CapSure™
Permanent Fixation System

Permanent Fixation Redefined

Advancing the Fixation Experience

Recipient of 2015 SLS’ Innovations of the Year recognition.

SOFT TISSUE REPAIR
Right Procedure. Right Product. Right Outcome.
Traditional Challenges in Permanent Fixation for Hernia Repair

Permanent fixation devices facilitate a strong long-term repair but may be associated with some challenges.

- Clinical complications from exposed metal points including adhesions to fasteners
- Difficulties securing large pore mesh may impact hernia repair outcomes
- Deployment challenges and device reliability issues can disrupt procedures

**Fastener Level Indicator**

Available in both 15 and 30 fastener count options

**Rotary Drive System**

Provides smooth efficient deployment

**Low Resistance Ergonomic Trigger**

Easy to use trigger with an audible click indicates that fastener is fully deployed

**Comfort Grip Handle**

Designed to fit wide range of surgeon hand sizes
**Confidence Redefined**

**BARD has redefined Permanent Fixation**

**CAPSURE™** provides surgeons the confidence they desire through strong and reliable fixation.

**Covered**
- Smooth polyetheretherketone (PEEK) cap eliminates exposed metal tip and helps minimize adhesions to the fastener*

**Strong**
- Fixates into Cooper’s ligament and underlying structures, similar to ProTack™

**Reliable**
- Comfortable handle and easy to deploy trigger
- Consistent fastener deployment and depth of tissue purchase
- Reliable, secure fixation regardless of mesh pore size
- Improved fixation with large pore meshes due to larger cap surface area of fastener versus ProTack™

* Preclinical data. Results may not correlate to performance in humans.

**37 cm Cannula Length**
Provides longer laparoscopic reach versus ProTack™ allowing for greater positioning, flexibility and access

**Redefined Fastener Design**

**316L stainless steel**
316L stainless steel is a surgical stainless steel commonly used in biomedical implants that are put under pressure including bone screws and prostheses.

**Smooth PEEK cap**
- Cap is made from polyetheretherketone (PEEK). PEEK is an inert organic thermoplastic polymer, considered an advanced biomaterial.
- PEEK is used in many medical implants including dental implants, heart valves and stents, and joint prostheses.
Designed for optimized clinical benefits

A 90 Day Preclinical Adhesion Study Demonstrated Stronger Results with the CapSure™ Fixation System vs. ProTack™ Fixation System

Evaluation of a Novel Permanent Capped Helical Coil Fastener in a Porcine Model of Laparoscopic Ventral Hernia Repair

Arnab Majumder, Mojtaba Fayezizadeh, William W. Hope, Yuri W. Novitsky • Surgical Endoscopy April 2016

- Significantly less adhesion coverage
- Greater percentage of properly engaged fasteners
- Greater mesh/tissue integration
- Shielding exposed fastener points on the visceral mesh surface with polymer caps is suggested by the data to reduce adhesion formation and aid in mesh fixation and integration.

30 day Laparoscopic Fastener Assessment

CapSure™ Fixation

ProTack™ Fixation

Average 30 vs. 90 day Diamond Adhesion Score

Significantly less adhesion coverage
Greater percentage of properly engaged fasteners
Greater mesh/tissue integration
Shielding exposed fastener points on the visceral mesh surface with polymer caps is suggested by the data to reduce adhesion formation and aid in mesh fixation and integration.

Technique-driven outcomes

CapSure™ fixation that supports your procedure of choice.

With Ventralight™ ST Mesh with Echo PS™ Positioning System in Laparoscopic Ventral Procedures

- Provides secure fixation in laparoscopic ventral procedures
- Penetrates and holds larger pore mesh as well as dual layer and/or smaller pore mesh
- Compatible in lap ventral with all BARD® mesh configurations including Ventralight™ ST, Composix™ L/P, and Ventrio™ ST

Preclinical data. Results may not correlate to performance in humans.

For access to the full article, please visit www.davol.com/CapSure-Study
**Strong Repair**

**CAPSURE™** fastener easily penetrates Cooper’s ligament and underlying structures, equivalent to ProTack™

**Equivalent Strength to ProTack™ at t₀, Greater Strength Over Time**

Burst strength testing demonstrated that in a porcine model **CAPSURE™** fixated **VENTRALIGHT™ ST Mesh** had a greater (4.3%) burst strength at t₀ and significantly higher (18.4%) peak burst strength at 6 weeks post-implantation than did ProTack™ fixated **VENTRALIGHT™ ST Mesh** at the same time point (p = .0088).

- Porcine abdominal wall tissue. Animal data may not correlate to performance in humans.
- Porcine 6 week implant study. Animal data may not correlate to performance in humans.

**With 3DMAx™ Light Mesh in Laparoscopic Inguinal Procedures**

- Able to fixate into Cooper’s ligament and underlying structures
- Facilitates ease in reapproximation of the peritoneum for a TAPP repair
Reliable

Better confidence in your delivery system performance

- Rotary drive system with a comfortable handle and easy to deploy trigger, with an average delivery force that is 30% less than ProTack™
- Consistent fastener deployment and depth of tissue purchase – preclinical studies demonstrated more favorable fastener seating results versus ProTack™
- Available in 15 and 30 fastener count devices providing significant savings per device over ProTack™, for repairs where 15 or less fasteners are required

CapSure™ Fasteners have 2X the mesh surface area coverage to hold mesh in place ensuring secure fixation and more visible fasteners. Bench testing with 3DMax™ Light demonstrates that CapSure™ is 15X more likely to retain large pore mesh versus ProTack™

1 Bench top data. Results may not correlate to performance in humans.
**CapSure™ Permanent Fixation System**

**Indications**

The CapSure™ Permanent Fixation System is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

**Contraindications**

1. Carefully inspect the area in the vicinity of the tissue being fastened to avoid inadvertent penetration of underlying structures such as bone, nerves, vessels, and viscera. Use of the CapSure™ Permanent Fixation System in the close vicinity of such underlying structures is contraindicated. For reference, the length of the fastener below the fastener head is 3.2 mm, the fastener head is another 1 mm (total 4.2 mm).

