Medtronic

Performance you can feel. Strength you can trust.

Trexon™ monofilament synthetic absorbable suture

By combining greater pliability†,[1] with 3-week-long tensile strength and absorption in 90 to 110 days,[1,2] Trexon™ sutures embody the next evolution in Medtronic wound closure offerings.

Important: Always refer to the instructions for use (IFU) supplied with products for complete instructions, indications, contraindications, warnings, and precautions. Trexon™ sutures are contraindicated for use in cardiovascular or neurological tissues and should not be used where extended approximation of tissue is required.
† Compared to legacy Biosyn™ sutures.

Features and benefits

Pliable, yet strong.

For surgeons seeking a more pliable suture supported by the strength they need, **Trexon™ sutures** deliver greater pliability over Biosyn™ sutures[1] while maintaining superior strength over the competition.[†,‡,1]

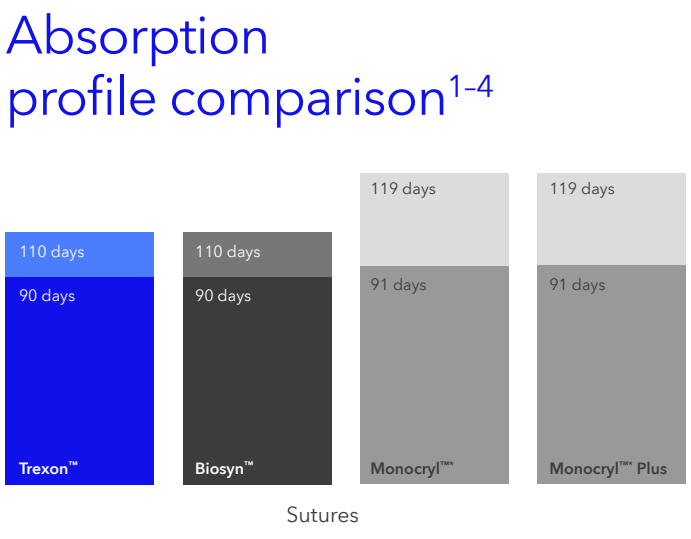
Trexon™ monofilament synthetic absorbable sutures provide:

- More pliability than legacy Biosyn™ sutures[1]
- Equivalent or superior pliability compared to Monocryl™* sutures[§,1] and Monocryl™* Plus sutures[1]
- An extra week of tensile strength during the critical early stages of wound healing compared to Monocryl™* and Monocryl™* Plus sutures[†,1]
- An absorption profile of 90–110 days,[1,2] comparable to the absorption rate of Monocryl™* and Monocryl™* Plus sutures (91–119 days)[3,4]

Unpack a memorable suture performance.

Trexon™ sutures offer **less memory out of the package** than Biosyn™ sutures,[1] with an updated packaging design aligned to industry standards and surgeons' needs.

Absorption profile comparison[1–4]



As with all surgical sutures, adverse effects include but are not limited to wound dehiscence, and failure to provide adequate wound support in sites where expansion, stretching, or distention occur.

Trexon™ sutures are contraindicated for use in cardiovascular or neurological tissues and should not be used where extended approximation of tissue is required.

† Benchtop testing may not be indicative of clinical performance. ‡ As compared to Monocryl™* Plus sutures and Monocryl™* sutures. § For sizes 1, 4/0, and 6/0.

Competitive comparison

Strength when your patients need it most.

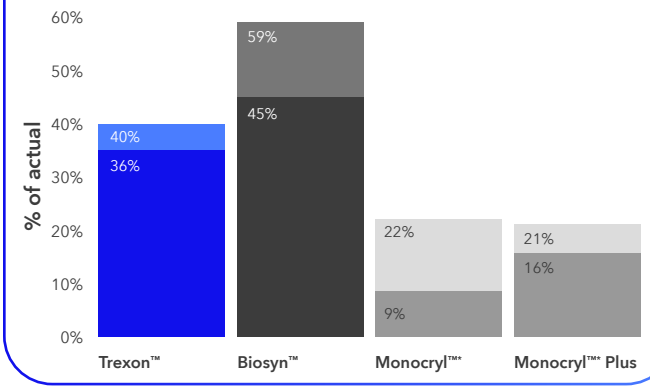
The closing stitch is a final, crucial step that demands both finesse and strength. We put Trexon™ sutures to the test so you can be confident in your patients' recovery.

