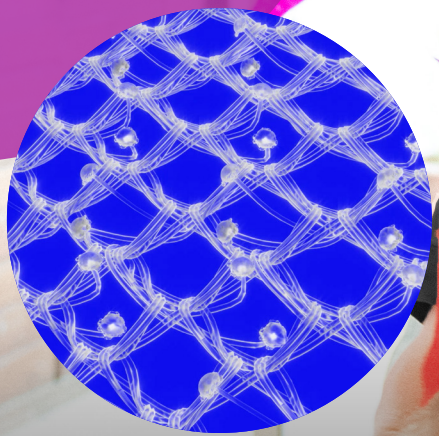
Medtronic

Resorbable mesh – reimagined.

Transorb™ self-gripping resorbable mesh

Designed with large pores and incorporating ProGrip™ technology, Transorb™ mesh provides superior strength[†,1,2] and supports excellent tissue integration[‡,2,3] in your open ventral hernia repairs. Meet the next generation of resorbable mesh.



†Compared to ProGrip™ self-gripping polyester mesh and Phasix™ mesh. Compared to a flat sheet mesh with the same level of suture fixation. Based on preclinical testing and benchtop studies, not necessarily indicative of human clinical outcomes. ‡Based on preclinical testing, not necessarily indicative of human clinical outcomes.

Risk statement: Mesh complications may include but are not limited to hematoma, seroma, infection, acute and chronic pain, extrusion/erosion, inflammation, and recurrence. See full risk statement on last page.

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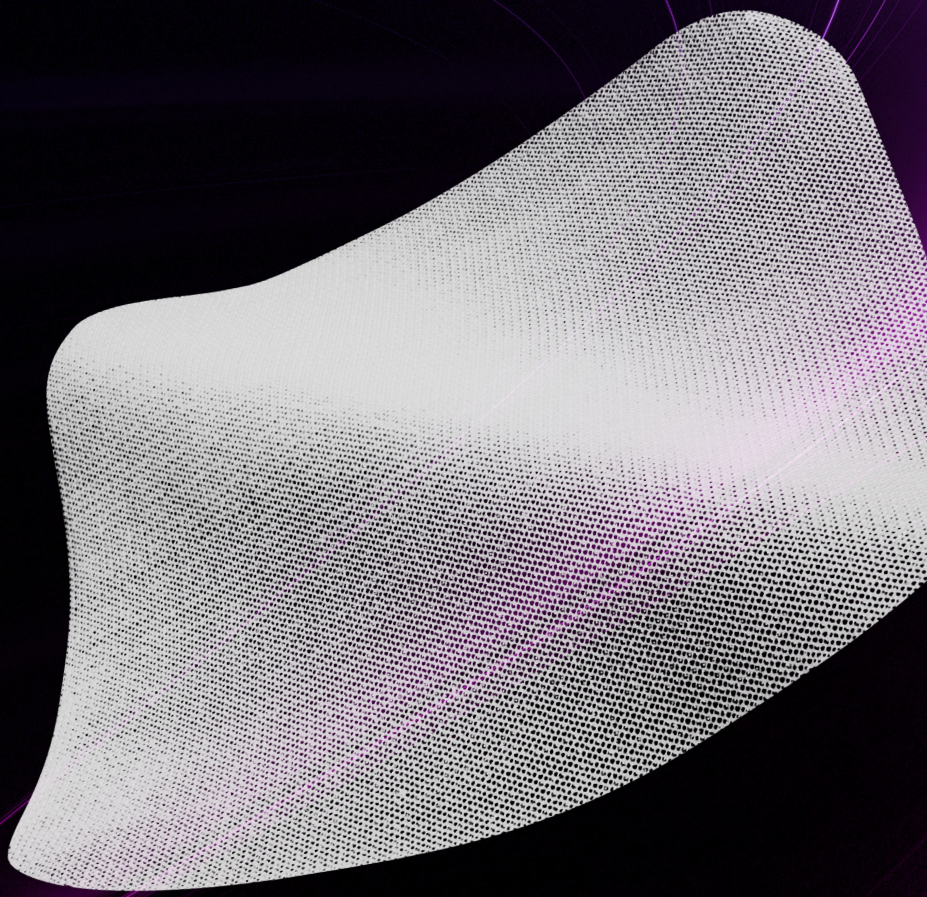
Strong – then gone.[†,2,4–6]

As the first and only[24] macroporous, fully resorbable synthetic mesh with ProGrip™ technology, Transorb™ mesh is resetting the standard. Constructed entirely of poly-L-lactide, poly-trimethylene carbonate (PLLA/TMC) copolymers,[2] it's made from nonanimal origin materials[2] and has microgrips on one side.



