

3DMax[™] Light Mesh

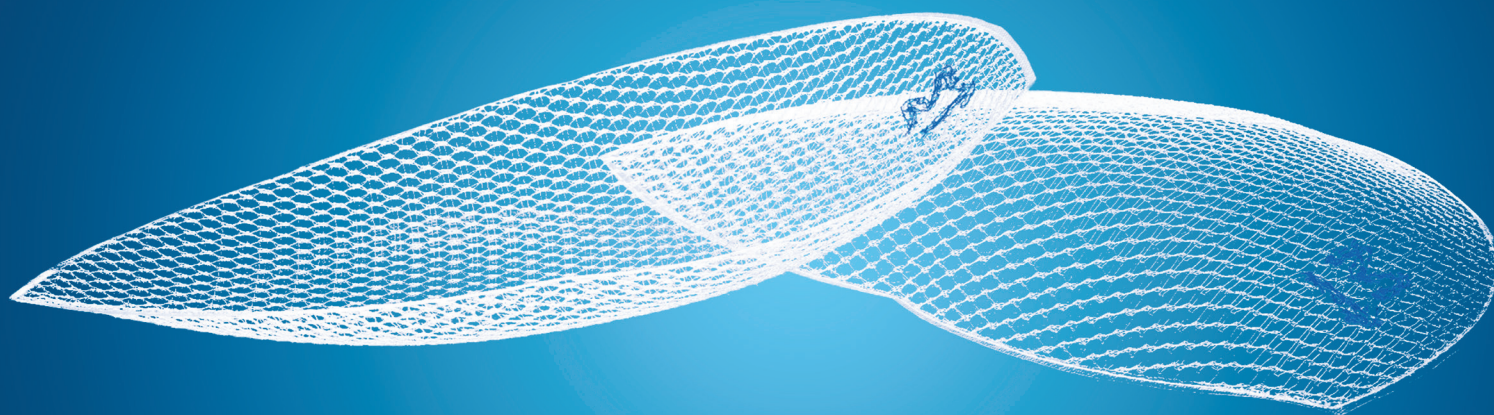
A Lightweight 3D-shaped Mesh for Laparoscopic Approaches
such as TAPP, TEP, and Robotic TAPP



See laparoscopic inguinal hernia repair in a whole new light

The unique shape of 3DMax™ Light Mesh was developed by a laparoscopic surgeon to conform to the inguinal anatomy and meet the specific challenges of laparoscopic hernia repair. The three-dimensional shape, sealed edge and medial orientation marker allow for easier positioning than

conventional flat mesh and also enhance the speed and simplicity of placement. This lighter-weight version of our popular 3DMax™ Mesh features a large pore knit. It is easy to deploy and provides excellent visibility while encouraging formation of a flexible and compliant abdominal wall.¹



3DMax™ Light Mesh is designed to conform to the inguinal anatomy and retain its shape following laparoscopic introduction.



Unique

- 3D shape developed by a laparoscopic surgeon
- Designed to conform to the inguinal anatomy
- Contour minimizes buckling that may be seen with flat mesh
- Design may reduce the need for fixation



Precise

- Sealed edge and medial orientation marker facilitate accurate placement and positioning
- Built-in memory maintains shape



