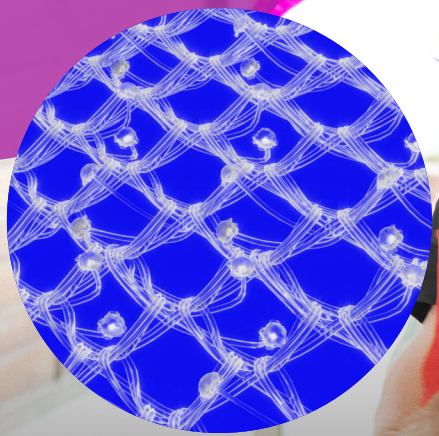
Medtronic

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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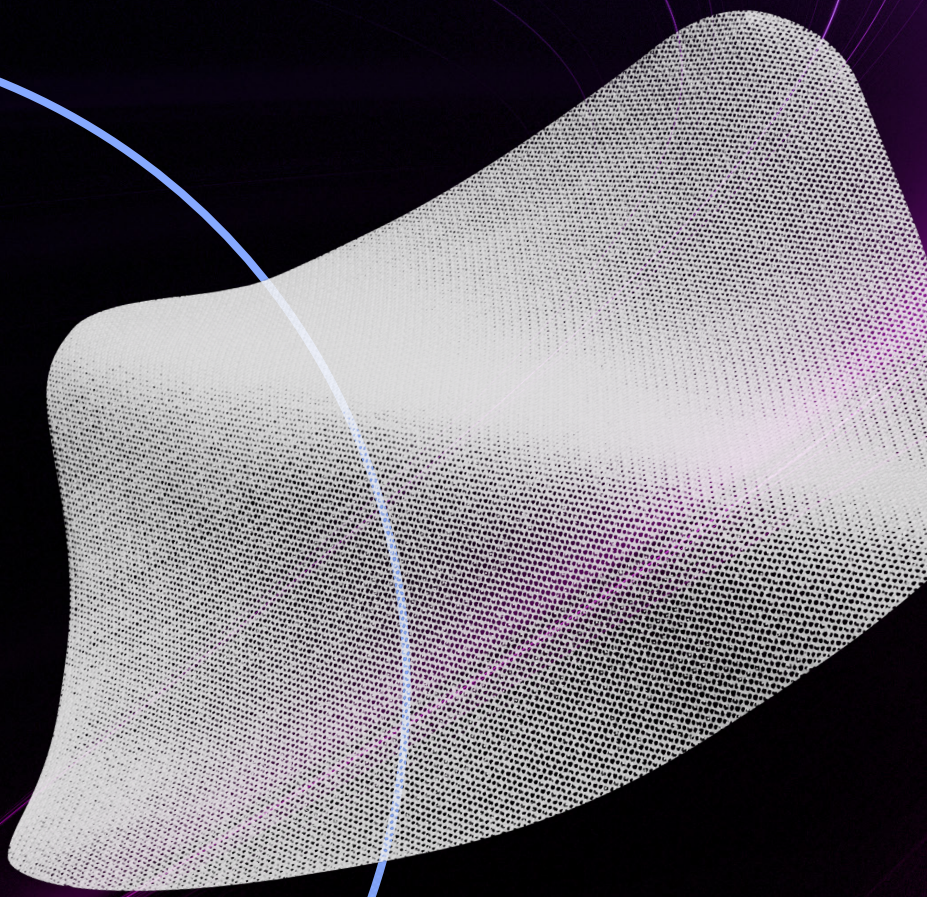
Strong – then gone.[†,2,4–6]

