U.S. DISTRICT COURT SOUTHERN DISTRICT OF MISSISSIPPI

PATRICK DOVE PLAINTIFF

v. CASE NO: 3:18-CV-3-CWR-FKB

DAVOL, INC., C.R. BARD, INC. ("aka" Bard), and BECTON DICKINSON ENTERPRISES INCORPORATED ("aka" BD) DEFENDANTS

JURY TRIAL DEMANDED

COMPLAINT

The Plaintiff, PATRICK DOVE by and through the undersigned counsel, hereby files this Complaint against the Defendants, DAVOL, INC. AND C.R. BARD, INC. a as a product liability lawsuit related to a dangerous mesh implant and states as follows:

JURISDICTION

1.

Complete diversity of citizenship exists pursuant to 28 U.S.C. § 1332(d) and the amount in controversy exceeds seventy-five thousand dollars (\$75,000.00) exclusive of interest and costs.

2.

Defendants, Davol, Inc. and C.R.Bard, Inc. has transacted business in Mississippi, committed tortious acts in Mississippi, made or performed contracts in Mississippi, made promises substantially connected to Mississippi and maintains a registered agent in Flowood, Mississippi. The registered agent for both defendants is CT Corporation System, 645 Lakeland East Drive, Suite 101, Flowood, Mississippi 39232. Therefore, this court has personal

jurisdiction over the Defendants pursuant to the Mississippi long arm statute. Miss. Code Ann. § 13-3-57 (2017). BD announced the purchase of C.R. Bard Inc. on April 23, 2017 and has continued to operate under the name C.R. Bard, Inc. in Mississippi.

VENUE

3.

Venue is proper in the judicial district pursuant to 28 U.S.C. §1391 (a) and (c) because Davol, Inc. and C.R. Bard, Inc. conducts business and sales activity in this judicial district and maintains its registered agent in Flowood, Mississippi and thus is subject to personal jurisdiction in this judicial district.

4

A substantial part of the tortious events and omissions giving rise to Plaintiff's claim occurred in Mississippi such that venue is proper in Mississippi.

PARTIES

5.

Plaintiff is a resident of Lauderdale County, Mississippi who experienced severe personal injuries, medical complications, and damages from the implantation of the Bard Ventralex mesh.

6.

Defendant, C.R. Bard, Inc., is and at all times relevant to this action licensed as a foreign corporation in Mississippi incorporated in New Jersey with a principal place of business at 730 Central Avenue, Murray Hill, Jew Jersey 07974.

Defendant, Davol, Inc., a subsidiary of C.R. Bard, Inc., is and at all times relevant to this action licensed as a foreign corporation in Mississippi incorporated in Delaware with a principal place of business at 100 Crossings Boulevard, Warwick, Rhode Island 02886.

8.

Defendant, Becton Dickinson Enterprises Incorporated ("aka" Becton Dickinson) is and at all times relevant to this action incorporated in New Jersey with a principal place of business at 1 Becton Drive, Franklin Lakes, New Jersey 07417-1815.

FACTUAL ALLEGATIONS

9.

Defendant, DAVOL designed, manufactured and distributed the Bard Ventralex hernia patch (hereinafter Ventralex patch) that was implanted in the Plaintiff's body.

10.

C.R. BARD, Inc., branded under the trade name "Bard" is a multinational developer, manufacturer, and marketer of medical technologies in the fields of vascular, urology, oncology, and surgical specialties.

11.

On April 23, 2017, Becton Dickinson agreed to purchase C.R. Bard, Inc. for Twenty Four Billion Dollars.

12.

Defendants through its agents, servants and employees, participated in the manufacture and delivery of the Ventralex Patch that was implanted into the Plaintiff's body on March 18, 2014 using an eight cm circular Bard mesh, PTFE side down and Marlex side up. A revision

surgery was performed on June 6, 2017 using ProLite MESH (15cm X 15cm) Lot # 409590 and ProLite MESH (7.5cm X 15cm) Lot # 404635.

13.

The FDA 510k application states, and defendants marketed and distributed, the Ventralex patch for use in all forms of hernia repair as well as to repair soft tissue deficiencies, including deficiencies caused by trocars.

14.

The Ventralex patch is a bilayer construction of a self-expanding patch containing two layers of polypropylene mesh stitched with polytetrafluorethylene (PTFE) monofilament to an expanded polytetrafluoroethylene (ePTFE) sheet. The mesh component is described as containing a "fully absorbable" recoil ring using SorbaFlex Memory Technology, an absorbable polydioxanone (PDO) monofilament.

