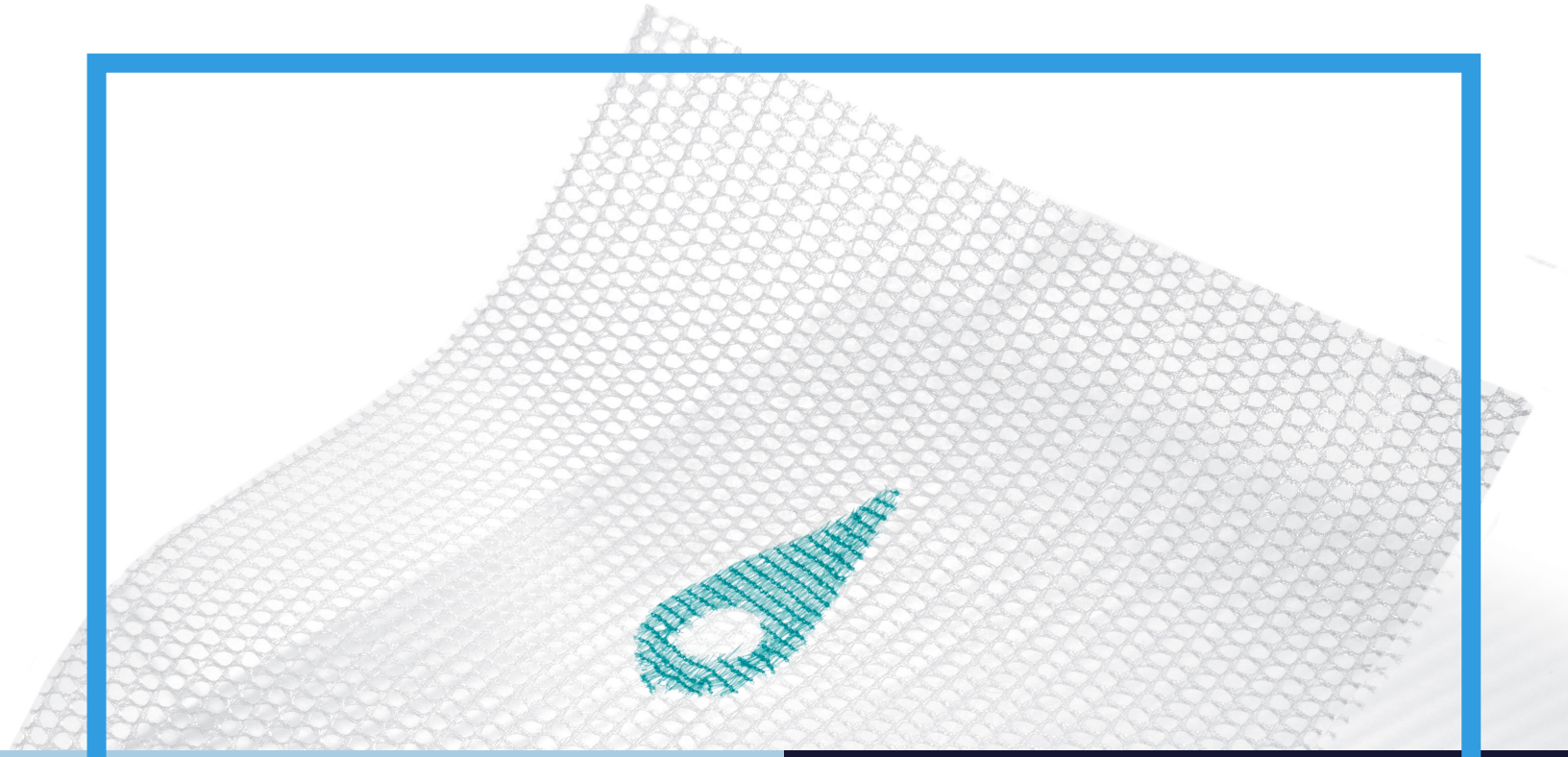


VALUE ANALYSIS COMMITTEE PRODUCT INFORMATION KIT

Versatex™ Monofilament Mesh

Macroporous flatsheet for preperitoneal hernia repair

Medtronic

Further, Together

HERNIA REPAIR

As the market leader in hernia repair, we continue to set new standards in:

- Innovation
- Quality
- Ease of use
- Value

Drawing on 20 years of cutting-edge biomedical engineering, we match our mastery of balanced mesh properties with our understanding of the needs of surgeons and patients. And we respond to the needs of hospitals by delivering products of consistent high quality — at a justifiable price.



