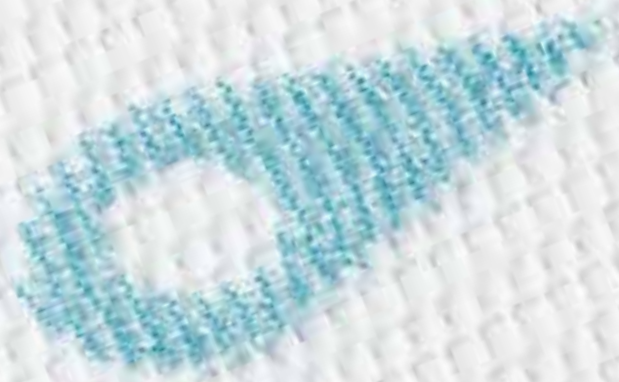




**VALUE
ANALYSIS
COMMITTEE**
PRODUCT
INFORMATION
KIT

Versatex™ Monofilament Mesh
Macroporous flatsheet for
preperitoneal hernia repair

HERNIA CARE ▪ **MESH** ▪ **FIXATION** ▪ **BIOLOGICS** ▪ **DISSECTION**



HERNIA REPAIR

We have established ourselves as the market leader in hernia repair, with innovations that continue to set new standards in quality, ease of use, and value. Drawing on 20 years of cutting-edge biomedical engineering, our mastery of balanced mesh properties is matched by our understanding of what best serves the needs of surgeons, patients, and hospitals. At the same time, we remain responsive to the needs of hospitals for products that deliver consistent high quality at a justifiable price.



TABLE OF CONTENTS

Product Introduction.....	6
Features and Benefits.....	8
Product Specifications	10
Value Proposition	12
Reimbursement	13
Competitive Products Overview	16
Materials Management.....	18
References	19

PRODUCT INTRODUCTION

Versatex™ Monofilament Mesh



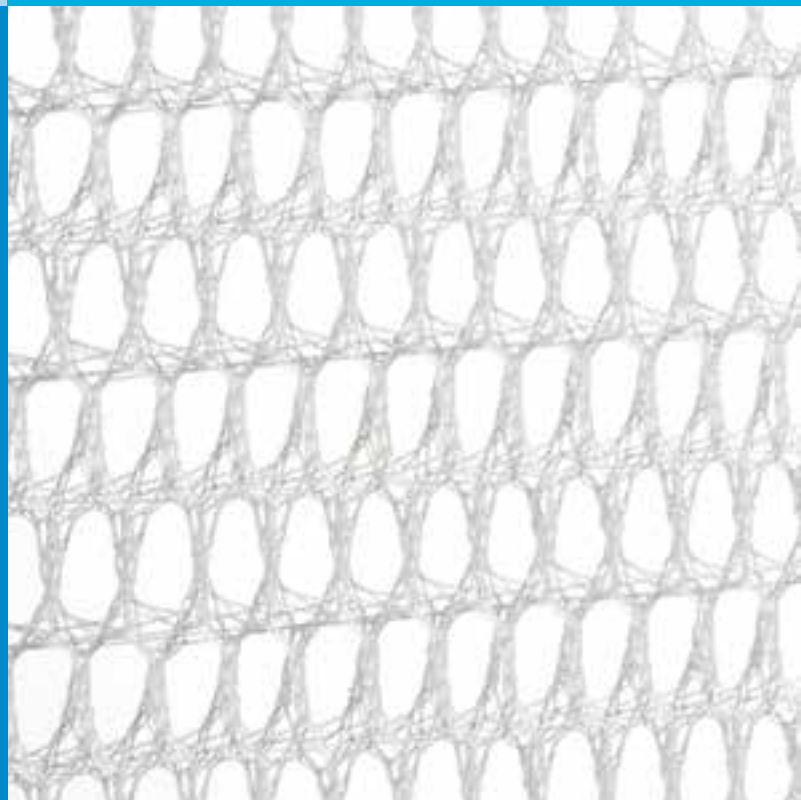
Why should a hospital purchase Versatex™ monofilament mesh?

