



BD[®] 3DMax[™] Mesh Family

Intelligent design that reduces the need for fixation



Non-fixation clinical evidence

Year	Author	Title	Journal	Number of Patients	Mean Follow-Up	Methods	Conclusion
2023	Elghadban, Hosam, Negm, Ahmed, Hisham, Islam, Elganash, Abd Elazim, Taki-Eldin, Ahmed	Fixation of Conventional Polypropylene Mesh Versus Non-fixation of 3D Mesh in Laparoscopic Transabdominal Preperitoneal (TAPP) Inguinal Hernia Repair: a Randomized Controlled Trial	Indian Journal of Surgery. Nov 2023	60	1 year	Lap TAPP - fixation with flat mesh x non fixation with 3D ⁺ Max Mesh	The non-fixation of 3DMax ⁺ Mesh in laparoscopic TAPP inguinal hernia repair is a feasible, safe option for surgical treatment of inguinal hernia with shorter mesh spreading time and reduced post-operative pain and chronic pain, without increasing complications or recurrence rates compared with the conventional fixation of polypropylene mesh.
2022	Ungureanu, Gingham, Stanculea, Iosifescu, Cristiana, Grigorean, Popescu, Dobre, Iordache	Surgical Outcome in Bilateral Inguinal Hernia Repair: Laparoscopic Total Extraperitoneal Approach (TEP) as Best Approach?	MAEDICA – a Journal of Clinical Medicine https://doi.org/10.26574/maedica.2023.18.4.598 2023; 18(4): 598-606	83 (not all 3D ⁺ Max Mesh)	3 months	Lap TEP non fixation	In bilateral inguinal hernia repair, laparoscopic TEP approach is an excellent option which offers considerable advantages for the patient. With proper mesh size and placement, recurrence is reduced, and also postoperative pain due to no fixation technique.
2020	Acar, A; Kabak, I; Tolun, HK; Canbak, T	Comparison between Mesh Fixation and Non-Fixation in Patients Undergoing Total Extraperitoneal Inguinal Hernia Repair	Nigerian Journal of Clinical Practice ; Volume 23 ; Issue 7 ; July 2020	178	45 months	Lap TEP fixation x non fixation	TEP seems to be a safe and effective surgical approach in inguinal hernia treatment with acceptable operation times and postoperative results. It was determined that not performing mesh fixation in the TEP application did not cause a statistical increase in morbidity and recurrence rates.
2018	IqbalSaleemMir, TajamulRashid, IrfanNazirMir, SuhailNazir, ImtiyazAli, MansoorUl Haq	Laparoscopic totally extraperitoneal repair of inguinal hernia using three-dimensional mesh: a 5 years experience at a tertiary care hospital in Kashmir, India	International Surgery JournalMirIS et al. Int Surg J. 2018 Mar;5(3):1016-1020	123	12 months (mean)	Lap TEP (considered "fixation" as the mesh insertion and deployment)	Laparoscopic inguinal mesh hernioplasty using 3DMax ⁺ Mesh is a viable alternative of hernioplasty with minimal post-operative pain and recurrence and using 3DMax ⁺ Mesh has a technical advantage of easy insertion in an anatomically correct position with minimal fixation.
2017	Golani, S., Middleton, P.	Long-term follow-up of laparoscopic total extraperitoneal (TEP) repair in inguinal hernia without mesh fixation	Hernia. 2017. 21:37-43	538	6 years	Lap TEP non fixation long term follow up.	This study includes long-term follow-up data of more than 5 years for patients having inguinal hernia repair by TEP technique without mesh fixation. This article concludes that the review conducted demonstrates that fixation of mesh with tacks or glue is unnecessary for TEP repair of inguinal hernia.
2017	Mommers, E. H. H., Hünen, D. R. M., van Hout, J. C. H. M., Guit, M., Wegdam, J. A., Nienhuijs, S. W., de Vries Reilingh, T. S.	Patient-reported outcomes (PROs) after total extraperitoneal hernia repair (TEP)	Hernia. 2017. 21:45-50	120	12 months	Lap TEP non fixation	Patients recovered well after TEP repair with a good quality of life and fast restore of function.
2015	M. Szymankiewicz, D. Bennett	An 8 Year Series Reporting the Success of an Un-fixated Bard 3D Max Mesh Laparoscopic TEP Inguinal Hernia Repair Technique	BJs 2015; 102 (S1): 127-301	212	36 months	Lap TEP non fixation	This study demonstrates that this is a reliable and safe technique that compares favorably with other techniques. Furthermore, there are some useful insights into patient experience that are not generally appreciated with modern follow up protocols.
2013	Ayiomamitis GD, Zaravinos A, Stathakis PC, Kouroumpas E, Georgiades P, Polymeneas G	Tacks-free Transabdominal Preperitoneal (TAPP) inguinal hernioplasty using an anatomic 3-dimensional lightweight mesh with peritoneal suturing: pain and recurrence outcomes — initial experience	Surgical Laparoscopy, Endoscopy and Percutaneous Techniques. 2013. 23:e150-e155	32	12,4 months	Lap TAPP – non tacker fixation (peritoneal suture)	It is demonstrated with this technique that there are no recurrences and the chronic pain is negligible.

