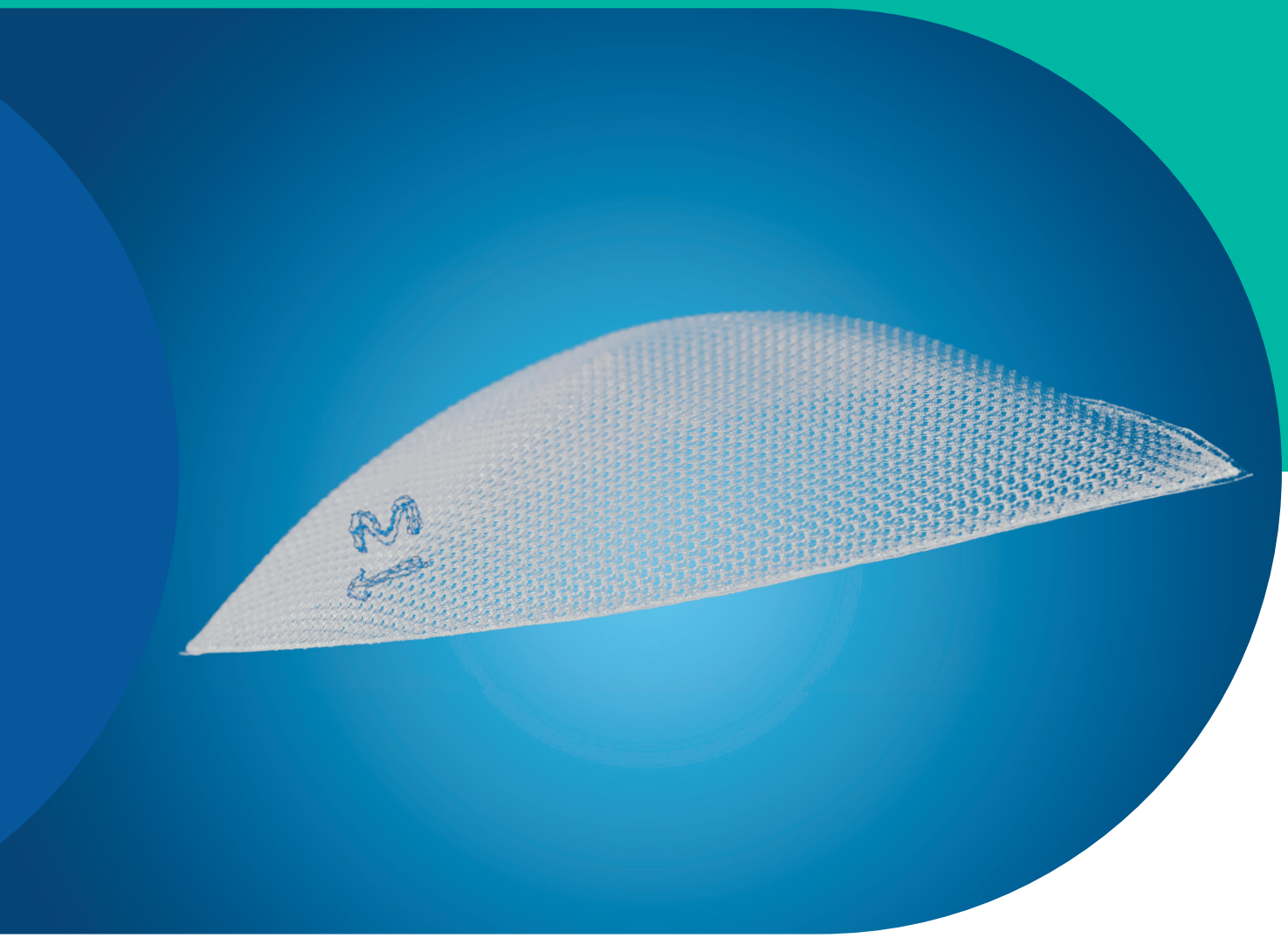

3DMax™ Mesh

A Clinically Proven Fixation-free Product for Laparoscopic Approaches Such as TAPP, TEP, and Robotic TAPP

BD

A true three-dimensional, anatomically formed mesh for use in laparoscopic inguinal hernia repair

3DMax™ Mesh was developed based on careful and precise anatomical research of the inguinal canal. The result is a truly unique prosthesis designed by a laparoscopic surgeon to meet the specific challenges of laparoscopic hernia surgery. The three dimensional, anatomically curved shape, sealed edge and medial orientation marker allow for easier positioning than a conventional flat mesh and also enhance the speed and simplicity of the placement.[2] The polypropylene mesh is made of widely spaced monofilament fibers which do not harbor bacteria like multifilament polyester fibers.[3] In a controlled clinical study of 500 3DMax™ Mesh hernioplasties, recurrences rates were found to be well below 1% and results indicated no postoperative neuralgia.[4]

3DMax™ Mesh is designed to conform to the inguinal anatomy and retain this shape following laparoscopic introduction, including a robotic approach.

Conformability

Unique 3D design precisely conforms to the inguinal anatomy

Easy positioning

Sealed edge and medial orientation marker ensure more accurate mesh alignment and less wrinkling than conventional flat mesh

No fixation

Eliminates need for fixation, which saves time and money

Reduced pain

Patients who received 3DMax™ Mesh without fixation used significantly less narcotic analgesia in the immediate post-operative period than those in whom flat mesh was fixed[1]

Applicable with various laparoscopic approaches

- TAPP
- TEP
- Robotic TAPP

Ordering information

Product code	Qty.	Description	Dimensions	
0115310	1/cs.	Medium left	8.5 cm x 13.7 cm	☐
0115311	1/cs.	Large left	10.8 cm x 16.0 cm	☐
0115312	1/cs.	X-large left	12.4 cm x 17.3 cm	☐
0115320	1/cs.	Medium right	8.5 cm x 13.7 cm	☐
0115321	1/cs.	Large right	10.8 cm x 16.0 cm	☐
0115322	1/cs.	X-large right	12.4 cm x 17.3 cm	☐

Indications. Bard® 3DMax™ 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 Bard® 3DMax™ Mesh as this may affect its effectiveness. 4. It is recommended to use a 10 mm internal diameter trocar to introduce a medium Bard® 3DMax™ Mesh, and an 11 mm internal diameter trocar to introduce a large Bard® 3DMax™ Mesh. The size of the extra-large Bard® 3DMax™ Mesh may inhibit deployment through a trocar. Use an appropriately sized trocar to allow mesh to slide down the trocar with minimal force. If mesh will not easily deploy down the trocar, remove trocar and insert mesh through incision. Reinsert trocar. 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 product package insert for more detailed safety information and instructions for use.

1) Koch et al. Randomized Prospective Study of Totally Extraperitoneal Inguinal Hernia Repair: Fixation Versus No Fixation of Mesh. Journal of the Society of Laparoendoscopic Surgeons. 2006:10:457-460.
2) Bell, Price. Laparoscopic Inguinal Hernia Repair Using an Anatomically Contoured Three-Dimensional Mesh. Surgical Endoscopy. 2003:17:1784-1788.
3) Amid, Shulman, Lichtenstein. Selecting Synthetic Mesh for the Repair of Groin Hernia. Postgraduate General Surgery. 1992:4:150-155.
4) Pajotin. Laparoscopic Groin Hernia Repair Using a Curved Prosthesis Without Fixation. Le Journal de Celio – Chirurgie. 1998:28:64-68.

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BD Switzerland Sarl, Terre Bonne Park – A4, Route De Crassier, 17, 1262 Eysins, Vaud. Switzerland.

bd.com