

C R BARD INC

C R Bard is a multinational medical technology company, specializing in vascular, urology, oncology and surgical technologies. The company has a long history and today is a worldwide enterprise with business operations in 90 countries.

The company sells a broad range of products to hospitals, individual healthcare professionals, extended care facilities and alternate site facilities on a global basis. In general, the company's products are intended to be used once and then discarded, or either temporarily or permanently implanted.

Outside the USA, Europe and Japan are the company's largest markets, while certain emerging markets in Asia and Latin America are the company's fastest growing and it specifically targets markets where clinicians drive purchasing decisions.

Bard is organized into six main divisions, selling more than 8000 products. The divisions all have their own headquarters in different parts of the USA. They are:

- Bard Access Systems Inc, with headquarters in Salt Lake City, Utah;
- Bard Electrophysiology Division, with headquarters in Lowell, Massachusetts;
- Bard Medical Division, with headquarters in Covington, Georgia;
- Bard Peripheral Vascular Inc, based in Tempe, Arizona;
- Bard Biopsy Systems, also based in Tempe, Arizona;
- Davol Inc, based in Warwick, Rhode Island.

Bard acquired Davol in 1980. This company was founded in Providence, Rhode Island in 1874, originally as producer of rubber medical and surgical devices. The Davol business specializes in soft tissue reconstruction.

Bard makes a range of products, including mesh devices that treat hernias, stents that prevent blood clots from travelling to the lungs, catheters that reduce hospital-acquired infections, thermoregulatory devices designed to monitor and control a patient's temperature and ports that delivery chemotherapy, reducing the frequent injections for children and adults.

The company's products are distributed domestically directly to hospitals and other healthcare institutions, as well as through numerous hospital/surgical supply and other medical speciality distributors with whom the company has distribution agreements.

In international markets, products are distributed either directly or through distributors, with the practice varying by country.

C R Bard Inc: essential information	
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Key figures:	Chairman and Chief Executive Officer: Timothy M. Ring
Traded on:	New York Stock Exchange (NYSE)
Workforce:	12 200 employees

BACKGROUND

Bard has grown from a one-man operation in New York City in 1907 to a global company with over 12 000 employees worldwide. At the beginning of the twentieth century, Charles Russell Bard was an American importer of French silks into New York City, but as a result of his own condition, he began research into the treatment of urinary discomfort.

The company was incorporated in 1923, sold on in 1926 and Bard himself died in 1934—the same year that Davol Rubber Co (now a division of Bard) started manufacturing the well-known Foley catheter, developed through collaboration between Charles Russell Bard and Dr Frederick Foley.

PRODUCTS

Medical division

Bard claims to be a market leader in urological drainage products. Its Medical division focuses on products to aid the urologist in surgically resolving conditions and diseases of the urinary tract. These include, but are not limited to, gaining access to the urinary tract; dilating urinary strictures; removing kidney stones; resection of the prostate; and providing temporary drainage.

Focusing primarily on urological drainage products, continence products and urological speciality products and prostate disease management, Bard Medical offers Foley catheters and trays, urine drain bags, urethral catheters and trays, irrigation products, leg bags, male external catheters and temperature-sensing catheters and equipment.

The division also provides a wide range of skin and wound care products, wound drainage products and a variety of speciality tubing products, including suction catheters, feeding tubes and nasogastric tubes.

Pelvic health

Bard's Women's Pelvic Health business unit offers treatments for stress urinary incontinence and pelvic prolapse. Some examples of the Bard product line include:

- Pelvisoft acellular collagen biomesh, for use in pelvic floor reconstruction;
- Avaulta Solo synthetic support system, with a soft knit in the central section to host tissue ingrowth;
- the Avaulta Plus synthetic support system comprising a porous, acellular, ultra-thin sheet of crosslinked collagen attached to a polypropylene mesh. This acts as a protective barrier between mucosal tissue and the mesh, but allows the ingrowth of host tissue.