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2013	Zhu J, Zhou Y, Yin YZ, Tian Y	Experience of transabdominal preperitoneal prosthesis for the treatment of inguinal hernia with Bard 3DMax [™] patch for twenty-six patients	Journal of Xinjiang Medical University	26	25.5 months	Lap TAPP non fixation	The follow-up period was 3 to 48 months, with an average of 25.5 months. All patients had no recurrence after the operation, and there were no serious complications such as neuralgia and intestinal obstruction.
2013	Zhang WG, An WD, Hu YZ, Deng ZH	Laparoscopic inguinal hernia repair using an anatomically contoured three-dimensional mesh without fixation: an analysis of 47 cases	Journal of Dalian Medical University	47	20.5 months	Open tension-free x Lap TAPP non fixation	Laparoscopic transabdominal preperitoneal patch implantation (TAPP) is safe Reliable, combined with three-dimensional patch (3D [™] Max Mesh patch) without fixation technology Surgery, although the cost is higher than tension-free hernia surgery, but the patient's postoperative recovery time short, low complication rate, more effective for recurrent hernias and bilateral hernias.
2012	Wang ZY, Wang RY, Zhang SL, et al	Using Bard 3DMax [™] Mesh in transabdominal preperitoneal laparoscopic repair: a report of 15 cases	Chinese Journal of General Practice, June 2012, Vol. 10, No. 6	15	6.5 months	Lap TAPP non fixation	Using Bard 3DMax [™] Mesh in laparoscopic TAPP can be performed safely and reliably. It also helped to shorten the operating time and reduces the complication rates of the operation. The procedure had advantages of faster postoperative recover, less pain, lower complications and recurrence rate.
2010	Li MJ, Hu YZ, Li JY, Xu P, Chen J, Wang CC	3DMax [™] Mesh Fixation-free Laparoscopic Inguinal Hernia Repair: A report of 55 cases	China Journal of Endoscopy	55	14 months	Lap TAPP and TEP non fixation	3DMax [™] Mesh fixation-free laparoscopic inguinal hernia repair surgery is safe and reliable. The operation is simple, and complication occurrence rates are low.
2006	Koch CA, Greenlee SM, Larson DR, HarringtonJR, Farley D	<u>Randomized prospective study of totally extraperitoneal inguinal hernia repair: fixation versus no fixation of mesh</u>	JSLs: Journal of the Society of Laparoendoscopic Surgeons. 2006. 10:457	40	19 months	Lap TEP fixation x non fixation	Elimination of tack fixation of mesh during laparoscopic TEP inguinal hernia repair significantly reduces the use of postoperative narcotic analgesia, hospital length of stay, and the development of postoperative urinary retention but does not lead to a significant reduction in postoperative pain. Eliminating tacks does not lead to an increased rate of recurrence.
2003	Bell RC, Price JG	<u>Laparoscopic inguinal hernia repair using an anatomically contoured three-dimensional mesh</u>	Surg Endosc. 2003. 17:1784-8	146	23 months	Lap TAPP non fixation	An anatomically contoured mesh for transabdominal preperitoneal hernia repair often requires no fixation, with minimal risk of neuropathy and less than a 0.5% patient-year recurrence rate. Recovery is excellent even with bilateral repair or some fixation.
1998	Pajotin P	Laparoscopic groin hernia repair using a curved prosthesis without fixation; a report on 500 cases	Le Journal de Coelio-Chirurgie	390	2 years	Lap TAPP non fixation	This series of 500 hernioplasties in 390 adults demonstrates good functional results and a low morbidity. The transperitoneal approach did not cause any early nor late bowel obstruction. The known recurrence rate is 0.6%. No neuralgia nor testicle atrophy have been observed.

15 studies from across the globe have examined **2,000 patients** who received 3DMax[™] Mesh family products without fixation.



The 3DMax™ Mesh family has a robust list of publications and over **5 million** implants worldwide.



75+
publications
from all over the globe¹



Over
5 million
implants
worldwide²

3DMax™ Mesh 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. **Please consult package inserts for more detailed safety information and instructions for use.**

3DMax™ Light Mesh 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. 8. This device is not for the use of repair of pelvic organ prolapse. 9. This device is not for the use of treatment of stress urinary incontinence. **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. 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 inserts for more detailed safety information and instructions for use.**

3DMax™ MID Anatomical Mesh 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 this mesh in infants, children or pregnant or breastfeeding women, whereby future growth may 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 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 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 mesh is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 6. This mesh 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 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. 8. This device is not for the use of repair of pelvic organ prolapse. 9. This device is not for the use of treatment of stress urinary incontinence. **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™ 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. **Adverse Reactions.** Possible complications may 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. **Please consult package inserts for more detailed safety information and instructions for use.**

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