AbsorbaTack™ 5 mm Absorbable Fixation Device
featuring the NEW ABSTACK30X

Value Analysis Committee
Product Information Kit
Unparalleled Commitment to Hernia Repair

Optimal patient outcomes are a priority in healthcare. Equally important are innovative product solutions that present the greatest efficacy and value to medical facilities. At Covidien, we offer a growing portfolio of hernia solutions, including fixation devices, balloon dissection and mesh, that are backed by diverse educational resources, expert clinical support and best-in-practice services.

Our expanding portfolio of procedure specific fixation products is developed through ongoing collaboration with medical professionals and is designed to combine superior economic efficiency with positive clinical outcomes for your patients.

We are proud that Covidien fixation devices are used by the nation’s highest rated hospitals and that over 60% of these hospitals use the AbsorbaTack™ fixation device.¹
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# Product Introduction

## Product Overview

**AbsorbaTack™ 5mm Absorbable Fixation Device**

The AbsorbaTack™ 5mm fixation device provides absorbable tack fixation designed for patient comfort and surgeon confidence and peace of mind during and after the procedure. AbsorbaTack™ provides strong, temporary mesh fixation while leaving no foreign material in the body over time. It requires no sharp piloting needle to deploy, eliminating the risk of inadvertent needlesticks in the OR due to the fixation device.

Why would a hospital purchase the AbsorbaTack™ 5mm fixation device?

<table>
<thead>
<tr>
<th>Economic Value and Efficiency</th>
<th>Our Commitment to Fixation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A comprehensive portfolio of fixation, dissection and mesh solutions offers opportunity for standardization and hospital efficiencies. Now reduces inventory requirements with 50% more tacks per device than the original product. Eliminates long-term cost related to needlestick injury, as it does not require a sharp piloting needle.</td>
<td>Covidien offers 20 years of leadership, innovation and excellence in developing a comprehensive, established hernia product line. We are proud that Covidien fixation devices are used by the nation’s highest rated hospitals and that over 60% of these hospitals use the AbsorbaTack™ fixation device.1</td>
</tr>
</tbody>
</table>

What are the competitive advantages of the AbsorbaTack™ 5mm fixation device?

<table>
<thead>
<tr>
<th>Designed With Patient Comfort in Mind</th>
<th>Fixation Strength</th>
<th>Peace of Mind</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Interim clinical study results showed a 54% reduction of pain from the preoperative baseline at 1 month follow up2</td>
<td>• Provides strong temporary mesh fixation, with retention strength comparable to the “gold standard” ProTack™ fixation device at 1 week and 2 months in an animal model3</td>
<td>• Reduces the likelihood of inadvertent needlesticks in the OR, since no sharp piloting needles are required for deployment</td>
</tr>
<tr>
<td>• Leaves no foreign material behind over time</td>
<td>• Longer tack length than ProTack™ fixation device (4.1mm vs. 3.8mm), and wide 5.1mm proximal wings that secure mesh firmly in place</td>
<td>• Potentially fewer visceral attachments than permanent tack fixation3</td>
</tr>
<tr>
<td>• No metal required for fixation</td>
<td>• Reliable tack deployment, with ratcheted mechanism providing tactile feedback when firing</td>
<td>• Violet tack with black-dot visualization feature to optimize visibility</td>
</tr>
<tr>
<td>• Supports a minimally invasive approach through 5mm shaft and easy-to-use design</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Product Introduction

Product Diagrams

ABSTACK30X 5 mm Fixation Device for Laparoscopic Hernia Repair

- New Flexible Cable Drive Mechanism and Shaft
- New Full Length Guide Spring
- New Metric Scale on Shaft

ABSTACK15 & ABSTACK30 5 mm Fixation Device for Laparoscopic Hernia Repair

- Point-and-shoot design
- Easy-to-use pistol grip for secure firing
- Ratcheted handle provides tactile feedback when firing

ABSTACK20S Short Fixation Device for Open Hernia Repair

- Designed to give surgeon ergonomic access to defect in open hernia repair

AbsorbaTack™ Tack

- Violet color and black-dot feature for improved visualization
- Absorbable PGLA tack is 4.1mm long for a secure repair
- 5.1mm proximal wings securely hold mesh to target tissue