It should be noted that Bard became the subject of lawsuits in 2011, with allegations that the Avaulta vaginal mesh used for the repair of pelvic organ prolapse caused painful complications. Some other products may be involved too (see product liability matters below).

Vascular

Bard's current vascular products cover a wide range of minimally invasive devices for the treatment of peripheral vascular disease and heart arrhythmias. The range includes interventional devices for the treatment of peripheral arterial, haemodialysis access and venous disease. Key surgical products, made by the Bard Peripheral Vascular division, include the following:

- expanded polytetrafluoroethylene (ePTFE) peripheral bypass vascular grafts, sold under such trade names as Distaflow and Dynaflow;
- ePTFE and polyurethane vascular access grafts, sold under a variety of trade names including Vectra and Venaflow;
- woven and knitted polyester vascular grafts, fabrics and felts. These include such brands as Sauvage filamentous fabrics, DeBakey double velour fabrics, DeBakey elastic knit fabrics and DeBakey woven fabrics, and are indicated for use in cardiovascular surgical procedures requiring patch graft angioplasty, such as carotid endarterectomy. These fabrics are also indicated for repair of certain intracardiac anomalies such as septal defects;
- carotid shunts;
- vascular probes;
- sizers, tapes, pouches and tunnelers.
- ePTFE patches, fabrics, felts and pledgets.

The patches are used for the repair and closure of the cardiovascular system. Felts are used in a range of applications for general, vascular and cardiac surgery—they are commonly used as a patch or buttress for sutures and as a material for replacement segments of the ventricular myocardium after resection. Pledgets are commonly used as buttresses under sutures when there is a possibility of sutures tearing through tissue.

Bard's key endovascular products include stents, stent grafts, vena cava filters and angioplasty balloons. The company also sells tracheobronchial stent grafts.

Davol

In addition, Davol makes a range of surgical products, including:

- hernia repair/reconstructive surgery prosthetics;
- synthetic and biological implants;
- permanent and absorbable surgical fixation;
- haemostasis products;

- performance irrigation systems including laparoscopic irrigation, arthroscopic distention, hysteroscopic distention and fluid management;
- orthopaedic pulsed lavage and pulsed lavage for wound management;
- orthopaedic autotransfusion;
- endoscopic suturing devices.

Davol specializes in comprehensive tissue reconstruction, offering a range of products and techniques for hernia repair, specialized surgical procedures, fixation and biological implants. Products include:

- implanted patches and fixation systems for hernia and other soft-tissue repairs;
- Irrigation devices for orthopaedic, laparoscopic and gynaecological procedures;
- Products for topical haemostasis.

Hernia repair

Bard's hernia repair implants include both synthetic and natural-tissue models and hernia implant fixation devices. Within the hernia implants line, products such as PerFix plug and 3D Max are used for inguinal hernia repair procedures, while the company also markets products for the repair of ventral hernias including the Ventrío, Ventralex and Composix LP hernia patches (some hernia implant products have been the subject of lawsuits, see below).

Bard's line of natural-tissue hernia products, including the Collamend FM and Allomax patches, are used to repair complex ventral hernias. In complex hernias, pre-existing infections or high risk of infection do not allow the use of synthetic mesh for the repair.

In 2009, the company acquired the rights to the XenMatrix product, a non-crosslinked regenerative porcine collagen matrix for hernia and abdominal wall repair. However, this was the subject of a product recall in January 2011 (see below).

In the same year, the company acquired the rights to sell the Allomax surgical graft, made from sterile, non-crosslinked regenerative human collagen matrix. Allomax is for soft-tissue repair, including hernia, abdominal wall and breast reconstruction following mastectomy procedures. A next-generation bioresorbable-tack fixation device, trademarked SorbaFix, for use in laparoscopic and open surgical procedures was also launched in 2009.

In the first quarter of 2010, the company launched its PermaFix product, a permanent anchor fixation device built on the SorbaFix platform.

