention (BSR) of the absorbable suture product lines, compared to their out-of-package knotted breaking force. We comment on how our results correlate to the manufacturer's BSR claims in the product's instructions for use, which (1) are based on in vivo models and (2) in some cases are reported in comparison to USP minimums instead of measured initial breaking force. An in vivo model may offer more clinically relevant performance in terms of pH maintenance (i.e., some absorbable sutures tend to release acid as they degrade—this would be neutralized in vivo, but in vitro requires regular buffer pH testing and exchange), as well as any contributions to suture degradation via enzymatic interaction and mechanical tension from the patient as he or she moves.

RECALLS AND HAZARDS

The following data is based on *Health Devices Alerts* records from January 2010 through May 2017.

***HDA* Record**	**Priority**	**Date of Last Update**	**Category**
A28533: Medtronic—Various Suture Products: Inner Packaging May Have an Incomplete Seal, Potentially leading to Premature Degradation of Suture Material	Normal	May 11, 2017	Sterility

Medtronic Sofsilk—Nonabsorbable, Natural, Braided Sutures

Rating

Product Details

- Name: Sofsilk
- Characteristics: Nonabsorbable braided, silk (fibroin)
- Date evaluated: July 2017
- Manufacturer: Medtronic Inc. [101809]

Product Description

1. These sutures are used to join together the opposing edges of a wound or incision.
2. Typical uses for this product line are:
    a) Skin closure
    b) Cardiovascular surgery
    c) Neurosurgery
    d) Ophthalmic surgery
3. Major product components:
    a) Natural, coated thread of varying lengths and diameters that holds wound or incision edges together for healing purposes.
    b) A suture needle to penetrate tissue and lay the suture material in its wake. The needle also facilitates knot-tying.
4. Typical location the device is used in:
    a) Operating rooms
    b) Emergency/trauma departments
    c) Doctors' offices

See the Evaluation Background on surgical sutures for a list of applicable specialties.

Significant Findings

We performed a variety of tests on these products, including physical testing, a review of product literature/specifications, and asking users for feedback on statistically significant findings. We focused our testing on performance and workflow. We did not specifically evaluate the sutures in our other customary categories—safety, patient experience, interoperability, or user experience. Those topics either were not relevant to our testing or were covered elsewhere. For example, safety-related characteristics such as strength and knot retention were addressed in our performance testing.

For more details, see the ECRI Institute's Testing section of our Evaluation Background on this technology.

PERFORMANCE—GOOD

Sofsilk sutures have been evaluated against ECRI Institute's performance criteria and found to meet all requirements.

WORKFLOW—GOOD

Sofsilk sutures met all standard packaging requirements and received a minor advantage for demonstrating minimal out-of-package memory.

Minor Advantage

1. Minimal out-of-package memory:
    a) Sofsilk unwound to most of its total length upon removal from packaging.
    b) This makes the suture easier to use immediately and does not require a clinician to take time to run the strand between thumb and forefinger to "remove the memory" before use.

FINDINGS: MEDTRONIC SOFSILK—NONABSORBABLE, NATURAL, BRAIDED SUTURES

Size	0	2/0	3/0
Performance			
Mean breaking force (N)	35.0	24.7	14.5
Standard deviation	1.4	0.7	0.6
Compared to Ethicon	+9%	+4%	NSD
Mean diameter (mm)	0.419	0.37	NM
Standard deviation	0.014	0.021	NM
Mean area (mm^2)	0.138	0.108	NM
Compared to Ethicon*	-3%	0%	NM
No. of knots slipped before breaking (out of 10)	0	0	0
Mean peak force before breaking or slipping (N)	35.4	25.7	13.7
Standard deviation	1.2	1.1	0.8
Compared to Ethicon	+11%	+12%	NSD
Workflow			
Out-of-package memory**	83.7%		
Standard deviation	4.2%		

NSD—No statistical difference with competing product.
NM—Not measured, because either (1) no significant differences in breaking force were identified in competing products, in which case we did not assess suture diameter consistency, or (2) not enough product was provided to us.
* Statistical significance was not calculated due to sample size.
** Higher numbers are considered better: A suture with zero memory would unfold completely and thus have a result of 100%.

PURCHASE COST FOR MEDTRONIC SOFSILK SUTURES

ECRI Institute analyzed detailed spend data for our member hospitals to determine (1) the average total number of sutures purchased annually by hospitals in each size cohort (based on number of beds) and (2) the percentage of total suture spend represented by this suture category. These figures were used to estimate an average spend for this product line.

