Hernia Fixation:

SecureStrap™*
Overview & Comparison
## Fixation Comparison

<table>
<thead>
<tr>
<th></th>
<th>Covidien</th>
<th>Ethicon</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type</strong></td>
<td>Permanent</td>
<td>Permanent</td>
</tr>
<tr>
<td><strong>Product</strong></td>
<td>ProTack™ Fixation Device</td>
<td>AbsorbaTack™ Fixation Device</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Material</strong></td>
<td>Titanium</td>
<td>PGLA</td>
</tr>
<tr>
<td><strong>Deployment</strong></td>
<td>Controlled Self-Tapping</td>
<td>Controlled Self-Tapping</td>
</tr>
<tr>
<td><strong>Protruding Mechanism/Sharp</strong></td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td><strong>Number of Tacks</strong></td>
<td>30</td>
<td>15,20,30</td>
</tr>
<tr>
<td><strong>Length (mm)</strong></td>
<td>3.3</td>
<td>5.1</td>
</tr>
<tr>
<td><strong>Retention Method</strong></td>
<td>Coil Threads</td>
<td>Screw Threads</td>
</tr>
<tr>
<td><strong>Able to Remove</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Shear Force</strong></td>
<td>1.76 kg¹</td>
<td>1.06 kg¹</td>
</tr>
<tr>
<td><strong>Strong fixation at any rotational orientation</strong></td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Codes</strong></td>
<td>174006</td>
<td>ABSTACK15 ABSTACK30 ABSTACK20S</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).²

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Expulsion Delivery Method

SecureStrap™:
- Spring-loaded mechanism\(^2\) pushes the strap into the tissue
- The strap leaves the shaft in excess of 4500 mm/s into air
- Protruding fork remains exposed if trigger is not cycled completely\(^\dagger\)

\(^\dagger\) Ethicon instructions for use requires the handle be squeezed completely and then released\(^2\)

ProTack™ and AbsorbaTack™ devices:
- No protruding mechanism repeatedly penetrating the tissue
- Only the tack enters the tissue by pulling itself in with the threads
Covidien tacks have a higher shear holding strength compared to Ethicon straps:

- **ProTack™** is 3X stronger than SecureStrap™* in bench top tests\(^1\)
- **AbsorbaTack™** is 80% stronger than SecureStrap™* in bench top tests\(^1\)
- Ethicon excludes ProTack™ from strength comparisons in marketing material\(^4\)

ProTack™ has a statistically significant difference in median holding strength in subcutaneous foam compared to SecureStrap™ (horizontal/vertical/warp/weft). (p<0.001)\(^1\)

AbsorbaTack™ has a statistically significant difference in median holding strength in subcutaneous foam compared to SecureStrap™ (horizontal and vertical) in the weft direction and SecureStrap™* (vertical) in the warp direction. (p<0.001)\(^1\)
Covidien tacks are more consistent than Ethicon straps in bench top tests:

- ProTack™ and AbsorbaTack™ deliver consistent holding force at any orientation\(^1\)
- SecureStrap™ holding force varies by 30% depending on rotational orientation\(^1\)

SecureStrap™* horizontal has a statistically significant difference in median holding strength in subcutaneous foam compared to SecureStrap™* (vertical). (p<0.001) \(^1\)

Ethicon marketing material: Two points of fixation and mid-plane symmetry required that [SecureStrap™*] data be collected horizontally and vertically\(^4\)

AbsorbaTack™ and Protack™: Single axis of fixation and axial symmetry has no horizontal or vertical orientation
## Fixating at Various Approach Angles

<table>
<thead>
<tr>
<th>Approach Angle:</th>
<th>90°</th>
<th>60°</th>
<th>45°</th>
<th>30°</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tack Entry Angle:</td>
<td>90°</td>
<td>90°</td>
<td>90°</td>
<td>90°</td>
</tr>
</tbody>
</table>

Indicative of results obtained when following respective IFUs

**• AbsorbaTack™ engages fully at various approach angles**  
**• SecureStrap™ engagement depends on strap orientation**

**AbsorbaTack™:** The IFU recommends that the distal tip of the shaft be at a right angle to the target tissue which is accomplished through appropriate force and counter pressure. As a result, the single axis tack design penetrates the material perpendicular to the surface at various approach angles.