Oncology

Bard is also a manufacturer of oncology products. These products include a wide range of devices used in the treatment and management of various cancers and other

diseases and disorders, such as speciality vascular access catheters and ports, vascular access ultrasound devices, dialysis access catheters and enteral feeding devices. The company's speciality vascular access products, used primarily for chemotherapy, serve a well-established market in which Bard holds a leading position. These include the peripherally inserted central catheters (PICCs).

PRODUCT RECALLS

In January 2011, Bard issued a voluntary recall of its XenMatrix product. The Class I recall was issued because of the discovery of contamination in some of the XenMatrix surgical grafts. Samples of the grafts were found to contain endotoxins that exceed the acceptable levels stipulated by the US Food and Drug Administration (FDA).

The company reported that the recall had a minor impact on net sales of soft tissue repair products in 2010.

PRODUCT LIABILITY MATTERS

Bard's Composix Kugel and certain other hernia repair implant products have been the subject of lawsuits for some years. These allege that defective products have caused serious symptoms. The company voluntarily recalled certain sizes and lots of these products beginning in December 2005. In June 2011, the company reached an agreement to settle the majority of its hernia product claims, but some litigation is likely to continue through 2013.

Lawsuits have also been filed against the company, alleging personal injuries associated with the use of certain of the company's surgical continence products for women, principally the Avaulta line of pelvic floor reconstruction products. This litigation is also continuing.

In addition, further product liability lawsuits have been filed or asserted against the company in various US federal and state jurisdictions, alleging personal injuries associated with the use of the company's vena cava filter products. This litigation is also set to continue throughout 2013.

Earlier settlements

The first trial concerning women's health products in one jurisdiction was completed in July 2012, resulting in a judgment against the company of about US\$3.6 million. However, Bard is appealing this decision and intends to go on defending other women's health product claims. The first filter product claim trial was completed in June 2012, resulting in a judgment for the company based on the finding that the Bard was not liable for the plaintiff's damages.

Beginning in December 2005 the company initiated, and later expanded, a voluntary product recall of certain of its Bard Composix Kugel mesh products intended for

ventral hernia repair. In connection with the recall, the FDA conducted several inspections of the company's Davol subsidiary and issued warning observations concerning quality control there. The company took corrective action to address the observations. In January 2010, the FDA notified the company that the observations had been satisfactorily resolved and closed out.

Similarly, in April 2010, the FDA notified the company that warning observations relating to its Humacao, Puerto Rico, facility had been satisfactorily resolved and closed out. The facility manufactures products for many of the company's divisions and subsidiaries, including soft-tissue repair products for Davol.

PARTNERSHIPS AND ACQUISITIONS

Bard continues to make acquisitions across its divisions. For example, in 2012 the company purchased Neomend Inc of Irvine, California, USA, as part of its surgical speciality products range. Neomend makes Progel surgical sealant for intraoperative sealing of air leaks in connection with thoracic surgery. Progel is the only such product with FDA approval. The sealant also has the *Conformité Européenne* (CE) mark for both lung sealing and as an anti-adhesion barrier.

In November 2011, the company acquired Medivance Inc of Louisville, Colorado, USA, the maker of the Arctic Sun system with ArcticGel pads for temperature the management of patients needing therapeutic hypothermia. During this quarter, Bard also acquired all of the outstanding shares of ClearStream Technologies Group plc for \$69.1 million. The Irish company – based in Enniscorthy – develops products used in angioplasty, so this acquisition adds to Bard's vascular product portfolio.

In July 2010, Bard acquired SenoRx Inc of Irvine, California, USA, for US\$213.5 million. SenoRx's portfolio includes products such as the EnCor stereotactic-guided and magnetic resonance imaging (MRI)-guided breast biopsy systems, the Gel Mark line of breast tissue markers and the Contura brachytherapy catheter, used in the treatment of breast cancer. The acquisition means that Bard can now offer products across all percutaneous breast biopsy and marker segments, in addition to providing a therapeutic device for site-specific partial breast irradiation following lumpectomy procedures.

