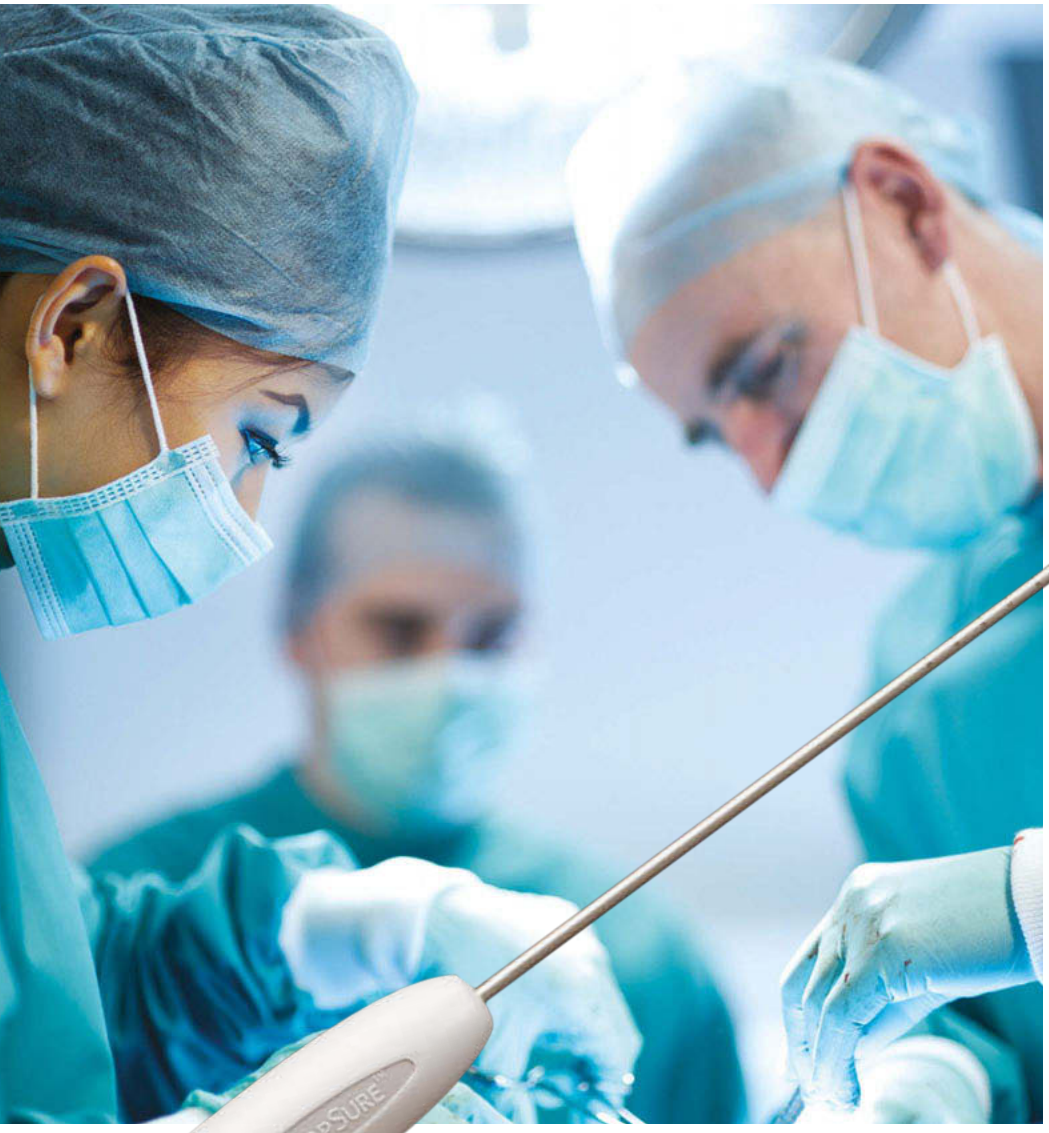
CapSure™
Permanent Fixation System

BARD
DAVOL INC.