**SecureStrap™:** The IFU does not require the distal tip of the shaft to be at a right angle to the tissue nor does it suggest rotational alignment of the strap relative to the angle of approach. As a result, the two prong strap design may not always penetrate the material perpendicular to the surface at various approach angles which may leave one barb exposed or only partially engaged.

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Fixating in Inguinal Hernia Repairs

Cooper’s ligament is 2-3 mm thick with a max observed thickness of 4mm

Recommended Tissue Thickness:
- SecureStrap™* 6.7 mm²
- AbsorbaTack™ 4.2 mm
- ProTack™ 4 mm

Dimensionally, AbsorbaTack™ & ProTack™ can fully engage in Cooper’s ligament whereas SecureStrap™* is too long to fully engage in Cooper’s ligament

Ethicon SecureStrap™* IFU
Warnings: The total distance from the surface of the tissue to the underlying bone, vessels, or viscera should be evaluated prior to application and should be a minimum of 6.7 mm.²
Precautions: Care should be taken in the application of external counter-pressure to avoid tissue compression between the end of the device and the location of counter-pressure of less than 6.7 mm.²
Contraindications: If the total distance from the surface of the tissue to the underlying structure is less than the minimum tissue thickness, or may be comprised to a total distance less than the minimum tissue thickness, use of the device is contraindicated.²

AbsorbaTack™ IFU Warnings & Precautions: A minimum of 4.2 mm thickness of tissue over underlying bone, vessels, or viscera is needed for full engagement of the tack.
ProTack™ IFU Contraindications: A minimum of 4 mm thickness of tissue over underlying bone, vessels, or viscera.
# Fixation Comparison Summary

<table>
<thead>
<tr>
<th>Feature</th>
<th>Covidien</th>
<th>Ethicon</th>
</tr>
</thead>
<tbody>
<tr>
<td>More complete fixation offering</td>
<td>✓</td>
<td>x</td>
</tr>
<tr>
<td>Permanent &amp; Absorbable, Short, 15s</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>No sharps/protruding deployment mechanism</td>
<td>✓</td>
<td>x</td>
</tr>
<tr>
<td>More value per device</td>
<td>✓</td>
<td>x</td>
</tr>
<tr>
<td>20% more tacks per device†</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Able to remove tack²</td>
<td>✓</td>
<td>x</td>
</tr>
<tr>
<td>Higher shear force¹</td>
<td>✓</td>
<td>x</td>
</tr>
<tr>
<td>Strong fixation regardless of orientation¹</td>
<td>✓</td>
<td>x</td>
</tr>
<tr>
<td>Dimensional compatibility with Cooper’s ligament¹</td>
<td>✓</td>
<td>x</td>
</tr>
<tr>
<td>Full engagement at various approach angles</td>
<td>✓</td>
<td>x</td>
</tr>
<tr>
<td>With appropriate counter pressure</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Strong and consistent fixation requires a Covidien tack not a strap**¹

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† ABSTACK30 compared to STRAP25

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Shear Holding Strength in Subcutaneous Foam\textsuperscript{1}

\begin{table}
\centering
\begin{tabular}{|l|c|c|c|}
\hline
          & Warp & Weft & Average of Warp & Weft \\
\hline
ProTack™  & 2.13 & 1.76 & 1.945          \\
AbsorbaTack™ & 0.88 & 1.06 & 0.97           \\
SecureStrap™* Average & 0.73 & 0.68 & 0.705          \\
SecureStrap™* Horizontal & 0.88 & 0.77 & 0.825          \\
SecureStrap™* Vertical & 0.58 & 0.59 & 0.585          \\
\hline
\end{tabular}
\end{table}
References


2. Ethicon SecureStrap™* Instructions for Use


4. Ethicon SecureStrap™ Marketing Material