Lighter weight

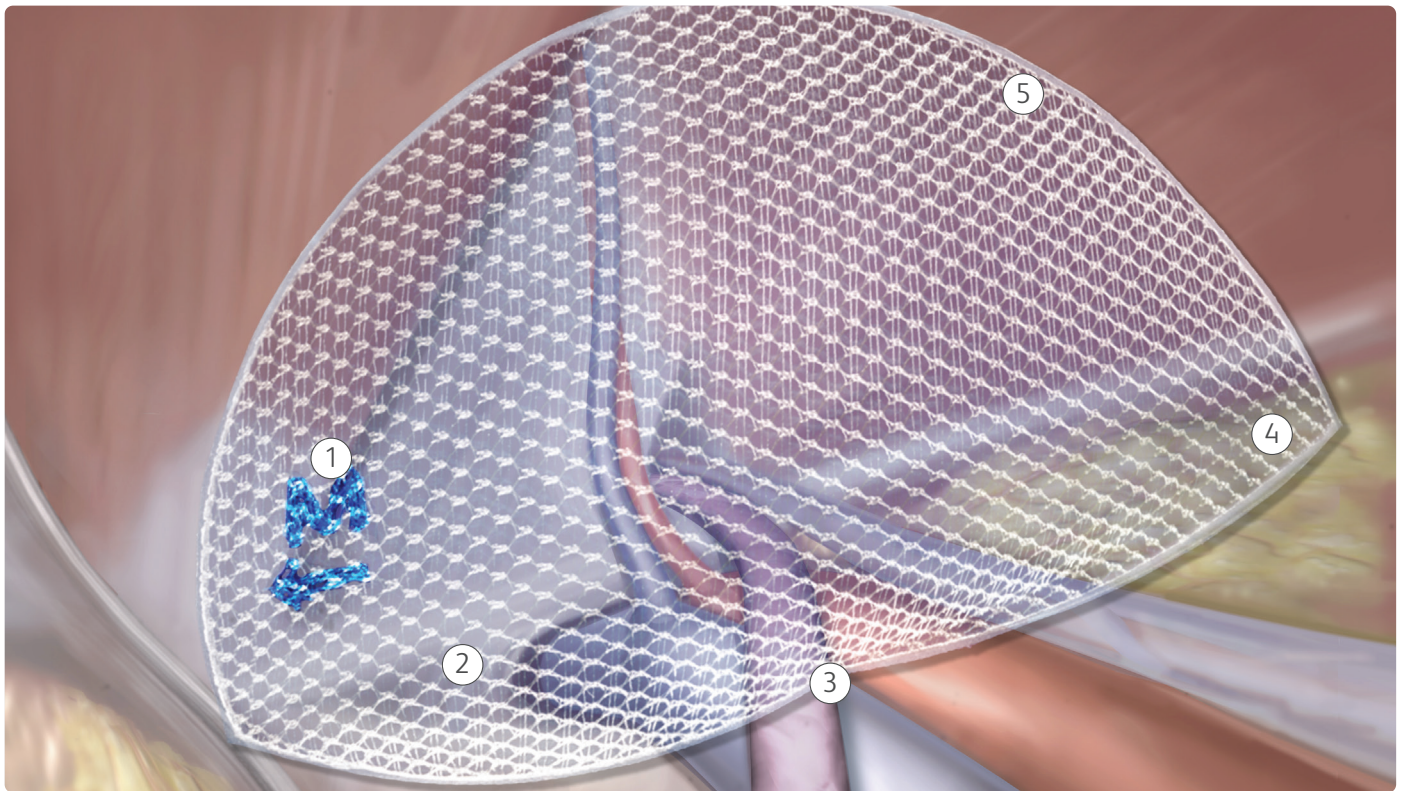
- Lighter-weight monofilament polypropylene mesh
- Large pore knit provides excellent visibility
- Encourages formation of a flexible and compliant abdominal wall¹

Unique

3DMax™ Light Mesh is a three-dimensional, anatomically-shaped mesh specifically designed for laparoscopic inguinal hernia repair.

The area of the inguinal anatomy is contoured and not at all flat. The unique shape of 3DMax™ Light Mesh is designed to conform to the anatomy and minimizes buckling that may be

seen with ordinary flat mesh, which may reduce the need for mechanical fixation.



