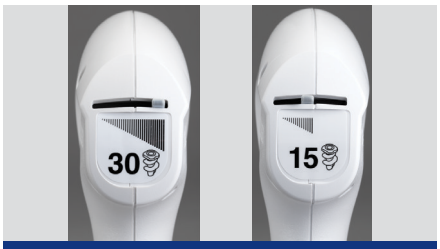
SorbaFix™ Absorbable Fixation System

BD

Smart Design.
Not Sharp Design.



Fastener gauge keeps track of fastener level.

Strong

- Repair strength approximately 7x greater than maximum Intraabdominal Pressure (IAP).[1,2,3]
- Threaded, hollow core allows for tissue ingrowth through interior of fastener.[3]

Consistent

- The consistent diameter of the threads from head to tip and fastener length are designed to maximize tissue engagement.
- Obturator assists in accurately piloting fastener through mesh and tissue

Reliable

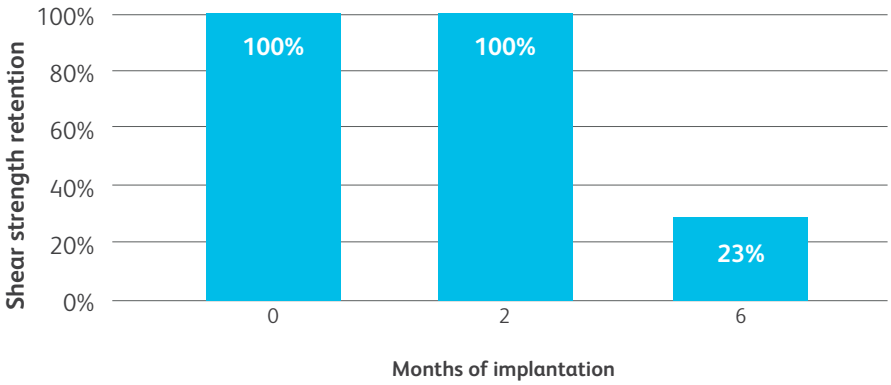
- Atraumatic blunt tip fastener with smooth head and no exposed points.
- Innovative mechanical design enables a durable delivery system.
- Absorption of the poly (D, L) – lactide (PLA) fasteners is nearly complete at approximately 12 months post implantation, leaving less foreign material behind.[3]

SorbaFix™ Absorbable Fixation System

The unique fastener design of the SorbaFix™ Absorbable Fixation System reduces the risk of sharp points are left behind in the patient. The 5 mm depth of tissue purchase and consistent thread diameter from head to tip help ensure maximum tissue engagement during open and laparoscopic procedures.

The SorbaFix™ Absorbable Fixation System has a 5 mm, low-profile delivery system that offers smooth deployment. Keeping track of the preloaded 15 or 30 fastener configurations is now easy with a new fastener gauge.

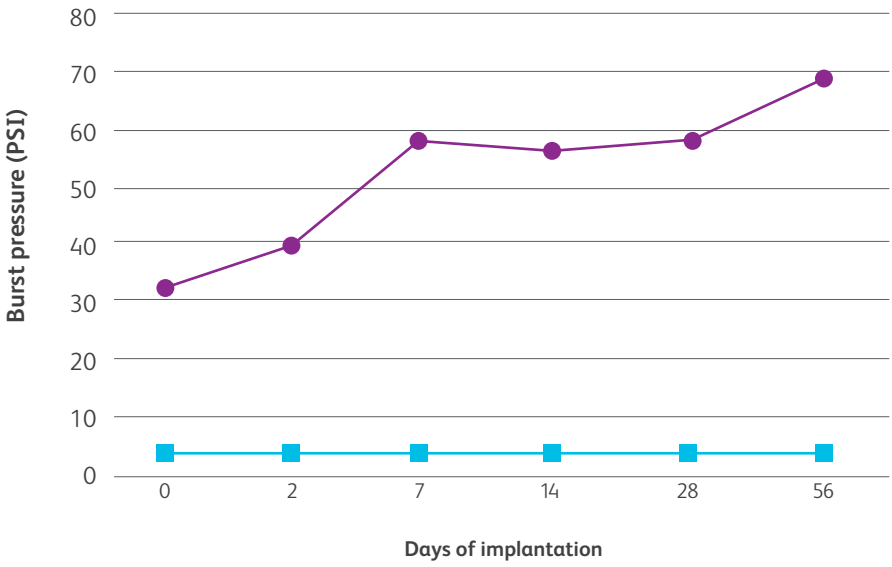
SorbaFix™ System shear strength*



Shear strength retention illustrates degradation of the SorbaFix™ fastener over time. The SorbaFix™ fastener retains 100% of its strength within the first two months, providing secure fixation during the initial healing period.

