BARD

DAVOL INC.

3DMax™ MID Anatomical Mesh

Contoured for Advanced Minimally Invasive Hernia Repair

Instructions for Use

℞ only

STERILE EO

Non-absorbable

PRODUCT DESCRIPTION

The 3DMax™ MID Anatomical Mesh is made from monofilament polypropylene and has an open pore design, which allows a prompt fibroblastic response through the interstices of the mesh. The three-dimensional (3D) curved design and preformed, semi-rigid edges help it conform to the inguinal anatomy. The orientation markings help to determine the orientation and position of the 3DMax™ MID Anatomical Mesh with regards to groin anatomy.

INDICATIONS

The 3DMax™ MID Anatomical 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 the device in infants, children or pregnant or breastfeeding women, whereby future growth will be compromised by use of such mesh material.
2. Literature reports that there may be a possibility for adhesion formation when polypropylene mesh is placed in direct contact with the bowel or viscera.

WARNINGS

1. **The use of any permanent mesh or patch in a contaminated or infected wound could lead to fistula formation and/or extrusion of the prosthesis.**
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 device.**
3. **If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with bodily fluids, discard mesh 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. **This device is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use.**
6. **This device has 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 device and may lead to device failure which may result in injury to the patient. Reuse, reprocessing, resterilization or repackaging may also create a risk of contamination of the device 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 device 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 prosthesis.
3. Do not cut or reshape the 3DMax™ MID Anatomical Mesh as this may affect its effectiveness.
4. Use an appropriately sized trocar to allow mesh to slide down the trocar with minimal force.

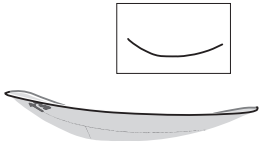
INSTRUCTIONS FOR USE

It is recommended to use 8 mm or larger internal diameter trocar* to introduce 3DMax™ MID Anatomical Mesh.

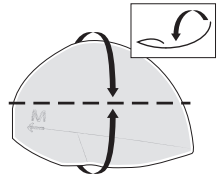
*If the trocar has a proximal cap, removing it can help facilitate insertion of the device. Insertion forces may vary depending on rolled device size and graspers/trocar used.

ROLLING AND INSERTING

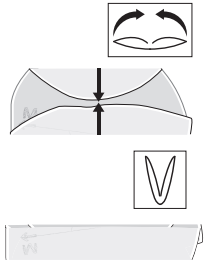
1. Lay the device on the table with the concave side facing up.



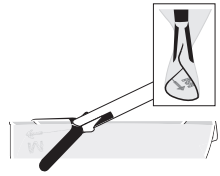
2. Roll the mesh edges inwards along the long axis towards the midline.



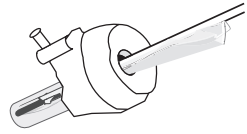
3. Then bring the rolled sides together to close the device.



4. Holding the rolled device, firmly grasp the leading edge with an atraumatic grasper or equivalent tool. Take care to grasp either end of the rolled device.



5. Insert the leading edge of the rolled device into the trocar. In one continuous movement, deploy the device into the abdomen. Please make sure the “M” is oriented towards the medial side of the inguinal space. Maintain visualization of the device via laparoscope as it is deployed into the abdomen.



Fixation may not be required, depending on the size of the defect, surgical technique used, the quality of the anatomical structures and tissue integrity. If you choose to fixate, Bard® permanent or absorbable fixation devices or non-absorbable monofilament sutures are recommended to properly secure the 3DMax™ MID Anatomical Mesh. If other fixation devices are used, they must be indicated for use in hernia repair. Care should be taken to avoid fixating on vessels and nerves.

ADVERSE REACTIONS

Possible complications include, but are not limited to, seroma, adhesion, hematoma, pain, infection, inflammation, extrusion, erosion, migration, fistula formation, allergic reaction, wound dehiscence and recurrence of the hernia or soft tissue defect.

TRACEABILITY

Traceability labels that identify the type, size, expiration date, and lot number of the mesh are attached to every package. A label should be affixed to the patient’s permanent medical record to clearly identify the mesh which was implanted.

SYMBOL DEFINITIONS

	Medium		Catalogue number
	Large		Batch code
	Extra large		Use-by date
	Left		Do not re-use
	Right		Do not resterilize
	Actual size		Sterilized using ethylene oxide
	Contents		Do not use if package is damaged
	Manufacturer		Non-absorbable
 only	U. S. Federal law restricts this device to sale by or on the order of a physician.		Consult Instructions for Use

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