Permanent Fixation Redefined



Advancing the Fixation Experience

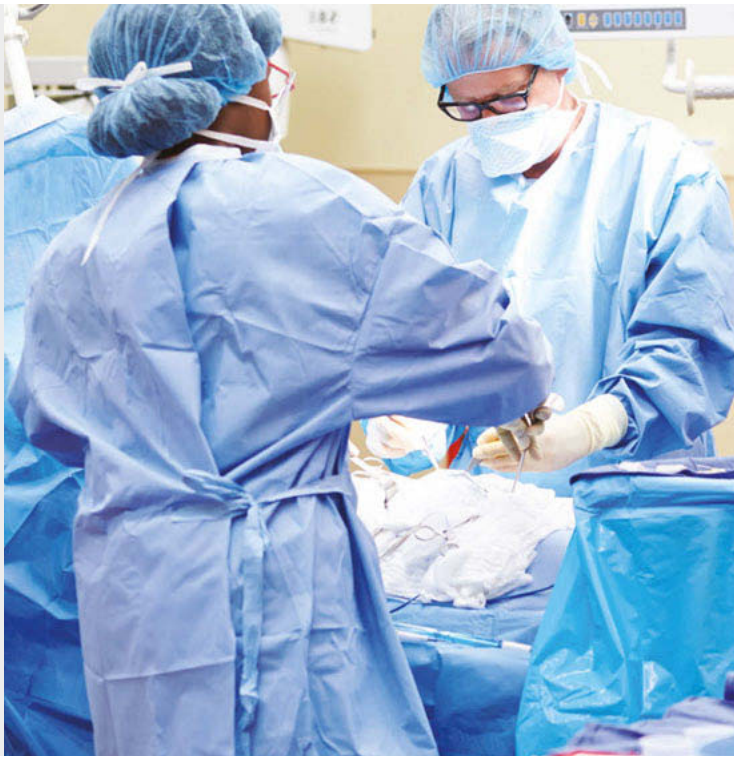
Recipient of 2015 SLS' Innovations of the Year recognition.

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

15 and 30

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

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

Metric Scale
Facilitates laparoscopic measurements

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

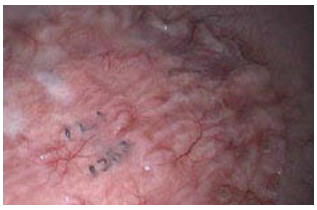
- Significantly less adhesion coverage
- Greater percentage of properly engaged fasteners
- Greater mesh/tissue integration
- Shielding exposed fastener points on the visceral mesh surface with polymer caps is suggested by the data to reduce adhesion formation and aid in mesh fixation and integration.

for access to the full article, please visit
www.davol.com/CapSure-Study

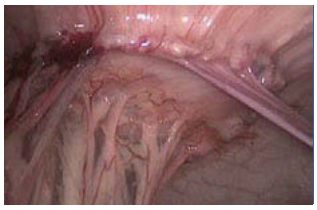
Preclinical data. Results may not correlate to performance in humans.