- **Yarn**[7]
  Knitted monofilament
- **Pore size**[‡,2]
  Large pore (1.4 mm × 1.4 mm)
- **Surface density**[‡,8]
  170 g/m^2
- **100% resorbable**
  Fully resorbs in 36 to 60 months post-implantation[†,2,6]

†Based on preclinical testing, not necessarily indicative of human clinical outcomes. ‡These are mean values measured from one batch, which may vary slightly within and between batches depending on the testing method used.

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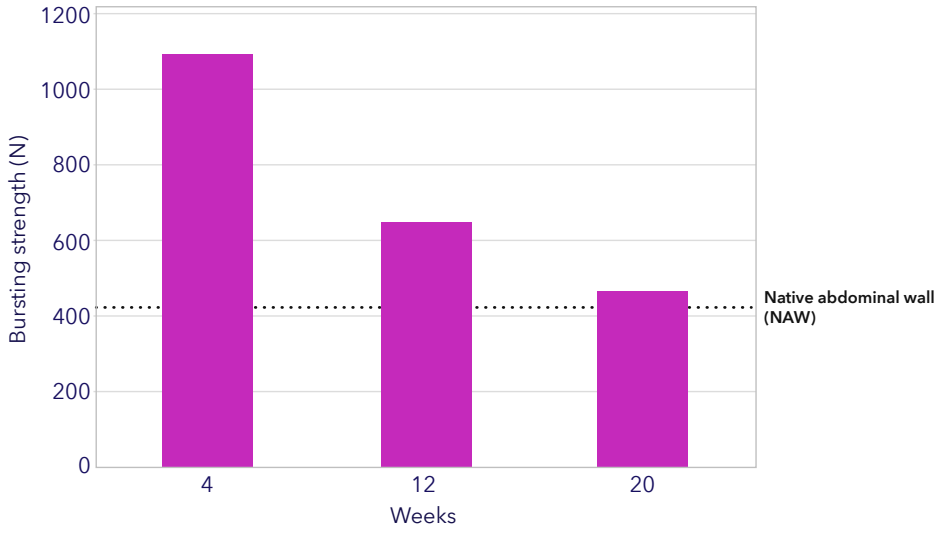
Superior strength.[†,1,2]

Transorb™ self-gripping resorbable mesh provides the robust reinforcement your patients need throughout the critical healing period – and then fully resorbs.

- **Stronger mesh:** A significantly higher tensile strength than Phasix™* mesh[‡,1]
- **Strong attachment:** Attachment force to the tissue is 1.6x stronger[§,◊,2] with ProGrip™ technology
- **Strong repair:** Macroporosity allows for excellent tissue ingrowth, providing mechanical strength to the defect repair[◊,2,9–11]
- **Strong when it matters:** Provides the same support as a permanent synthetic mesh during the critical healing period, while gradually resorbing into the body over time[◊,¶,2,6]

Repair with Transorb™ mesh is as strong as the native abdominal wall (NAW) at 20 weeks.[◊,2,4]

In vivo results – animal model performance
4, 12, and 20 weeks post-implantation



†Compared to ProGrip™ self-gripping polyester mesh and Phasix™* mesh. Compared to a flat sheet mesh with the same level of suture fixation. Based on preclinical testing and benchtop studies, not necessarily indicative of human clinical outcomes.

‡Based on benchtop studies, not necessarily indicative of human clinical outcomes.

§Compared to a flat sheet mesh with the same level of suture fixation.

◊Based on preclinical testing, not necessarily indicative of human clinical outcomes.