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PRODUCT INTRODUCTION

Versatex™ Monofilament Mesh



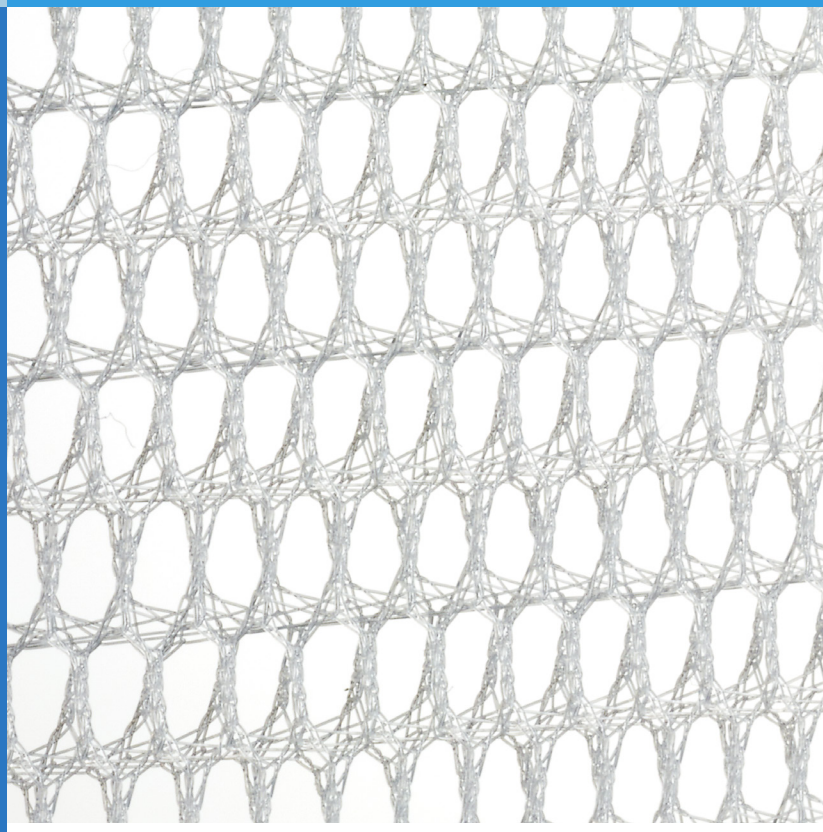
Why should a hospital purchase Versatex™ monofilament mesh?

Surgical Focus

Versatex™ monofilament mesh offers a balanced combination of macroporosity, surface density, and mechanical strength for successful hernia repair.[1-4] The high macroporosity offers enhanced mesh transparency to improve anatomy visualization, and the centering and orientation marking facilitates mesh positioning.[5,6]

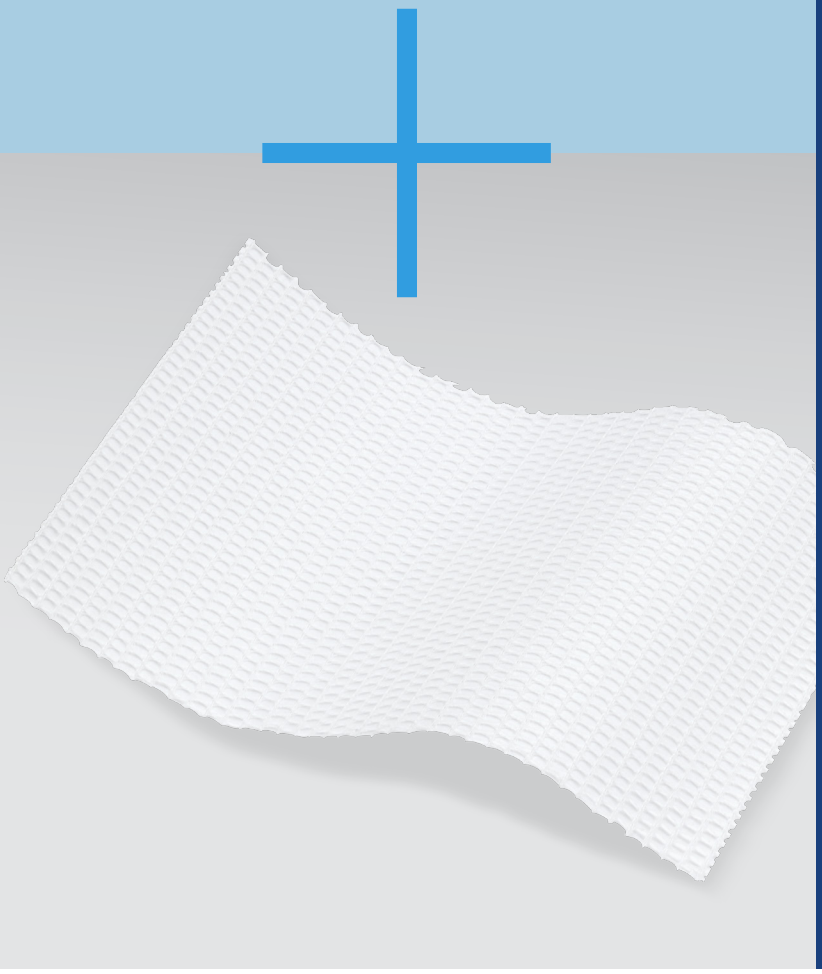
Economic Value

Versatex™ monofilament mesh is available in comprehensive flat sheet range for small, medium, and large open ventral and open/laparoscopic inguinal hernia repair.[6,7] The versatile range allows product standardization of procedures and helps optimize efficiency in the hospital with flexible stocking options of single- and three-unit packages.[7]



† Marking available for mesh sizes ≥ 15 x 15 cm.
‡ Based on effective porosity vs. Bard™* Mesh, Bard™* Soft Mesh, PROLENE™*, PROLENE™* Soft, Mersilene™*, Optilene™* LP, Parietex™ 3D, SurgiPro™ range, Parietene™, Parietex™ Lightweight, and Parietene™ Light.