Surgical Focus

Versatex™ monofilament mesh offers a balanced combination of macroporosity, surface density, and mechanical strength for successful hernia repair.^{1-3,7} The high macroporosity offers enhanced mesh transparency to improve anatomy visualization, and the centering and orientation marking facilitates mesh positioning.^{*,9,6,11}

Economic Value

Versatex™ monofilament mesh is available in comprehensive flat sheet range for small, medium, and large open ventral and open/lap inguinal hernia repair.^{10,11} The versatile range allows product standardization of procedures and helps optimize efficiency in the hospital with flexible stocking options of single and 3-unit packages.¹⁰



FEATURES AND BENEFITS



Smart design

Innovative features for streamlined performance in preperitoneal hernia repair.

- Hydrophilic, monofilament textile^{7,9}
- Base textile with exclusive 3D construct⁷
- Macroporous (2.1 x 3.0 mm) with hexagonal shape^{1,7,8}
- Medium weight (64 g/m²)^{1,7}
- Robust mechanical strength with balanced softness and rigidity^{3,4,7,11}
- Comprehensive range for open ventral and open/lap inguinal defects^{10,11}
- Flexible stocking options available in single and 3-unit packaging¹⁰

Smart handling

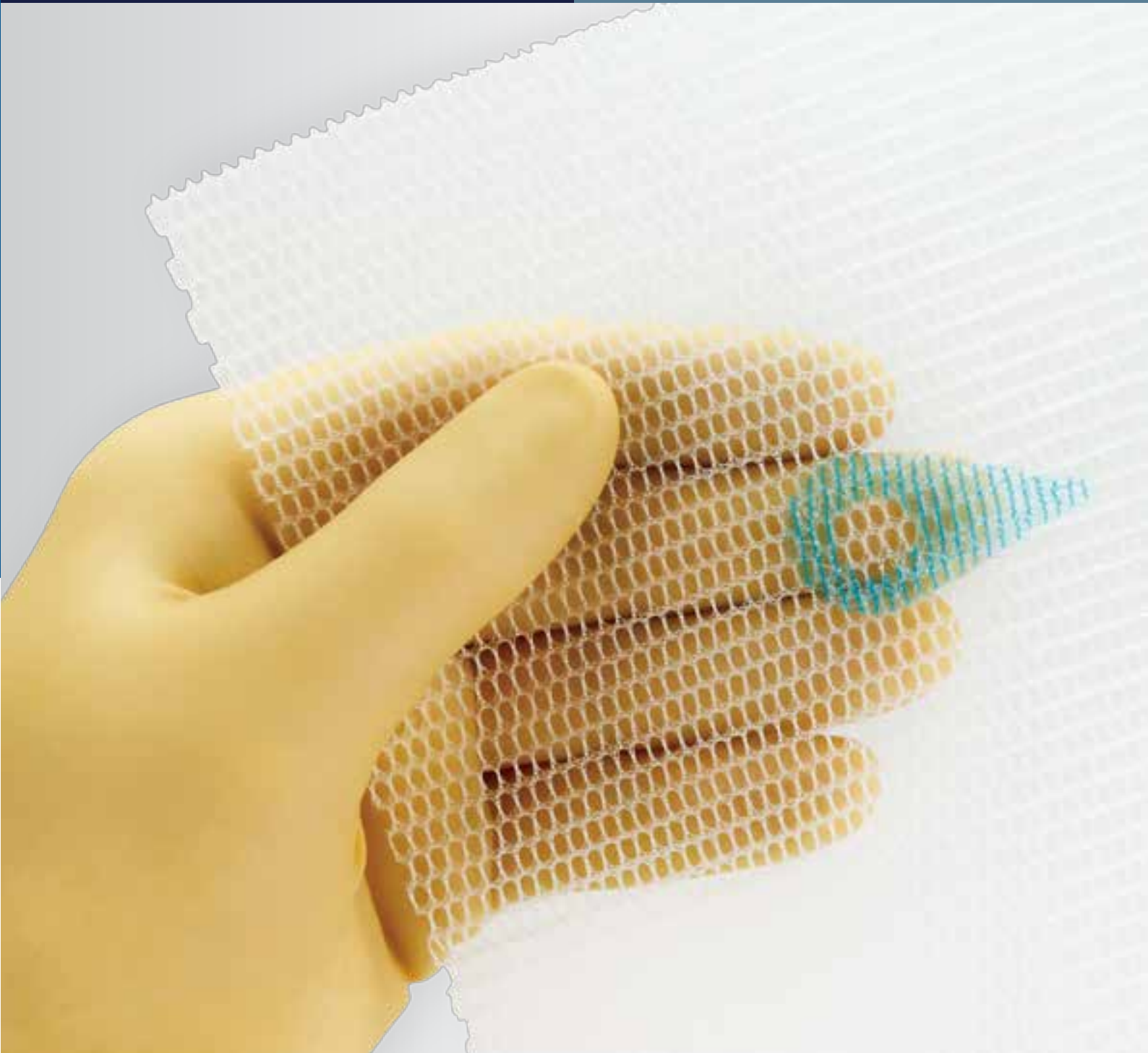
Experience ease of use in preperitoneal hernia repair