¶Compared to ProGrip™ self-gripping polyester mesh in simulated in vitro conditions at 20 weeks.

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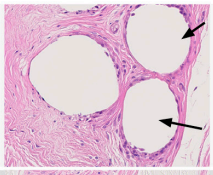
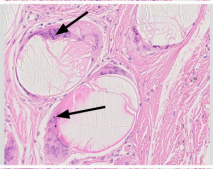
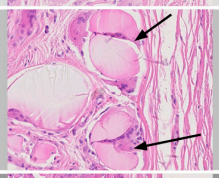
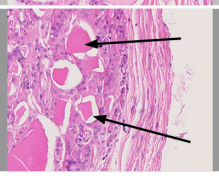
Repairs. Reinforces. Resorbs.[†,2,6,9–11]

Uniform fixation.[2] Excellent tissue integration.[†,2,3] Transorb™ self-gripping resorbable mesh is designed to reduce the risk of common hernia repair complications, giving you and your patients confidence in positive outcomes.

Tissue response and mesh degradation profile[†,2,6]

In vivo results: Animal model performance

6 months		• No signs of fiber fragmentation • Complete tissue integration & tissue ingrowth
Approx. 24 months (Approx. 2 years)		• Visible microscopic degradation signs of fiber fragments appear • Macrophages and giant cell recruitment as fiber fragmentation process is initiated
30–36 months (2.5–3 years)		• Accelerated fiber fragmentation in progress • Macrophages and giant cells present inside and on the fiber fragment surfaces, initiate cell-mediated elimination process
36–48 months (3–4 years)		• Mesh is essentially degraded • Microscopic fiber particles appear as engulfed by macrophages and giant cells leading to cell-mediated elimination process called phagocytosis – the final step of degradation

- **Between 0 to 5 months,** Transorb™ self-gripping resorbable mesh provides abdominal wall reinforcement during the critical wound healing phase while gradually transferring abdominal wall load to the healed tissue.
- **At 18 to 24 months,** mesh degradation is nearly complete.
- The remaining mesh fibers are essentially resorbed in **36 to 60 months** post-implantation. The total resorption period depends on numerous factors, including unique patient physiology.

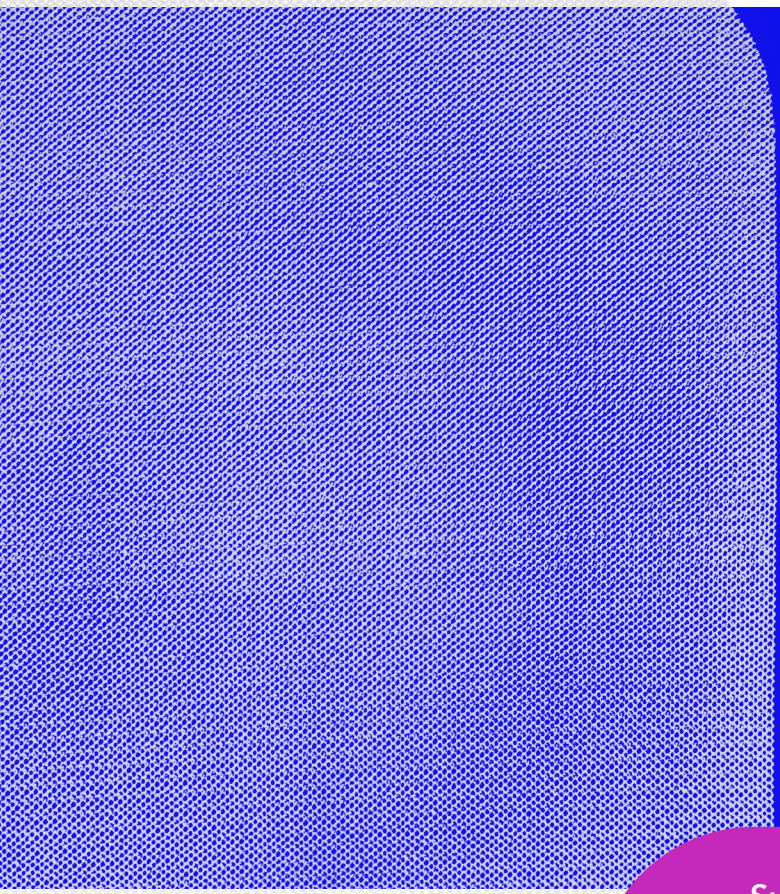
Pore size matters. Transorb™ is macroporous, with a large pore size of 1.4 mm × 1.4 mm.[‡,2] Large pores are associated with a reduced risk of infection and shrinkage,[2,9,11] as well as reduced seroma formation.[†,2,12]

†Based on preclinical testing, not necessarily indicative of human clinical outcomes.

