STERNAL ZIPFIX® SYSTEM

For fast and stable fixation of the sternum
Flexible and easy to handle

Excellent closure strength and stability

Biocompatible, PEEK

MR Safe as implanted**

The Sternal ZIPFIX System enables fast sternal closure with consistent tension along a sternotomy or fracture of the sternum.

The system primarily consists of PEEK (polyetheretherketone) implants and an application instrument.

* Mechanical test data on file at DePuy Synthes. Mechanical test results may not necessarily be indicative of clinical performance.

**Please refer to device insert for full instructions.
Construct strength comparison*

Dynamic Test¹

Maximum load to reach 500,000 cycles (more than 3 weeks of healing†).

ZIPFIX construct demonstrates a higher resistance to fatigue failure compared to stainless steel wire.

Fatigue load*

Dynamic Test²

ZIPFIX survives:
- Over 1 million cycles (more than 6 weeks of bone healing†)
- A higher number of loading cycles than stainless steel wires

Cut-through test*

Yield load in “poor-quality bone” until cut-through.*

ZIPFIX provides increased resistance to implant cut-through in the sternum compared to stainless steel wire.

ZIPFIX has larger implant-to-bone contact area compared to stainless steel wire to reduce risk of bone cut-through.

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¹ Constructs loaded cyclically in tension in lateral direction. All tests were performed on stainless steel pins to simulate the sternum.
² Implant loaded cyclically in tension in lateral direction. All tests were performed in polyoxymethylene (copolymer) blocks to simulate the sternum.
† The estimate for the amount of cycles at 300N represents fracture healing based on 14.1 breaths per minute. 300N represents the maximum load on a single implant during an aggressive cough.


* Mechanical test data on file at Synthes. Mechanical test results may not necessarily be indicative of clinical performance.
Indications

The DePuy Synthes Sternal ZIPFIX® System is intended for primary or secondary closure/repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion.

Please refer to package insert for the full list of contraindications, warnings, precautions, and/or possible adverse events.

Product Information

<table>
<thead>
<tr>
<th>Sternal ZIPFIX Implants</th>
<th>Sternal ZIPFIX Instrument Set (01.501.006)</th>
</tr>
</thead>
<tbody>
<tr>
<td>08.501.001.01S</td>
<td>68.501.001 Sternal ZIPFIX, with Needle, sterile</td>
</tr>
<tr>
<td>08.501.001.05S</td>
<td>03.501.080 Sternal ZIPFIX, with Needle, sterile 5-pack</td>
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<td>08.501.001.20S</td>
<td>398.903 Sternal ZIPFIX, with Needle, sterile, 20 pack</td>
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Limited Warranty and Disclaimer: DePuy Synthes CMF products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

Not all products are currently available in all markets.

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