- Mesh transparency for improved anatomy visualization during placement and fixation.^{9,6}
- Centering and orientation marking facilitates mesh positioning.^{*,11}
- Flexibility for easy mesh handling and abdominal wall conformability.¹¹

Smart repair

Designed to offer excellent hernia repair performance^{^,§,3,4,7}

- 3D macroporous structure with hexagonal pore shape delivers reinforced textile strength and facilitates excellent tissue ingrowth^{†,4,7}
- Balanced combination of macroporosity, surface density, and mechanical strength for successful hernia repair^{1-3,7}
- Designed for improved mesh integration and reduced complications related to mesh shrinkage and scar plate formation^{†,4,7}

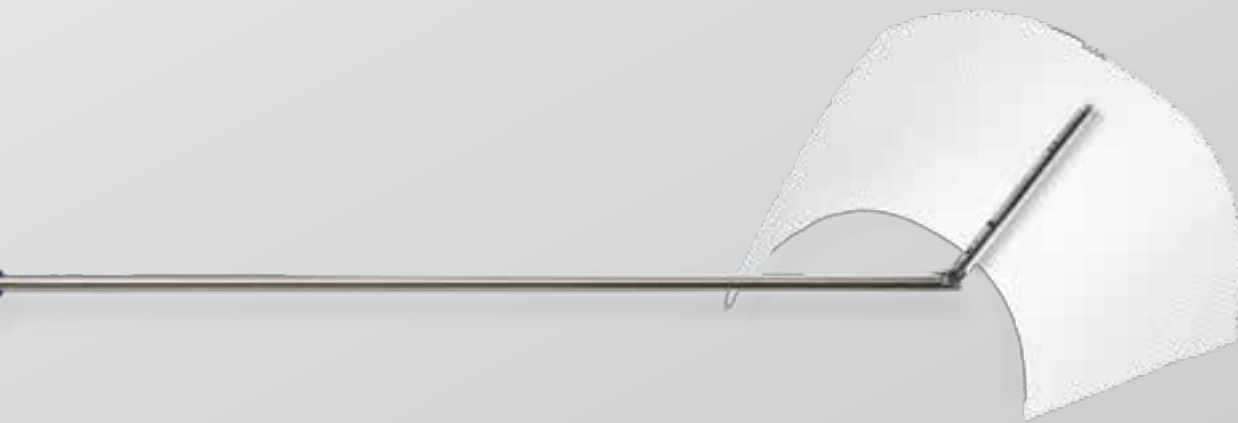


PRODUCT SPECIFICATIONS



Indication 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

- 3D textile non-absorbable monofilament polyester (PET)
– base textile
- 2D textile non-absorbable monofilament polyester (PET)
– green marking textile*

Pore size⁷

- 2.1 mm x 3.0 mm

Pore shape⁷

- Hexagon

Sterilization method

- Gamma radiation

Shelf life

5 years

Weight⁷

- Surface density (64 g/m²)

Mesh-fixation device compatibility

- Compatible with current fixation devices on the market including ReliaTack™ articulating reloadable fixation device^{††,11,14-16}