As the first and only 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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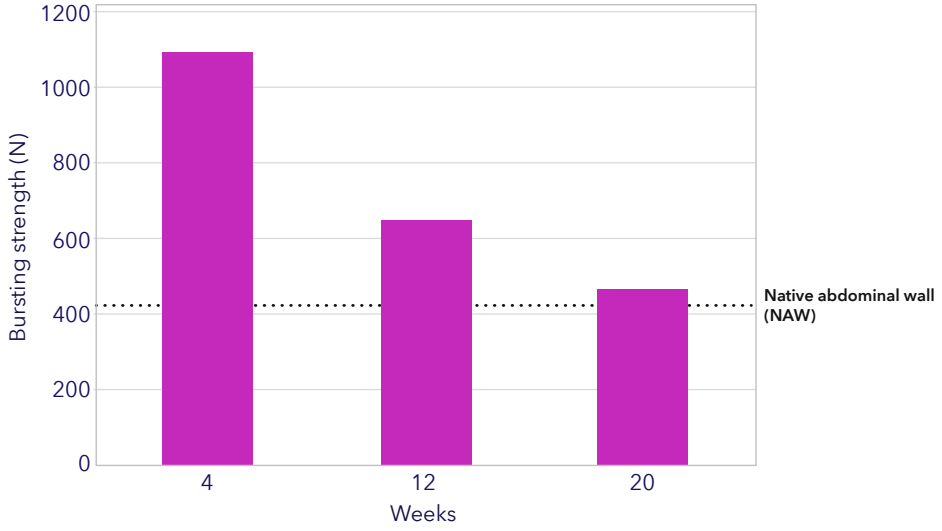
Superior strength.[†,1,2]

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]
- **Stronger attachment:** Attachment force to the tissue is 1.6x stronger[§,◊,2] with ProGrip™ technology
- **Stronger 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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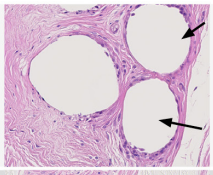
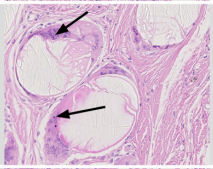
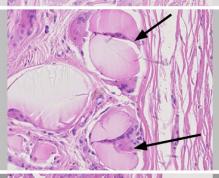
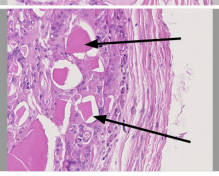
Repairs. Reinforces. Resorbs.[†,2,6,9–11]

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.

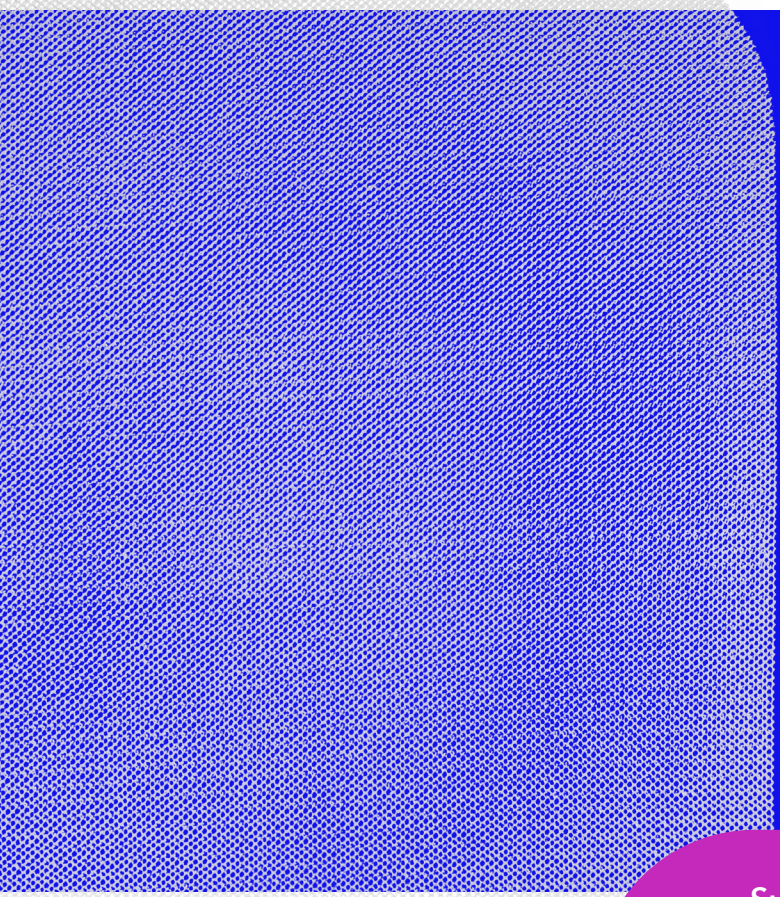
Pore size matters. Transorb™ is macroporous, with a large pore size of 1.4 mm × 1.4 mm.[‡,2] Large pores are associated with a reduced risk of infection and shrinkage,[2,9,11] as well as reduced seroma formation.[†,2,12]