Product Specifications

<table>
<thead>
<tr>
<th>Device Type:</th>
<th>Fixation device with absorbable, implantable tacks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material Composition:</td>
<td>Absorbable synthetic polyester copolymer derived from lactic and glycolic acid, poly (glycolide-co-L-lactide) (PGLA), dyed with D&amp;C Violet No. 2.</td>
</tr>
<tr>
<td>Description:</td>
<td>Sterile, single-use device for fixation of prosthetic material, such as mesh, to soft tissue. The device is offered with 15 and 30 absorbable tacks with a long shaft, and 20 absorbable tacks with a short shaft.</td>
</tr>
</tbody>
</table>
SEP 28 2007

510(k) Summary of Safety and Effectiveness

SUBMITTER: United States Surgical, a division of Tyco Healthcare Group LP
150 Glover Avenue
Norwalk, CT 06856
Tel No.: (203) 845-1000

CONTACT PERSON: Daniel Campion
Associate II, Regulatory Affairs

DATE PREPARED: July 10, 2007

TRADE/PROPRIETARY NAME: Syneture™ Absorbable Tack and Applicator

COMMON/USUAL NAME: Absorbable Tack and Applicator

CLASSIFICATION NAME: Implantable Staple

PREDICATE DEVICE(S): AbsorbaTack™ and Applicator (K071061)
E-Z Tac™ (K061585)

DEVICE DESCRIPTION: The Syneture™ Absorbable Tack and Applicator are sterile single use devices for the fixation of prosthetic material, such as hernia mesh, onto soft tissue. The Absorbable Tack is formed from synthetic polyester derived from a lactic acid and glycolic acid copolymer. The Applicator is offered with a range of 5 to 20 tacks.

INTENDED USE: The Syneture™ Absorbable Tack and Applicator are intended for fixation of prosthetic material to soft tissue in various minimally invasive and open general surgical procedures, such as hernia repair.

TECHNOLOGICAL CHARACTERISTICS: The Syneture™ Absorbable Tack and Applicator is identical to the predicate device in terms of intended use and mode of operation.

PERFORMANCE DATA: Performance testing was conducted to verify that the Syneture™ Absorbable Tack and Applicator is safe and effective and performs as intended.
Covidien
9 Ms. Renee Borgessano
Manager, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K123109
Trade/Device Name: ABSORBATACT™ Absorbable Fixation Device
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: October 03, 2012
Received: October 04, 2012

Dear Ms. Borgessano:

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. 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 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
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/index/index.html](http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/index/index.html) 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/MedicalDevices/Safety/ReportaProblem/default.htm](http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm) 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 (301) 796-7100 or at its Internet address [http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm](http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm).

Sincerely yours,

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

Enclosure
Indications for Use

510(k) Number (if known): K123109

Device Name: ABSORBATACK™ Absorbable Fixation Device

Indications For Use:

The device is intended for fixation of prosthetic material to soft tissue in various minimally invasive and open surgical procedures such as hernia repair.

Prescription Use ___ X ___ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K123109
INSTRUCTIONS FOR USE

The standard device may be inserted through a 5 mm or larger (with the use of a converter) cannula for incisions as small as 3 mm. The device is inserted, fixed, and manipulated by simple surgical techniques. The device was designed, tested, and manufactured for single patient use only. Reuse or reprocessing of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or re-sterilize this device.

WARNING: A MINIMUM OF 4.2 MM THICKNESS OF TISSUE OVER UNDERLYING BONE, VESSELS, OR VISCERA IS NEEDED FOR FULL ENGAGEMENT OF THE TACK. MATERIAL THICKNESS SHOULD BE CAREFULLY EVALUATED PRIOR TO APPLICATION OF THE DEVICE.

WARNING: APPROPRIATE FORCE SHOULD BE APPLIED TO THE HANDLE OF THE DEVICE, WHEN PLACING TACKS. EXCESSIVE FORCE COULD RESULT IN DAMAGE TO THE TISSUE AND/OR THE MATERIAL BE FIXATED.

WARNING: PRIOR TO TACK DEPLOYMENT ENSURE THAT THE DISTAL END OF THE TACK IS AT A RIGHT ANGLE TO THE TARGETED TISSUE TO FACILITATE APPROPRIATE INSERTION OF THE TACK. AFTER THE DEPLOYMENT (WHICH OCCURS FULL DEPLOYMENT OF THE TACK TO THE SURFACE OF THE MATERIAL BE FIXATED.