Our testing revealed:

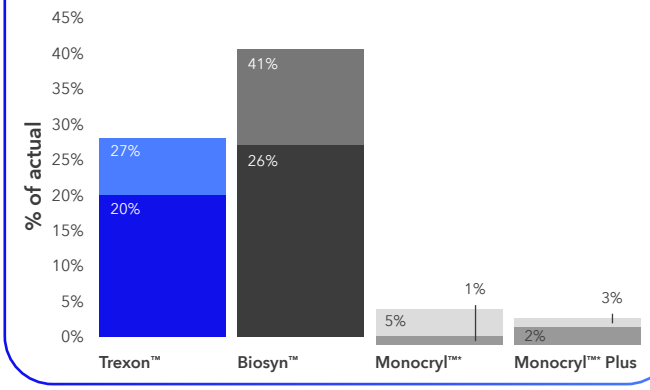
- Superior tensile strength out of the package compared to Monocryl™* and Monocryl™* Plus sutures†,[1]
- Significantly higher knot pull strength than both Monocryl™* and Monocryl™* Plus sutures at two and three weeks[1]
- Superior strength during the critical early stages of wound healing compared to the competition‡,[1]
- Equivalent or superior tensile strength out of the package than legacy Biosyn™ sutures§,[1]

Monofilamet synthetic absorbable sutures – tensile strength comparison◊,[1]				
Time frame	**Trexon™ sutures**	**Biosyn™ sutures**	**Monocryl™* sutures**	**Monocryl™* Plus sutures**
2 weeks	36–40% of knot pull strength	45–59% of knot pull strength	9–22% of knot pull strength	16–21% of knot pull strength
3 weeks	20–27% of knot pull strength	26–41% of knot pull strength	1–5% of knot pull strength	2–3% of knot pull strength

Knot pull strength range at 2 weeks◊,[1]



Knot pull strength range at 3 weeks◊,[1]



As with all surgical sutures, adverse effects include but are not limited to wound dehiscence, and failure to provide adequate wound support in sites where expansion, stretching, or distention occur.

As with all surgical sutures, adverse effects include but are not limited to wound dehiscence, unspecified infection, foreign body reaction, and hypersensitivity/ allergic reaction.

† For sizes 1, 2/0, and 4/0. ‡ Benchtop testing may not be indicative of clinical performance. As compared to Monocryl™* Plus sutures and Monocryl™* sutures. § For sizes 2/0, 4/0, and 6/0. ◊ Data ranges are average knot pull strength across sizes 1, 2/0, 4/0, and 6/0.

Instructions for use (IFU)

Medtronic

Trexon™

Monofilament Synthetic Absorbable Suture

PT00225172

(92)PT00225172

en

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

Trexon™ monofilament synthetic absorbable sutures (Trexon™ sutures) are prepared from a synthetic polyester composed of glycolide, dioxanone, and trimethylene carbonate. Trexon™ sutures are available undyed and dyed violet.

Qualitative and Quantitative Data	
*Maximum amount of absorbable polyester monofilament	0.0038 g
*Maximum amount of D&C Violet #2 colorant	0.000008 g

*Maximum amounts per centimeter when using the largest size suture (Size 1). All amounts are approximate, g=grams.

The target population is the general population of surgical candidates. Clinical evidence supporting safety and performance has not been established in pediatric, pregnant women, or breast-feeding women populations for this device. Surgeons should consider patient factors before deciding if the device is suitable for use.

Intended users are healthcare professionals who have been trained in surgical procedures and techniques involving absorbable sutures.