30 day Laparoscopic Fastener Assessment

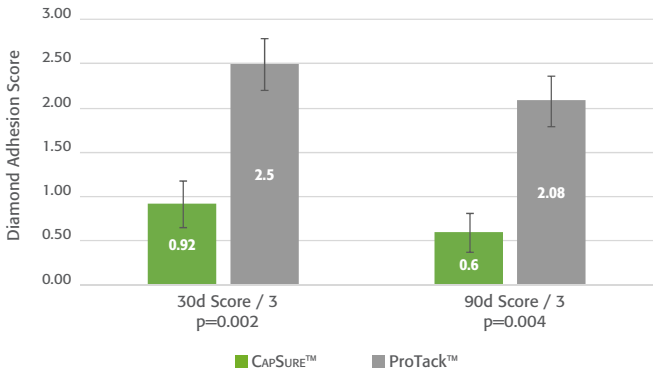
CapSure™ Fixation



ProTack™ Fixation



Average 30 vs. 90 day Diamond Adhesion Score

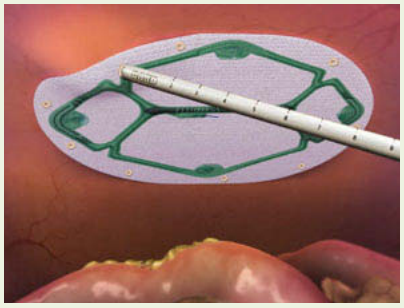


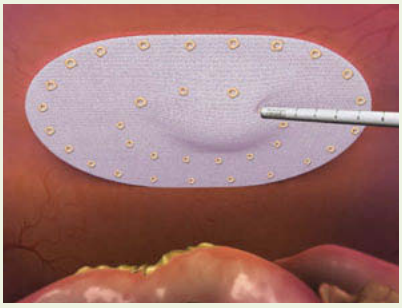
Technique-driven outcomes

CapSure™ fixation that supports your procedure of choice.

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

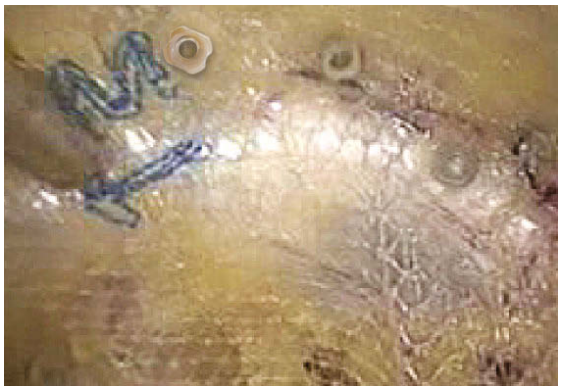
- Provides secure fixation in laparoscopic ventral procedures
- Penetrates and holds larger pore mesh as well as dual layer and/or smaller pore mesh
- Compatible in lap ventral with all Bard® mesh configurations including Ventralight™ ST, Composix™ L/P, and Ventrio™ ST





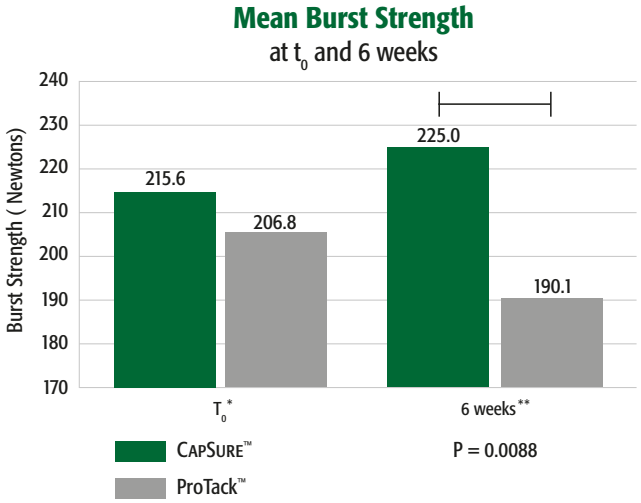
Strong Repair

CapSure™ fastener easily penetrates Cooper's ligament and underlying structures, equivalent to ProTack™



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

Equivalent Strength to ProTack™ at t_0, Greater Strength Over Time



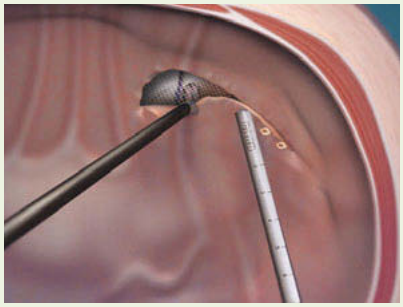
Burst strength testing demonstrated that in a porcine model CapSure™ fixated Ventralight™ ST Mesh had a greater (4.3%) burst strength at t_0 and significantly higher (18.4%) peak burst strength at 6 weeks post-implantation than did ProTack™ fixated Ventralight™ ST Mesh at the same time point (p = .0088).