VALUE PROPOSITION

Value proposition for excellent hernia repair performance

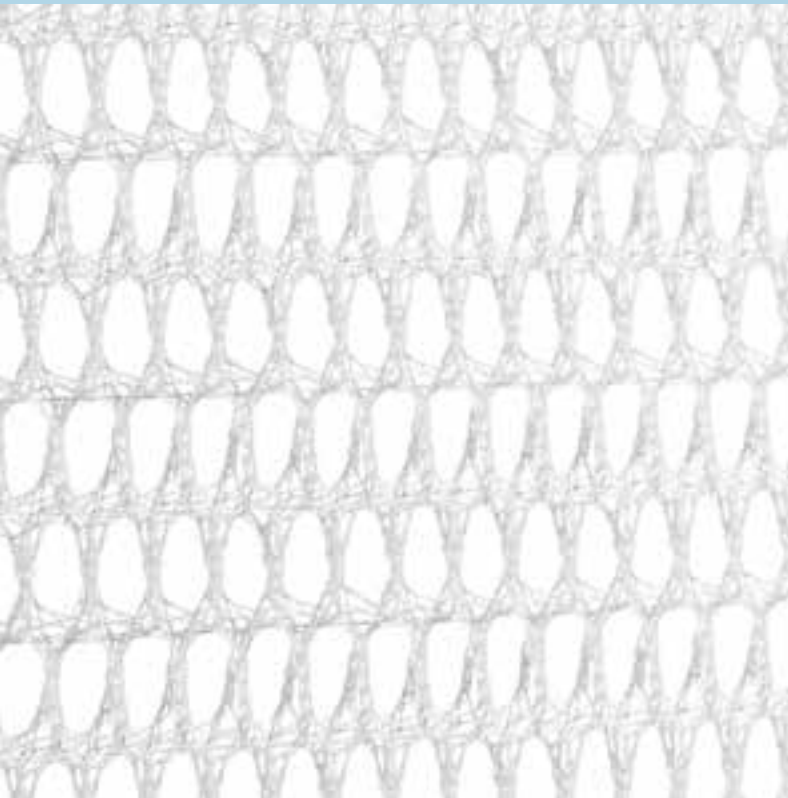
Versatex™ monofilament mesh is designed to offer excellent hernia repair performance with improved mesh integration and reduced complications related to mesh shrinkage and scar plate formation.^{†,§,^,3,4,7}

The biocompatible mesh is composed of polyester material with 3D macroporous structure and hexagonal pore shape.^{1,7,13}

Polyester material and large pore size (macroporosity) are the main determinants of local tissue tolerance, i.e., successful mesh integration and favorable tissue response.^{†,4,5}

- **The 3D structure delivers reinforced textile strength and polyester's hydrophilic nature facilitates excellent tissue ingrowth^{†,4,7}**
- **The large hexagonal pore shape delivers strongest tissue ingrowth and most favorable tissue response^{††,†,2}**

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 meshes in polyester material do not cause more complications (recurrence and infection rate) than polypropylene.^{6,8,12}



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

ICD-9-CM Volume 3 Hospital Procedure Codes (Inpatient)

Inguinal Hernia (Laparoscopic)

Procedure Code	Description
17.11	Laparoscopic repair of direct inguinal hernia with graft or prosthesis
17.12	Laparoscopic repair of indirect inguinal hernia with graft or prosthesis
17.13	Laparoscopic repair of inguinal hernia with graft or prosthesis, not otherwise specified
17.21	Laparoscopic bilateral repair of direct inguinal hernia with graft or prosthesis
17.22	Laparoscopic bilateral repair of indirect inguinal hernia with graft or prosthesis
17.23	Laparoscopic bilateral repair of inguinal hernia, one direct and one indirect, with graft or prosthesis
17.24	Laparoscopic bilateral repair of inguinal hernia with graft or prosthesis, not otherwise specified

REIMBURSEMENT

Incisional/Ventral Hernia (Open)

Procedure Code	Description
53.51	Incisional hernia repair
53.59	Repair of other hernia of anterior abdominal wall
53.61	Other open incisional hernia repair with graft or prosthesis
53.69	Other and open repair of other hernia of anterior abdominal wall with graft or prosthesis

Inguinal Hernia (Open)

Procedure Code	Description
53.00	Unilateral repair of inguinal hernia, not otherwise specified
53.01	Other and open repair of direct inguinal hernia
53.02	Other and open repair of indirect inguinal hernia
53.03	Other and open repair of direct inguinal hernia with graft or prosthesis
53.04	Other and open repair of indirect inguinal hernia with graft or prosthesis
53.05	Repair of inguinal hernia with graft or prosthesis, not otherwise specified
53.1	Bilateral repair of inguinal hernia, not otherwise specified
53.11	Other and open bilateral repair of direct inguinal hernia
53.12	Other and open bilateral repair of indirect inguinal hernia
53.13	Other and open bilateral repair of inguinal hernia; one direct and one indirect
53.14	Other and open bilateral repair of direct inguinal hernia with graft or prosthesis
53.15	Other and open bilateral repair of indirect inguinal hernia with graft or prosthesis
53.16	Other and open bilateral repair of inguinal hernia; one direct and one indirect with graft or prosthesis
53.17	Bilateral inguinal hernia repair with graft or prosthesis, not otherwise specified

