3DMax™ Mesh Family

Product information kit

BD

Proven science.

BD is a global medical technology company that is *advancing the world of health*™ by improving medical discovery, diagnostics and the delivery of care.

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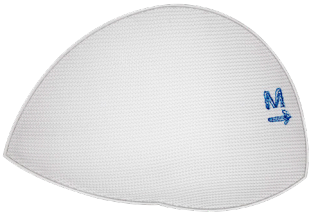
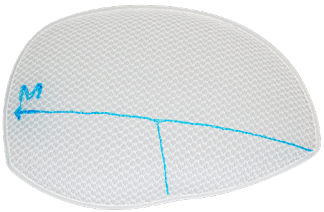


BD® 3DMax™ Mesh



3DMax™ MID Anatomical Mesh

3DMax™ Light Mesh

Product overview

3DMax™ Mesh portfolio features

Simple

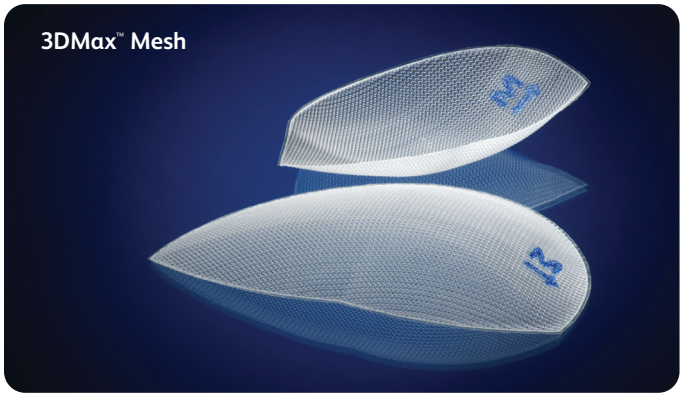
- 3D shape designed to conform to the inguinal anatomy.
- Fixation is not required with 3DMax™ Mesh.

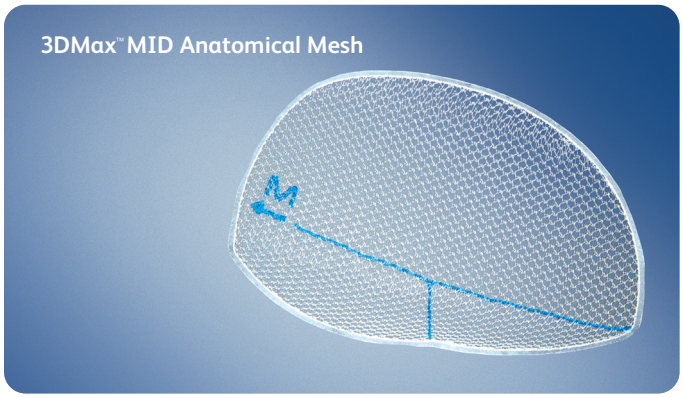
Precise

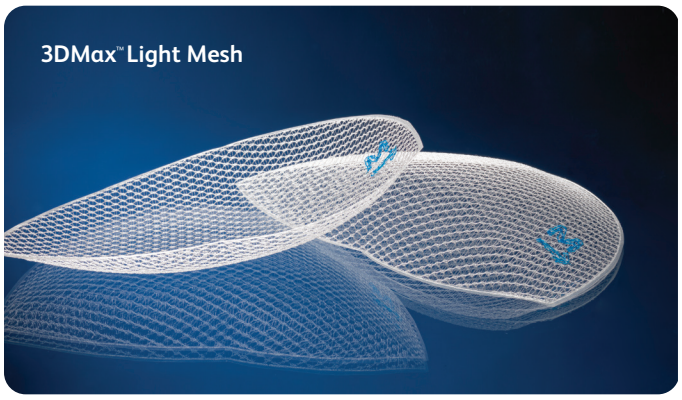
- Sealed edge and medial orientation marker facilitate accurate placement and positioning.
- Mesh design maintains shape.
- Anatomical orientation lines help guide mesh positioning and placement.

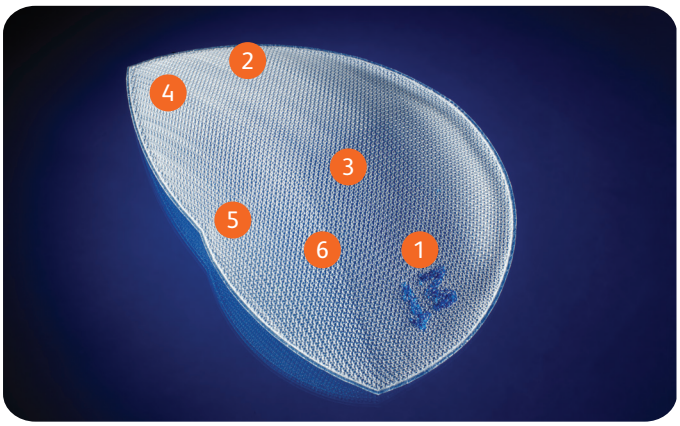
Offers different weight profile

- Monofilament polypropylene mesh.
- Available in full spectrum of weight– 3DMax™, 3DMax™ MID, and 3DMax™ Light.
- Large pore knit on the 3DMax™ MID and 3DMax™ Light allows direct visualization of underlying anatomy.









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

3DMax™ Mesh portfolio overview

1. Robust list of publications

Current clinical compendium references more than 75 publications from a variety of journals across the globe[1].

2. Over 5 million implants worldwide

3DMax™ Mesh family history of usage has been demonstrated since 1999.

3. Anatomically designed

A true three-dimensional, anatomically formed mesh designed to precisely conform to the inguinal anatomy minimizing the need for fixation, preventing mesh buckling, wrinkling and migration, retaining its shape following laparoscopic introduction.[2,3]

Designed to be used in minimally invasive hernia approaches such as:

- TAPP
- TEP
- Robotic TAPP

4. Can be used without fixation

3DMax™ Mesh laparoscopic or robotic use without fixation has been associated with improved clinical outcomes:

- Low rate of hernia recurrence.[2,3,4,5,6]
- Reduced post-operative complications.[5,6]
- Reduced patient post-op pain.[3]
- Reduced length of stay.[3]

3DMax™ Light Mesh

[1] **3DMax™ Mesh family clinical compendium BD-132634**

5. BD is a trusted partner

BD Advanced Repair and Reconstruction portfolio covers all techniques from open hernia repair, to laparoscopic repair, to robotic repair. Having a wide range of available products allows surgeons to choose the most appropriate product for each individual situation, to improve patient outcomes.

In addition to the clinical and supply chain benefits that are commonly associated with using a single vendor, BD offers surgeons assistance in becoming comfortable selecting the most suitable product for each patient and scenario and other product support that make it an efficient and cost-effective choice.