†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.

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.

Mesh properties comparison

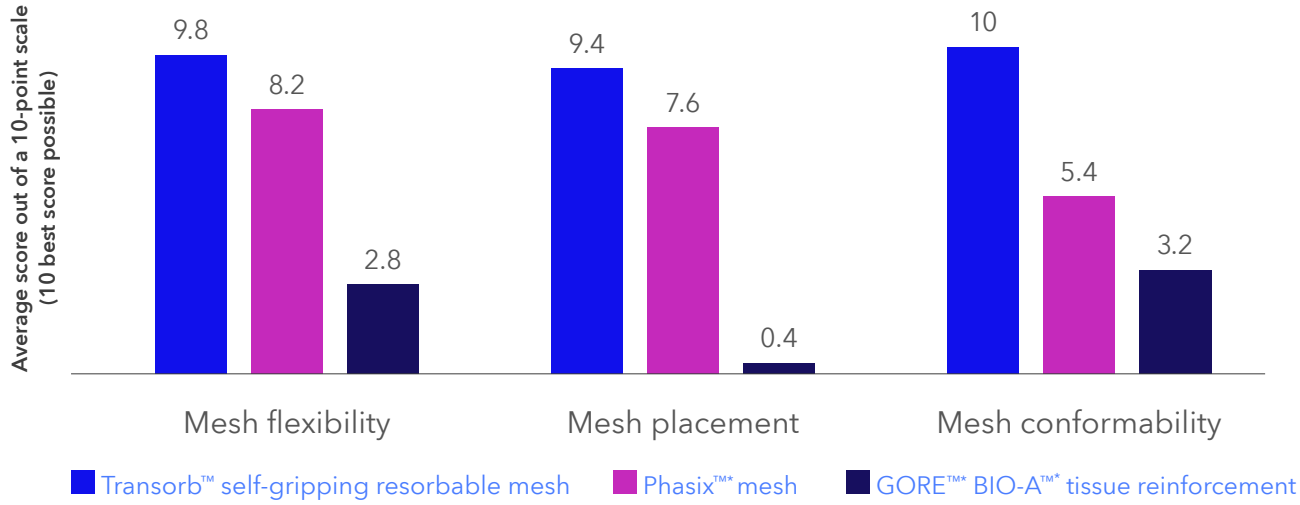
	Transorb™ self-gripping resorbable mesh	Phasix™* mesh	GORE™* BIO-A™* tissue reinforcement/GORE™* Enform™* extraperitoneal biomaterial
Materials	Poly-L-lactide, poly-trimethylene carbonate copolymer (PLLA/TMC) with grips on one side[7]	Poly-4-hydroxybutrate (P4HB)[21]	Polyglycolide/trimethylene carbonate 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	Should be complete by 6–7 months[23] Degraded via a combination of hydrolytic and enzymatic pathways
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 is the vendor payment address?	**A:** Medtronic Surgical Innovations 60 Middletown Ave, North Haven, CT 06473
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, GORE™* BIO-A™* tissue reinforcement, Tigr™* matrix mesh, and GORE™* Enform™* extraperitoneal biomaterial.
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: List all diagnosis-related groups (DRGs) that this product may be used for.	**A:** Please visit https://www.medtronic.com/covidien/en-us/support/reimbursement/advanced-surgical.html for the latest information on reimbursement and coding for Medtronic hernia mesh products.
Q: Provide all relevant reimbursement information including which insurance companies reimburse for this product.	**A:** Please visit https://www.medtronic.com/covidien/en-us/support/reimbursement/advanced-surgical.html for the latest information on reimbursement and coding for Medtronic hernia mesh products.
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: Does this product meet any third-party environmental certifications such as Green Seal™*, Energy Star™*, WaterSense, Green Label, or Forest Stewardship Certified?	**A:** No.
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.

