Bard PowerPort Heart Device

The Bard PowerPort® is one of many implantable port devices designed, manufactured, and sold by Bard Access Systems, Inc.[1]

This device is comprised of two main parts:[1]

1. The port itself, which is made from titanium, is triangular-shaped and has one or two self-sealing silicone septums (also called access points). A small incision is necessary to place the port beneath the skin, usually on the chest area.

2. A catheter, which is a thin flexible tube made from a material called Chronoflex®, a polyurethane polymer.[2] This catheter is connected to the port and goes inside one of the big blood vessels of the body, with its tip ending in a major vein next to the heart.

What Is The Bard Powerport® Device Used For?

The main function of the Bard PowerPort® and other similar devices is to provide quick and easy access to the vascular system (blood vessels) in case of required long-term or repeated intravenous (IV) infusion of:[1,3,4]

- Medications, including painkillers, antibiotics, anesthetics, and chemotherapy, among other drugs.
- Fluids, such as saline or dextrose (sugar) solutions.
- Blood products, such as plasma or platelets.
- Nutrients.
- Contrast media, which is a special dye that allows better visualization of your organs during radiology procedures or imaging tests.

This port also allows for the withdrawal of blood samples, thus protecting peripheral veins (for instance the veins from the arms or hands) from damage derived from recurrent puncture wounds from needles.

What Seems To Be The Problem With This Device?

Despite the many advantages of this device and the allegations of safety claimed by its manufacturer, the Bard PowerPort® has been at the center of controversy since it was made public that Bard managed to conceal multiple reports of PowerPort® failure through the FDA Alternative Summary Reporting program, a currently halted program that allowed manufacturers to conceal device failures from patients and health professionals.[5,6]

Allegedly, the Bard PowerPort® has a defective design that makes it more likely to fracture and migrate to other parts of the body after implantation due to early deterioration of the catheter caused by a substance called barium sulfate.[6,7]

Barium sulfate is a metal that is mixed with the Chronoflex® polyurethane polymer when manufacturing the catheter. This substance is used to increase the absorption of X-rays, thus allowing for better visualization of the device inside the body when using imaging techniques.[8]

However, studies have shown that when exposed to the bloodstream, barium sulfate starts to slowly disintegrate, thus causing microscopic irregularities on the surface of the catheter which can increase the risk of infection and can eventually result in its fracture.[9]

Because of this design defect, the Bard PowerPort® can malfunction in different ways and lead to several potential complications, such as:

Infection

Catheter-related or port-related infections may be local, affecting only the port pocket, or can spread through the whole body (sepsis).[10-12]

Several studies have reported that infections are the most common complication after implantation of a port system, and its incidence is around 2 to 5% depending on catheter location and the individual's immune status.[6,13-17]

Furthermore, the defective design and consequent deterioration of the Bard PowerPort® device often result in tiny cracks in the catheter that enables the buildup of microorganisms, thus increasing the risk of infection.[6,9]

Catheter Fractures And Migration

In some cases, migration of the catheter may occur. This means that the catheter moved from its original position, leading to potential heart problems such as arrhythmia (irregular heartbeat), venous thrombosis (when a blood clot forms in a vein), or even life-threatening issues.[12,18-21]

In some cases, a thrombus can form around the catheter tip, obstructing it. Catheter-related thrombosis is a common occurrence and has an incidence of around 1.5% to 3%.[11,12,17,18]

Although venous port migration is rare, it can occur in some cases[19]. In a study made in Taiwan, it was reported that the Bard port had a migration rate of up to 6.7% when compared to another type of port, and the migration risk was higher for males and for

individuals with lung cancer. Furthermore, migration of the port occurred in an average of 35 days after implantation.[22]

Some studies have reported the occurrence of fractures of the Bard PowerPort® catheter and the subsequent migration of those broken pieces into the bloodstream (embolism), which can cause life-threatening complications.[11,23]

Perforation Of Organs, Blood Vessels, And Tissue

When a fracture of the Bard PowerPort® catheter occurs, the broken pieces may travel through the bloodstream and can potentially cause damage, lacerations, or perforations to the blood vessels, tissues, and/or organs throughout the body, including the heart.[24-26]

Other Complications

Other complications that have been related to the use of the Bard PowerPort® device include:[1,6,10,11]

- Air embolism (a potentially serious condition caused by air bubbles entering into a blood vessel)
- Allergic reaction
- Bleeding
- Cardiac tamponade (a medical emergency caused by the accumulation of fluids in the sac that surrounds the heart)
- Catheter or port erosion through the skin
- Damage or breakage of the port due to pinch-off syndrome (compression of the device between the clavicle and first rib)
- Device rotation or flipping
- Endocarditis (inflammation of the inner lining of the heart)
- Extravasation (leakage of medications or fluids from the port into the surrounding tissue)
- Hematoma (bruising)
- Hemothorax (build-up of blood around the lungs)
- Hydrothorax (build-up of fluid around the lungs)
- Inflammation, scarring, or necrosis (death of the tissue) of the skin over the implant area
- Intolerance to the port
- Nerve damage
- Pneumothorax (build-up of air around the lungs)
- Severe and persistent pain at or around the port pocket site

These complications can be classified as early (happened in the first 30 days after implant) or late (happened more than 30 days after implant). Additionally,

complications can be further classified into minor or major, depending on the impact they have on the individual's health.

Minor complications do not result in a hospital stay or medical therapy for more than 24 hours, nor do they require surgical or interventional therapy; while major complications require surgery or interventional therapy, a prolonged hospital stay, or medical therapy for more than 24 hours, or may even result in death.[21]

In most cases, complications can be successfully managed with medical treatment, but in some cases, surgical removal of the device is warranted.

Lawsuits Involving The Bard Powerport® Device

The FDA issued a recall of some Bard PowerPort® catheters in 2020 due to potential malfunctions and encouraged individuals to seek replacement of their implanted PowerPort® devices. The recall was terminated in February 2022.[27]

Several lawsuits have been filed against Bard, claiming that despite the company's knowledge about the potential defects and failures of their Powerport® Devices, they still promoted them as safe and effective, thus failing to provide adequate warnings to patients and healthcare providers about the potential health hazards and associated risks when implanting and using a Powerport® device.[6]

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