"Standardizing mesh type saved $1.5 million."

Source: Formula for successful cost control includes hard data plus surgeon champion. OR Manager (2014). 30(4):14-18.

"The most meaningful cost reduction strategies will involve standardization of clinical care and elimination of variation in patient procedures. This will be a multi-year, ambitious journey requiring strong physician, management and board leadership."

Source: "Doing More with Less: Credit Implications of Hospital Transition Strategies in Era of Reform." Moody's Investors Service. May 9, 2012.

"Partnering with Bard allowed both biologics and synthetics to be standardized with one vendor. As added value, Bard has been a market leader in surgical meshes for years, and this partnership comes with an intrinsic degree of confidence, because they are being used widely with success and trusted across the country".

Source: Miller, S G and Bourque, M, "PPI Value Analysis and Standardization Success Through Vendor Partnering: A Case Study of Hernia Mesh Savings and Quality Improvement at Thomas Jefferson University Hospital." Healthcare Value Analysis & Utilization Management Magazine (2016) 4.1: 8-12. Web.

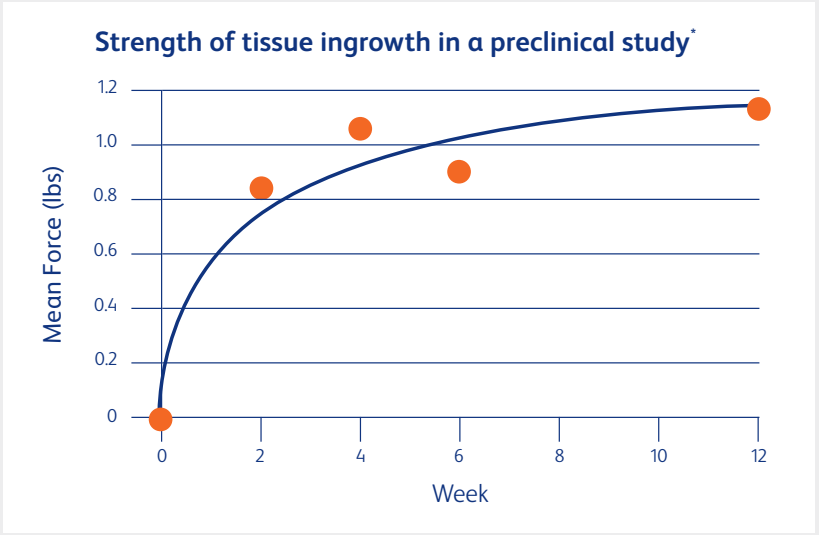
1. Product technology – polypropylene

The 3DMax™ Mesh family combines polypropylene mesh with an inguinal anatomical contour.

Uncoated monofilament polypropylene mesh.

- Over 40 years of proven results in hernia repair.
- Provides a long-term repair.

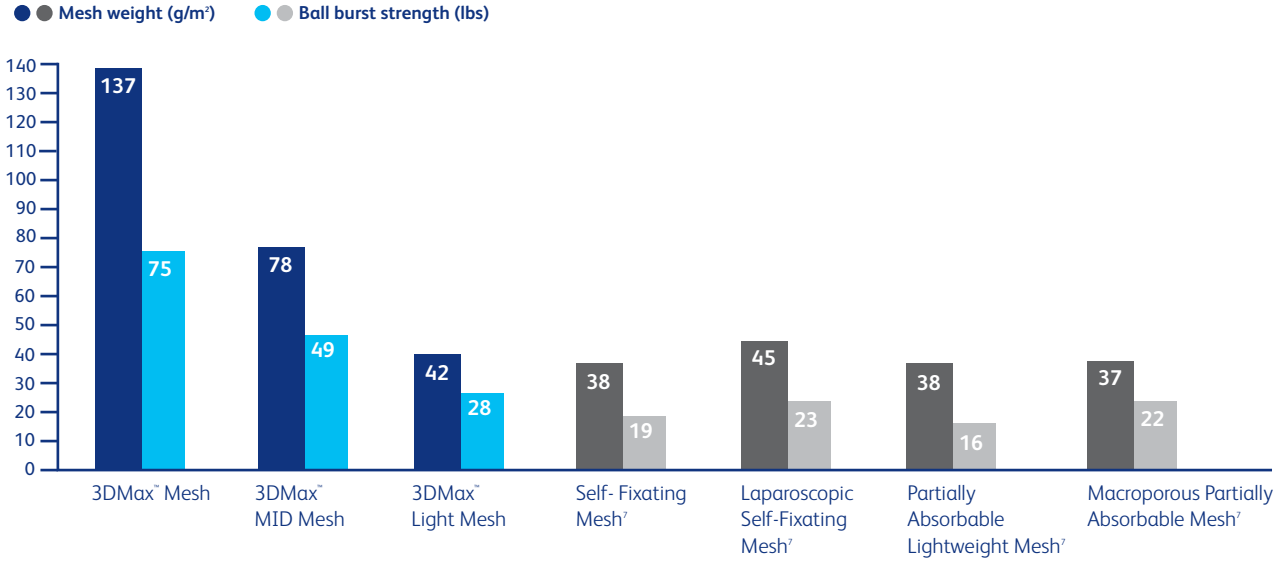
74% of the 12 week strength is achieved by 2 weeks postoperatively.*



* Majercik, S. et al. Strength of tissue attachment to mesh after ventral hernia repair with synthetic composite mesh in a porcine model. *Surg Endosc.* 2006 Nov;20(11):1671-4. Results may not correlate to performance in humans.

Logarithmic regression curve of mean force of lap-shear strength as a function of time.

2. Mesh weight versus burst strength[7]



Economic value

The inguinal region is not completely flat, presenting varied contours.

The three-dimensional shape, with a sealed edge and a marker in medial orientation, facilitates the positioning when compared to a conventional flat panel. The design allows simpler application and reduced placement speed, potentially reducing the total time of procedure.[2]

3DMax™ was expressly designed to conform the inguinal anatomy, reducing the need for mechanical fixation[2,3,4,5,6]

Benefits may include:

- Decrease in surgical procedure time.[2]
- Fewer post-surgical complications.[3]
- Fewer recurrences.[4]

Competitive overview

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

Feature & Benefits[8]	3DMax™ Mesh	3DMax™ Light Mesh	3DMax™ MID Anatomical Mesh	Other Synthetic Anatomical Mesh	Laparoscopic Self-fixating Mesh
Material	Monofilament polypropylene			Monofilament polypropylene	Monofilament polyester
Shape	3D shape -Fully contoured to conform to inguinal anatomy			3-D patented anatomical shape	Flat mesh
Designed to fit through the 8mm robotic trocar	N	Y	Y	N	Y
Medial orientation markings to facilitate positioning	Y	Y	Y	Y	N
Designed to pop open, enabling easier placement and positioning	Y	Y	Y	Y	N
Transparency - Ability to see through, visualization of underlying anatomy	N	Y	Y	Y	N
Can be used without fixation	Y	Y	Y	Y	Y
Self-fixating	N	N	N	N	Y
Need hydration before use	N	N	N	N	Y
Can be cut	N	N	N	N	Y (consider additional fixation)

BD is committed to providing you with educational programs designed to help you meet your desired outcome.