FEATURES AND BENEFITS



Smart design

Innovative features for streamlined performance in preperitoneal hernia repair

- Hydrophilic, monofilament textile[4,8]
- Base textile with exclusive 3-D construct[4]
- Macroporous (2.1 x 3.0 mm) with hexagonal shape[1,4,9] Medium weight (64 g/m^2)[1,4]
- Robust mechanical strength with balanced softness and rigidity[3,4,6,10]
- Comprehensive range for open ventral and open/ laparoscopic inguinal defects[6,7]
- Flexible stocking options available in single- and three-unit packaging[7]

† Based on effective porosity vs. Bard™* Mesh, Bard™* Soft Mesh, PROLENE™*, PROLENE™* Soft, Mersilene™*, Optilene™* LP, Parietex™ 3D, SurgiPro™ range, Parietene™, Parietex™ Lightweight, and Parietene™ Light.
‡ Marking available for mesh sizes ≥ 15 x 15 cm.
§ 3-D microporous design facilitates excellent tissue integration and reduced complications related to mesh shrinkage, foreign body reaction, and scar plate formation.
Ω Based on preclinical study.
†† As demonstrated in porcine hernia model.

Smart handling

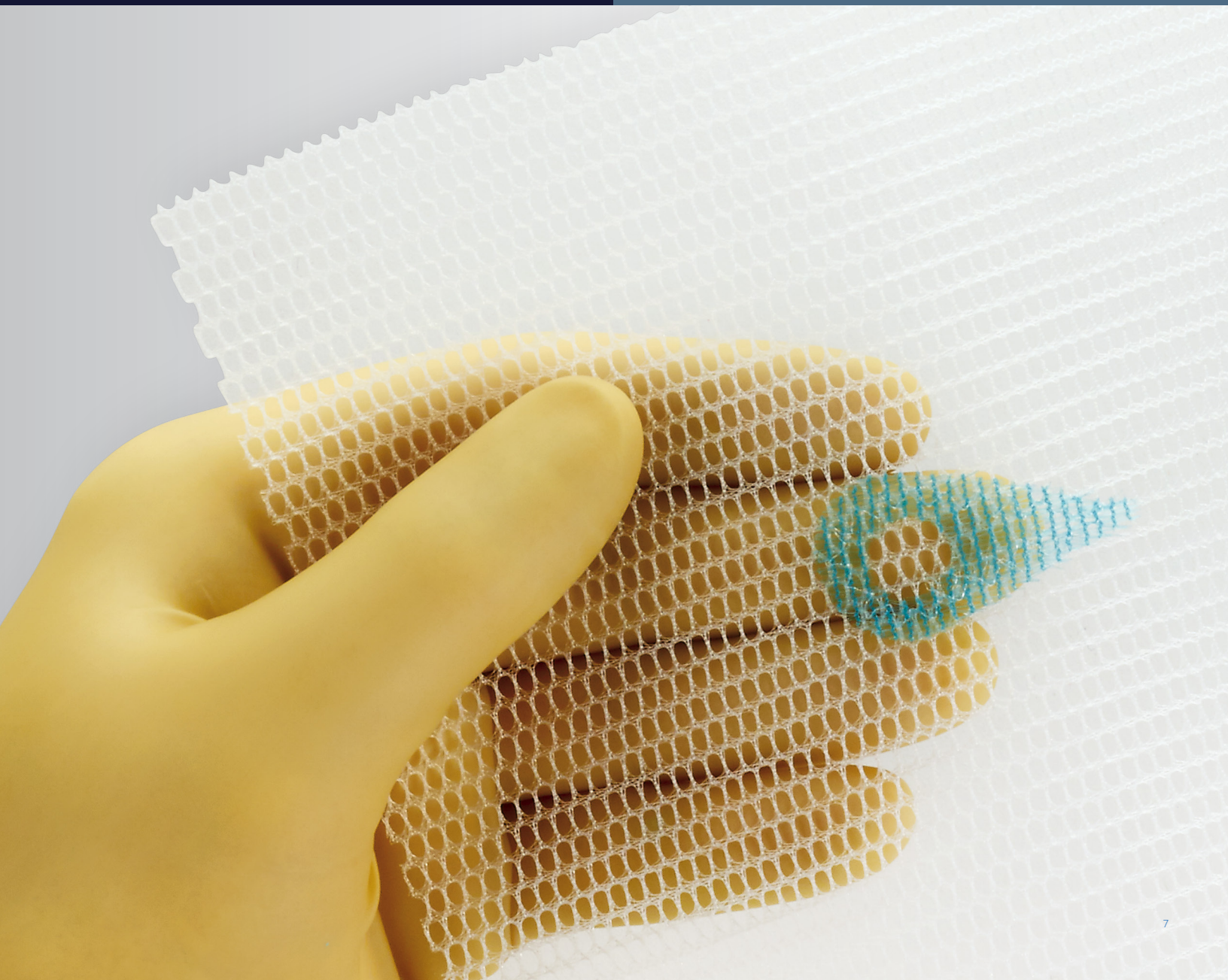
Experience ease of use in preperitoneal hernia repair