FDA 510(k) clearance letter

February 13, 2024

Sofradim Production
Mickaël Nicolas
Principal Regulatory Affairs Specialist
116, Avenue du Formans
Trévoux, 01600, France

Re: K233661
Trade/Device Name: Transorb™ Self-Gripping Resorbable Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OWT, OOD, FTL
Dated: November 14, 2023
Received: November 15, 2023

Dear Mickael Nicolas:

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).

FDA 510(k) clearance letter

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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

Digitally signed by Tek N. Lamichhane -S
Date: 2024.02.13 07:48:57 -05'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and 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

Enclosure

Instructions for use (IFU)

Medtronic

Transorb™

Self-Gripping Resorbable Mesh

PT00190367

(99)7500346

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY

IMPORTANT!

This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

This device was designed, tested and manufactured for single patient use only. Reuse and/or reprocessing and/or re-sterilization of this device may lead to its failure, subsequent patient injury and may create the risk of contamination and patient infection. Do not reuse, reprocess or re-sterilize this device.

DESCRIPTION

Transorb™ self-gripping resorbable mesh is designed for ventral hernia repair when placed in an extraperitoneal space by open surgical approach.

Transorb™ self-gripping resorbable mesh is made of a fully resorbable bi-dimensional Poly-L-lactide, poly-trimethylene carbonate copolymer (PLLA/TMC) monofilament textile with monofilament PLLA/TMC absorbable grips on one side.

Transorb™ self-gripping resorbable mesh is available in different shapes and sizes.

Mesh composition:

Poly-L-lactide, poly-trimethylene carbonate copolymer (PLLA/TMC) monofilament yarn (up to 21g).

The detailed composition refers to the estimated maximum amount of each material and substance to which patient can be exposed when 1 unit of the largest size of Transorb™ self-gripping resorbable mesh is implanted (i.e 40 x 30 cm). These amounts will be less for smaller sizes or if the mesh is trimmed by the practitioner prior to implantation.

Transorb™ self-gripping resorbable mesh is a macro-porous mesh knitted from resorbable monofilament PLLA/TMC yarns. It has been designed to reinforce soft tissues where weakness exists by providing strength and tissue integration throughout the expected healing period. Transorb™ self-gripping resorbable mesh has absorbable PLLA/TMC grips on one side that facilitate positioning and contribute to fixation. The PLLA/TMC mesh and grips degrade and resorb in vivo by hydrolysis and are metabolized by the body into CO_2 and H_2O.

The macro-porous textile provides strength required to withstand biomechanical stresses throughout the healing period, while allowing for tissue ingrowth. As the textile integrates, host tissue ingrowth is intended to provide strength to the repair.

Preclinical studies showed that the mesh maintains mechanical characteristics to reinforce the abdominal wall in vivo for at least 20 weeks and progressively resorbs.

Preclinical studies showed that the grips contribute to the fixation of the mesh to surrounding tissue in vivo for at least 4 weeks.

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.

INDICATIONS

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.

CONTRAINDICATIONS

Because Transorb™ self-gripping resorbable mesh is fully absorbable, it should not be used where permanent support is required.

As Transorb™ self-gripping resorbable mesh will not stretch to accommodate growth, its use is not appropriate in patients in a period of growth or pregnancy.