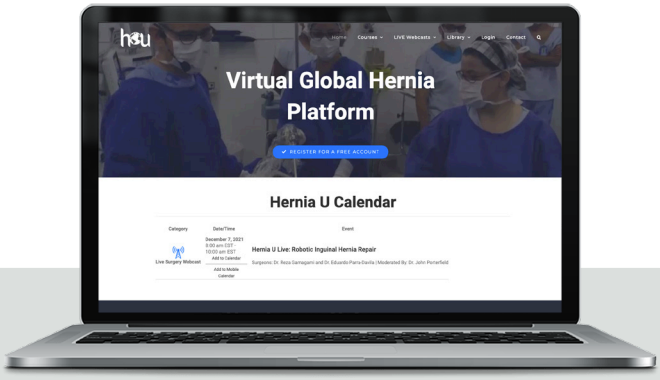
Your needs. Your schedule. Your peers.

BD surgical education programs are designed to provide you with focused and flexible modalities providing in-depth education on products and techniques intended to help you optimize patient care.

- Instruction from leading surgeon experts in surgical techniques.
- Opportunities to discuss and review surgical experience with peers.
- Interactive exchanges with expert surgeons on specific topics.

5. Surgical education

CONNECT. INTERACT. LEARN.



Hernia U is the only virtual global hernia platform where surgeons from around the world can instantly access numerous courses and tools to further their Hernia education.

[Free and available for everyone](https://www.herniau.com/)

https://www.herniau.com/

HERNIA A TO Z FUNDAMENTALS

Our first online course consisting of modules and live surgeries that cover the essentials in Hernia surgery for both ventral and inguinal-now offered in both English and Spanish.

HERNIA A TO Z ADVANCED

The next course after Fundamentals consisting of modules and live surgeries where our faculty will be sharing challenging cases together with their best practices.

HERNIA U LIVE

Broadcasts from different locations with a globally respected KOL. These are opportunities to learn and interact with colleagues through the moderator and chat box.

VIDEO LIBRARY

We have been recording past LIVE broadcasts and store them here so our surgeons can return and learn about Hernia Surgery from the industry leaders.

HERNIA U PODCASTING

We have interviewed some of our global KOLs to learn more about why they do what they do.

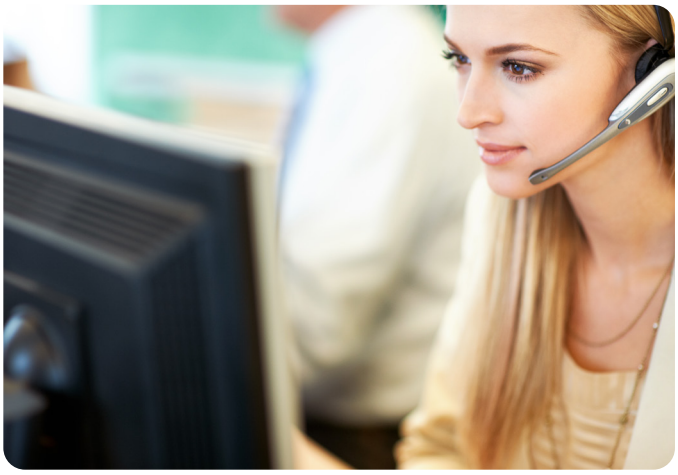
Committed to a successful partnership.

Healthcare economics and new policies have changed the way you do business. It's imperative to work with a partner who understands your challenges, and who delivers both value and devices that support best-in-class patient care. BD partners benefit from highly personalized and impactful support when they take advantage of the full line of surgery products.

Dedicated resources to support you and your use of BD products.

Access

As a BD partner, one of your key benefits is receiving dedicated customer service and personalized support. Whether it's placing orders, answering billing questions, finding cross-references or providing requested documentation, your dedicated Customer Service specialist is on call for you.



Medical Information Services (MIS)

Medical Information Services was created to assist you and address your needs as a medical provider in today's changing healthcare environment. This unique support team from BD will answer your questions and provide you with technical and clinical information on procedures involving BD products.

Our support staff consists of knowledgeable health professionals, including surgeons, prepared to answer your questions and provide necessary resources.

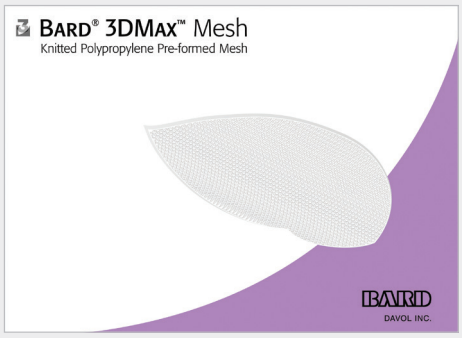
BD Medical Information Services:
medical.information@bd.com

Contact your local BD sales representative for more information.

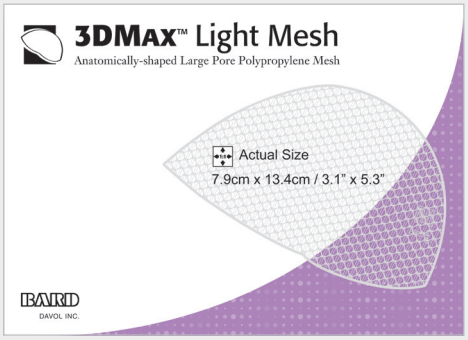
7. Appendix

Packaging overview

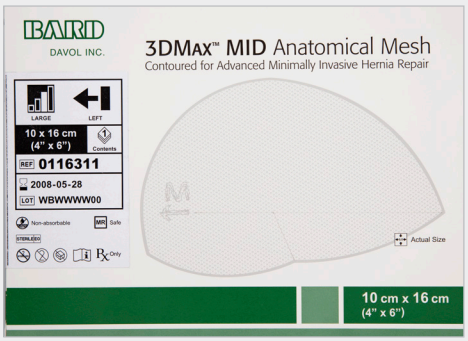
3DMax™ Mesh



3DMax™ Light Mesh

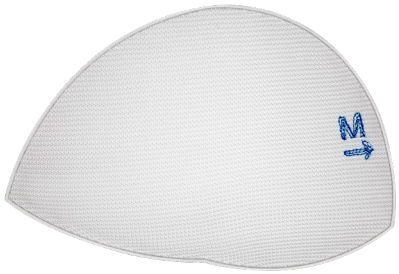


3DMax™ MID Anatomical Mesh



Disclaimer: The data presented herein is not intended to imply clinical product performance and/or circumvent sound clinical judgment.