- Mesh transparency for improved anatomy visualization during placement and fixation[5,†]
- Centering and orientation marking facilitates mesh positioning[6,‡]
- Flexibility for easy mesh handling and abdominal wall conformability[6]

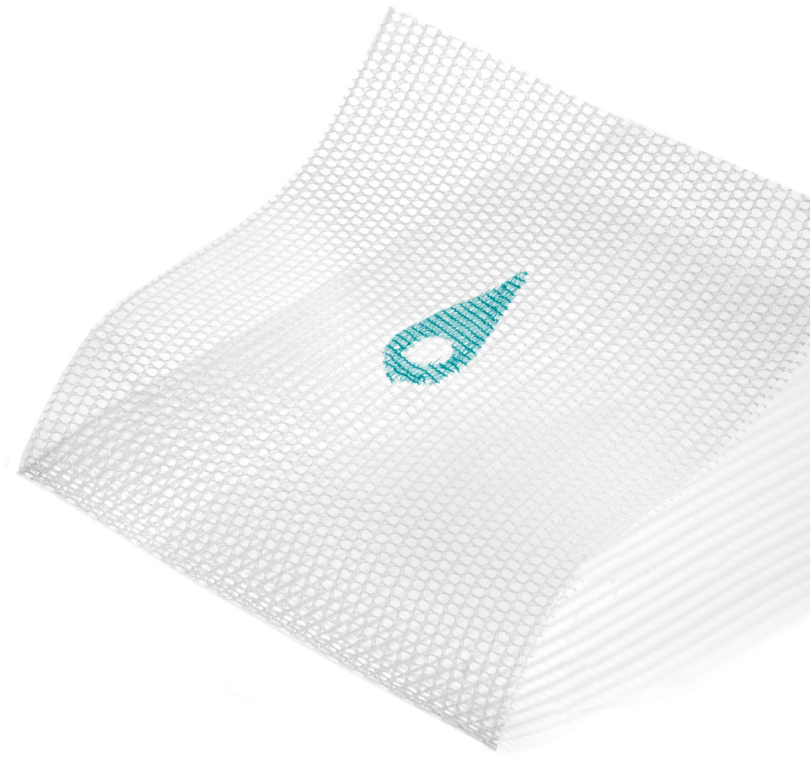
Smart repair

Designed to offer excellent hernia repair performance[3,4,10,§,Ω]

- 3-D macroporous structure with hexagonal pore shape delivers reinforced textile strength and facilitates excellent tissue ingrowth[4,10,††]
- Balanced combination of macroporosity, surface density, and mechanical strength for successful hernia repair[1-4]
- Designed for improved mesh integration and reduced complications related to mesh shrinkage and scar plate formation[4,10,††]



PRODUCT SPECIFICATIONS



Indications for use

Versatex™ monofilament mesh is intended for the repair of abdominal wall hernias or other fascial deficiencies that require the addition of a reinforcing material



Material composition

- 3-D textile nonabsorbable monofilament polyester (PET) – base textile
- 2-D textile nonabsorbable monofilament polyester (PET) – green marking textile†

Pore size[4]

- 2.1 x 3.0 mm

Pore shape[4]

- Hexagon

Sterilization method

- Gamma radiation

Shelf life

- 5 years

Weight[4]

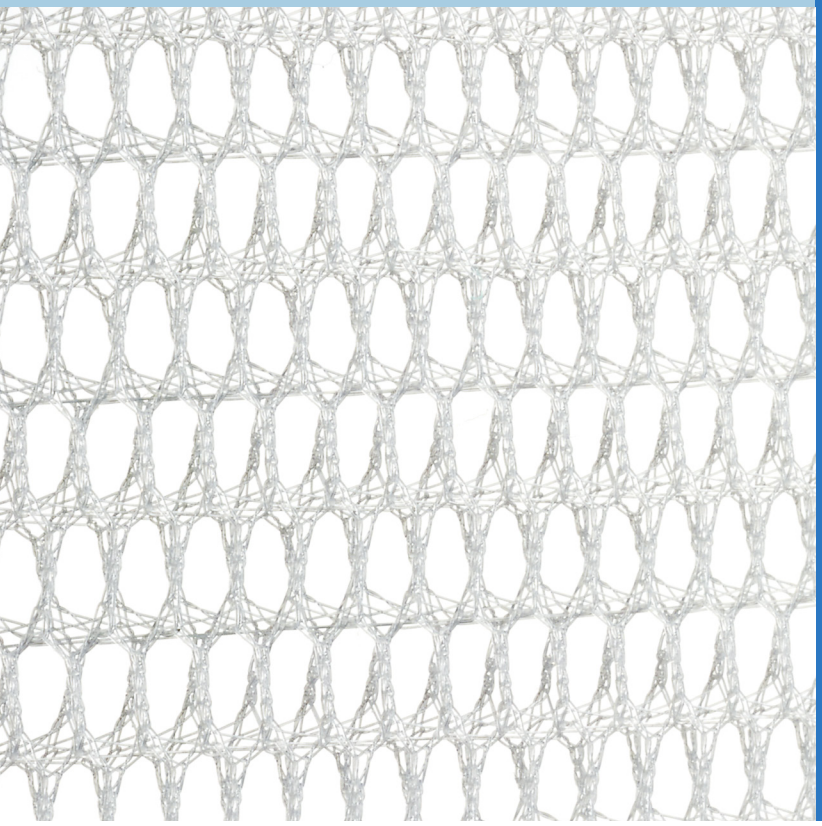
- Surface density (64 g/m^2)