Hospital Size (No. of Beds)	Average Annual Sutures Purchased, Total	Nonabsorbable Natural Braided Sutures as a Percentage of Total Sutures Purchased	Estimated Annual Spend
Small (<100)	500	8%	$3,300
Medium (100-600)	2,500	10%	$40,000
Large (>600)	10,000	11%	$120,000

DISCUSSION OF KEY MANUFACTURER CLAIMS

Medtronic Claim	Category	ECRI Institute Perspective
Wax coating allows smooth, multiple-pass rundown, and minimizes breakage.	Performance	**Unknown.** We have no data or information to support an opinion. All silk sutures have a wax or silicone coating intended for this purposes. ECRI Institute did not evaluate tissue drag or fraying as part of this Evaluation.

RECALLS AND HAZARDS

The following data is based on *Health Devices Alerts* records from January 2010 through May 2017.

HDA Record	Priority	Date of Last Update	Category
A16119 01: Cardinal Health—Covidien SOFSILK, SURGILON, and TI-CRON Nonabsorbable Sutures: Sterile Barrier May Be Compromised	High	June 21, 2011	Sterility
A16119: Covidien—SOFSILK, SURGILON, and TI-CRON Nonabsorbable Sutures: Sterile Barrier May Be Compromised	High	June 7, 2011	Sterility

Medtronic Surgilon and Ti-Cron—Nonabsorbable, Synthetic, Braided Sutures

Ratings

SURGILON

TI-CRON

Product Details

- Name: Surgilon and Ti-Cron
- Characteristics:
  - Surgilon: Nonabsorbable braided, nylon
  - Ti-Cron: Nonabsorbable braided, polyester
- Date evaluated: July 2017
- Manufacturer: Medtronic Inc. [101809]

Product Description

1. These sutures are used to join together the opposing edges of a wound or incision.
2. Typical uses for these product lines are:
   a) Surgilon
      (1) Skin closure
      (2) Neurosurgery
      (3) Gynecology
   b) Ti-Cron
      (1) General surgery
      (2) Hernia repair
      (3) Orthopedics
      (4) Cardiovascular valve replacement
3. Major product components:
   a) Synthetic thread of varying lengths and diameters that holds wound or incision edges together for healing purposes.
   b) A suture needle to penetrate tissue and lay the suture material in its wake. The needle also facilitates knot-tying.
4. Typical location the device is used in:.
   a) Operating rooms
   b) Emergency/trauma departments
   c) Doctors' offices

See the Evaluation Background for a list of applicable specialties.

Significant Findings

We performed a variety of tests on these products, including physical testing, a review of product literature/specifications, and asking users for feedback on statistically significant findings. We focused our testing on performance and workflow. We did not specifically evaluate the sutures in our other customary categories—safety, patient experience, interoperability, or user experience. Those topics either were not relevant to our testing or were covered elsewhere. For example, safety-related characteristics such as strength and knot retention were addressed in our performance testing.

For more details, see the ECRI Institute's Testing section of our Evaluation Background on this technology.

PERFORMANCE

Surgilon—Poor. Surgilon sutures have been evaluated against ECRI Institute's performance criteria and met most requirements; however, they failed our knot security test.

FINDINGS: MEDTRONIC SURGILON AND TI-CRON—NONABSORBABLE, SYNTHETIC, BRAIDED SUTURES

	Surgilon			Ti-Cron		
Size	0	2/0	4/0	1	0	2/0
Performance						
Mean breaking force (N)	41.2	21.9	11.4	50.5	33.4	30.0
Standard deviation	2.2	1.1	0.6	2.9	1.0	1.5
Compared to Ethicon	+19%	-8%	+13%	-14%	-20%	NSD
Mean diameter (mm)	0.429	0.347	0.224	0.460	0.393	NM
Standard deviation	0.030	0.022	0.010	0.007	0.007	NM
Mean area (mm^2)	0.145	0.095	0.039	0.166	0.121	NM
Compared to Ethicon*	+5%	-14%	-7%	-14%	-12%	NM
No. of knots slipped before breaking (out of 10)	0	0	9	0	0	0
Mean peak force before breaking or slipping (N)	40.1	23.0	7.5	47.6	33.6	28.3
Standard deviation	3.0	0.8	2.3	4.0	3.6	2.1
Compared to Ethicon	NSD	-7%	-26%	NSD	NSD	+20%
Workflow						
Out-of-package memory**	87.7%			88.3%		
Standard deviation	3.8%			0.5%		

NSD—No statistical difference with competing product.
NM—Not measured, either because (1) no significant differences in breaking force were identified in competing products, in which case we did not assess suture diameter consistency, or (2) not enough product was provided to us.
* Statistical significance was not calculated due to sample size.
** Higher numbers are considered better: A suture with zero memory would unfold completely and thus have a result of 100%.