Ordering Codes

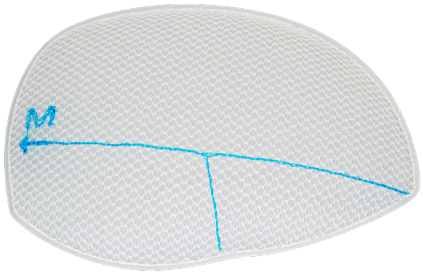


3DMax™ Mesh

Ordering information		
Product Item ID	Description	Qty.
0115310	Left, Medium – 8.5 cm x 13.7 cm (3" x 5")	1/cs.
0115311	Left, Large – 10.8 cm x 16 cm (4" x 6")	1/cs.
0115312	Left, Extra-Large – 12.4 cm x 17.3 cm (5" x 7")	1/cs.
0115320	Right, Medium – 8.5 cm x 13.7 cm (3" x 5")	1/cs.
0115321	Right, Large – 10.8 cm x 16 cm (4" x 6")	1/cs.

3DMax™ Light Mesh

Ordering information		
Product Item ID	Description	Qty.
0117310	Left, Medium – 7.9 cm x 13.4 cm (3.1" x 5.3")	1/cs.
0117311	Left, Large – 10.3 cm x 15.7 cm (4.1" x 6.2")	1/cs.
0117312	Left, Extra-Large – 12.2 cm x 17.0 cm (4.8" x 6.7")	1/cs.
0117320	Right, Medium – 7.9 cm x 13.4 cm (3.1" x 5.3")	1/cs.
0117321	Right, Large – 10.3 cm x 15.7 cm (4.1" x 6.2")	1/cs.

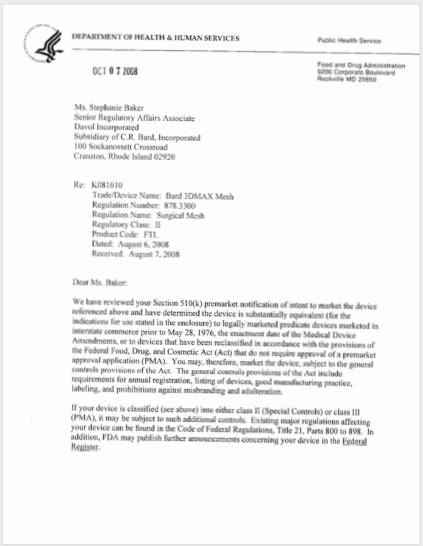


3DMax™ MID Anatomical Mesh

Ordering information		
Product Item ID	Description	Qty.
0116310	Left, Medium – 8 cm x 14 cm (3" x 5")	1/cs.
0116311	Left, Large – 10 cm x 16 cm (4" x 6")	1/cs.
0116312	Left, Extra-Large – 12 cm x 17 cm (5" x 7")	1/cs.
0116320	Right, Medium – 8 cm x 14 cm (3" x 5")	1/cs.
0116321	Right, Large – 10 cm x 16 cm (4" x 6")	1/cs.

510(k) Clearance

3DMax™ Mesh



DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 7 2008

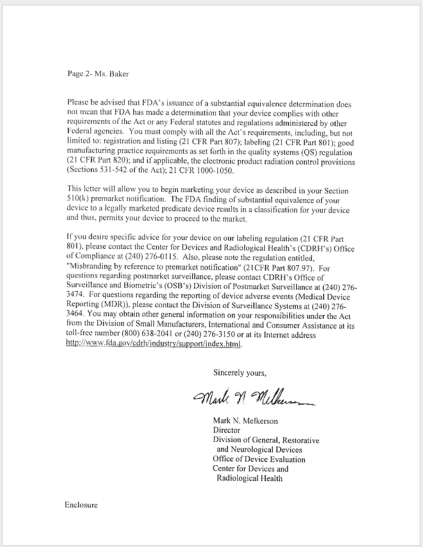
Ms. Stephanie Baker
Senior Regulatory Affairs Associate
Davol Incorporated
Subsidiary of C.R. Bard, Incorporated
100 Sockanossett Crossroad
Cranston, Rhode Island 02920

Re: K081010
Trade/Device Name: Bard 3DMAX Mesh
Regulation Number: 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTL
Dated: August 6, 2008
Received: August 7, 2008

Dear Ms. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Page 2- Ms. Baker

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

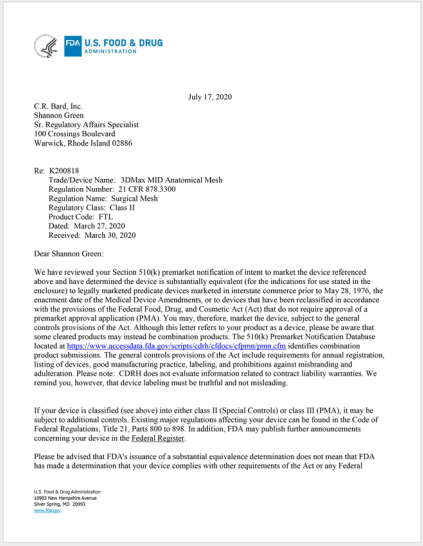
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

3DMax™ MID Anatomical Mesh



U.S. FOOD & DRUG ADMINISTRATION

July 17, 2020

C.R. Bard, Inc.
Shannon Green
Sr. Regulatory Affairs Specialist
100 Crossings Boulevard
Warwick, Rhode Island 02886

Re: K200818
Trade/Device Name: 3DMax MID Anatomical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTL
Dated: March 27, 2020
Received: March 30, 2020

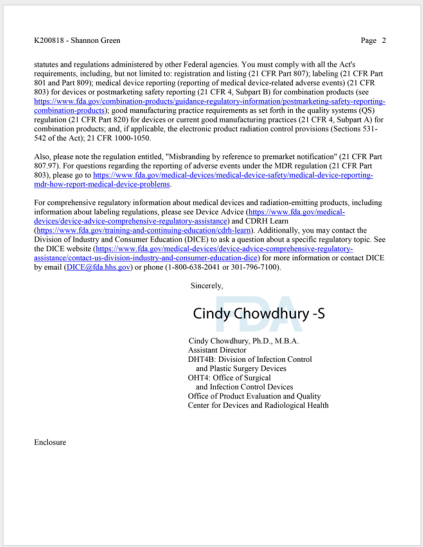
Dear Shannon Green:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov



K200818 - Shannon Green — Page 2

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

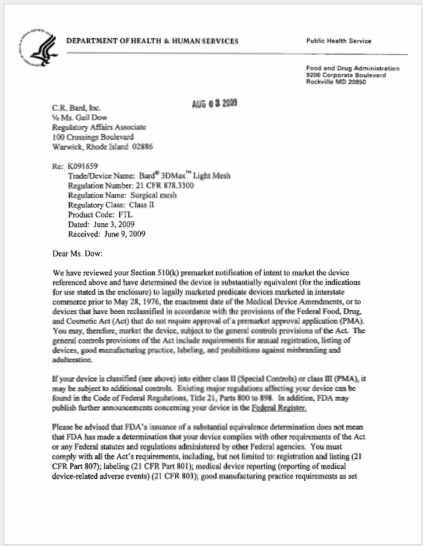
Sincerely,

Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

3DMax™ Light Mesh



DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 3 2009

C.R. Bard, Inc.
⅛ Ms. Gail Dow
Regulatory Affairs Associate
100 Crossings Boulevard
Warwick, Rhode Island 02886

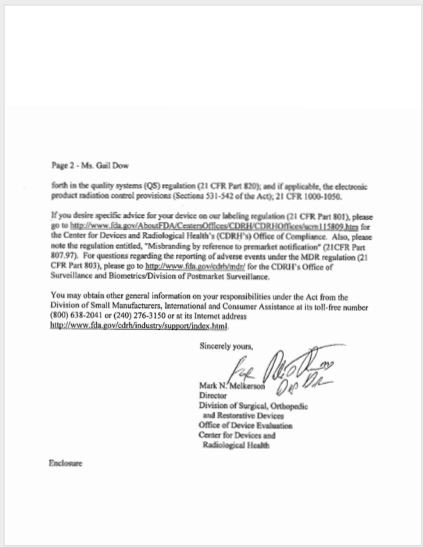
Re: K091659
Trade/Device Name: Bard® 3DMax™ Light Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL
Dated: June 3, 2009
Received: June 9, 2009

Dear Ms. Dow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set



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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Clinical compendium

Year	Author	Title	Journal	Number of Patients	Mean Follow-Up
2024	V. C. Nikolian, X. Pereira, L. Arias-Espinosa, A. N. Bazarian, C. G. Porter, J. R. Henning, F. Malcher	Primary abandonment of the sac in the management of scrotal hernias: a dual-institution experience of short-term outcomes	*Hernia.* Aug;28(4):1225-1230. doi: 10.1007/s10029-024-03009-9	67	6 months
2024	Hayward, Romilly, Jacob J. Smith, Christos Kontovounisios, Shengyang Qiu, and Oliver J. Warren	Laparoscopic totally extraperitoneal hernia repair in patients with a history of previous abdominopelvic surgery	*Front Surg.* 2022 May 20:9:900843.	3, 6, 12 months	6 months
2024	Shao, X., Cheng, T., Shi, J., Zhang, W., Li, J	The effect of internal orifice narrowing in laparoscopic inguinoscrotal hernia repair to prevent seroma formation: a prospective double-blind randomized controlled trial	*Surg Endosc.* 2024. 38:1823-1834	262	6 months
2023	Yun Suk Choi , Kyeong Deok Kim , Moon Suk Choi, Yoon Seok Heo, Jin Wook Yi *,† and Yun-Mee Choe	Initial Experience of Robot-Assisted Transabdominal Preperitoneal (TAPP) Inguinal Hernia Repair by a Single Surgeon in South Korea	*Medicina.* 2023, 59, 582.	6 weeks	Not specified
2023	J. L. Faessen, E. S. R. Duijsings, E. G. Boerma, P. P. H. L. Broos, R. van Vugt & J. H. M. B. Stoot	The first experience with the Dextile anatomical mesh in laparoscopic inguinal hernia repair	*Hernia.* (2023) 27:1203–1208	956	8 weeks (3 months for pain)
2023	DL Lima, V Viscarret, R Nogueira, JPG Kasakewitch, R Berk, P Sreeramoju, F Malcher.	Does the Weight Matter? Short-Term Outcomes of Lightweight Versus Heavyweight Three-Dimensional Anatomical Mesh in Minimally Invasive Inguinal Hernia Repair	*Journal of laparoendoscopic & advanced surgical techniques.* Part A. 2023 Oct;33(10):944-948	447	90 days
2023	Xiao, Y., Zuo, X., Li, H., Zhao, Y., Wang, X.	Impact of titanium-coated polypropylene mesh on functional outcome and quality of life after inguinal hernia repair	*Heliyon.* 2023 Jun 29;9(7):e17691	658	2 years
2023	Jeroukhimov, Igor, Dykman, Daniel, Hershkovitz, Yehuda, Poluksht, Natan, Nesterenko, Vladimir, Yehuda, Amir Ben, Stephansky, Albert, Zmora, Oded	Chronic pain following totally extra-peritoneal inguinal hernia repair: a randomized clinical trial comparing glue and absorbable tackers	*Langenbecks Arch Surg.* 2023 May 12;408(1):190.	208	1 year
2023	Jung, Sungwoo, Lee, Jin Ho, Lee, Hyung Soon	Early outcomes of robotic transabdominal preperitoneal inguinal hernia repair: a retrospective single-institution study in Korea	*Journal of Minimally Invasive Surgery.* 2023. 26:128	21	1 week + additional follow up as needed
2023	Zhuang, Lin, Li, Yuanjiu, He, Wei, Zhou, Xiaodong, Chen, Yan, Wang, Xiaozhong, Wang, Bo, Xu, Xuezhong, Wu, Kejia, Zhang, Qiutao	Therapeutic efficacy of programmed spatial anatomy of the myopectineal orifice in total extraperitoneal hernioplasty: a retrospective study	*Scientific Reports.* 2023 Feb 15;13(1):2711	121	6 months
2023	ÖNER, M.	Comparison of Absorbable Tuckers and N-Butyl Cyanoacrylate Glue in Mesh Fixation for Laparoscopic Extraperitoneal Inguinal Hernia Repair: A Single General Surgeon's Experience	*Namik Kemal Med J.* 2023;11(4):379-384	226	6 months
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
2022	Shi, Xiaoyu, Luan, Fengming	Clinical Data Analysis for Treatment of Adult Inguinal Hernia by TAPP or TEP	*Front Surg.* 2022 May 20:9:900843.	686	1 year
2022	Shahraki, Masoud Sayadi, Mahmoudieh, Mohsen, Keleidari, Behrooz, Melali, Hamid, Sharbu, Zakaria	The Effect of Internal Mesh Fixation and External Fixation (Inguinal Hernia Truss) on Postoperative Complications in Patients with Inguinal Hernia Undergoing Totally Extraperitoneal Laparoscopic Hernioplasty	*Adv Biomed Res.* 2022 Jun 29:11:49	64	6 months
2022	Salas-Parra, R. D., Lima, D. L., Pereira, X., Cavazzola, L. T., Sreeramoju, P., Malcher, F.	Robotic Inguinal Hernia Repair After Prostatectomy: How to Navigate Safely	*Surgical Laparoscopy, Endoscopy and Percutaneous Techniques.* 2022. 32:66-72	15	1 month
2022	Morito, Atsushi, Kosumi, Keisuke, Kubota, Tatsuo, Yumoto, Shinsei, Matsumoto, Takashi, Mima, Kosuke, Inoue, Mitsuhiro, Mizumoto, Takao, Miyanari, Nobutomo, Baba, Hideo.	Investigation of risk factors for postoperative seroma/hematoma after TAPP	*Surg Endosc.* 2022. 36:4741-4747	359	Not specified
2022	Gutlic, Allan, Rogmark, Peder, Gutlic, Nihad, Petersson, Ulf, Montgomery, Agneta	Pain with sexual activity at 1 and 3 years: Comparing total extraperitoneal with Lichtenstein inguinal hernia repair in a randomized setting (TEPLICH trial)	*Surgery.* 2022. 172:1463-1470	243	3 years
2022	Suzuki, Y., Wakasugi, M., Mikamori, M., Tamaoka, K., Nakahara, Y., Tei, M., Furukawa, K., Ohtsuka, M., Masuzawa, T., Akamatsu, H	Long-term outcomes of single-incision versus multiport laparoscopic totally extra-peritoneal inguinal hernia repair: a single-institution experience of 186 consecutive cases	*Surgery Today.* 2022. 52:114-119	186	5 years
2022	Katoh, R., Ogawa, H., Takada, T., Ozawa, N., Suga, K., Osone, K., Okada, T., Shiraishi, T., Sano, A., Sakai, M., Sohda, M., Shirabe, K., Tsushima, Y., Saeki, H.	Significance of routine preoperative prone computed tomography for predicting intractable cases of inguinal hernias treated by transabdominal preperitoneal repair	*Medicine (United States).* 2022. 101:E31917	48	1 month