INPATIENT DRG PAYMENT RATES

Inguinal: Open or Laparoscopic

MS-DRG [®]	MS-DRG Title
350	Inguinal & Femoral Hernia Procedures w MCC
351	Inguinal & Femoral Hernia Procedures w CC
352	Inguinal & Femoral Hernia Procedures w/o CC/MCC

Incisional: Open or Laparoscopic

MS-DRG [®]	MS-DRG Title
353	Hernia Procedures Except Inguinal & Femoral w MCC
354	Hernia Procedures Except Inguinal & Femoral w CC
355	Hernia Procedures Except Inguinal & Femoral w/o CC/MCC

\\PFS Relative Value Files, RVU15A (12-23-14), effective July 1, 2015.



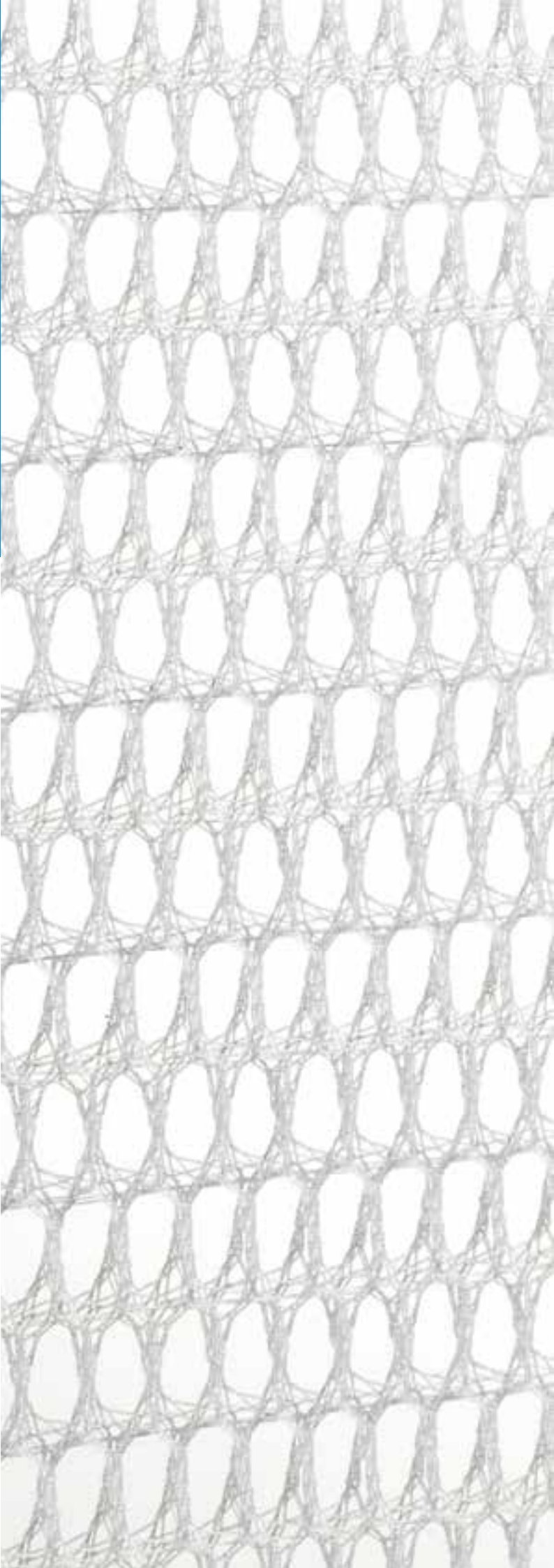
COMPETITIVE PRODUCTS OVERVIEW

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).^{1,4,5,7}

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.^{6,10,11}

	Versatex™ Monofilament Mesh	BARD™ Soft Mesh	BARD™ Mesh	PROLENE™ Soft Mesh	PROLENE™ Mesh	ULTRAPRO™ After Absorption of polyglactone 25	Parietex™ 3D Mesh	Parietex™ Lightweight Mesh
Structure ⁸	3D	2D	2D	2D	2D	2D	3D	2D
Composition ⁸	Monofilament	Monofilament	Monofilament	Monofilament	Monofilament	Monofilament	Multifilament	Monofilament
Material ⁸	Polyester	Polypropylene	Polypropylene	Polypropylene	Polypropylene	Polypropylene	Polyester	Polyester
Pore Size ⁸	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) ⁸	64	41	99	42	76	34	85	45
Marking to Facilitate Positioning	Yes	No	No	No	No	Yes	No	No
Portfolio Range [±]	11 x 6 cm— 50 x 50 cm	10 x 5 cm— 30.5 x 30.5 cm	10 x 2.5cm— 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

± 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.^{1,3,7,8}

- Greater macroporosity compared to current non-absorbable flat sheet meshes^{1,8}
- Medium-weight surface density (64 g/m²)^{1,7}
- Mechanical strength values are higher or within the same range of current non-absorbable flat sheet meshes on the market^{1,8}

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/lap hernia repair.^{10,11} The monofilament flat sheet mesh has flexible stocking options with references available in 1- and 3-unit packages.¹⁰

Ordering information

[medtronic.com/covidien/products/hernia-repair](https://www.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. Cobb W, Lomanto D, Lecuire 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.
 5. Based on internal test report #T2306CR022a assessing safety and local tolerance. October 2014.
 6. Based on internal test report #T2306CR044a evaluating design for improved visualization during placement. March 2015.
 7. Based on internal test report #T2306CR062a/TEX044d evaluating 3DS/3DV textile characterization. April 2015.
 8. Based on internal test report #T2306CR042b assessing physical and mechanical properties of Versatex™ vs. current meshes on the market. April 2015.