Trexon™ sutures meet all requirements established by the United States Pharmacopeia (USP) and the European Pharmacopeia (EP) for synthetic absorbable surgical sutures, except for USP suture diameter, with the allowable oversize described in the table below.

Maximum Average Suture Oversize in Diameter (mm) from USP		
USP Size	**USP Size Designation (mm)**	**Maximum Average Diameter Oversize from USP (mm)**
6-0	0.070 – 0.099	0.050
5-0	0.100 – 0.149	0.050
4-0	0.150 – 0.199	0.050
3-0	0.200 – 0.249	0.090
2-0	0.300 – 0.349	0.050
0	0.350 – 0.399	0.100
1	0.400 – 0.499	0.071

INDICATIONS FOR USE

Trexon™ Monofilament Synthetic Absorbable Sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular and neurological surgery.

INTENDED PURPOSE

The intended purpose of the suture is soft tissue approximation and/or ligation.

CLINICAL BENEFITS

Trexon™ sutures provide the clinical benefit of soft tissue approximation and/or ligation to promote wound healing and/or prevent content leakage at the ligation site.

The Summary of Safety and Clinical Performance (SSCP)

The Summary of Safety and Clinical Performance (SSCP) for this device can be found at https://ec.europa.eu/tools/eudamed. Search for the SSCP using the manufacturer and device name and the following elements as applicable: device model, reference number, and catalog number.

ACTIONS

Trexon™ sutures elicit a minimal acute inflammatory reaction in tissues, followed by gradual encapsulation of the suture by fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of Trexon™ sutures occurs by means of hydrolysis where the suture is broken down to glycolic acid, ß-hydroxybutyric acid, glyoxylate, glycine, and carbon dioxide which are subsequently absorbed and metabolized by the body.

Absorption begins as a loss of tensile strength without appreciable loss of mass. Studies indicate minimum tensile strength averages for Trexon™ sutures are approximately 50-60% of USP and EP knot strength at two weeks and approximately 25-35% of USP and EP at three weeks post-implant. Absorption of Trexon™ sutures is essentially complete between 90 and 110 days.

CONTRAINDICATIONS

This suture, being absorbable, should not be used where extended approximation of tissue is required.

WARNINGS

1. This device is provided STERILE for single-use only. Sterile unless packaging has been opened or damaged. Visually inspect the package before use. Do not reuse, reprocess, or resterilize this device. Reuse, reprocessing and/or resterilization may compromise the structural integrity of the device or may create the risk of contamination, patient infection, permanent impairment or life-threatening injury.
2. Before employing Trexon™ sutures for wound closure, healthcare professionals should consider the characteristics of the wound and absorption profile of the suture as the risk of wound dehiscence may vary with the site of application and the suture material used.
3. As with any foreign body, prolonged contact of any suture with salt solutions may result in calculus formation.
4. Acceptable surgical practice must be followed with respect to drainage and closure of contaminated or infected wounds.
5. The use of this suture may be inappropriate for patients with any conditions which, in the opinion of the surgeon, may cause or contribute to delayed wound healing.
6. The use of supplemental nonabsorbable sutures should be considered by the surgeon in the closure of sites subject to expansion, stretching or distention, or requiring additional support.
7. The device needle contains nickel that may cause allergic reaction.

PRECAUTIONS

1. In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.
2. Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon.
3. The use of additional throws may be particularly appropriate when knotting monofilaments.
4. Skin sutures which must remain in place longer than 7 days may cause localized irritation and should be snipped off or removed as indicated.
5. Under some circumstances, notably orthopedic procedures, immobilization by external support may be employed at the discretion of the surgeon.
6. Consideration should be taken in the use of absorbable sutures in tissue with poor blood supply as suture extrusion, delayed absorption, and sterile abscess may occur.
7. Discard open, unused sutures in accordance with end user's sharps containment, handling, and disposal procedures.
8. Dispose of used sutures in accordance with the end-user's medical and biological waste disposal requirements. "Sharps" should be disposed of in accordance with end user's sharps containment, handling, and disposal procedures. Use caution during handling and disposal to avoid injury.