‡These are mean values measured from one batch, which may vary slightly within and between batches depending on the testing method used.

Risk statement: Mesh complications may include but are not limited to hematoma, seroma, infection, acute and chronic pain, extrusion/erosion, inflammation, and recurrence. See full risk statement on last page.

Position in place. It's that efficient.[†,‡,§,2,13,14]



With its self-gripping ProGrip™ technology and superior conformability,[◊,15] Transorb™ mesh can bring efficiencies to your open ventral hernia procedures while delivering a strong, fully resorbable hernia repair.[†,2,4–6]

- **Resorbable microgrips:** Uniform fixation points across the mesh surface[2] may limit the need for additional fixation.[†,13]
- **Mesh transparency:** Excellent transparency aids in the visualization of underlying anatomic structures for easier placement and repositioning.[‡,14,15]
- **Overall ease of use:** Transorb™ self-gripping resorbable mesh allows for an easier mesh placement and fixation vs. flat sheet meshes with no grips.[§,2,14]

Supple. Stable. Secure. The textile properties of Transorb™ mesh provide a balance of softness and rigidity,[◊,15] while ProGrip™ technology increases mesh contact with the tissue[§,¶,12,16,17] and prevents shifting during placement.[#,18,19]

†Based on preclinical testing, not necessarily indicative of human clinical outcomes.
‡Based on feedback from 6 surgeons, conducted in lab setting with pigs.
§The use of additional suture fixation is recommended to limit the risk of hernia recurrence.
◊Compared to Phasix™ mesh and Gore™ BIO-A™ tissue reinforcement. Based on feedback from 5 surgeons.
¶Based on preclinical studies, animal data is not necessarily indicative of human clinical outcomes.
#Based on benchtop studies, not necessarily indicative of human clinical outcomes.

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Mesh properties comparison

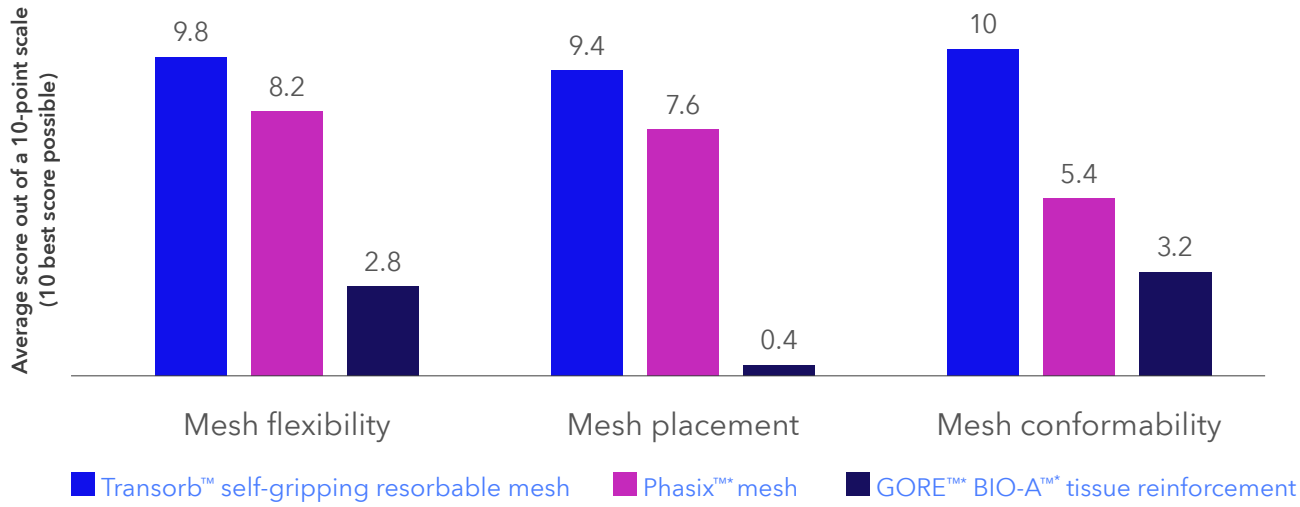
	Transorb™ self-gripping resorbable mesh	**Phasix™* mesh**	**GORE™* BIO-A™* tissue reinforcement**
Materials	**Poly-L-lactide, poly-trimethylene carbonate copolymer (PLLA/TMC) with grips on one side[7]**	Poly-4-hydroxybutrate (P4HB)[21]	Polyglycolide/trimethylene carbonate copolymer (PGA-TMC)[23]
Resorption	**Mesh degradation nearly complete in 18–24 months, remaining fibers essentially resorbed in 36–60 months†,[2,6]** **Degradation by hydrolysis**	Essentially complete within 12–18 months[21] Degradation by hydrolysis[24]	Should be complete by 6–7 months[23] Degraded via a combination of hydrolytic and enzymatic pathways[24]
Pore size	**Large pore (1.4 mm × 1.4 mm)‡,[2]**	Small pore (0.9 mm × 0.7 mm)[22]	Micro pore (matrix structure)[23]
ProGrip™ technology	**Yes** Grips are present over the entire mesh surface to help maintain the device in place during abdominal wall closure[18,20] and may limit the need for additional fixation†,[13]	No	No

