

Medtronic

More than a 3D mesh

Dextile™ anatomical mesh

Designed for

- more anatomical
- more coverage
- more porosity
- more conformity



The ideal shape
for optimal inguinal
hernia repair.¹⁻³

Designed with you and your patients in mind

Our goal is to always provide you with innovative solutions that enhance your surgical experience and improve patient outcomes. That's why we created the Dextile™ anatomical mesh.

Its ideal shape, transparency, and handling make it easy to use.^{1,3,5-7}



Dextile™ anatomical mesh



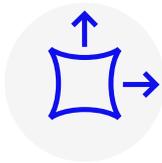
More design*

The 3-D patented anatomical shape conforms with the contours each side of the inguinal region^{1,3,8} and allows positioning of the mesh without fixation.^{1,6,†}



More technology*

Dextile™ anatomical mesh is made from non-absorbable macroporous monofilament polypropylene textile.^{1,4,5,10} It has a unique structure that keeps its shape after trocar passage.^{1-3,8}



More coverage*

The shape of the mesh allows a wide coverage of the myopectineal orifice to minimize risk of recurrence.^{1,3,6,8}



More porosity*

A large pore size of >1mm supports excellent tissue ingrowth.^{6,9}



More transparency*

Large pore size also enables visualization of surrounding anatomy during surgery.^{1,5,7,9}

* When compared to main competitor.

† Depending on the size of the defect, patient conditions, and procedure.

The benefits of real anatomical design^{3,8}

Dextile™ anatomical mesh offers an ideal shape, wide coverage, and anatomical compliance for optimal patient outcomes.^{1,6,8}

It's designed for efficient trocar introduction, positioning, and placement to adapt with the contours of the inguinal anatomy.^{1-3,6,7,10}

Monofilament polypropylene textile knitted with good balance between softness & rigidity¹²

Sealed edge maintains the shape after trocar passage, and helps with ease of handling^{1,2,9,11}

Large pore size offers excellent tissue integration^{5,7,9}

Green "Medial Line" letters facilitate mesh orientation towards patient's midline^{1,3}

ML

Inferior flap adapts to inguinal anatomy

3-D anatomical shape for wide coverage of myopectineal orifice^{1,6}

Anatomical design with reinforced contours makes it possible to position the mesh without fixation^{13,†}

Unsealed inferior edge improves anatomical compliance^{1,3,6,†}

ML = Medial Line

† Depending on the size of the defect, patient conditions, and procedure.

Product specifications

We designed Dextile™ anatomical mesh for effective hernia repair.

Specifically for minimally invasive – including conventional TAPP and TEP and robotic TAPP surgical approach – inguinal hernia surgery.⁴

Mesh composition

Dextile™ anatomical mesh is made from non-absorbable monofilament polypropylene textile.¹⁻³ It has exclusive structure that keeps its shape after trocar passage.

That design makes intraoperative mesh handling easy and inguinal hernia repair efficient.^{1,3,6}

This includes:

- Unique textile knit pattern which is soft, yet rigid¹²
- Thermoformed 3-D shape with distinct sealed edges^{3,8}
- Large pore size for transparency¹⁴