INDICATIONS

The AbsorbaTack™ 5 mm device is a sterile, single use device for fixation of prosthetic material, such as mesh, to soft tissue. The tack is constructed of an absorbable synthetic polyester copolymer derived from lactic acid and glycolic acid and is dyed with D&C Violet No. 2. The device is offered with 15 or 30 absorbable tacks with a long shaft and 20 absorbable tacks with a short shaft.

CONTRAINDICATIONS

1. Do not use if package is opened or damaged.
2. Do not use the AbsorbaTack™ fixation device on tissue(s) which cannot be inspected visually for the fixation site to be fixated.
3. Do not use in ischemic or necrotic tissue.
4. Do not use in procedures where soft tissue fixation would not normally be used.
5. Do not use in procedures where permanent fixation is desired.
6. Do not use in procedures where hemostasis is needed for full deployment of the tack.
7. Do not use the standard device in procedures where soft tissue fixation would not normally be used.
8. Do not use the standard device in procedures where permanent fixation is desired.
9. Always inspect the fixation site to ensure hemostasis. Minor bleeding may be controlled with manual pressure.
10. Do not use product if temperature dot on package is black.

TECHNICAL SPECIFICATIONS

The AbsorbaTack™ 5 mm fixation device includes 15 shafts (5 mm long) and 20 absorbable tacks with a short shaft. The device is offered with 15 or 30 absorbable tacks with a long shaft.

1. Grip the handle of the device and press the distal end of the shaft against the mesh at the location where fixation is desired.
2. WARNING: APPROPRIATE FORCE SHOULD BE APPLIED TO THE HANDLE OF THE DEVICE, WHEN PLACING TACKS. EXCESSIVE FORCE COULD RESULT IN DAMAGE TO THE TISSUE AND/OR THE MATERIAL BE FIXATED.
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4. Prior to tack deployment ensure that the distal end of the device is at a right angle to the targeted tissue to facilitate appropriate insertion of the tack. After the deployment (which occurs full deployment of the tack to the surface of the material being fixated)
5. It is recommended that the device be inserted through a 5 mm or larger (with the use of a converter) cannula for incisions as small as 3 mm.
6. The device is inserted, fixed, and manipulated by simple surgical techniques.

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6. The device is inserted, fixed, and manipulated by simple surgical techniques.
Interim results show 54% reduction in pain postop from preop baseline at 1 month follow up²

Interim results of this prospective double-blind study show:
- Mean preoperative VAS scores were 3X higher when compared to postoperative VAS scores at 1 month for the absorbable fixation group.
- Mean VAS scores were reduced by 54% postoperatively (p=0.047) for the absorbable fixation group from the preop baseline at 1 month follow up.

AbsorbaTack™ is the first absorbable fixation device to show a reduction in pain based on interim study results.

**Technical Data**

**Fixation Strength**

- AbsorbaTack™ fixation strength was shown to be comparable to that of the ProTack™ fixation device at 1 week and at 2 months in an animal model.\(^1\)


- AbsorbaTack™ is twice as strong\(^\circ\) as the SorbaFix™ absorbable fixation system tack out of the package.\(^13\)

- AbsorbaTack™ remains stronger\(^\circ\) than the SorbaFix™ absorbable fixation system tack through 6 weeks.\(^\circ\)

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AbsorbaTack™ is more than 170% stronger\(^\circ\) than the SorbaFix™ absorbable fixation system tack at 4 weeks.

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\(^\circ\) Source: Covidien Internal Test Data. Data on File. Strength claim based on results of Covidien-sponsored in vitro testing comparing the shear strength of the AbsorbaTack™ fixation device tack with that of the SorbaFix™ absorbable fixation device tack. All tacks were immersed in a water bath and shear strength testing was performed at each time point. Data and claims based on a minimum of 70 samples of the AbsorbaTack™ fixation device tack (7 separate lots) at each time point and a minimum of 10 samples of the SorbaFix™ absorbable fixation system tack (3 separate lots) at each time point.
The AbsorbaTack™ Fixation Device: Peace of mind during and after the procedure

- At 1 week, in a prospective study of 25 Sprague-Dawley rats, AbsorbaTack™ fixation demonstrated a 70% lower visceral attachments score (p <0.0001) when compared to permanent tack fixation.