15.

The Bard Ventralex mesh was actually made of materials, which are biologically incompatible with human tissue and react negatively and sometimes dangerously with a large number of those on whom it is used. Defendant knew or should have known that their Product was unreasonably harmful.

16.

Defendants knew that the technology used in the laminate layers would delaminate as evidenced by folding, shriveling, curling up on edges, and generally causing a separation of layers of the patch.

17.

The scientific evidence Defendant knew or should have known of demonstrates that the mesh is incompatible with human tissue and often causes a negative immune response in patients implanted with the Bard Ventrilex, including Plaintiff. The Ventralex patch is constructed with a

polypropylene monofilament containing a resin-based polypropylene not suitable for human implantation.

18.

On information and belief, and discovery will show, the resin-based polyproplylene when implanted in the body can cause certain continuous chemical reactions resulting in abnormal wound healing complications, bleeding, chronic serum discharge, severe abdominal pain and the eventual breakdown and disintegration of the bilayer Ventralex mesh.

10

With knowledge of the mesh defects, Bard Ventralex marketed to the medical community and to patients as a safe, effective, and reliable medical device, implanted by safe and effective, minimally invasive surgical techniques, and is safer and more effective as compared to other products. See Exhibit "A".

20.

Defendants knowingly, willfully and with the full intent to conceal, did conceal their awareness that resin-based polypropylene was not suitable for human implantation.

21.

Defendant failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risk associated with the Bard Ventralex mesh.

22.

The Bard Ventralex mesh as designed, manufactured, distributed, sold and/or supplied by Defendant was defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing.

Defendants negligently failed, or willfully refused, to ensure their own profits at the expense and risk of Plaintiff, to disclose the defective and dangerous condition of their Ventralex patch.

24.

As a result of having the Bard Ventralex mesh implanted, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone additional surgical procedures to repair damage caused by the Bard Ventralex mesh, has suffered economic loss, including but not limited to, obligations for medical services and expenses, lost income, and other damages.

CAUSES OF ACTION COUNT I: NEGLIGENCE

25.

Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

26.

Defendant had a duty to individuals, including the Plaintiff, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling their Bard Ventralex mesh products.

27.

Defendant breached its due to its customers, including Plaintiff, by failing to design, manufacture, market, label, package and/or sell its Product in such a manner as the exercise of reasonable care would dictate.

As a direct and proximate result of Defendant's negligence Plaintiff has experienced significant physical injury, mental and physical pain and suffering, permanent injury, has undergone additional surgical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

COUNT II: STRICT LIABILITY-DESIGN DEFECT

29.

Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

30.

The Product implanted in Plaintiff was not reasonably safe for its intended uses and was designed in a defective manner so as to be hazardous and harmful to the human body.

31.

As a direct and proximate result of the mesh's aforementioned defects as described herein, Plaintiff has experienced significant physical injury, mental and physical pain and suffering, permanent injury, has undergone additional surgical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

32.

Defendant is strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product(s).

COUNT III: STRICT LIABILITY MANUFACTURING DEFECT

Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein

34.

The Product implanted in Plaintiff was not reasonably safe for its intended use and was manufactured defectively due to having deviated materially from Defendant's design specifications.

35.

The deviations from design specs resulted in defective manufacturing which posed unreasonable risks of serious bodily harm to customers, including the Plaintiff.

36

As a direct and proximate result of the mesh's aforementioned defects as described herein, Plaintiff has experienced significant physical injury, mental and physical pain and suffering, permanent injury, has undergone additional surgical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

37.

Defendant is strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product(s).

COUNT IV: BREACH OF EXPRESS WARRANTY

38

Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein

39.

Defendant made assurances as described herein to the general public, hospitals and health care professionals that the Product was safe and reasonably fit for its intended purposes.

The Plaintiff and/or health care provider chose the Product based upon Defendant's warranties and representations regarding the safety and fitness of the product.

41.

The Plaintiff, individually and/or by and through his health care providers, reasonably relied upon Defendant's express warranties and guarantees that the product was safe, merchantable, and reasonably fit for its intended purposes.

42.

Defendant reached these express warranties because the product was unreasonably dangerous and defective as described herein and not as Defendant had represented.

43.

Defendant's breach of its express warranties resulted in the implantation of an unreasonably dangerous and defective product.

44.