POSSIBLE COMPLICATIONS

The possible complications associated with the use of Transorb™ self-gripping resorbable mesh are those typically associated with surgically implantable meshes: hematoma, seroma, infection, acute and chronic pain, extrusion/erosion, inflammation, recurrence, and/or allergic reaction to the components of the product.

The incidence and severity of complications may depend on numerous factors, including but not limited to the type and size of the defect, the mesh fixation, the surgical technique and patient-related factors (e.g., comorbidities) . A thorough assessment of each patient's medical history and condition should be made to determine the suitability for implantation of this device. The treatment of complications may require one or more revision surgeries, that may not necessarily resolve the complications and may pose risks of subsequent complications. Being an implant designed to integrate into tissues, significant dissection may be required in case it needs to be removed, in part or in whole.

It is important that patients are given complete information regarding possible complications.

Any adverse event or serious incident that occurs in relation to the device should be reported to the manufacturer and/or the competent authority in which the patient is established, as applicable per the federal, national or local regulations.

WARNINGS

1. The compatibility of Transorb™ self-gripping resorbable mesh with trocars and laparoscopic instruments has not been established. Transorb™ self-gripping resorbable mesh is not recommended for passage through a trocar; product damage may occur.
2. Do not place the mesh in direct contact with the viscera. Direct contact with the viscera may lead to risks of adhesions, fistula formation and bowel obstruction. Do not implant the mesh in an intra-peritoneal position.
3. When implanting in a pre-peritoneal site, the mesh shall not be placed with the grips towards the peritoneum, adhesion may develop if grips are in contact with bowels. The self-gripping side of the mesh can be differentiated from the smooth non-gripping side visually or through tactile feel.
4. When implanting in a pre-peritoneal site, complete coverage of the mesh with peritoneum should be achieved to minimize the risks of adhesion.
5. The placement of Transorb™ self-gripping resorbable mesh as a bridging device is not recommended. When using Transorb™ self-gripping resorbable mesh, the defect shall be closed.
6. The choice of the mesh size is determined by the surgeon. The mesh should assure necessary overlap beyond the margins of the defect according to the surgeon's practice. When possible, a minimum of 5 cm overlap over the edges of the initial defect is recommended.
7. The use of additional suture fixation is recommended to limit the risk of hernia recurrence.
8. Transorb™ self-gripping resorbable mesh should not be overly stretched when it is being put in place in order to maintain the elasticity and the porosity of the reinforcement. During fixation, a moderate and equal tension should be applied in all directions in order to account for wound shrinkage during the healing process.
9. To avoid injury, careful attention is required if fixating the device in the presence of nerves or vessels.
10. For women planning future pregnancies, the surgeon should be aware that this product may not stretch significantly as the patient grows but will disappear completely after 36 to 60 months.
11. The use of any synthetic mesh in a contaminated or infected site could lead to additional complications and it is not recommended. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require removal of the mesh.
12. The safety and effectiveness of Transorb™ self-gripping resorbable mesh have not been established in the repair of parastomal hernia.
13. The safety and effectiveness of Transorb™ self-gripping resorbable mesh has not been evaluated in the presence of malignancies in the abdominopelvic cavity.
14. Transorb™ self-gripping resorbable mesh is not intended for repair of chest wall defects.
15. Transorb™ self-gripping resorbable mesh is not intended for repair of pelvic organ prolapse and treatment of stress urinary incontinence.
16. Do not use the device past the labeled expiration date. The device is provided in a single sterile package and intended for single use only. Upon receipt of shipment, ensure that the packaging is not open or damaged and retains its sealed integrity. Do not use the device if the package is opened or damaged or if the integrity of the packaging appears compromised.
17. The package contains a desiccant. It is neither intended to be used in combination with the device nor during the surgery.
18. Open the packaging only for the placement of the mesh and handle the latter using clean sterile gloves and instruments.
19. Unused product, explant and packaging may be a potential biohazard. Handle and dispose them with the necessary precautionary measures in accordance with accepted medical practices and with applicable local, state and federal laws and regulations on disposal of packaging and medical waste. / Unused portions of the mesh should be discarded. If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard mesh with care to prevent risk of transmission of viral and other infections.