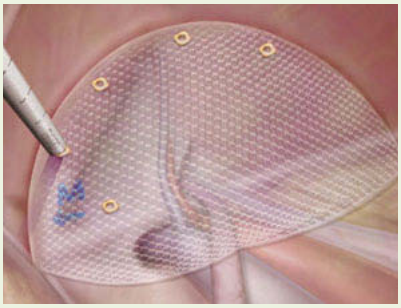
* Porcine abdominal wall tissue. Animal data may not correlate to performance in humans

** 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

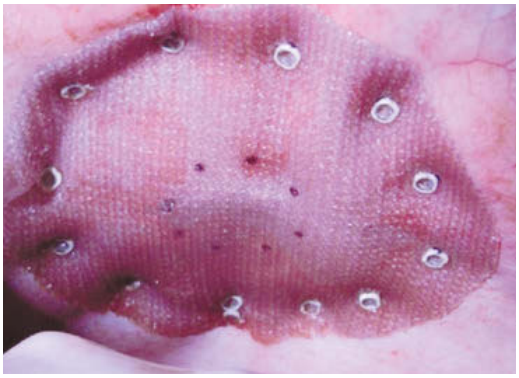




Reliable

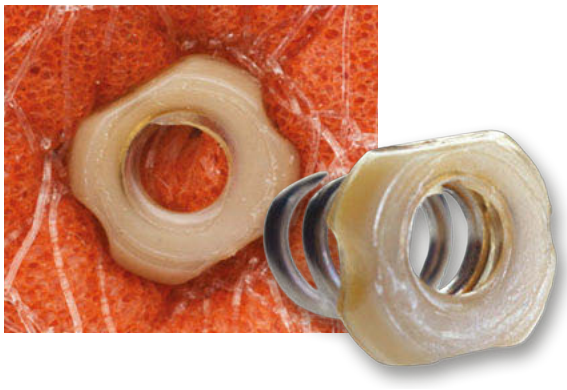
Better confidence in your delivery system performance

- Rotary drive system with a comfortable handle and easy to deploy trigger, with an average delivery force that is 30% less than ProTack™ [1]
- Consistent fastener deployment and depth of tissue purchase – preclinical studies demonstrated more favorable fastener seating results versus ProTack™ [1]
- Available in 15 and 30 fastener count devices providing significant savings per device over ProTack™, for repairs where 15 or less fasteners are required



Results may not correlate to performance in humans.

CapSure™
in Bard Soft Mesh



ProTack™
in Bard Soft Mesh

Fasteners demonstrated in artificial tissue

- 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]

1 Bench top data. Results many 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 prosthesis.
2. Do not apply sharp, heat emitting, or ultrasonic tools (such as scissors, needles, tackers, diathermic tools, etc.) to the Echo PS™ Positioning System.
3. Ventralight™ ST Mesh is the only permanent implant component of the device. The inflation adapter and syringe are to be kept external to the patient and discarded after use. The Echo PS™ Positioning System (including the balloon, all connectors, and inflation tube) is to be removed from the patient and appropriately discarded as it is not part of the permanent implant.

Precautions
1. Do not trim the mesh. This will affect the interface between the mesh and positioning system.

Adverse Reactions
Possible complications include seroma, 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. The use of any permanent mesh or patch in a contaminated or infected wound could lead to fistula formation and/or extrusion of the prosthesis.
2. 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.

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.

CapSure™ Permanent Fixation System

Comparison Summary

The new gold standard in permanent fixation

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

Ordering Information

CapSure™ Permanent Fixation System

Catalog Number	Configuration	Qty	
0113230	30 Permanent Fasteners	5/case	☐
0113215	15 Permanent Fasteners	5/case	☐

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.

Purchase Order Number _____ Date _____

Catalog Number(s) _____ Quantity _____

Surgeon's Signature _____

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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