- At 2 months, AbsorbaTack™ fixation demonstrated a 60% lower visceral attachments score (p <0.0001) than permanent tack fixation.³

- The full study included randomized fixation groups of transfacial fixed suture, ProTack™ fixation device, AbsorbaTack™ fixation device and I-Clip™.


* Based on an animal model. Total attachment score was calculated by adding up points from the parameters of attachment extent, type, tenacity, and organ involvement. The authors note "With regard to the adhesions caused by the various fixation elements, we again draw attention to the fact that animal experiments have their natural limitations, and the results cannot be directly extrapolated to the human setting." (Hollinsky et al, 2009).

The AbsorbaTack™ Fixation Device: Peace of mind during and after the procedure

### Technical Data

**Peace of Mind**

Demonstrated 60-70% fewer visceral attachments compared to permanent tack fixation³

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<table>
<thead>
<tr>
<th></th>
<th>Covidien AbsorbaTack™ 5mm Fixation Device</th>
<th>Bard Davol SorbaFix™ Absorbable Fixation System††</th>
</tr>
</thead>
<tbody>
<tr>
<td>No sharp piloting needle after all tacks/staples have been deployed</td>
<td>☑</td>
<td>✗</td>
</tr>
<tr>
<td>Eliminates the likelihood of inadvertent needlesticks due to fixation device</td>
<td>☑</td>
<td>✗</td>
</tr>
<tr>
<td>No sharps-related language in the device instructions for Use</td>
<td>☑</td>
<td>✗</td>
</tr>
</tbody>
</table>

†† SorbaFix™ Absorbable Fixation System, Instructions for Use.
Reflecting Covidien’s more than 20 years of experience in hernia repair, the AbsorbaTack™ portfolio offers an innovative product designed with patient comfort, surgeon confidence and safety in mind—backed by clinical experience and scientific evaluation.

### Absorbable Fixation

<table>
<thead>
<tr>
<th>Absorbable Fixation for Hernia Repair: Clinical Experience⁴</th>
<th>Experience of Mark Meese, MD and Dean Mikami, MD:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Webcast, 2009</td>
<td>• Each had completed more than 100 procedures at the time of webcast and discussed their clinical experience.</td>
</tr>
<tr>
<td></td>
<td>• Resorption of the tack allows the mesh to promote fast and strong tissular ingrowth.</td>
</tr>
<tr>
<td></td>
<td>• Fewer seroma formations and decrease in complaints of postoperative pain as compared to use of nonresorbable tacks.</td>
</tr>
<tr>
<td></td>
<td>• No recurrence was observed by either surgeon.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Laparoscopic Resorbable Mesh Fixation – Assessment of an Innovative Disposable Instrument Delivering Resorbable Fixation Devices: I-Clip™⁵</th>
<th>Final Results of a Prospective Multicentre Clinical Trial:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hernia, 2008</td>
<td>• Fixation quality was good to very good in 100% of ventral hernias and in 85-92% of inguinal hernias.</td>
</tr>
<tr>
<td></td>
<td>• At 1 month, 90% of patients (94/104) were totally pain-free (VAS score: 0), and only 10 patients reported low pain (VAS scores: 0.3-3.1). At 1 year, 98% of patients (102/104) were totally pain-free.</td>
</tr>
<tr>
<td></td>
<td>• At 1 year, no recurrence or mesh sepsis was observed.</td>
</tr>
<tr>
<td></td>
<td>• The Covidien I-Clip™ absorbable fixation device predates the introduction of AbsorbaTack™. This study was cited to illustrate how absorbable fixation yields positive results; it is not intended to be directional.</td>
</tr>
</tbody>
</table>