**Precautions**

1. Adequate counter pressure should be applied on the target area. Avoid placing hand or finger directly over the area where fastener is being deployed to prevent injury.
2. Use caution when applying the CapSure™ fastener over or in proximity to underlying bone, vessels, nerves, or viscera. The intended fixation site should be assessed to ensure that while the tissue is compressed the total distance from the surface of the tissue to any underlying structures is greater than the length of the CapSure™ fastener.

**Adverse Reactions**

Adverse reactions and potential complications associated with fixation devices such as the CapSure™ Permanent Fixation System may include, but are not limited to the following: hemorrhage, pain, edema and erythema at wound site; septicemia/infection; hernia recurrence/wound dehiscence, erosion and allergic response in patients with known sensitivities to PEEK and metals contained in 316L stainless steel, including chromium, nickel, copper, and iron.

**Ventralight™ ST Mesh with Echo PS™ Positioning System**

**Indications**

Ventralight™ ST Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias.

The Echo PS™ Positioning System is intended to be used to facilitate the delivery of soft tissue prostheses during laparoscopic hernia repair.

**Contraindications**

1. Do not use the Ventralight™ ST Mesh with Echo PS™ Positioning System in infants or children whereby future growth will be compromised by use of such material.
2. Do not use Ventralight™ ST Mesh with Echo PS™ Positioning System for the reconstruction of cardiovascular defects.
3. Literature reports there may be a possibility for adhesion formation when the polypropylene is placed in direct contact with the bowel or viscera.

**Warnings**

1. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the prosthesis. An unresolved infection may require removal of the device.
2. Do not use polypropylene mesh in infants and children, whereby future growth will be compromised by use of such material.

**Precautions**

1. Do not cut or reshape the 3DMax™ Light Mesh as this may affect its effectiveness.
2. If fixation is used, care should be taken to ensure that the mesh is adequately fixated to the abdominal wall. If necessary, additional fasteners and/or sutures should be used.

**Adverse Reactions**

Possible complications include seromas, adhesions, hematomas, inflammation, extrusion, fistula formation and recurrence of the hernia or soft tissue defect.

**3DMax™ Light Mesh**

**Indications**

The 3DMax™ Light Mesh is indicated for use in the reinforcement of soft tissue where weakness exists, in the repair of inguinal hernias.

**Contraindications**

1. Literature reports that there may be a possibility for adhesion formation when polypropylene mesh is placed in direct contact with the bowel or viscera.
2. Do not use polypropylene mesh in infants and children, whereby future growth will be compromised by use of such material.

**Warnings**

1. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require removal of the device.
2. Do not cut or reshape the 3DMax™ Light Mesh as this may affect its effectiveness.

**Precautions**

1. Do not cut or reshape the 3DMax™ Light Mesh as this may affect its effectiveness.
2. If fixation is used, care should be taken to ensure that the mesh is adequately fixated to the abdominal wall. If necessary, additional fasteners and/or sutures should be used.

**Adverse Reactions**

Possible complications include seromas, adhesions, hematomas, inflammation, extrusion, fistula formation and recurrence of the hernia or soft tissue defect.
Comparison Summary
The new gold standard in permanent fixation

<table>
<thead>
<tr>
<th>Features</th>
<th>ProTack™</th>
<th>CapSure™</th>
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<tbody>
<tr>
<td>Fastener material</td>
<td>Titanium</td>
<td>316L stainless steel coil with smooth PEEK head</td>
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<tr>
<td>Fastener configuration</td>
<td>Helical coil 2 1/2 revolutions</td>
<td>Helical coil with integrated polymer head 4 revolutions</td>
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<tr>
<td>Fastener head</td>
<td>None Exposed metal tip</td>
<td>Polymer (PEEK) head No exposed metal tip</td>
</tr>
<tr>
<td>Wire diameter and depth of purchase</td>
<td>0.025” 3.2 mm</td>
<td>0.018” 3.2 mm</td>
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<tr>
<td>Preclinical data demonstrating design minimizes adhesions to the fastener</td>
<td>No</td>
<td>Yes</td>
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<tr>
<td>Fixates into Cooper's ligament and underlying structures</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Provides optimal fixation with large pore mesh</td>
<td>Not optimized for use with large pore mesh</td>
<td>Yes</td>
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<tr>
<td>Fastener level indicator</td>
<td>None</td>
<td>Yes</td>
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<tr>
<td>15 and 30 count option</td>
<td>30 count only</td>
<td>Yes</td>
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Ordering Information

Order Form

- Please add these marked products to my preference card.
- I would like to have these marked products in stock.
  (Reference catalog numbers checked)
- I would like to trial these marked products.

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To learn more, contact your local BARD Representative or call 1.800.556.6275.

Please consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions and instructions for use.

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