†Based on preclinical testing, not necessarily indicative of human clinical outcomes.
‡These are mean values measured from one batch, which may vary slightly within and between batches depending on the testing method used.

Risk statement: Mesh complications may include but are not limited to hematoma, seroma, infection, acute and chronic pain, extrusion/erosion, inflammation, and recurrence. See full risk statement on last page.

What do surgeons think?

Transorb™ self-gripping resorbable mesh has been rated superior than Phasix™* mesh and GORE™* BIO-A™* tissue reinforcement in terms of flexibility, placement, and conformability.†,15



†Based on feedback from 5 surgeons.

"Better tissue contact, more conformability, easier handling versus Phasix™*."

–General surgeon in the U.S. (currently uses Phasix™*)

"I like the large pore size, the bigger the better – you can see, but it is all about the tissue [ingrowth]."

–General surgeon in the U.S. (currently uses Phasix™*)

"This is an absolute 10! You're basically getting ProGrip™ that's resorbable. That's great."

–General surgeon in the U.S. (currently uses Phasix™*)

"This longer timeline means it will be stronger and you will end up with better tissue strength and better integration."

–General surgeon in the U.S. (currently uses Phasix™*)

Risk statement: Mesh complications may include but are not limited to hematoma, seroma, infection, acute and chronic pain, extrusion/erosion, inflammation, and recurrence. See full risk statement on last page.

Value analysis committee

Common questions and answers about Transorb™ self-gripping resorbable mesh

Q: Is there equipment required or involved with the use of this product?	**A:** It requires the use of related equipment for open extraperitoneal ventral hernia repair procedures.
Q: What are the indications for use?	**A:** Transorb™ self-gripping resorbable mesh is intended to be used for the reinforcement of abdominal wall soft tissues where weakness exists in open procedures involving ventral hernia repair.
Q: Where is the safety infromation located?	**A:** Safety information can be found in the IFU.
Q: What packaging does this product come in and what is the unit of measure (e.g., 5 per box)?	**A:** The mesh is packaged into a Tyvek™ envelope with a polypropylene tray to facilitate handling; then into a sealed foil pouch that forms the sterile barrier and that includes a desiccant which is neither intended to be used in combination with the device nor during the surgery. Secondary packaging consists of a commercial cardboard envelope. The mesh product is packaged in single units (1 per box).
Q: What routine maintenance/cleaning is required?	**A:** None. The product is single-use only.
Q: What other clinical areas will implant, manage, maintain, or access this product?	**A:** No other clinical areas.
Q: What does this item replace and/or compete with in the market?	**A:** Phasix™* mesh, and GORE™* BIO-A™* tissue reinforcement.
Q: Is this product sterile?	**A:** Yes. The mesh is a sterile single-use device. It is sterilized by ethylene oxide, and it is not for reuse or resterilization.
Q: Does this product or its packaging contain mercury or latex?	**A:** No.
Q: What is the minimum order quantity for this product or for your company?	**A:** You may order as needed.
Q: What procedure does this product support?	**A:** Open extraperitoneal ventral hernia repair.