### Needlestick Safety

<table>
<thead>
<tr>
<th>Sharps-related Percutaneous Injuries⁴</th>
<th>Clinical Literature on Needlesticks in the OR:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infect Control Hosp Epidemiol, 2004</td>
<td>• The Centers for Disease Control and Prevention (CDC) estimates that each year 384,325 needlesticks and other sharps-related percutaneous injuries are sustained by hospital-based healthcare personnel.</td>
</tr>
<tr>
<td></td>
<td>• CDC reports an average of 1,000 sharps injuries a day.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>&quot;Hospitals Should Comply With Requirements for the Adoption of Safer Surgical Technologies&quot;⁷</th>
<th>Increase in Sharps Injuries in Surgical Settings vs. Nonsurgical Settings After Passage of National Needlestick Legislation:</th>
</tr>
</thead>
<tbody>
<tr>
<td>JACS, 2010</td>
<td>• 23% of all sharps injuries were associated with the surgical setting.</td>
</tr>
<tr>
<td></td>
<td>• Of surgical injuries, 32.6% were to surgeons, surgical residents and fellows; 30.3% to operating room nurses; and 37.1% to surgical technicians.</td>
</tr>
<tr>
<td></td>
<td>• Despite legislation, surgical injuries increased while nonsurgical injuries decreased significantly.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>&quot;The Costs of Preventing Needlesticks With Safer Devices and Training Are Important Topics for Future Research&quot;⁸</th>
<th>A Study of Needlestick Injuries in the United States:</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAOHN Journal, 2005</td>
<td>• Two retrospective studies found higher incidence of injury among surgical residents and medical students.</td>
</tr>
<tr>
<td></td>
<td>• Total cost of a needlestick injury is estimated to range up to $3,766, excluding the cost of treating the long-term complications such as HIV and hepatitis B and C infections.</td>
</tr>
<tr>
<td></td>
<td>• Lifetime cost of treatment is estimated to range from $80,902 to $371,600 for HIV; from $39,654 to $70,678 for hepatitis B; and from $8,589 to $23,044 for hepatitis C.</td>
</tr>
</tbody>
</table>
Covidien has developed comprehensive online reimbursement resources for hernia and abdominal repair. You can reference the interactive US Hernia Reimbursement Guide at covidien.com/hernia for the most up-to-date codes and reimbursement rates.
Competitive Information

Competitive Products Overview

Embodying Covidien’s 20-year commitment to helping surgeons excel in their hernia repair practice, the AbsorbaTack™ 5mm fixation device is the ideal choice for secure, temporary mesh fixation in soft tissue repair. Please refer to the chart below to compare the AbsorbaTack™ 5mm fixation device to other absorbable fixation devices.

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>Covidien AbsorbaTack™ 5mm Fixation Device</th>
<th>Bard Davol SorbaFix™ Absorbable Fixation System</th>
<th>Ethicon SECURESTRAP™ 5mm Absorbable Fixation Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>SPECIFICATIONS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LAUNCH</td>
<td>2007</td>
<td>2009</td>
<td>2010</td>
</tr>
<tr>
<td>TACK/STRAP DESIGN</td>
<td>Screw-in tack requires no piloting sharps to place; smooth head with proximal wings sits flush against mesh.</td>
<td>Blunt-tip tack with no exposed points, threaded hollow core. Uses an obturator with piloting tip to place.9</td>
<td>Strap design requires 2 metal pins to deploy the strap and uses two points of fixation to straddle mesh pores and fibers.10,11</td>
</tr>
<tr>
<td>TACK DIMENSIONS</td>
<td>5.1mm (total length) 4.1mm (inserted length) 1.0mm (profile) 5.1mm (proximal wings provide surface area to hold mesh in place)</td>
<td>6.7mm (total length) 6.0mm (inserted length)12 0.85mm (profile)</td>
<td>7.2mm (total length) 6.7mm (inserted length)10 0.5mm (profile)</td>
</tr>
<tr>
<td>NUMBER OF TACKS/STRAPS PER DEVICE</td>
<td>15 or 30 tacks (long shaft); 20 tacks (short shaft)</td>
<td>15 or 30 tacks9</td>
<td>25 straps10</td>
</tr>
<tr>
<td>TACK REMOVAL</td>
<td>Tack can be unscrewed if necessary.</td>
<td>Tack can be unscrewed if necessary. SorbaFix™ IFU: “If the device locks and cannot be separated from a fastener that has been deployed into tissue, you may rotate the device counter-clockwise to free the device.”</td>
<td>Straps must be cut. SECURESTRAP™ IFU: “If necessary, the straps may be dislodged from the mesh by cutting the strap with a laparoscopic scissor. Pull the mesh away from the strap and leave the strap in the tissue to resorb.”</td>
</tr>
</tbody>
</table>
## Competitive Information