*BD Bench data on file

Burst pressure over time in a porcine model[3]



Minimal degradation of the fastener during the healing period, along with aggressive tissue ingrowth, maintains burst pressures at approximately 7x the Intraabdominal Pressure (IAP) requirement needed for the repair.[1,2]

SorbaFix™ Absorbable Fixation System average burst pressure

Physiological burst pressure specification

Ordering information

Prodoct code	Qty.	Configuration
0113116	5/case	30 Absorbable Fasteners
0113115	5/case	15 Absorbable Fasteners

1. Twardowski ZJ, Khanna R, Nolph KD, et al. Intraabdominal pressures during natural activities in patients treated with continuous ambulatory peritoneal dialysis. Nephron. 1986;44(2):129-35. **2.** Cobb WS, Kercher KW, Heniford BT. The argument for lightweight polypropylene mesh in hernia repair. Surg Innov. 2005 Mar;12(1):63-9. **3.** Data generated from a preclinical study using the SorbaFix™ Absorbable Fixation System and Composix™ L/P Mesh. Data on file. RPT3797163. Results may not correlate to performance in humans.

SorbaFix™ Absorbable Fixation System

Indications: The SorbaFix™ Absorbable Fixation System is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during laparoscopic surgical procedures, such as hernia repair. **Contraindications:** 1. This device is not intended for use except as indicated. 2. Do not use this device where hemostasis cannot be verified visually after application. 3. Contraindications associated with laparoscopic surgical procedures relative to mesh fixation apply, including but not limited to: • Fixation of vascular or neural structures • Fixation of bone and cartilage • Situations with insufficient in-growth of tissue into the mesh over time, which could result in inadequate fixation once the fastener is resorbed. 4. Carefully inspect the area in the vicinity of the tissue being fastened to avoid inadvertent penetration of underlying structures such as nerves, vessels, viscera, or bone. Use of the SorbaFix™ Absorbable Fixation System in the close vicinity of such underlying structures is contraindicated. For reference, the length of the fastener is 6.0 mm, the fastener head is another 0.7 mm (total 6.7 mm). **Warnings:** 1. The SorbaFix™ Absorbable Fixation System is intended for Single Use Only – DO NOT RESTERILIZE. Reuse, reprocessing, re-sterilization, or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient. Reuse, reprocessing, re-sterilization, or repackaging may also create a risk of contamination of the device 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 device may lead to injury, illness, or death of the patient or end user. This product is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 2. Do not use beyond the expiration date on the package. 3. Do not use if the center of the temperature indicator is black. 4. As with any implant material the presence of bacterial contamination may enhance bacterial infectivity. Accepted surgical practices must be followed with respect to drainage and closure of infected or contaminated wounds. 5. Users should be familiar with surgical procedures and techniques involving synthetic absorbable materials before employing SorbaFix™ Absorbable Fixation System fasteners for wound closure, as the risk of wound dehiscence may vary with the site of application and the material used. 6. The device may not fixate through prosthetics derived from biologic material such as xenografts and allografts. Prosthetics should be evaluated for compatibility prior to use. 7. To prevent patient injury from the piloting tip, stay clear of vessels, nerves, bowel, and viscera when entering the surgical site, manipulating tissue, and fixating mesh. After use, the SorbaFix™ Absorbable Fixation System may be a potential biohazard. This device has a piloting tip, which should be considered a sharp even when the device is not actuated. Handle and dispose of in accordance with any local and federal laws regarding medical waste and sharps disposal requirements to prevent sharps injuries. **Precautions:** 1. Please read all instructions before using the SorbaFix™ Absorbable Fixation System. 2. Only persons having adequate medical training and familiarity with surgical techniques should perform surgical procedures. Consult the medical literature relative to technique, complications, and hazards prior to any surgical procedure. 3. The SorbaFix™ Absorbable Fixation System can be used with most 5 mm trocars. Ensure compatibility by inserting the device into the trocar prior to introduction into the patient. The SorbaFix™ Absorbable Fixation System should enter and exit the trocar easily without excessive force. The use of too much force could damage the instrument. 4. Counter pressure should be applied on the target area. Avoid placing hand/finger directly over the area where the fastener is being deployed to prevent injury. 5. Insertion of fasteners into some collagenous structures such as ligaments and tendons is possible but is NOT possible directly into bone or cartilage. This may damage the device. 6. Avoid excessive trigger force as this may damage the device. 7. If the device locks, remove the device from the patient and lightly tap the trigger forward toward the tip to release. 8. If the device locks and cannot be separated from a fastener that has been deployed into tissue, you may rotate the device counterclockwise to free the device. The locked device should then be discarded, and a new device should be used. 9. If the fastener does not deploy properly, remove the device from the patient and test the device in air to ensure proper fastener deployment. Once proper fastener deployment is confirmed, the device may be reinserted into the patient. 10. The safety and effectiveness of SorbaFix™ Absorbable Fixation System have not been evaluated or established in pregnant or breast feeding women. 11. This device contains the following substance(s) defined as CMR 1B in a concentration above 0.1% weight by weight: Cobalt; CAS No. 7440-48-4; EC No. 231-158-0. Current scientific evidence supports that medical devices manufactured from stainless-steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects. For more information, please consult the ECHA website: https://echa.europa.eu/home. **Adverse reactions:** Adverse reactions and potential complications associated with fixation devices such as the SorbaFix™ Absorbable Fixation System may include, but are not limited to the following: hemorrhage; pain, edema, and erythema at wound site; allergic reaction to Poly (D, L)-lactide; septicemia/infection; hernia recurrence/ wound dehiscence.

Contact a BD sales representative to schedule an appointment or visit bd.com for more information.

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