MRI SAFETY INFORMATION

The Trexon™ suture, with needle removed, is MR Safe. A patient with these sutures can be scanned safely immediately after placement of the suture(s). There is no detectable image artifact caused by the suture.

ADVERSE REACTIONS

While every attempt has been made to reduce patient and user risks, all surgeries using this device carry some residual risk, even when used by trained physicians. The potential adverse reactions associated with the use of Trexon™ sutures are: unspecified infection, foreign body reaction, hypersensitivity/allergic reaction, fistula, wound dehiscence, hemorrhage/blood loss/bleeding, ischemia, peritonitis, tissue breakdown, exposure to body fluids, and foreign body in patient.

In the event that a serious incident has occurred related to device use, immediately report the event to Covidien, the competent authorities, and any other regulators as required.

HOW SUPPLIED

Trexon™ sutures are available undyed (natural) or dyed violet in USP and EP sizes 1 (4 Metric) through 6-0 (0.7 Metric). The sutures are supplied sterile, in pre-cut lengths or ligating reels, non-needled or affixed to various needle types. The sutures are available in one or more strands per package, in box quantities of one, two and three dozen.

Store at room temperature.

MORE INFORMATION

This device needle contains the following substance(s) defined as CMR 1B in a concentration above 0.1% weight by weight: Cobalt; CAS No. 7440-48-4; EC No. 231-158-0. Current scientific evidence supports that medical devices manufactured from cobalt alloys or stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.

STERILE EO **en:** Sterilized using ethylene oxide
en: Single sterile barrier system
en: Single use
Rx ONLY **en:** Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.
en: Do not resterilize
en: Do not use if package is damaged

en: Consult instructions for use
en: Caution, consult accompanying documents
MD **en:** Medical device
MR **en:** MR safe
en: Made from 100% recycled fibres. Minimum 35% post-consumer content.
7440-48-4 **en:** Contains hazardous substances
REF **en:** Catalogue number
en: Manufacturer
en: Use-by Date
LOT **en:** Batch code
en: Date of Manufacture
en: Package quantity

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+1 763 514 4000

2026-05 Rev. 01

IFU(s) current as of XX/2026 when this brochure was approved by Medtronic. For the most current IFU(s), please consult product packaging or contact your sales rep.

FDA 510(k) clearance letter

May 28, 2026

Medtronic
Lacee Levesque
Regulatory Affairs Manager
60 Middletown Ave.
North Haven, Connecticut 06473

Re: K253530
Trade/Device Name: Trexon™ Monofilament Synthetic Absorbable Suture
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM
Dated: April 30, 2026
Received: April 30, 2026

Dear Lacee Levesque:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the

Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

TEK N. LAMICHHANE -S

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Ordering information

Choose a suture made for high standards.