Year	Author	Title	Journal	Number of Patients	Mean Follow-Up
2022	Barta, B., Dumitras, M., Bucur, S., Giuroiu, C., Zlotea, R., Constantin, M. M., Madan, V., Constantin, T., Iorga, C. R.	Extraperitoneal Laparoscopic Approach in Inguinal Hernia-The Ideal Solution?	*J Clin Med.* 2022. 11:5652	493	10 days
2021	Bilezikian, JA; Tenzel, PL; Johnson, RG; Powers, WF; Hope, WW	A preliminary evaluation of two different meshes in minimally invasive inguinal hernia surgery	*Surg Endosc.* 2021. 35:1342–1347	24 (out of 48)	12 months
2021	Phuoc Van Nguyen, Minh Quang Dao, Quyet Van Ha, Thuong Van Pham, Truong Van Nguyen, Thang Quyet Tran, Anh Thuy Tran, Son Ngoc Vu, Hien Van Nguyen	Laparoscopic Totally Extraperitoneal Repair Using Three-dimension Mesh to Treat Bilateral Inguinal Hernia in Adults	*World Journal of Laparoscopic Surgery.* Volume 14 , Issue 3 (Sep–Dec, 2021)	50	21.4 ± 11.8 months
2021	Wakasugi, M., Hasegawa, J., Ikeda, Y.	Single-incision laparoscopic totally extraperitoneal inguinal hernia repair with tumescent local anesthesia: report of more than 2000 procedures at a day-surgery clinic	*Surgery Today.* 2021. 51:545-549	2148	12 months
2021	Takayama, Yuichi, Kaneoka, Yuji, Maeda, Atsuyuki, Takahashi, Takamasa, Kiriyama, Muneyasu, Seita, Kazuaki.	Short- and Long-Term Outcomes of Transabdominal Preperitoneal, Open Mesh Plug and Open Tissue Inguinal Hernia Repair	*World Journal of Surgery.* 2021. 45:730-737	1813	26 months
2021	Lee, Kanghee, Lee, Jin Ho, Nam, Soomin, Chong, Jae Uk, Lee, Hyung Soon.	Outcomes of open versus single-incision laparoscopic totally extraperitoneal inguinal hernia repair using propensity score matching: A single institution experience	*PLoS One.* 2021 Jan 28;16(1):e0246189	477	1 day
2021	Fang, Haizong, Lin, Ronggui, Lin, Xianchao, Lu, Fengchun, Yang, Yuanyuan, Wang, Congfei, Chen, Yanchang, Huang, Heguang.	Drainage decreases the seroma incidence in laparoscopic transabdominal preperitoneal (TAPP) hernia repair for large inguinoscrotal hernias	*Asian Journal of Surgery.* 2021. 44:544-548	246	12 and 17.5 months according to the group
2021	Corthals, Simon, Van Cleven, Stijn, Uyttebroek, Ortwin, de Carvalho, Luis Abreu, Vanlander, Aude, Berrevoet, Frederik.	Quality of life after open versus laparoscopic preperitoneal mesh repair for unilateral inguinal hernias	*Asian Journal of Surgery.* 2021. 44:1266-1273	204	36.5 and 32 months according to the group
2021	J. M. Cabrera-Bermón, J. L. Cuba-Castro, C. Monje-Salazar, N. Martos-Rojas, F. Ramos-Muñoz y R. de Luna-Díaz	Laparoscopic inguinal hernia repair in major outpatient surgery. The time is now.	*CIR MAY AMB.* 2021. Vol 26, N.º 4	100	1 year
2020	Acar, A; Kabak, I; Tolan, 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
2020	Hou Haisheng1, Yang Li2, Yan Xiaowei1	Efficacy of 3DMax mesh versus common mesh for laparoscopic inguinal hernia repair	*Chinese Journal of Tissue Engineering Research.* 2020. Vol. 24, Issue (28): 4588-4592.	142	2 years
2020	Alarcón, I., Balla, A., Soler Frías, J. R., Barranco, A., Bellido Luque, J., Morales-Conde, S.	Polytetrafluoroethylene versus polypropylene mesh during laparoscopic totally extraperitoneal (TEP) repair of inguinal hernia: short- and long-term results of a double-blind clinical randomized controlled trial	*Hernia.* 2020 Oct;24(5):1011-1018.	52	60 months
2020	Bajpai, R. R., Razdan, S., Sanchez-Gonzalez, M. A..	Simultaneous robotic assisted laparoscopic prostatectomy (RALP) and inguinal herniorrhaphy (IHR): proof-of-concept analysis from a high-volume center	*Hernia.* 2020. 24:107-113	143	36 months
2020	Takayama, Yuichi, Kaneoka, Yuji, Maeda, Atsuyuki, Takahashi, Takamasa, Uji, Masahito	Laparoscopic transabdominal preperitoneal repair versus open mesh plug repair for bilateral primary inguinal hernia	*Annals of Gastroenterological Surgery.* 2020. 4:156-162	107	22 and 40 months according to the groups
2020	Aghayeva, Afag, Benlice, Cigdem, Bilgin, Ismail A., Bengur, Fuat B., Bas, Mustafa, Kirbiyik, Ebru, Aytac, Erman, Baca, Bilgi.	Laparoscopic totally extraperitoneal vs robotic transabdominal preperitoneal inguinal hernia repair: Assessment of short- and long-term outcomes	*The International Journal of Medical Robotics and Computer Assisted Surgery.* 2020 Aug;16(4):e2111	86	24 months
2020	Kuge, Hiroyuki, Yokoo, Takashi, Uchida, Hideki, Yamaoka, Kentaro, Yoshikawa, Shusaku	Learning curve for laparoscopic transabdominal preperitoneal repair: A single-surgeon experience of consecutive 105 procedures	*Asian journal of endoscopic surgery.* 2020. 13:205-210	100	33.5 months
2019	M.R. Arnold, K.M. Coakley, E.J. Fromke, S.A. Groene, T Prasad, P. D. Colavita, V.A. Augensterin, K.W. Kercher, B.T. Heniford	Long-term assessment of surgical and quality-of-life outcomes between lightweight and standard (heavyweight) three-dimensional contoured mesh in laparoscopic inguinal hernia repair.	*Surgery.* 2019 Apr;165(4):820-824.	1424	3DMax Light – 21.8 months, 3DMax – 7.2 months
2019	Gutlic, N., Gutlic, A., Petersson, U., Rogmark, P., Montgomery, A.	Randomized clinical trial comparing total extraperitoneal with Lichtenstein inguinal hernia repair (TEPLICH trial)	*British Journal of Surgery.* Volume 106, Issue 7, June 2019, Pages 845–855	480	3 years