Ti-Cron—Good. Ti-Cron sutures have been evaluated against ECRI Institute's performance criteria and found to meet all requirements.

Major Disadvantage

1. Surgilon knots failed by slip:
    a) Nine out of 10 size 4/0 Surgilon sutures failed ECRI Institute's knot security test, allowing a knot to entirely slip rather than holding until it breaks.
    b) A knot that is tied in a snug surgeon's knot should not fail via slip (i.e., the trimmed "ears" slide through all throws of the knot, thus coming undone). This type of failure could result in patient harm, such as bleeding, or in extreme cases, death.

WORKFLOW—GOOD

Both Surgilon and Ti-Cron met all standard packaging requirements and received a minor advantage for demonstrating minimal out-of-package memory.

Minor Advantage

1. Minimal out-of-package memory:
    a) Both Surgilon and Ti-Cron unwound to most of their total length upon removal from packaging.
    b) This makes the suture easier to use immediately and does not require a clinician to take time to run the strand between thumb and forefinger to "remove the memory" before use.

PURCHASE COST FOR MEDTRONIC SURGILON AND TI-CRON SUTURES

ECRI Institute analyzed detailed spend data for our member hospitals to determine (1) the average total number of sutures purchased annually by hospitals in each size cohort (based on number of beds) and (2) the percentage of total suture spend represented by this suture category. These figures were used to estimate an average spend for this product line.

Hospital Size (No. of Beds)	Average Annual Sutures Purchased, Total	Nonabsorbable Synthetic Braided Sutures as a Percentage of Total Sutures Purchased	Estimated Annual Spend
Small (<100)	500	7%	$8,100
Medium (100-600)	2,500	7%	$34,000
Large (>600)	10,000	6%	$140,000

DISCUSSION OF KEY MANUFACTURER CLAIMS

Medtronic Claim	Category	ECRI Institute Perspective
Surgilon		
Maximum flexibility of the strand.	Performance	**Unknown, but the benefit is not likely significant.** Similar to all braided sutures, the strand was not difficult to knot or manipulate during testing.
Excellent security with snug and flattened knots.	Performance	**ECRI Institute does not agree.** We found a major disadvantage regarding Surgilon knot security.
Excellent handling.	Performance	**Unknown, but the benefit is not likely significant.** Similar to all braided sutures, the strand was not difficult to knot or manipulate during testing.
Excellent and consistent knotting strength.	Performance	**ECRI Institute agrees.** Surgilon met our required criteria for suture breaking force. Strength was not consistently higher than the competing product line in all sizes.
Ti-Cron		
Impregnated silicone coating for smooth and secure knot run-down, excellent performance and handling, minimal tissue drag and trauma.	Performance	**ECRI Institute partially agrees.** Ti-Cron handled easily during knotting and did not fail via slip. Tissue drag and trauma were not evaluated.
High tensile strength for reliable, consistent performance.	Performance	**ECRI Institute agrees.** Ti-Cron met our required criteria for suture breaking force. While its breaking force was higher than the USP threshold for its size, Ti-Cron was either comparable to or less strong than its competing product line, depending on size.

RECALLS AND HAZARDS

The following data is based on *Health Devices Alerts* records from January 2010 through May 2017.