- ① Medial orientation marker
- ② Crest corresponds to axis of inguinal ligament
- ③ Notch aligns with external iliac vessels
- ④ Lateral point facilitates alignment
- ⑤ Sealed edge facilitates mesh placement

Laparoscopic surgeons report on their experience with the unique shape of Bard™ 3DMax™ Mesh:

“Mechanical fixation is associated with pain syndromes, and mesh migration may occur without fixation of flat prostheses. An anatomically contoured mesh using no or minimal fixation would avoid these problems.”

R.C.W. Bell, M.D., et al., Swedish Medical Center, Englewood, CO⁵

“Its shape prevents curling.”

Philippe Pajotin, M.D., Polyclinic duParc, Cholet, France^{3,7}

“Once inside the abdomen it recovers its shape, thus making positioning easier.”

Philippe Pajotin, M.D., Polyclinic duParc, Cholet, France^{2,7}

“Inserting preformed, tackless mesh does not appear to make the operation more difficult.”

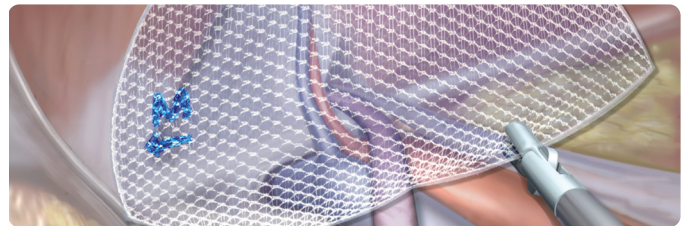
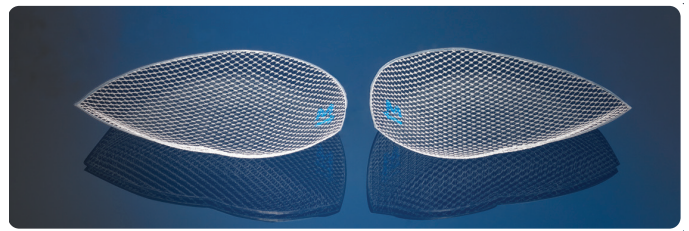
Cody Koch, et al., Mayo Clinic, Rochester, MN⁶

Precise

The design of 3DMax™ Light Mesh facilitates proper mesh placement and positioning.

The 3D design allows the mesh to conform to the inguinal anatomy and features a sealed edge and a medial orientation marker that facilitates proper mesh alignment and positioning which also enhances the speed and simplicity of placement.

Adequate mesh coverage is a significant part of a successful laparoscopic inguinal hernia repair. 3DMax™ Light Mesh is available in a variety of sizes and in left and right orientations to help you meet the individual needs of your patients.

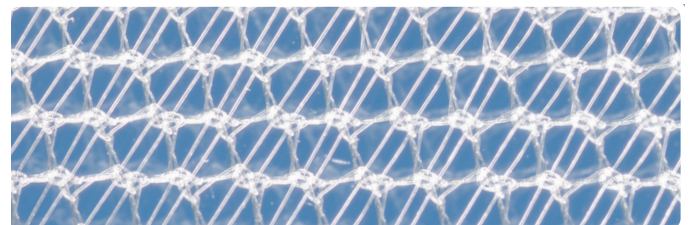


Lighter weight

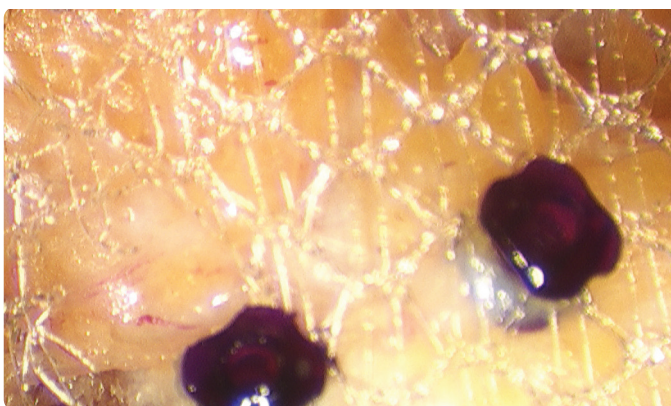
3DMax™ Light Mesh offers surgeons the same shape and performance features as 3DMax™ Mesh in a lighter-weight design.