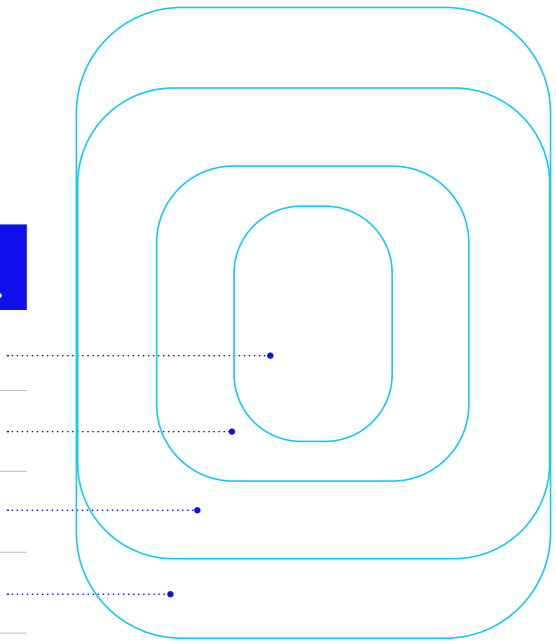
Frequently asked questions (FAQ)

Q: What evidence supports improved patient outcomes for this product/procedure?	**A:** ProGrip™ technology helps to maintain the Transorb™ mesh in contact with the tissue, supporting an excellent tissue integration.[†,2,3] Large pore size allows for excellent tissue ingrowth[†,2,9–11] and is associated with a reduced risk of infection and shrinkage.[2,9,11] Mesh transparency aids visualization of underlying anatomic structures, reducing the risk of injury to vessels and nerves during mesh fixation.[‡,14] Designed for long-term support, with full resorption over time, for a strong repair.[†,2]
Q: Is clinical training or privileging required for this product?	**A:** This product is intended to be used by trained and licensed physicians. Please follow instructions provided in the IFU.
Q: At the end of life, this product will be disposed of through which EPA-designated waste streams?	**A:** Not applicable, except for product returned due to complaints. Those products are considered biological wastes.
Q: Are there any known safety issues or recalls for this product?	**A:** No.
Q: What is the shelf life of this product?	**A:** 3 years.

†Based on preclinical testing, not necessarily indicative of human clinical outcomes.
‡Based on feedback from 6 surgeons, conducted in lab setting with pigs.

It’s time to reimagine resorbable mesh.

Order code	Description	Dimensions	Qty.
TSB1510	Poly-L-lactide, poly-trimethylene carbonate (PLLA/TMC) copolymers with grips on one side	15 cm × 10 cm (5.9 in × 3.9 in)	1
TSB2020	Poly-L-lactide, poly-trimethylene carbonate (PLLA/TMC) copolymers with grips on one side	20 cm × 20 cm (7.9 in × 7.9 in)	1
TSB3030	Poly-L-lactide, poly-trimethylene carbonate (PLLA/TMC) copolymers with grips on one side	30 cm × 30 cm (11.8 in × 11.8 in)	1
TSB4030	Poly-L-lactide, poly-trimethylene carbonate (PLLA/TMC) copolymers with grips on one side	40 cm × 30 cm (15.7 in × 11.8 in)	1



We’re always here to support you and your patients.
Contact your Medtronic representative or visit us at medtronic.ca to bring Transorb™ self-gripping resorbable mesh to your OR.