7. Appendix

Year	Author	Title	Journal	Number of Patients	Mean Follow-Up
2019	Ruze, Rexiati, Yan, Zhibo, Wu, Qunzheng, Zhan, Hanxiang, Zhang, Guangyong.	Correlation between laparoscopic transection of an indirect inguinal hernial sac and postoperative seroma formation: a prospective randomized controlled study	*Surg Endosc.*2019. 33:1147-1154	159	3 months
2019	Yan, Z., Liu, Y., Ruze, R., Xiong, Y., Han, H., Zhan, H., Wang, M., Zhang, G	Continuation of low-dose acetylsalicylic acid during perioperative period of laparoscopic inguinal hernia repair is safe: results of a prospective clinical trial	*Hernia.* 2019. 23:1141-1148	901	3 months
2018	Tripodi D, Zhang X, Wan Y, Berhane I, Corral M	A Retrospective Analysis of Tack Use With Progrip® Laparoscopic Self-Fixating Mesh and 3dmax™ Mesh in Outpatient Hospital Inguinal Hernia Repair Procedures	*Value In Health.* 21(2018) S1–S268		Not specified
2018	IqbalSaleemMir1,TajamulRashid2,IrfanNazirMir1*,SuhailNazir1,ImtiyazAli1,MansoorUl Haq1	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 Journal.* 2018 Mar;5(3):1016-1020	123	12 months (mean)
2018	Iraniha, Andrew, Peloquin, Joshua	Long-term quality of life and outcomes following robotic assisted TAPP inguinal hernia repair	*Journal Of Robotic Surgery.* 2018. 12:261-269	82	36 months
2018	Nagahisa, Yoshio, Kawashima, Ryuju, Matsumoto, Ryu, Harada, Masaki, Hashida, Kazuki, Okabe, Michio, Kawamoto, Kazuyuki.	Feasibility of a novel tacking method of securing mesh in transabdominal preperitoneal inguinal hernia repair: Secure tacking against recurrence	*Asian Journal of Endoscopic Surgery.* 2018. 11:385-391	391	Not specified
2018	Wang, Yu-huan, Fu, Jiong, Chen, Qing-feng, Wang, Dong-xu, Jiang, Wei, Chen, Zheng	Short-term effect of laparoscopic assisted total extraperitoneal repair with small-incision for large inguinal hernia in adults.	*Biomedical Research.* 2018; 29 (9): 1768-1773	66	6 months
2018	Matsuda, Akihisa, Miyashita, Masao, Matsumoto, Satoshi, Sakurazawa, Nobuyuki, Kawano, Youichi, Kuriyama, Sho, Sekiguchi, Kumiko, Ando, Fumihiko, Matsutani, Takeshi, Uchida, Eiji	Laparoscopic transabdominal preperitoneal repair for strangulated inguinal hernia	*Asian Journal Of Endoscopic Surgery.* 2018. 11:155-159	33	30 days
2017	Kuldeep S, Anand S, Megha S	A prospective study comparing flat polypropylene mesh and 3D monofilament mesh in laparoscopic mesh hernioplasty.	*International Journal of Contemporary Medicine Surgery and Radiology.* 2017 2(2): 53-57	60	1-6 months
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
2017	Kalra, Tarun, Soni, Rajesh Kumar, Sinha, Ajit.	Comparing Early Outcomes using Non Absorbable Polypropylene Mesh and Partially Absorbable Composite Mesh through Laparoscopic Transabdominal Preperitoneal Repair of Inguinal Hernia	*J Clin Diagn Res.* 2017 Aug; 11(8): PC13–PC16	60	3 months
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
2017	Schjøth-Iversen, L., Refsum, A., Brudvik, K. W.	Factors associated with hernia recurrence after laparoscopic total extraperitoneal repair for inguinal hernia: a 2-year prospective cohort study.	*Hernia.* 21(5), 729-735	1047	2 years
2017	Sakon, M., Sekino, Y., Okada, M., Seki, H., Munakata, Y	Laparoscopic inguinal hernioplasty after robot-assisted laparoscopic radical prostatectomy	*Hernia.* 2017. 21:745-748	40	11.2 months
2016	K. Tanoue, H. Okino, M. Kanazawa, K. Ueno	Single-incision laparoscopic transabdominal preperitoneal mesh hernioplasty: results in 182 Japanese patients	*Hernia.* 2016 (20): 797-803	182	587 days
2016	Priyanka Tiwari, Juneed Lankar, Prasanna Kumar Reddy	Contoured 3D mesh in laparoscopic inguinal hernia repair: does it reduce inguinodynia?	*MedCrave Online Journal of Surgery (MOJS)*	48	3 months
2016	Pradeep Prakash, Virinder Kumar Bansal, Mahesh Chandra Misra, Divya Babu, Rajesh Sagar,1 Asuri Krishna,2 Subodh Kumar, Vimi Rewari,3 and Rajeshwari Subramaniam3	A prospective randomised controlled trial comparing chronic groin pain and quality of life in lightweight versus heavyweight polypropylene mesh in laparoscopic inguinal hernia repair	*J Minim Access Surg.* 2016 Apr-Jun; 12(2): 154–161.	140	3 months
2016	Ludwig, Wesley W., Sopko, Nikolai A., Azoury, Saïd C., Dhanasopon, Andrew, Mettee, Lynda, Dwarakanath, Anirudh, Steele, Kimberley E., Nguyen, Hien T., Pavlovich, Christian P	Inguinal Hernia Repair During Extraperitoneal Robot-Assisted Laparoscopic Radical Prostatectomy	*Journal of Endourology.* 2016. 30:208-211	59	33 months
2015	M. Szymankiewicz, D. Bennett	An 8 Year Series Reporting the Success of an Un-fixated Bard 3D Max Mesh Laparoscopic TEPP Inguinal Hernia Repair Technique	*BJS.* 2015; 102 (S1): 127-301	212	36 months