The large pore knit makes this mesh less than 50% of the weight of 3DMax™ Mesh, but does not sacrifice the consistent performance of monofilament polypropylene mesh. The large pore knit also provides excellent visibility while encouraging formation of a flexible and compliant abdominal wall.'

Lighter weight without sacrificing strength

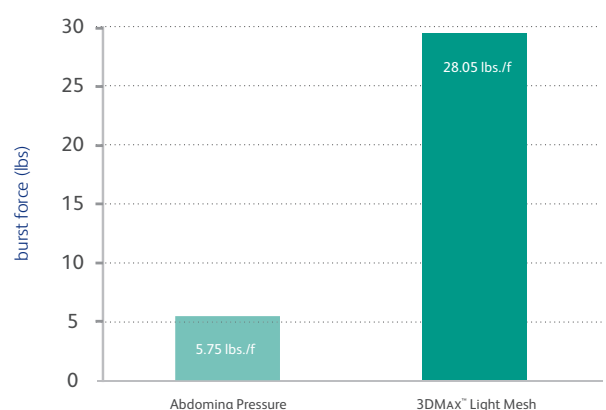


New lighter-weight, large pore construction with cross-weave

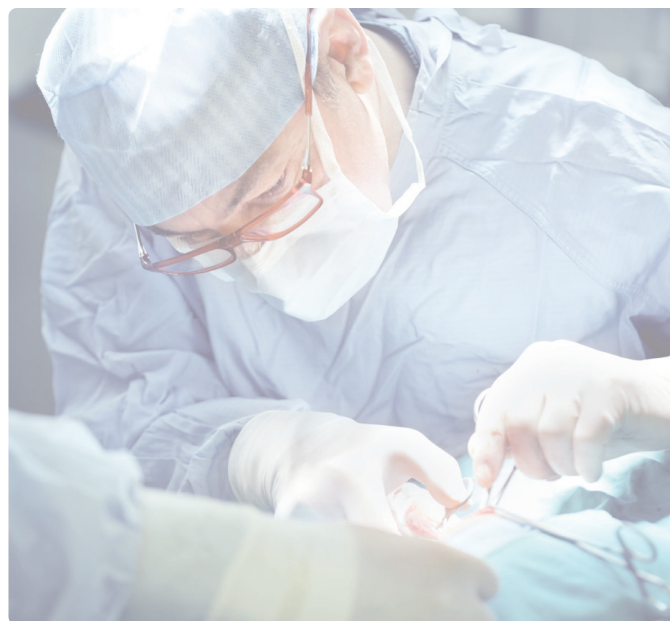


A cross-weave through each pore enhances security when mesh is used with mechanical fixation®

Burst strength



Product code	Qty.	Description	Dimensions	
0117310	1/cs.	Left, Medium	7.9 cm x 13.4 cm 3.1" x 5.3"	<input type="checkbox"/>
0117311	1/cs.	Left, Large	10.3 cm x 15.7 cm 4.1" x 6.2"	<input type="checkbox"/>
0117312	1/cs.	Left, Extra-Large	12.2 cm x 17.0 cm 4.8" x 6.7"	<input type="checkbox"/>
0117320	1/cs.	Right, Medium	7.9 cm x 13.4 cm 3.1" x 5.3"	<input type="checkbox"/>
0117321	1/cs.	Right, Large	10.3 cm x 15.7 cm 4.1" x 6.2"	<input type="checkbox"/>
0117322	1/cs.	Right, Extra-Large	12.2 cm x 17.0 cm 4.8" x 6.7"	<input type="checkbox"/>