PRECAUTIONS

- Users should be familiar with surgical procedures and techniques involving the use of surgical mesh before employing this device. Only physicians qualified in the appropriate surgical techniques should use this device.
- This device should only be used by experienced practitioners who do so under their own responsibility.

OPERATING STEPS

- The mesh is provided in sterile packaging. The packaging is to be checked for any damage before use. Do not use the mesh if the packaging is opened or damaged. The mesh is to be handled according to accepted aseptic practices.
- Transorb™ self-gripping resorbable mesh may be cut to shape or size desired for each specific application.

CAUTION: The mesh is to be positioned so its edges extend beyond the margins of the defect; when possible, a minimum of 5 cm overlap over the edges of the initial defect is recommended.

CAUTION: When implanting in a pre-peritoneal site, the mesh shall not be placed with the grips towards the peritoneum, adhesion may develop if grips are in contact with bowels. The self-gripping side of the mesh can be differentiated from the smooth non-gripping side visually or through tactile feel.

- Transorb™ self-gripping resorbable mesh shall be fixated. Fixation should be performed depending on surgical procedure, size of defect and patient conditions. The textile self-gripping feature facilitates positioning and contributes to fixation for at least 4 weeks.

CAUTION: The use of additional fixation is recommended to limit the risk of hernia recurrence.

- It is recommended to fixate Transorb™ self-gripping resorbable mesh with sutures at a distance approximately 1 cm from the edge of the mesh.
- Other fixation methods than sutures have not been evaluated for use with Transorb™ self-gripping resorbable mesh.

STERILIZATION METHOD

Sterile single-use device. Sterilized by ethylene oxide. Do not resterilize.

FOLLOW-UP

Transorb™ self-gripping resorbable mesh is intended for permanent implantation. It is not intended to be removed, repaired or replaced in normal conditions of use. It does not require particular follow-up. Necessity and modalities of patient follow-up shall be determined by exerting medical judgment and per accepted medical practice inherent to the surgery.

STORAGE

Transorb™ self-gripping resorbable mesh does not require any special storage conditions.

MAGNETIC RESONANCE IMAGING (MRI) COMPATIBILITY

Transorb™ self-gripping resorbable mesh poses no known hazards resulting from exposure to any magnetic resonance (MR) environment. It is classified as MR safe.

TRACEABILITY

A traceability label is attached to every device package which identifies the type and lot number of the device. This label should be affixed to the patient's permanent medical record to clearly identify the device which was implanted.

A patient implant card is also supplied with every device package. It shall be provided at discharge to the patient who has been implanted with the device if required by applicable federal, national or local regulations. This patient implant card includes information allowing the identification of the device and a website address from which the patient can access additional information.

STERILE EO Sterilized using ethylene oxide	REF Catalogue number
Single sterile barrier system with protective packaging inside	Manufacturer
Single use	Use-by date
Rx ONLY Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.	LOT Batch code
Do not resterilize	Date of manufacture
Do not use if package is damaged	Patient identification
Consult instructions for use	Date
Caution	Health care center or doctor
Biological risks	Patient information website
MD Medical device	UDI Unique device identifier
MR MR safe	