Year	Author	Title	Journal	Number of Patients	Mean Follow-Up
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
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
2013	M Wakasugi, H Akamatsu, M Tori, S Ueshima, T Omori, M Tei, T Masuzawa, T Nishida	Short-term outcome of single-incision laparoscopic totally extra-peritoneal inguinal hernia repair	Asian Journal Of Endoscopic Surgery. 2013: 143 -146	34	7.1 months
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
2013	Buckley, F. Paul, Vassaur, Hannah, Monsivais, Sharon, Sharp, Nicole E., Jupiter, Daniel, Watson, Rob, Eckford, John.	Comparison of outcomes for single-incision laparoscopic inguinal herniorrhaphy and traditional three-port laparoscopic herniorrhaphy at a single institution	*Surg Endosc.* 2014. 28:30-35	205	Not specified
2012	Wang ZY, Wang RY, Zhang SL, et al	Using Bard 3DMax™ Mesh in transabdominal preperitoneal laparoscopic repair: a report of 15 cases		15	6.5 months
2012	HANG Yun, CHEN Xin, LI Jian-wen	Laparoscopic inguinal hernia repair: a report of 2056 cases		2056 (not all 3DMax)	35 days
2011	Gong, Ke, Zhang, Nengwei, Lu, Yiping, Zhu, Bin, Zhang, Zhanzhi, Du, Dexiao, Zhao, Xia, Jiang, Haijun.	Comparison of the open tension-free mesh-plug, transabdominal preperitoneal (TAPP), and totally extraperitoneal (TEP) laparoscopic techniques for primary unilateral inguinal hernia repair: a prospective randomized controlled trial	*Surg Endosc.* 2011. 25:234-239	164	15 months
2011	Khaleal, Fadil, Berney, Christophe.	The role of fibrin glue in decreasing chronic pain in laparoscopic totally extraperitoneal (TEP) inguinal hernia repair: a single surgeon's experience	*ANZ Journal of Surgery.* 2011. 81:154-158	233	6 months
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
2010	Jutte, Ewoud H., Cense, Huib A., Dur, Alphons H. M., Hunfeld, Michiel A. J. M., Cramer, Biron, Breederveld, Roelf S.	A pilot study for one-stop endoscopic total extraperitoneal inguinal hernia repair	*Surg Endosc.* 2010. 24:2730-2734	52	2 weeks
2009	Chen D-LL, J.; Zheng, C.	Clinical application of 3DMax patch in the laparoscopic inguinal hernia repair.	*Chinese Journal of Practical Surgery*	68	3-24 months
2008	Finley. D, Savatta. D, Rodriguez.E, Kopelan. A, Ahlering.T	Transperitoneal robotic-assisted laparoscopic radical prostatectomy and inguinal herniorrhaphy	*J Robotic Surg. 2008* 1:269–272 DOI 10.1007/s11701-007-0051-9	837	12.5 months
2007	Lee, Benjamin C., Rodin, David M., Shah, Ketul K., Dahl, Douglas M.	Laparoscopic inguinal hernia repair during laparoscopic radical prostatectomy	*BJU international.* 2007. 99:637-639	40	10 months
2006	Koch CA, Greenlee SM,Larson DR, HarringtonJR, Farley D	Randomized prospective study of totally extraperitoneal inguinal hernia repair: fixation versus no fixation of mesh	*JSLS: Journal of the Society of Laparoendoscopic Surgeons.* 2006. 10:457	40	19 months
2004	Alfredo Moreno-Egea, MD; José Antonio Torralba Martínez, MD; Germán Morales Cuenca, MD; et al	Randomized Clinical Trial of Fixation vs Nonfixation of Mesh in Total Extraperitoneal Inguinal Hernioplasty	*Arch Surg.* 2004. 139(12):1376-1379	170	24 months
2004	Feliu, X., Torres, G., Viñas, X., Martínez-Ródenas, F., Fernández-Sallent, E., Pie, J.	Preperitoneal repair for recurrent inguinal hernia: Laparoscopic and open approach	*Hernia.* 2004. 8:113-116	188	12 months
2003	Bell RC, Price JG	Laparoscopic inguinal hernia repair using an anatomically contoured three-dimensional mesh	*Surg Endosc.* 2003. 17:1784-8	146	23 months
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

Instructions for use

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.

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.

7. Appendix

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 product labels and instruction for use for indications, contraindications, hazards, warnings, and precautions.

References

1. 3DMax™ Mesh Family clinical compendium **2.** Bell RCW, Price JG. Laparoscopic inguinal hernia repair using an anatomically contoured three-dimensional mesh. *Surg Endosc.* 2003 Nov;17(11):1784-8. **3.** Koch CG, S.; Larson, D.; Harrington, J.; Farley, D. Randomized prospective study of totally extraperitoneal inguinal hernia repair: Fixation vs no fixation of mesh. *JSLS.* 2006 Oct-Dec;10(4):457-60. **4.** Pajotin. Laparoscopic Groin Hernia Repair Using a Curved Prosthesis Without Fixation. Le Journal de Celio – Chirurgie. 1998:28:64-68. **5.** Li M-JH, Y.; Li, J.; Xu, P.; Chen, J.; Wang, C. (2010) Experience of laparoscopic inguinal hernia repair using 3DMax mesh without fixation: a report of 55 cases China Journal of Endoscopy. **6.** Chen D-LL, J.; Zheng, C. (2009) Clinical application of 3DMax patch in the laparoscopic inguinal hernia repair: a report of 68 cases Chinese Journal of Practical Surgery. **7.** Preclinical data on file, results may not correlate to performance in humans. Other products ball burst strength are tested post absorption of absorbable component. **8.** Information source: Products' IFUs and brochures.

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BD Switzerland Sarl
Terre Bonne Park – A4, Route De Crassier, 17, 1262 Eysins, Vaud, Switzerland
T: + 41 21 556 300

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See full product labeling for complete Instructions For Use and important safety information.

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