 9. 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.
 10. Based on internal report #T2306CR043a assessing size and shape comparison chart. March 2015.
 11. Based on Versatex™ monofilament mesh evaluation by surgeons for design validation. Internal report #T2306CR053b. March 2015.
 12. Based on internal meta-analysis comparing PET vs PP. Internal report #T2306CR061a. April 2015.
 13. Based on biological evaluation report BIO054-b for Versatex™ monofilament mesh. Internal report #2306. February 2015.
 14. Based on internal report #T2306CR040a evaluating compatibility of Versatex™ monofilament mesh with AbsorbaTack™ 30X. February 2015.
 15. Based on internal report #T2306CR050a assessing compatibility of type 3DS/3DV textile with different fixation means. February 2015.
 16. Based on internal test report #T2306CR060a evaluating compatibility of Versatex™ monofilament mesh with ReliaTack™ articulating reloadable fixation device. February 2015.
- [†] As demonstrated in porcine hernia model.
- [‡] Based on preclinical study.
- [§] 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 ≥ 15x15 cm.
- ^{||} 3D macroporous design facilitates excellent tissue integration and reduced complications related to mesh shrinkage, foreign body reaction and scar plate formation
- ^{¶¶} Recurrence and infection rate with polyester meshes is equivalent to polypropylene meshes.
- ^{¶¶¶} Based on meta-analysis performed internally.
- ^{¶¶¶¶} Compared to square and diamond shape pore.
- ^{¶¶¶¶¶} Based on benchtop compatibility testing of Versatex™ monofilament mesh with AbsorbaTack™, AbsorbaTack™ 30X, ProTack™, SecureStrap™, SorbaFix™.
- ^{¶¶¶¶¶¶} 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, Ultrapro™ after poliglecaprone 25 full absorption.

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



Our comprehensive product portfolio can enhance your hernia repair procedures.

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

© 2016 Medtronic. All rights reserved. Medtronic, Medtronic logo and Further, Together are trademarks of Medtronic.
™** Third party brands are trademarks of their respective owners. All other brands are trademarks of a Medtronic company.
16-eu-versatex-vac-pack-906279

Medtronic



Use scan app to read

For more information, please visit
medtronic.eu/product-catalog

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

© 2016 Medtronic. All rights reserved. Medtronic, Medtronic logo and Further, Together are trademarks of Medtronic.
™** Third party brands are trademarks of their respective owners. All other brands are trademarks of a Medtronic company. 16-eu-versatex-vac-pack-906279

To find out more about
hernia care products please visit
medtronic.eu/herniacare