Order code	Product description	Size	Color	Strands	Length (in)	Box quantity	Needle type
CY811P	Trexon™ 2/0 30" VL GS-21	2/0	Violet	1	30	36	GS-21
CY843P	Trexon™ 2/0 30" UD GS-21	2/0	Undyed	1	30	36	GS-21
CY883P	Trexon™ 2/0 30" VL GS-22	2/0	Violet	1	30	36	GS-22
CY904P	Trexon™ 0 36" VL GS-25	0	Violet	1	36	36	GS-25
CY953P	Trexon™ 2/0 36" UD GS-21	2/0	Undyed	1	36	36	GS-21
CY954P	Trexon™ 0 36" UD GS-21	0	Undyed	1	36	36	GS-21
GY121P	Trexon™ 4/0 30" VL V-20	4/0	Violet	1	30	36	V-20
GY122P	Trexon™ 3/0 30" VL V-20	3/0	Violet	1	30	36	V-20
GY123P	Trexon™ 2/0 30" VL V-20	2/0	Violet	1	30	36	V-20
GY321P	Trexon™ 4/0 30" UD V-20	4/0	Undyed	1	30	36	V-20
GY322P	Trexon™ 3/0 30" UD V-20	3/0	Undyed	1	30	36	V-20
GY323P	Trexon™ 2/0 30" UD V-20	2/0	Undyed	1	30	36	V-20
SY5627P	Trexon™ 4/0 18" UD P-12	4/0	Undyed	1	18	12	P-12
SY5628P	Trexon™ 3/0 18" UD P-12	3/0	Undyed	1	18	12	P-12
SY5637P	Trexon™ 4/0 30" UD P-12	4/0	Undyed	1	30	12	P-12
SY5638P	Trexon™ 3/0 30" UD P-12	3/0	Undyed	1	30	12	P-12
SY5678P	Trexon™ 4/0 30" UD P-14	4/0	Undyed	1	30	36	P-14
SY5679P	Trexon™ 4/0 18" UD P-14	4/0	Undyed	1	18	24	P-14
SY5679GP	Trexon™ 3/0 30" UD P-14	3/0	Undyed	1	30	12	P-14
SY5687P	Trexon™ 5/0 18" UD P-13	5/0	Undyed	1	18	12	P-13
SY5690P	Trexon™ 4/0 18" UD P-13	4/0	Undyed	1	18	12	P-13
SY632P	Trexon™ 3/0 30" VL C-23	3/0	Violet	1	30	36	C-23
SY633P	Trexon™ 4/0 30" VL C-23	4/0	Violet	1	30	36	C-23
SY691P	Trexon™ 4/0 30" UD C-13	4/0	Undyed	1	30	36	C-13
SY693P	Trexon™ 3/0 30" UD C-14	3/0	Undyed	1	30	36	C-14
SY791P	Trexon™ 4/0 30" VL C-13	4/0	Violet	1	30	36	C-13
SY822P	Trexon™ 3/0 30" UD C-13	3/0	Undyed	1	30	36	C-13
SY823P	Trexon™ 2/0 30" UD C-14	2/0	Undyed	1	30	36	C-14
SY922P	Trexon™ 3/0 30" VL C-13	3/0	Violet	1	30	36	C-13
SY923P	Trexon™ 2/0 30" VL C-14	2/0	Violet	1	30	36	C-14
UY202P	Trexon™ 5/0 30" VL CV-23	5/0	Violet	1	30	36	CV-23
UY203P	Trexon™ 4/0 30" VL CV-23	4/0	Violet	1	30	36	CV-23
UY204P	Trexon™ 3/0 30" VL CV-23	3/0	Violet	1	30	36	CV-23
UY214P	Trexon™ 4/0 30" UD CV-23	4/0	Undyed	1	30	36	CV-23

Strong sutures.
Confident closure.

Trexon™ sutures are among the latest evolutions in the Medtronic wound closure portfolio that put surgeons' needs and expectations first. With a complete range of sizes, lengths, and needle pairings, you can be assured of finding the right suture to meet your high standards.

Feel the difference of superior pliability.†,1

Contact your Medtronic representative or visit us at **medtronic.com/trexon** to experience the future of suture.

Trexon™ sutures are contraindicated for use in cardiovascular or neurological tissues and should not be used where extended approximation of tissue is required.

† Compared to legacy Biosyn™ sutures.

1. Based on internal engineering report RE00582176 Rev B, Trexon™ claims report. April 2026.
2. Trexon™ monofilament synthetic absorbable suture [instructions for use]. Mansfield, MA: Medtronic; 2025.
3. Monocryl™* violet monofilament (poliglecaprone 25) synthetic absorbable suture [instructions for use]. Somerville, NJ: Ethicon, Inc.; 1996.
4. Monocryl™* Plus antibacterial (poliglecaprone 25) synthetic absorbable suture [instructions for use]. Somerville, NJ: Ethicon, Inc.; 2005.

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