Mesh-fixation device compatibility

- Compatible with current fixation devices on the market including ReliaTack™ articulating reloadable fixation device[6,11-13,‡]

†Marking available for mesh sizes ≥ 15 x 15 cm.
‡Based on benchtop compatibility testing of Versatex™ monofilament mesh with AbsorbaTack™, AbsorbaTack™ 30X, ProTack™, SECURESTRAP™*, and SorbaFix™*.

VALUE PROPOSITION



Value proposition for excellent hernia repair performance

Versatex™ monofilament mesh offers excellent hernia repair performance with improved mesh integration and reduced complications related to mesh shrinkage and scar plate formation.[3,4,10,†,‡,§]

The biocompatible mesh is composed of polyester material with 3-D macroporous structure and hexagonal pore shape.[1,4,14]

Polyester material and large pore size (macroporosity) are the main determinants of local tissue tolerance, i.e., successful mesh integration and favorable tissue response.[10,15,†]

- **The 3-D structure delivers reinforced textile strength and polyester's hydrophilic nature facilitates excellent tissue ingrowth[4,10,†]**
- **The large hexagonal pore shape delivers strongest tissue ingrowth and most favorable tissue response[2,†,Ω]**

Further, polyester-based meshes have been used for 15 years with excellent clinical outcomes in regards to recurrence and infection rate. A meta-analysis demonstrated that polyester meshes do not cause more complications (recurrence and infection rate) than polypropylene meshes.[16,††,‡‡]

† As demonstrated in porcine hernia model.
‡ Based on preclinical study.
§ 3-D microporous design facilitates excellent tissue integration and reduced complications related to mesh shrinkage, foreign body reaction, and scar plate formation.
Ω Compared to square and diamond shape pore.
†† Recurrence and infection rates with polyester messes are equivalent to those of polypropylene meshes.
‡‡ Based on internal meta-analysis.

REIMBURSEMENT

CPT Procedure Codes

Inguinal hernia (laparoscopic)

CPT HCPCS Code	Procedure Description	MPFS (CF=&35.7547) Fac/Non-Fac	APC Class	APC Descriptor	Hospital Outpatient Rate	ASC
49650	Laparoscopy, surgical; repair initial inguinal hernia	$441.21	131	Level II Laparoscopy	$3,779.40	$2,070.94
49651	Laparoscopy, surgical; repair recurrent inguinal hernia	$573.86	131	Level II Laparoscopy	$3,779.40	$2,070.94

Incisional/ventral hernia (open)

CPT HCPCS Code	Procedure Description	MPFS (CF=&35.7547) Fac/Non-Fac	APC Class	APC Descriptor	Hospital Outpatient Rate	ASC
49560	Repair initial incisional or ventral hernia; reducible	$760.86	154	Hernia/Hydrocele Procedures	$2,675.43	$1,466.02
49561	Repair initial incisional or ventral hernia; incarcerated or strangulated	$573.86	154	Hernia/Hydrocele Procedures	$2,675.43	$1,466.02
49565	Repair recurrent incisional or ventral hernia; reducible	$760.86	154	Hernia/Hydrocele Procedures	$2,675.43	$1,466.02
49566	Repair recurrent incisional or ventral hernia; incarcerated or strangulated	$573.86	154	Hernia/Hydrocele Procedures	$2,675.43	$1,466.02