Link to *HDA* Record	Priority	Date of Last Update	Category
A16119 01: Cardinal Health—Covidien SOFSILK, SURGILON, and TI-CRON Nonabsorbable Sutures: Sterile Barrier May Be Compromised	High	June 21, 2011	Sterility
A16119: Covidien—SOFSILK, SURGILON, and TI-CRON Nonabsorbable Sutures: Sterile Barrier May Be Compromised	High	June 7, 2011	Sterility

Medtronic P-12 Premium Reverse Cutting and V-20 Taper Point Suture Needles

Ratings

P-12 PREMIUM REVERSE CUTTING

V-20 TAPER POINT

Product Details

- Name: P-12 premium reverse cutting and V-20 taper point needles (Note: ECRI Institute chose these two types of needles as they had the highest usage among both manufacturers we evaluated.)
- Characteristics:
  - P-12: 3/8 circle, 19 mm long, 0.023-inch diameter, Edgellant
  - V-20: 1/2 circle, 26 mm long, 0.025-inch diameter, Surgalloy
- Date evaluated: July 2017
- Manufacturer: Medtronic Inc. [101809]

Product Description

1. These needles are used to join together the opposing edges of a wound or incision. Typical uses for each product line are:
   a) P-12 premium reverse cutting
      (1) Used for skin and subcuticular closure, plastic surgery, and ophthalmic surgery
      (2) Has a cutting edge on the outer curvature of the needle to pierce tissue as it is rotated
   b) V-20 taper point
      (1) Used for soft tissue closure such as fascia, bowel, and muscle
      (2) No cutting edge; designed to separate, rather than cut, tissue fibers, which helps prevent leaks upon closure
2. Consists of a suture needle with varying tip and body geometries to penetrate tissue and lay the suture material in its wake.
3. These products are typically used in the following locations:
   a) Operating rooms
   b) Emergency/trauma departments
   c) Doctors' offices

See the Evaluation Background on surgical sutures for a list of applicable specialties.

Significant Findings

We performed a variety of tests on this product, including physical testing, a review of product literature/specifications, and asking users for feedback on statistically significant findings. We focused our Evaluation on performance and workflow. We did not specifically evaluate the needles in our other customary categories—safety, patient experience, interoperability, or user experience. Those topics were not within the scope of our testing.

For more details, see the ECRI Institute's Testing section of our Evaluation Background on this technology.

PERFORMANCE—GOOD

Medtronic's taper point and premium reverse cutting needles have been evaluated against ECRI Institute's performance criteria and found to meet all requirements.

WORKFLOW—GOOD

Medtronic's taper point and premium reverse cutting needles have been evaluated against ECRI Institute's workflow criteria and found to meet all requirements regarding proper package labeling, which allows easy identification of the package contents.

Recalls and Hazards

A search of ECRI Institute's *Health Devices Alerts* database for "Medtronic," "Covidien," "taper point," and "reverse cutting" from January 2010 through May 2017 found no relevant records.

FINDINGS: MEDTRONIC P-12 PREMIUM REVERSE CUTTING AND V-20 TAPER POINT SUTURE NEEDLES

	P-12 Premium Reverse Cutting			V-20 Taper Point		
Size (diameter, inches)	0.023			0.025		
Needle penetration test phase	Early (penetrations 1-3)	Mid (penetrations 14-16)	Late (penetrations 28-30)	Early (penetrations 1-3)	Mid (penetrations 14-16)	Late (penetrations 28-30)
Needle sharpness—force required for penetration compared to Ethicon (g-f)*	15 g-f more force	18 g-f more force	20 g-f more force	6 g-f less force	10 g-f more force	5 g-f more force
Needle sharpness compared to Ethicon, %	~-21%	~-23%	~-25%	~+8%	~-11%	~-5%
Needle strength—resistance to bending compared to Ethicon, g-cm**	+77			+69		
Needle strength compared to Ethicon, %	+12%			+10%		

* Grams of penetration force required; lower values are advantageous.
** Gram-centimeters required to bend the curved needle until it yields; higher values are advantageous.

DISCUSSION OF KEY MANUFACTURER CLAIMS

Medtronic Claim	Category	ECRI Institute Perspective
Edgellant material is a premium needle alloy designed to enhance needle strength.	Performance	**ECRI Institute agrees.** Medtronic's needles were more resistant to bending in our testing than their competitors (see our findings table above).
Edgellant material is sharp enough to penetrate with minimal resistance and carry suture through tissue with minimal trauma.	Performance	**ECRI Institute does not agree.** From feedback we have received, the Edgellant needle is sharp enough. However, in our testing, the premium reverse cutting suture needles required noticeably more, and thus not minimal, force to penetrate a tissue surrogate than competing needle types. Tissue trauma was not assessed as part of this Evaluation.
Edgellant is flexible to bend before breaking.	Performance	**Unknown.** We have no data or information to support an opinion. ECRI Institute did not assess ductility as part of this Evaluation.

ECRI Institute
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