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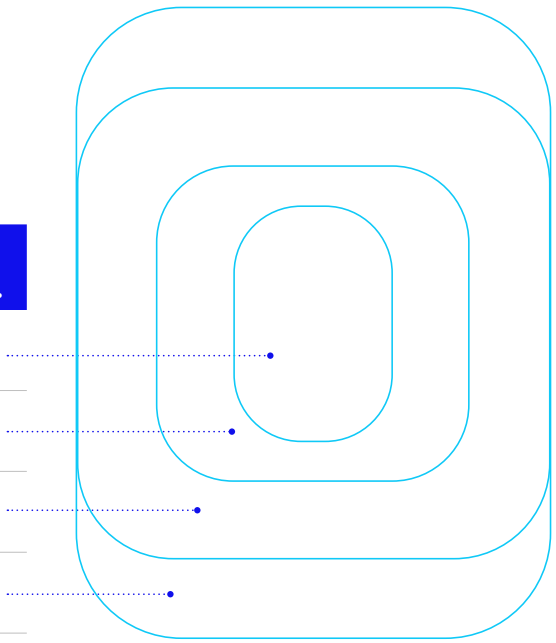
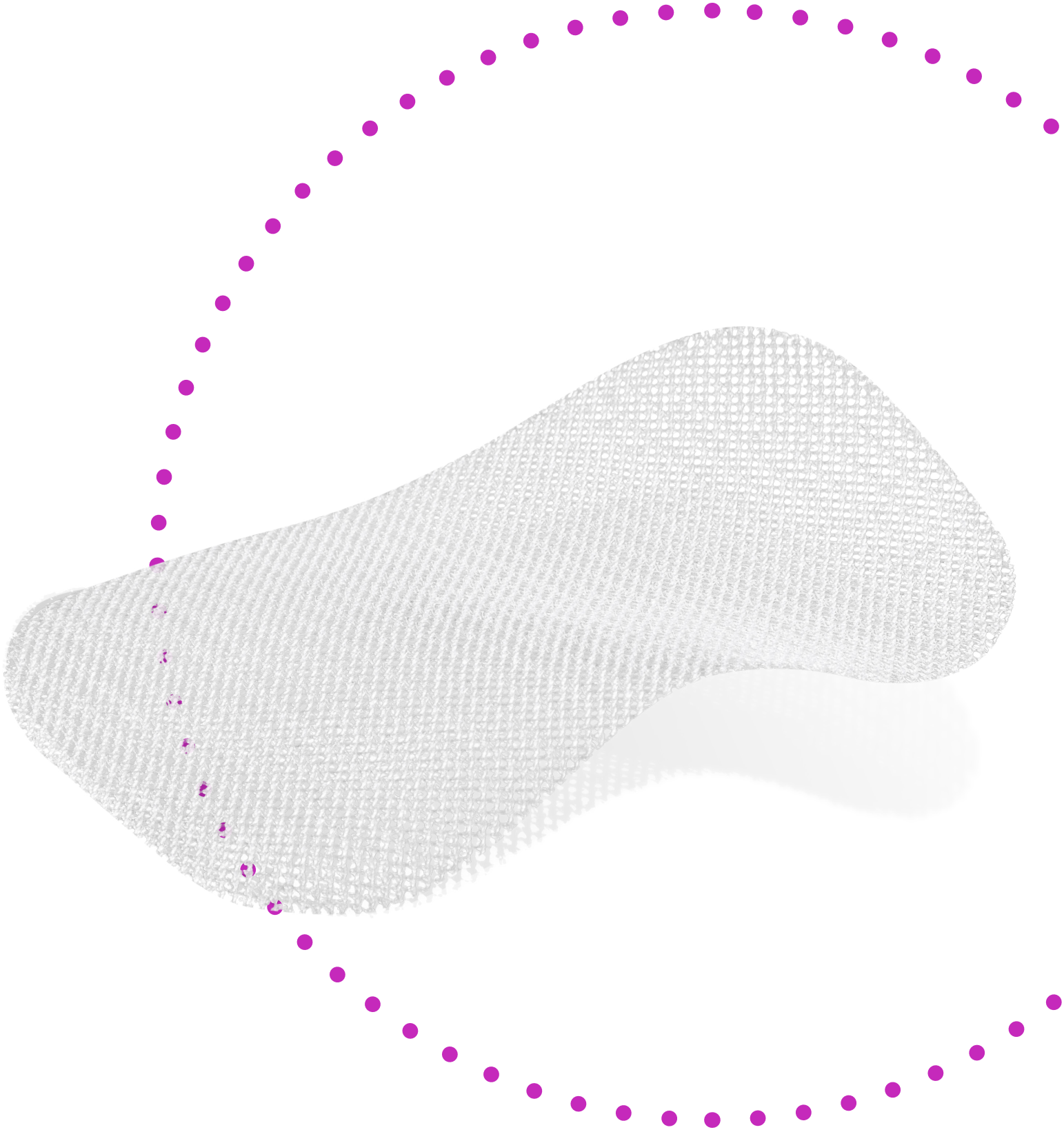
It’s time to reimagine resorbable mesh.