Pore size¹⁴

- Large pore
- >1 mm

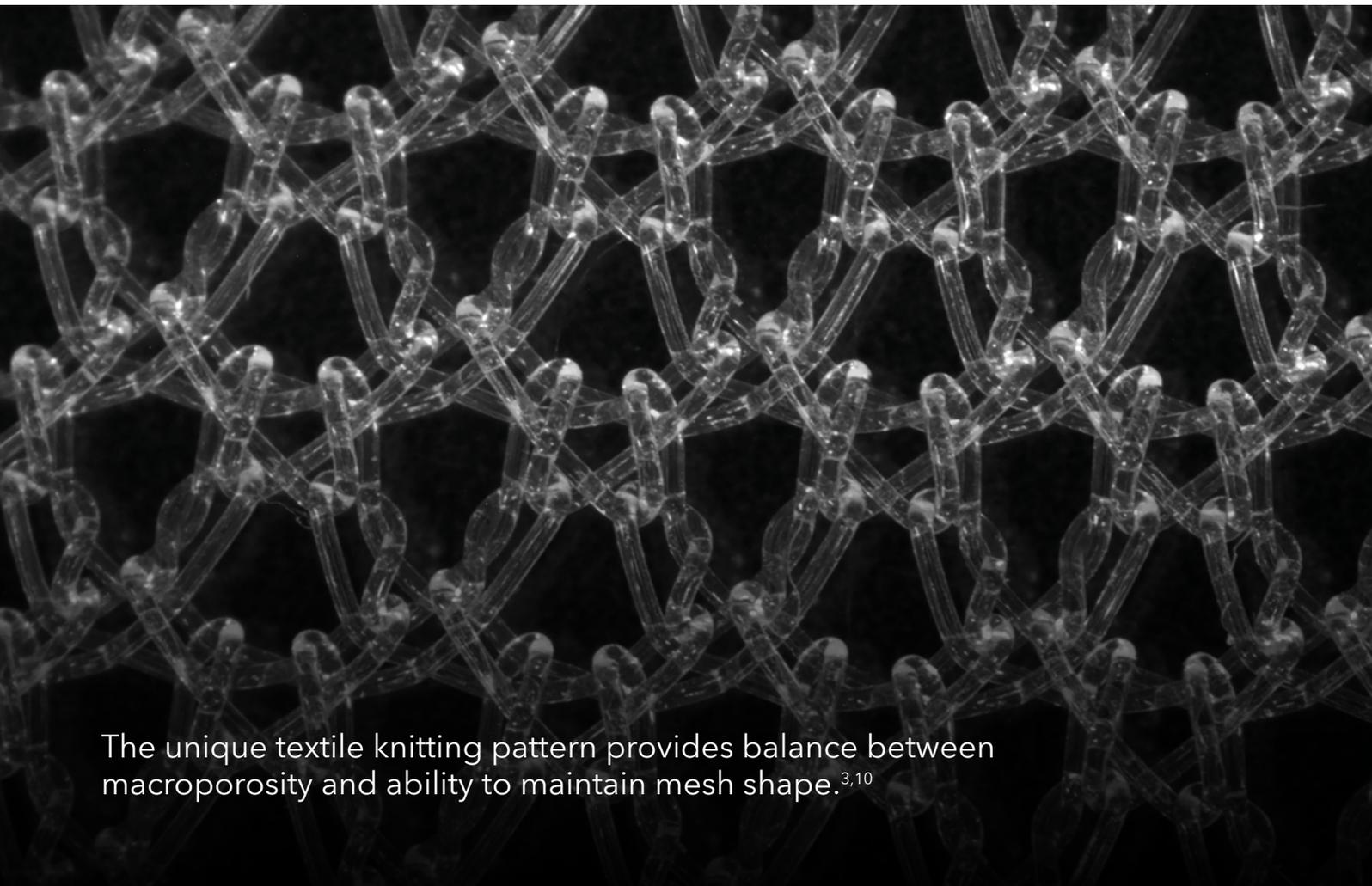
Density⁵

- Heavyweight
- >90 g/m²

Sterilization

The mesh is:

- A sterile single-use device
- Sterilized by ethylene oxide
- Not resterilizable



The unique textile knitting pattern provides balance between macroporosity and ability to maintain mesh shape.^{3,10}

How it compares

The Dextile™ anatomical mesh proved to be the balanced solution when it came to handling properties, anatomical coverage, and transparency.^{1,2,6,7,10,12,†}

| | Dextile™ anatomical mesh | 3D Max™ | 3D Max™ Light™ |
|---|--------------------------------------|--------------------------------------|--------------------------------------|
| Ease of use ^{1,2,6,11,12,16,†,‡} | ✓ ✓ ✓ | ✓ ✓ ✓ | ✓ |
| Anatomical coverage ^{1,6,†} | ✓ ✓ ✓ | ✓ | ✓ |
| Transparency ^{1,5,†} | ✓ ✓ | ✓ | ✓ ✓ ✓ |
| Density classification ¹² | Heavyweight; >90 g/m ² | Heavyweight; >90 g/m ² | Lightweight; <50 g/m ² |
| Pore size ¹⁴ (mm) | Large pore; 1.1 x 1.6 | Small pore; 0.9 x 0.7 | Large pore; 2.4 x 0.7 2.0 x 1.3 |

More technology, greater value

These combined characteristics in Dextile™ anatomical mesh are designed to provide more efficient inguinal hernia repair compared to the competition.^{1-3,5-7,9}

† Based on cadaver lab testing involving twelve US and EU surgeons with strong 3DMAX™ and 3DMAX™ Light experience.