Indications. The 3DMax™ Light Mesh is indicated for use in the reinforcement of soft tissue where weakness exists, in the repair of inguinal hernias. **Contraindications.** 1. Do not use this mesh in infants, children, or pregnant women, whereby future growth may be compromised by use of such materials. 2. The use of this mesh has not been studied in pregnant or breastfeeding women. 3. Literature reports that there may be a possibility for adhesion formation when polypropylene is placed in direct contact with the bowel or viscera. **Warnings.** 1. The use of any synthetic mesh or patch in a contaminated or infected wound can lead to fistula formation and/or extrusion of the mesh. 2. 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. 3. If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard with care to prevent risk of transmission of viral infections. 4. To prevent recurrences when repairing hernias, the mesh should be sized with appropriate overlap for the size and location of the defect, taking into consideration any additional clinical factors applicable to the patient. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue. 5. The mesh is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 6. This mesh had been designed for single use only. Reuse, reprocessing, resterilization, or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the mesh and may lead to mesh failure which may result in injury to the patient. Reuse, reprocessing, resterilization,

or repackaging may also create a risk of contamination of the mesh and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the mesh may lead to injury, illness or death of the patient or end user. 7. To avoid injury, careful attention is required if fixating the mesh in the presence of nerves, vessels, or the spermatic cord. Fastener penetration into underlying tissue containing nerves or blood vessels may result in the need for medical/surgical intervention, cause serious injury or permanent impairment to a body structure. **Precautions.** 1. Please read all instructions prior to use. 2. Only physicians qualified in appropriate surgical techniques should use this mesh. 3. Do not cut or reshape the 3DMax™ Light Mesh as this may affect its effectiveness. 4. Use an appropriately sized trocar to allow mesh to slide down the trocar with minimal force. 5. If fixation is used, Bard® permanent or absorbable fixation devices or nonabsorbable monofilament sutures are recommended to properly secure the device. If other fixation devices are used, they must be indicated for use in hernia repair. 6. If fixation is used, care should be taken to ensure that the mesh is adequately fixated to the abdominal wall. If necessary, additional fasteners and/or sutures should be used. **Adverse Reactions.** Possible complications may include, but are not limited to, seroma, adhesions, hematomas, pain, infection, inflammation, extrusion, erosion, migration, fistula formation, allergic reaction and recurrence of the hernia or soft tissue defect.

Please consult package insert for more detailed safety information and instructions for use.

- 1) Data generated from an animal and/or bench study. Data on file. Results may not correlate to performance in humans.
- 2) Pajotín. Laparoscopic Groin Hernia Repair Using a Curved Prosthesis Without Fixation. Le Journal de Celio – Chirurgie. 1998:28:64-68.
- 3) Pajotín. Shaped Preformed Prosthesis in the Pantal Repair of Inguinal Hernias by Trans-pentoneal Laparoscopy. Le Journal de cello-chinargie. 1996:17:73-75.
- 4) Koch, Greenlee, et al. Randomized Prospective Study of Totally Extraperitoneal Inguinal Hernia Repair: Fixation Versus No Fixation. Journal of the Society of Laparoendoscopic Surgeons, October 2006:10(4):457-460.
- 5) Bell, Price. Laparoscopic Inguinal Hernia Repair Using an Anatomically Contoured Three-Dimensional Mesh. Surgical Endoscopy, 2003:17:1784-1788.
- 6) This image is from a cadaver lab using 3DMax™ Light Mesh. Data on file. 3DMax, AlloMax, Bard, CollaMend, Composix, CruraSoft, Davol, Dulex, Kugel, MK, PerFix, PermaSorb, SorbaFix, Ventralex, Ventrío, Visilex and XenMatrix are trademarks and/or registered trademarks of C. R. Bard, Inc., or an affiliate. Sepremesh is a registered trademark of Genzyme Corporation licensed to C. R. Bard, Inc., or an affiliate. Please consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions and instructions for use.
- 7) Dr. Pajotín receives royalties for this product from Davol Inc.



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