References
1. Based on internal report #1203CR764a, Phasix™* mesh vs. Transorb™ self-gripping resorbable mesh – ball burst statistical comparison. October 2021. **2.** Vestberg R, Lecuivre J, Radlovic A, Payet E, Bayon Y, Bouré L. A novel self-gripping long-term resorbable mesh providing temporary support for open primary ventral and incisional hernia. *J Mater Sci Mater Med.* 2023;34(11):59. **3.** Based on internal report #BIO111-a, Biological evaluation report: Transorb™ self-gripping resorbable mesh and Deternia™† self-gripping resorbable mesh. October 1, 2021. **4.** Based on internal report #1203CR709, Comparison of abdominal hernia meshes evaluated in a porcine ventral abdominal wall defect model: A pivotal study. November 2023. **5.** Based on internal report#1203CR510a, Mémorandum: Degradation mechanism of resorbable mesh. June 2020. **6.** Based on internal report #1203CR462a, Evaluation of Transorb™ self-gripping resorbable mesh and Deternia™† self-gripping resorbable mesh degradation and associated local tissue effects. November 2023. **7.** Transorb™ Self-Gripping Resorbable Mesh [instructions for use]. Trévoux, France: Medtronic; 2024. **8.** Based on internal report #1203CR701, Fabrication of RM for design validation. **9.** Brown CN, Finch JG. Which mesh for hernia repair? *Ann R Coll Surg Engl*. 2010;92(4):272–278. **10.** Lake SP, Ray S, Zihni AM, Thompson DM Jr, Gluckstein J, Deeken CR. Pore size and pore shape--but not mesh density--alter the mechanical strength of tissue ingrowth and host tissue response to synthetic mesh materials in a porcine model of ventral hernia repair. *J Mech Behav Biomed Mater*. 2015;42:186–197. **11.** Weyhe D, Cobb W, Lecuivre J, et al. Large pore size and controlled mesh elongation are relevant predictors for mesh integration quality and low shrinkage--Systematic analysis of key parameters of meshes in a novel minipig hernia model. *Int J Surg.* 2015;22:46–53. **12.** Jin J, Schomisch S, Rosen MJ. In vitro evaluation of the permeability of prosthetic meshes as the possible cause of postoperative seroma formation. *Surg Innov*. 2009;16(2):129–133. **13.** Based on internal report #1203CR867, Evaluation and comparison of meshes fixation strengths in a porcine model at four weeks after implantation: pivotal study. November 2023. **14.** Based on internal report #1203CR738, Transorb™ self-gripping resorbable mesh design validation lab – marketing questionnaire. October 2021. **15.** Based on internal report #1203CR774, Transorb™ self-gripping resorbable mesh congress VOC. November 2021. **16.** He C, Lu J, Ong MW, Lee DJK, Tan KY, Chia CLK. Seroma prevention strategies in laparoscopic ventral hernia repair: a systematic review. *Hernia*. 2020;24(4):717–731. **17.** Based on internal report #1203CR749, Evaluation and comparison of Meshes fixation forces in a Porcine Model for marketing purpose. November 2023. **18.** Based on internal report #1203CR621a, Design verification activities associated with DI-261 (ex vivo gripping test without fixation). November 2020. **19.** Based on internal report #1203CR750, Transorb™ self-gripping resorbable mesh – marketing evaluation form. October 2021. **20.** Based on internal report #1203CR752a, Design validation and summative usability evaluation of Transorb™ self-gripping resorbable mesh – additional study. October 2021. **21.** Phasix™* Mesh Fully Resorbable Implant for Soft Tissue Reconstruction [instructions for use]. Warwick, RI: C. R. Bard, Inc.; 2010. **22.** Based on internal report #1203CR499a, Physical and mechanical characterization of Bard Phasix™* mesh. March 2020. **23.** GORE™* BIO-A™* Tissue Reinforcement [instructions for use]. Flagstaff, AZ: W. L. Gore & Associates, Inc.; 2008. **24.** Data on file.

† "Deternia" is a Medtronic internal project name for "Transorb self-gripping resorbable mesh".

Medtronic

99 Hereford Street
Brampton, Ontario, L6Y 0R3
Toll-free: 800.268.5346
Tel: 905.460.3800

medtronic.ca

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.

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