‡ Ease of use includes trocar introduction, deployment and positioning.

Clinician feedback

We collaborated with more than 100 HCPs worldwide, held roundtable discussions, and conducted market research.

That information helped us create the Dextile™ anatomical mesh which offers enhanced anatomical compliance and easy intraoperative handling.¹⁻³

“It’s easier to insert through the trocar and has better medial and inferior coverage compared to 3DMax™”

Laparoscopic surgeon in U.S.;
previous 3D Max™ user

“This is a true anatomical mesh-pursues the natural boundaries of the myopectineal orifice.”

General surgeon in Columbia;
previous 3D Max™ user



Ordering information

| Item Number | Description | Dimensions | Size | Qty |
|-------------|---|--------------------------|---------|-----|
| DXT1309AL | Dextile™ anatomical mesh 13 x 9 cm Left X1 | 13 x 9 cm (5.1" x 3.5") | Medium | 1 |
| DXT1309AR | Dextile™ anatomical mesh 13 x 9 cm Right X1 | 13 x 9 cm (5.1" x 3.5") | Medium | 1 |
| DXT1510AL | Dextile™ anatomical mesh 15 x 10 cm Left X1 | 15 x 10 cm (5.9" x 3.9") | Large | 1 |
| DXT1510AR | Dextile™ anatomical mesh 15 x 10 cm Right X1 | 15 x 10 cm (5.9" x 3.9") | Large | 1 |
| DXT1612AL | Dextile™ anatomical mesh 16 x 12 cm Left X1 | 16 x 12 cm (6.3" x 4.7") | X-Large | 1 |
| DXT1612AR | Dextile™ anatomical mesh 16 x 12 cm Right X1 | 16 x 12 cm (6.3" x 4.7") | X-Large | 1 |

Mesh complications may include but are not limited to seroma, hematoma, recurrence, inflammation, infection, acute and chronic pain, extrusion/erosion. 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. It is recommended not to cut Dextile™ anatomical mesh as it may affect its effectiveness.

1. Based on internal report, Dextile™ anatomical mesh, surgeon interview report. July 2019.
2. Based on internal report #43008CR326, Support for marketing claims related to Dextile™ anatomical mesh handling. August 2019.
3. Based on internal test report #43008CR268, Design output file Merlin. February 2019.
4. Based on internal report #43008CR343, Robotically assisted inguinal hernia surgery-review considering Dextile™ anatomical mesh. September 2019.
5. Based on internal report #43008CR336, Support for marketing claims related to the Dextile™ anatomical mesh transparency. August 2019.
6. Based on internal report #43008CR339, Support for marketing claims related to surface of Dextile™ anatomical mesh vs. competitors. August 2019.
7. Weyhe D, Cobb W, Lecuire 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. July 2015.
8. Based on Medtronic patent #US-20180318057-A1, Prosthesis for inguinal hernia repair. November 2018.
9. Based on Phycher report #IMP-Toxsys-1 month-PH-19-0218 final report. August 2019.
10. Dextile™ Anatomical Mesh [instructions for use]. Trévoux, FR: Sofradim Production; 2019.
11. Based on internal report #43008CR316a, Evaluation of Dextile™ anatomical mesh through human cadaver lab – PRL design validation. July 2019.
12. Based on internal report #43008CR337, Support for marketing claims related to bending and density of Dextile™ anatomical mesh vs. competitors. August 2019.
13. Hernia Surge Group. International guidelines for groin hernia management. Hernia. 2018 Feb; 22(1):1-165. doi: 10.1007/s10029-017-1668-x.
14. Based on internal report #43008CR315, Dextile™ anatomical mesh vs 3DMax™* light mesh: mesh physical and mechanical comparison, 510(k). August 2019.
15. Deeken CR, Abdo MS, Frisella MM, Matthews BD. Physicomechanical evaluation of polypropylene, polyester, and polytetrafluoroethylene meshes for inguinal hernia repair. American college of surgeons. 2011;212(1):68-79.
16. Based on internal report #43008CR344, Support to marketing claim related to Dextile™ Anatomical Mesh ease of use vs Bard 3DMax™* Light. August 2019.

To learn more about the Dextile™ anatomical mesh, please contact your local Medtronic representative.

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Important: Please refer to the package insert for complete instructions, contraindications, warnings and precautions.

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