<table>
<thead>
<tr>
<th></th>
<th>Covidien AbsorbaTack™ 5mm Fixation Device</th>
<th>Bard Davol SorbaFix™ Absorbable Fixation System</th>
<th>Ethicon SECURESTRAP™ 5mm Absorbable Fixation Device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CLINICAL EFFICACY</strong></td>
<td>Clinically proven pain reduction. Interim clinical study results showed a 54% reduction of pain (p=0.047) from the preoperative baseline at 1 month follow up.(^2) In market since 2007. Millions of tacks deployed.</td>
<td>Limited clinical data available. In market since 2009.</td>
<td>Limited clinical data available. In market since 2010.</td>
</tr>
<tr>
<td><strong>RETENTION STRENGTH &amp; SHEAR FORCE</strong></td>
<td>1.06 kg(^1)</td>
<td>Tack is half as strong as the AbsorbaTack™ fixation device tack out of the package, and 58.8% as strong as AbsorbaTack™ fixation device tack at 4 weeks.(^13)</td>
<td>0.77 / 0.59 kg(^{14})</td>
</tr>
<tr>
<td><strong>MINIMUM TISSUE THICKNESS REQUIRED</strong></td>
<td>4.2mm</td>
<td>6.0mm</td>
<td>6.7mm</td>
</tr>
<tr>
<td><strong>SHARP PILOTING NEEDLE REQUIRED?</strong></td>
<td>No.</td>
<td>Yes. SorbaFix™ IFU: “The device should be considered a sharp during handling and disposal.”</td>
<td>No. Design requires 2 metal pins to deploy the strap.</td>
</tr>
<tr>
<td><strong>ABSORPTION PROFILE</strong></td>
<td>Significant absorption rate seen in 3 to 5 months. Absorption is essentially complete prior to 12 months.</td>
<td>Absorption is nearly complete at 12 months.(^9)</td>
<td>Polymer blend is essentially absorbed within 12 months.(^11)</td>
</tr>
<tr>
<td><strong>VISUALIZATION</strong></td>
<td>Violet tack with black-dot visualization feature.</td>
<td>Violet tack(^12)</td>
<td>Violet strap(^10)</td>
</tr>
</tbody>
</table>

\(^{1}\) SecureStrap™ (horizontal) has a statistically significant difference in median holding strength in foam compared to SecureStrap™ (vertical). (p<0.001)\(^{14}\)
# Competitive Information

## Device Delivery Comparison

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>Covidien AbsorbaTack™ 5mm Fixation Device</th>
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<tbody>
<tr>
<td><strong>SPECIFICATIONS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>METHOD OF TACK DELIVERY</strong></td>
<td>Spiral. 5mm shaft and easy-to-use design. Controlled placement of tacks through point-and-shoot design.</td>
<td>Spiral. 5mm shaft. Low-profile delivery system has obturator and piloting tip to create engagement space for firing.</td>
<td>Spring-loaded deployment strap system.</td>
</tr>
<tr>
<td><strong>HANDLE</strong></td>
<td>Ergonomic pistol-grip handle. Ratcheted mechanism provides tactile feedback during firing.</td>
<td>Pistol-grip handle.</td>
<td>Spring-loaded trigger handle with low-strap indicator and lockout feature.</td>
</tr>
<tr>
<td><strong>SHAFT LENGTH</strong></td>
<td>36cm (long shaft) 18cm (short shaft)</td>
<td>36cm</td>
<td>36cm</td>
</tr>
</tbody>
</table>
Packaging Overview

Box Dimensions: 52.5mm x 22mm x 3mm
Each box contains a single, individually packaged device.
6 DEVICES included per case.

Product Order Codes

<table>
<thead>
<tr>
<th>Ordering Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABSTACK30X</td>
<td>NEW 5mm Single Use Abs Fix Device w/ 30 tacks</td>
</tr>
<tr>
<td>ABSTACK15</td>
<td>5mm Single Use Abs Fix Device w/ 15 tacks</td>
</tr>
<tr>
<td>ABSTACK30</td>
<td>5mm Single Use Abs Fix Device w/ 30 tacks</td>
</tr>
<tr>
<td>ABSTACK20S</td>
<td>5mm Single Use Abs Fix Device w/ 20 tacks, Short</td>
</tr>
</tbody>
</table>

Ordering Information

COVIDIEN PRODUCTS WEBSITE: www.covidien.com/hernia
CUSTOMER SERVICE: 1-800-722-8772
We hope that this comprehensive information packet has been helpful to you in facilitating your decision making process. If you have any questions or concerns or if you would like additional information, please contact your Covidien Sales Representative.
AbsorbaTack™ 5mm Absorbable Fixation Device