As a direct and proximate result of the mesh's aforementioned defects as described herein, Plaintiff has experienced significant physical injury, mental and physical pain and suffering, permanent injury, has undergone additional surgical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

COUNT V: BREACH OF IMPLIED WARRANTY

45.

Plaintiff incorporates the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein

46.

Defendant impliedly warranted that the subject mesh was merchantable and was fit for the ordinary purposes for which it was intended.

When the mesh was implanted in the Plaintiff to treat a hernia, the product was being used for the ordinary purpose for which it was intended.

48.

Plaintiff, individually and/or by and through his providers, relied upon Defendant's implied warranties of merchantability in consenting to have the subject mesh implanted.

49.

The Defendant breached these implied warranties of merchantability because the Product implanted in Plaintiff was neither merchantable nor suited for their intended uses as warranted.

50.

Defendant's breach of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product which placed Plaintiff's health and safety in jeopardy.

51.

As a direct and proximate result of Defendant's breach of the aforementioned implied warranties, Plaintiff has experienced significant physical injury, mental and physical pain and suffering, permanent injury, has undergone additional surgical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

WHEREFORE, Plaintiff PATRICK DOVE demands judgment for damages from the Defendant for an amount in excess of Seventy-Five Thousand Dollars (\$75,000.00) together with interests and costs.

REQUEST FOR JURY TRIAL

The Plaintiffs herein request trial by jury of all issues triable by right.

Dated, this the 2nd day of January 2018.

Respectfully Submitted,

PATRICK DOVE

By: /s/ Tina M. Bullock_

TINA M. BULLOCK (MBN 103114)

PLAINTIFF ATTORNEYS: Tina M. Bullock, Esq.(MBM 103114) DIAZ LAW FIRM 208 Waterford Square, Suite 300 Madison, Mississippi 39110

Telephone: 601-607-3456 Fax: 601-607-3393

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VENTRALEX Hernia Patch

Umbilical Hernia Repair – Featuring SorbaFlex™ Memory Technology 01/02/18 Page 1 of 4





A clinically proven umbilical hernia repair solution.

The Ventralex™ Hernia Patch is a self-expanding polypropylene and ePTFE patch that allows for an intraabdominal, tension-free repair. This technique is designed to eliminate the lateral dissection typically required for preperitoneal placement, which may help minimize post op pain. Deep placement of the prosthetic also allows for a strong repair and less chance of recurrence.

Easy

Technique and Placement

- Simple deployment technique
- Tension-free intraabdominal repair
- · Minimum fixation required

Efficient

Positioning Pocket and Strap

- Pocket and strap facilitates placement, positioning and fixation
- SORBAFLEX[™] Memory Technology allows the patch to "spring open," lay flat to maintain shape and then fully absorbs over time*

Proven

Materials and Clinical Data

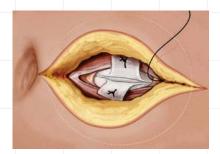
 Clinically supported technique since 2002 with peer-reviewed published clinical studies

Easy.

Simple deployment technique is clinically proven for reliable umbilical hernia repairs.







- · Designed for intraabdominal repairs of umbilical and other small ventral hernias
- Intraabdominal placement eliminates the lateral dissection typically required for preperitoneal placement
- Post op pain may be reduced due to the minimal dissection required to secure the prosthesis

Ideal for trocar site closures

Herniation into a trocar site, along with Richter's hernias, may occur even if the anterior fascia above the defect has been closed. The smallest Ventralex™ Hernia Patch allows for an intraabdominal, tension-free repair not requiring transfacial suturing.

Efficient.

The Ventralex™ Hernia Patch's proven design aids placement, positioning and fixation.



Unique positioning pocket aids in proper placement, positioning, and lateral fixation.



Special positioning strap and SORBAFLEX™ Memory Technology help assure that the patch lays flat against the abdominal wall.



Three sizes available for coverage of larger defects to smaller trocar site closures.

SORBAFLEX™ memory technology allows the patch to "spring open" and lay flat to maintain shape. The SORBAFLEX™ memory technology fully absorbs over time.

Proven.

The Ventralex[™] Hernia Patch combines materials used in general surgery for many years to deliver proven benefits to you and your patients.

Monofilament polypropylene mesh for a strong repair

With over 40 years of proven results in hernia repair, monofilament polypropylene allows a fast fibrotic response. This results in strong tissue incorporation into the abdominal wall, providing a long-term repair with minimized recurrence.