REIMBURSEMENT

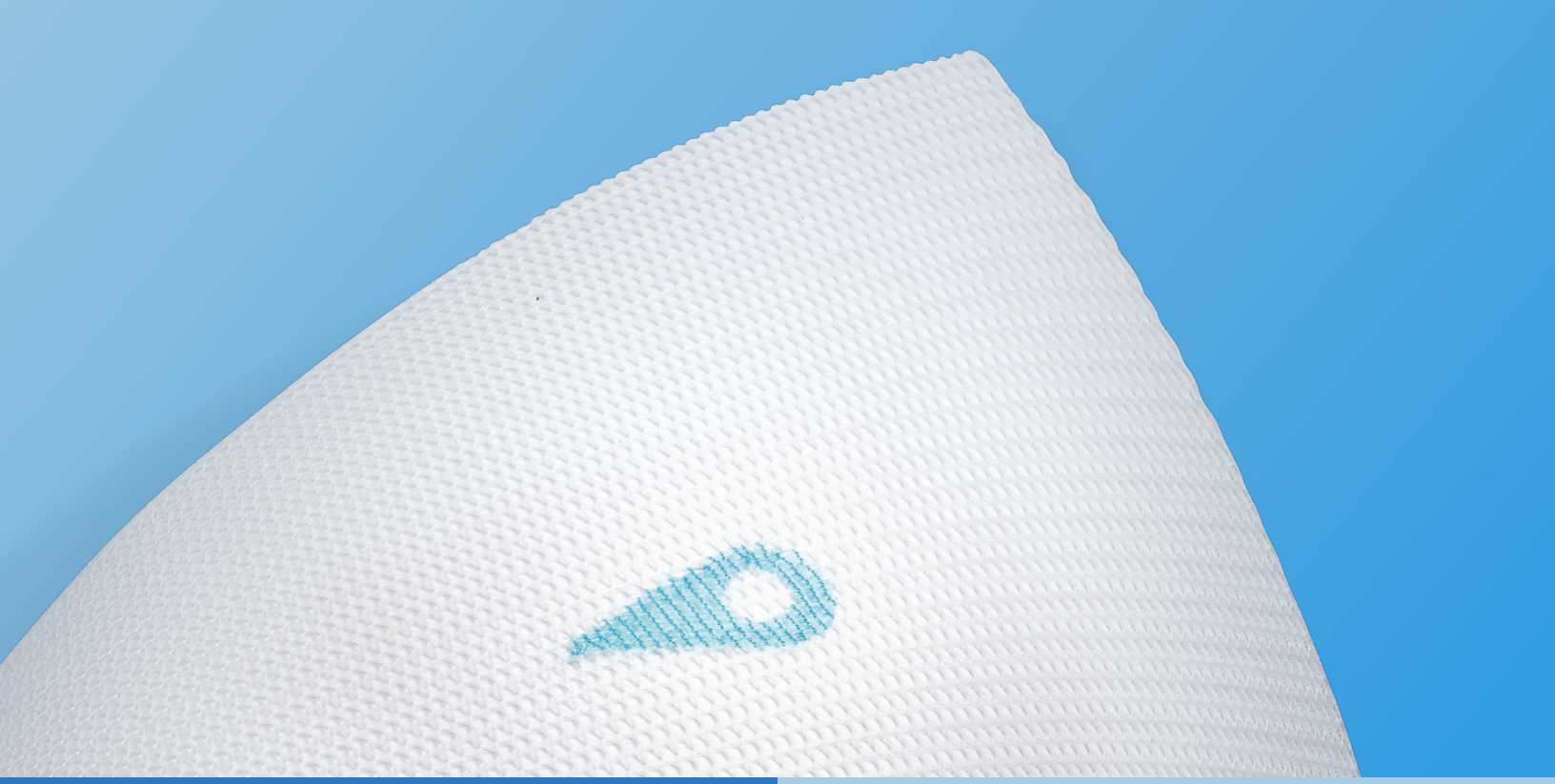
Note that different types of hernia may use the same ICD-10-PCS procedure code if the repair technique is the same. The type of hernia being repaired is differentiated by the ICD-10-CM diagnosis codes, not necessarily by the ICD-10-PCS procedure codes.

Incisional/ventral hernia

CPT HCPCS Code	Procedure Description	MPFS (CF=&35.7547) Fac/Non-Fac	APC Class	APC Descriptor	Hospital Outpatient Rate	ASC
49560	Repair initial incisional or ventral hernia; reducible	$768	5341	Peritoneal & Abdominal Procedures	$2,911	$1,333
49561	Repair initial incisional or ventral hernia; incarcerated or strangulated	$968	5341	Peritoneal & Abdominal Procedures	$2,911	$1,333
49565	Repair recurrent incisional or ventral hernia; reducible	$799	5361	Level 1 Laparoscopy	$4,489	$2,097
49566	Repair recurrent incisional or ventral hernia; incarcerated or strangulated	$977	5361	Level 1 Laparoscopy	$4,489	$2,097

Inguinal hernia

CPT HCPCS Code	Procedure Description	MPFS (CF=&35.7547) Fac/Non-Fac	APC Class	APC Descriptor	Hospital Outpatient Rate	ASC
49520	Repair recurrent inguinal hernia, any age; reducible	$657	5341	Peritoneal & Abdominal Procedures	$2,911	$1,333
49561	Repair initial incisional or ventral hernia; incarcerated or strangulated	$573.86	5341	Peritoneal & Abdominal Procedures	$2,911	$1,333
49565	Repair recurrent incisional or ventral hernia; reducible	$760.86	5341	Peritoneal & Abdominal Procedures	$2,911	$1,333
49650	Laparoscopy, surgical; repair initial inguinal hernia	$446	5361	Level 1 Laparoscopy	$4,489	$2,097
49651	Laparoscopy, surgical; repair recurrent inguinal hernia	$578	5361	Level 1 Laparoscopy	$4,489	$2,097