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.com/transorb to bring Transorb™ self-gripping resorbable mesh to your OR.**



Risk statement

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.

WARNING:

- The compatibility of Transorb™ self-gripping resorbable mesh with trocars and laparoscopic instruments has not been established. Transorb™ self-gripping resorbable mesh is not recommended for passage through a trocar; product damage may occur.
- Do not place the mesh in direct contact with the viscera. Direct contact with the viscera may lead to risks of adhesions, fistula formation and bowel obstruction. Do not implant the mesh in an intraperitoneal position.
- When implanting in a pre-peritoneal site, the mesh shall not be placed with the grips towards the peritoneum, adhesion may develop if grips are in contact with bowels. The self-gripping side of the mesh can be differentiated from the smooth non-gripping side visually or through tactile feel.
- When implanting in a pre-peritoneal site, complete coverage of the mesh with peritoneum should be achieved to minimize the risks of adhesion.
- The placement of Transorb™ self-gripping resorbable mesh as a bridging device is not recommended. When using Transorb™ self-gripping resorbable mesh, the defect shall be closed.
- Transorb™ self-gripping resorbable mesh should not be overly stretched when it is being put in place in order to maintain the elasticity and the porosity of the reinforcement. During fixation, a moderate and equal tension should be applied in all directions in order to account for wound shrinkage during the healing process.
- To avoid injury, careful attention is required if fixating the device in the presence of nerves or vessels.
- The use of additional suture fixation is recommended to limit the risk of hernia recurrence.
- For women planning future pregnancies, the surgeon should be aware that this product may not stretch significantly as the patient grows but will disappear completely after 36 to 60 months.
- The use of any synthetic mesh in a contaminated or infected site could lead to additional complications and it is not recommended. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require removal of the mesh.
- The safety and effectiveness of Transorb™ self-gripping resorbable mesh have not been established in the repair of parastomal hernia.
- Transorb™ self-gripping resorbable mesh is not intended for repair of chest wall defects.
- Transorb™ self-gripping resorbable mesh is not intended for repair of pelvic organ prolapse and treatment of stress urinary incontinence.
- The safety and effectiveness of Transorb™ self-gripping resorbable mesh has not been evaluated in the presence of malignancies in the abdominopelvic cavity.

ADVERSE EFFECTS:

The possible complications associated with the use of Transorb™ self-gripping resorbable mesh are those typically associated with surgically implantable meshes: hematoma, seroma, infection, acute and chronic pain, extrusion/erosion, inflammation, recurrence, and/or allergic reaction to the components of the product.

The incidence and severity of complications may depend on numerous factors, including but not limited to the type and size of the defect, the mesh fixation, the surgical technique and patient-related factors (e.g., comorbidities). A thorough assessment of each patient's medical history and condition should be made to determine the suitability for implantation of this device. The treatment of complications may require one or more revision surgeries, that may not necessarily resolve the complications and may pose risks of subsequent complications. Being a permanent implant designed to integrate into tissues, significant dissection may be required in case it needs to be removed, in part or in whole. It is important that patients are given complete information regarding possible complications.

CONTRAINDICATIONS:

- Because Transorb™ self-gripping resorbable mesh is fully absorbable, it should not be used where permanent support is required.
- As Transorb™ self-gripping resorbable mesh will not stretch to accommodate growth, its use is not appropriate in patients in a period of growth or pregnancy.

Please refer to IFU for complete risk information.

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