Open Pore Mesh Design 35x Magnification

SORBAFLEX™ Memory Technology

- Polydioxanone (PDO) monofilament is commonly used in other well-known surgical products (e.g. suture)
- · Unique in its flexibility and tensile strength, it facilitates patch insertion and proper placement
- Absorption via hydrolysis is essentially complete in 24-32 weeks*



These images are from a porcine study using the Ventrio™ Hernia Patch which contains the same SORBAFLEX™ Memory Technology.*

VENTRALEX[™] Mesh in Umbilical/Epigastric Hernia Repairs: Clinical Outcomes and Complications *Hernia*/2008 Aug;12(4):379-83.

D.F. Martin, R.F. Williams, T.Mulrooney, and G.R. Voeller**

Highlights:

- 88 patients (69 males, 19 females) were evaluated from 2003-2006 and 89 VENTRALEX™ Hernia Patches were placed
- 0 hernia recurrences
- 93% of patients sent home the same day as the surgery

Clinically supported technique since 2002 with over 1 million implants worldwide and peer-reviewed published clinical studies all add up to proven reliability.

^{*} Preclinical data on file at C. R. Bard. Results may not correlate to performance in humans.

VENTRALEX™ Hernia Patch Patch Fled 01/02/18 Page 4 of

VENTRALEX™ Hernia Patch

Indications

The BARD® VENTRALEX™ Hernia Patch is intended for use in all forms of hernia repair requiring reinforcement with a nonabsorbable support material. The small BARD® VENTRALEX™ Hernia Patch (4.3 cm/1.7 in) is also intended to repair soft tissuedeficiencies, including deficiencies caused by trocars.

Contraindications

Do not use the Bard® Ventralex™ Hernia Patch in infants or children, whereby future growth will be compromised by use of such mesh material. Do not use the Bard® Ventralex™ Hernia Patch for the reconstruction of cardiovascular defects. Literature reports that there is a possibility for adhesion formation when the polypropyleneis placed in contact with the bowel or viscera.

Warnings

Do not cut or reshape any portion of the Bard® Ventralex™ Hernia Patch (as this could affect its effectiveness), except for the monofilament polypropylene positioning strap. Care should be taken not to cut or nick the Sorbaflex™ PDO Monofilament. If the recoil ring is cut or damaged during insertion or fixation, additional complications may include bowel or skin perforation and infection. Follow proper rolling techniques for all patches as described in these instructions for use as other rolling techniques may potentially compromise the Sorbaflex™ PDO Monofilament. Ensure proper orientation; the solid white surface (ePTFE) must be oriented against the bowel or sensitive organs. Do not place the mesh surface against the bowel. There is a possibility for adhesion formation when mesh (including strap) is placed in direct contact with the bowel or viscera.

Adverse Reactions

Possible complications include seroma, adhesions, hematoma, inflammation, extrusion, fistula formation, infection, allergic reaction, and recurrence of the hernia or soft tissue defect. If the SORBAFLEX™ PDO Monofilament is cut or damaged during insertion or fixation, additional complications may include bowel or skin perforation and infection.

Catalog Number	Quantity	Shape	Diameter	
0010301	2/cs.	Small Circle with Strap	1.7" x 1.7" (4.3 cm x 4.3 cm)	
0010302	2/cs.	Medium Circle with Strap	2.5" x 2.5" (6.4 cm x 6.4 cm)	
0010303	2/cs.	Large Circle with Strap	3.2" x 3.2" (8.0 cm x 8.0 cm)	

☐ Please add these marked product	ts to my preference card
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Please consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions and instructions for use.

"Dr Guy Voeller is a paid consultant to Davol, Inc.
Bard, Davol, SorbaFlex and Ventralex are trademarks and/or registered trademarks of C. R. Bard, Inc. or an affiliate. Sepramesh is a registered trademark of Genzyme Corporation licensed to C. R. Bard, Inc. or an affiliate.

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JS 44 (Rev. 06/17)

CIVIL COVER SHEET

3:18-CV-3-CWR-FKB

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS				DEFENDANTS															
PATRICK DOVE				DAVOL INC, C.R.BARD INC, BECTON DICKINSON ENTERPRISES INCORPORATED															
(b) County of Residence of First Listed Plaintiff LAUDERDALE, MS (EXCEPT IN U.S. PLAINTIFF CASES) (c) Attorneys (Firm Name, Address, and Telephone Number)				County of Residence of First Listed Defendant UNION, NJ (IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED. Attorneys (If Known)															
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