In May 2010, the company, through its wholly-owned subsidiary, Bard Holdings Ltd, acquired the remaining 15% of the common shares that it did not already own of its Malaysian manufacturing operation, Bard Sendirian Berhad, for US\$25.9 million.

Finally, in April 2010, the company acquired all of the outstanding stock of FlowCardia Inc for US\$80.1 million. This is a privately-held company that designs and manufactures endovascular products used in the treatment of chronic total occlusions (CTOs). FlowCardia's products complement Bard's percutaneous transluminal angioplasty products and peripheral stents. FlowCardia's clinically-proven catheters, trademarked

Crosser, deliver vibrational energy, enabling physicians to cross CTOs and allow for subsequent therapies, such as balloon angioplasty, stent implantation and atherectomy.

RESEARCH AND DEVELOPMENT

The company's research and development (R&D) expenditure – including purchased research and development – totalled US\$203.2 million in 2012 and US\$185.4 million in both 2011 and 2010. It totalled \$179.6 million in 2009 and \$199.1 million in 2008. The 2012 R&D expense as a percentage of net sales was 6.9% and Bard expects this to increase in future years.

FINANCIAL PERFORMANCE

C R Bard: financial performance 2007–2012

Financial year (US\$ million)	2007	2008	2009	2010	2011	2012
Net sales	2202.0	2452.1	2534.9	2720.2	2896.4	2958.1
Net income	406.4	419.3	461.4	509.6	328.0	530.1

Bard posted net sales to US\$2958.1 million in 2012, a 2% increase in comparison with 2011. About 82% of the 2012 net sales were derived from product lines in which the company has a number one or number two market share position. Vascular sales remained flat at around US\$845 million, while urology sales were up 3% at US\$757.8 million and surgical specialties were up 1% at US\$455.1 million.

C R Bard: net sales by division 2007–2012

Financial year (US\$ million)	2007	2008	2009	2010	2011	2012
Vascular	539.6	643.1	681.5	755.9	842.4	845.0
Urology	658.9	708.5	700.3	718.1	734.8	757.8
Oncology	558.6	646.6	678.7	724.8	779.5	812.4
Surgical Specialties	363.5	368.2	387.8	434.6	450.0	455.1
Other	81.4	85.7	86.6	86.8	89.7	87.8

OUTLOOK

The company's strategy of targeting markets where clinicians drive purchasing decisions, of focusing investments in fast-growing and/or under-served markets and of offering a broad portfolio of products is clearly working.

Bard has also been engaged in restructuring, under the auspices of a plan inaugurated in the fourth quarter of 2012 and which is expected to last until the end of 2013. This means elimination of certain positions and other employee layoffs worldwide. In the fourth quarter of 2012, associated costs came to US\$19.2 million pre-tax.

The medical technology industry is highly competitive and Bard faces major challenges. In common with other medical technology companies in the USA, Bard warns that it is not yet clear what impact healthcare reform in the USA will have on its business. The company estimates that the proposed excise tax of 2.3% on US sales of most medical devices, which will begin in 2013, will amount to some US\$40 million.

The company also continues to face expensive difficulties with lawsuits alleging defects in some of its products, along with patent infringement lawsuits, notably against **W L Gore**. All of this litigation looks set to continue through much of 2013. Bard warns in its 10-K Securities and Exchange Commission (SEC) filing for 2012 that the final resolution of these matters remains uncertain.

The FDA's decision regarding pelvic organ prolapse has also been another concern for the company. In July 2011, the agency issued a safety statement warning that the surgical placement of mesh through the vagina to repair pelvic organ prolapse may expose patients to greater risk than other surgical options. Doctors and their patients are now advised to consider alternatives to transvaginal mesh devices such as Bard's Avaulta.