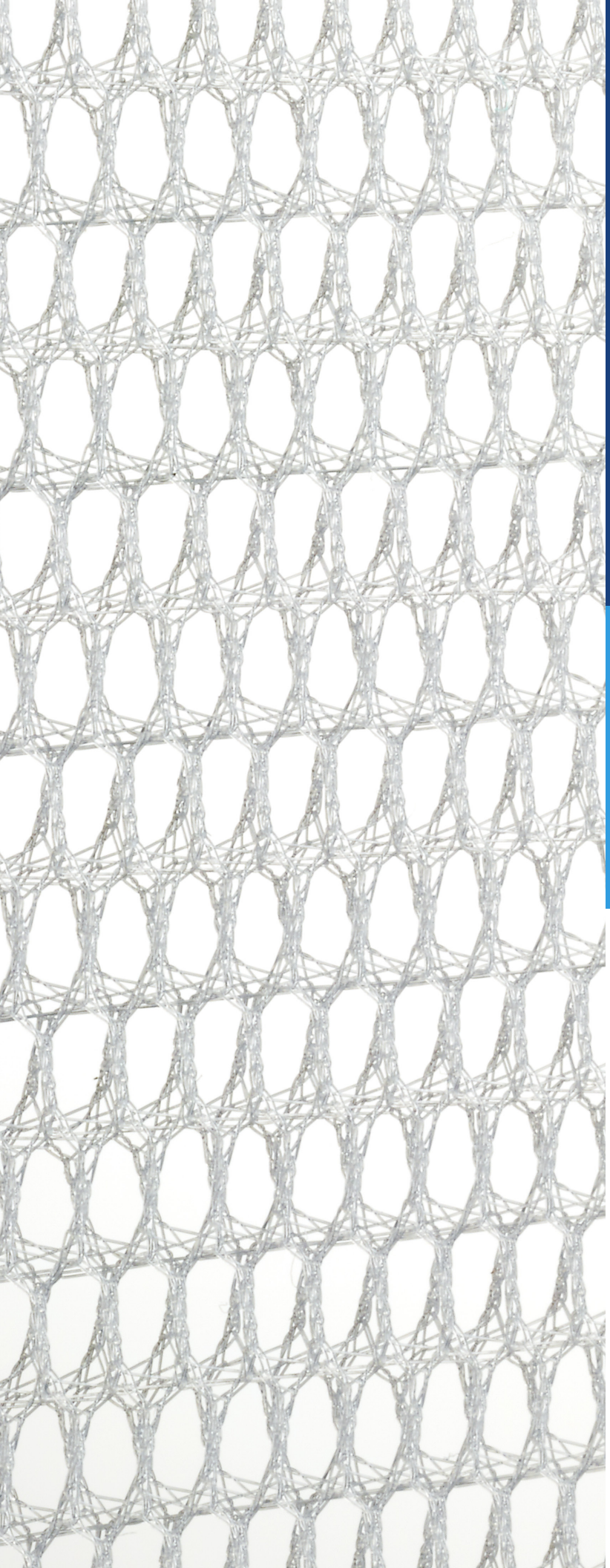
COMPETITIVE PRODUCT OVERVIEW

Versatex™ monofilament mesh is composed of polyester material with large pore size (macroporosity), which are the main determinants of local tissue tolerance (successful mesh integration and favorable tissue response).[4,10,15,†]

Additionally, Versatex™ monofilament mesh is designed to simplify intra-operative handling for surgeons through improved visualization, ease of mesh positioning, and a wide selection of mesh sizes.[5-7]

	Versatex™ Monofilament Mesh	BARD™* Soft Mesh	BARD™* Mesh	PROLENE™* Soft Mesh	PROLENE™* Mesh	ULTRAPRO™* after absorption of poliglecaprone 25	Parietex™ 3D Mesh	Parietex™ Lightweight Mesh
Structure[9]	3-D	2-D	2-D	2-D	2-D	2-D	3-D	2-D
Composition[9]	Monofilament	Monofilament	Monofilament	Monofilament	Monofilament	Monofilament	Multifilament	Monofilament
Material[9]	Polyester	Polypropylene	Polypropylene	Polypropylene	Polypropylene	Polypropylene	Polyester	Polyester
Pore Size[9]	2.1 x 3.0 mm	3.0 x 1.0 mm (triangle shape) 3.0 x 0.7 mm (rectangle shape)	0.9 x 0.7 mm	2.4 x 1.7 mm	1.0 x 0.7 mm	2.3 x 3.4 mm	1.9 x 2.4 mm	1.5 x 1.5 mm
Surface Density (g/m^2)[9]	64	41	99	42	76	34	85	45
Marking to Facilitate Positioning	Yes	No	No	No	No	Yes	No	No
Portfolio Range[Ω]	11 x 6 cm– 50 x 50 cm	10 x 5 cm– 30.5 x 30.5 cm	10 x 2.5 cm– 15 x 15 cm	15 x 15 cm– 35.6 x 30 cm	10 x 2.5 cm– 30 x 30 cm	11 x 6 cm– 30 x 30 cm	12 x 8 cm– 50 x 50 cm	11 x 6 cm– 45 x 30 cm

† As demonstrated in porcine hernia model.
‡ Based on effective porosity vs. Bard™* Mesh, Bard™* Soft Mesh, PROLENE™*, PROLENE™* Soft, Mersilene™*, Optilene™* LP, ParietexTM 3D, SurgiPro™ range, Parietene™, Parietex™ Lightweight, and Parietene™ Light.
§ Based on benchtop testing and comparison of obtained mean values and standard deviations vs. Bard™* Soft Mesh, PROLENE™** Soft, Parietex™ 3-D, Parietene™ Light, Parietex™ Lightweight, and Ultrapro™* after poliglecaprone 25 full
Ω Competitive portfolio range information accessed from respective company website/ product catalog in August 2015



Versatex™ monofilament mesh offers a balanced combination of macroporosity, surface density, and mechanical strength for successful preperitoneal hernia repair.[1,3,4,9]

- Greater macroporosity compared to current nonabsorbable flat sheet meshes[9,†,‡]
- Medium-weight surface density (64 g/m^2)[1,4]
- Mechanical strength values are higher or within the same range of current nonabsorbable flat sheet meshes on the market[9,§]

MATERIALS MANAGEMENT



Packaging information

Versatex™ monofilament mesh is available in a wide range of shapes and sizes to accommodate small, medium, and large open ventral and open/laparoscopic hernia repair.[6,7] The monofilament flat sheet mesh has flexible stocking options with references available in one- and three-unit packages.[7]

Ordering information

medtronic.com/covidien/products/hernia-repair

Product Codes	Shape	Size	Centering and Orientation Marking	Units per Package
VTX1106	Rectangular	11 x 6 cm	No	1
VTX1106X3	Rectangular	11 x 6 cm	No	3
VTX1510	Rectangular	15 x 10 cm	No	1
VTX1510X3	Rectangular	15 x 10 cm	No	3
VTX1515	Square	15 x 15 cm	No	1
VTX1515X3	Square	15 x 15 cm	No	3
VTX1515M	Square	15 x 15 cm	Yes	1
VTX1515MX3	Square	15 x 15 cm	Yes	3
VTX2020M	Square	20 x 20 cm	Yes	1
VTX3030M	Square	30 x 30 cm	Yes	1
VTX4530M	Rectangular	45 x 30 cm	Yes	1
VTX5050M	Square	50 x 50 cm	Yes	1

References

1. Deeken CR, Abdo MS, Frisella MM, Matthews BD. Physicomechanical evaluation of polypropylene, polyester, and polytetrafluoroethylene meshes for inguinal hernia repair. *J Am Coll Surg.* 2011;212(1):68-79.
2. Lake S, 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.
3. Based on Versatex™ monofilament mesh IFU.
4. Based on internal test report #T2306CR062a/TEX044d evaluating 3DS/3DV textile characterization. April 2015.
5. Based on internal test report #T2306CR044a evaluating design for improved visualization during placement. March 2015.
6. Based on internal report #T2306CR053b, Versatex™ monofilament mesh evaluation by surgeons for design validation. March 2015.
7. Based on internal report #T2306CR043a assessing size and shape comparison chart. March 2015.
8. Lefranc O, Bayon Y, Montanari S, Gravagna P, Therin M. Reinforcement material in soft tissue repair: key parameters controlling tolerance and performance — current and future trends in mesh development. In: von Theobald P, et al, eds. *New Techniques in Genital Prolapse Surgery.* London, UK: Springer: 2011:275-287.
9. Based on internal test report #T2306CR042b assessing physical and mechanical properties of Versatex™ vs. current meshes on the market. April 2015.
10. Cobb W, Lomanto D, Lecuivre J, Weyhe D, et al. Comparative analysis of the performance of a series of meshes based on weight and pore size in a novel mini-pig hernia model. Hernia Repair 2013, American Hernia Society; Orlando, FL, March 13-16, 2013.
11. Based on internal report #T2306CR040a evaluating compatibility of Versatex™ monofilament mesh with AbsorbaTack™ 30X. February 2015.
12. Based on internal report #T2306CR050a assessing compatibility of type 3DS/3DV textile with different fixation means. February 2015.
13. Based on internal test report #T2306CR060a evaluating compatibility of Versatex™ monofilament mesh with ReliaTack™ articulating reloadable fixation device. February 2015.
14. Based on internal report #2306, biological evaluation report BIO054-b for Versatex™ monofilament mesh. February 2015.
15. Based on internal test report #T2306CR022a assessing safety and local tolerance. October 2014.
16. Based on internal meta-analysis comparing PET vs PP. Internal report #T2306CR061a. April 2015.

Always refer to the Instructions for Use packaged with the product for complete instructions, indications, contraindications, warnings and precautions.



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