Executive Summary

Unmet Need

- Midline sternotomy provides optimal access to the heart and lungs, making it the preferred technique for performing surgeries such as coronary artery bypass graft (CABG), valve repair, open heart, and the repair of trauma-induced sternal fracture. However, sternotomy patients may experience wound healing complications, including sternal instability, wound infections, and mediastinitis (inflammation of the tissues in the mid-chest) that can result in severe morbidity.

- The current standard for sternal closure remains circlage wire fixation. However, circlage wire fixation of midline sternotomy under normal physiologic loads can be inadequate and lead to sternal separation. Bacterial contamination in the face of sternal separation and instability can then progress to deep sternal wound infection (DSWI) and mediastinitis. The merits of increased sternal stability and decreased incidence of non-union, mal-union, and infection have led to paradigm shifts away from wire fixation.

- Alternative techniques to traditional wiring may reduce the incidence of post-operative complications, such as DSWI, sternal instability, and sternal dehiscence.

- The Sternal ZIPFIX® System is a cable tie system and an alternative to steel wire fixation. Using a peri-sternal suturing technique, the Sternal ZIPFIX System allows for a fast sternal closure. The Sternal ZIPFIX System is wider than wire, spreading distraction forces over a larger contact area for closure stability. Additionally, each Sternal ZIPFIX System implant can be secured with consistent tension along the length of the sternum by using the Sternal ZIPFIX System Application Instrument.

Clinical Evidence Supporting STERNAL ZIPFIX System

- A retrospective study comparing patients who received wires (n=548) or the Sternal ZIPFIX System (n=238) and underwent cardiac surgery with midline sternotomy showed that, although the proportion of patients with body mass index (BMI) > 30 kg/m² and diabetes was significantly higher in the Sternal ZIPFIX System group, no significant between-group differences were observed in DSWI occurrence. However, DSWI was more likely to necessitate surgical debridement in patients in the wire group (4 out of 5 cases) than the Sternal ZIPFIX System group (2 out of 6 cases).

- A retrospective study comparing 95 patients closed with the Sternal ZIPFIX System vs 498 closed with conventional wires was conducted. At the time Sternal ZIPFIX System was introduced at the authors’ institution, there was an increase in the infection rate, which prompted the authors to research whether infections were related to the device.

- Total infection rate was 6.1% over the 12 months including both superficial wound infections and deep sternal infections, (5 in the Sternal ZIPFIX System group and 31 in the conventional wire group). The use of Sternal ZIPFIX System did not show significant influence on ‘overall’ infection (odds ratio: 0.067, confidence interval: 0.04–9.16, P = 0.72). In addition, investigators found no sternal instability in the Sternal ZIPFIX System group and 4 patients with sternal instability in the conventional wire group.

- In two observational studies, researchers concluded that the Sternal ZIPFIX System was safe and easy to use and suitable for patients at high risk for sternal wound complications.

- Klotz et al described their experience using the Sternal ZIPFIX System in 16 severely obese patients (BMI >33 kg/m²) who underwent CABG or valve surgery. Wound dehiscence occurred in 2 patients; both required vacuum assisted closure-therapy. Researchers did not observe sternal instability in any patients. The investigators concluded that the Sternal ZIPFIX System is a fast and easy closure technique, does not extend procedure time, and facilitates a secure sternal closure in severely obese patients.
Biomechanical Evaluations of the Sternal ZIPFIX System

The Sternal ZIPFIX System provides higher construct strength and resistance to fatigue failure than a USP 5 single wire.\textsuperscript{12}

Mechanical tests comparing the Sternal ZIPFIX System’s resistance to cut-through to that of stainless steel wires showed that the Sternal ZIPFIX System can resist a greater load before cut-through occurs.\textsuperscript{13,14*}

Economic Implications of Sternal Closure and Complications

Economic analyses have demonstrated that sternal wound complications have a substantial effect on both healthcare costs and hospital length of stay (LOS), with costs almost tripling and LOS increasing anywhere from 1.5 times to almost tripling.\textsuperscript{15,16}

Reimbursement and Quality Implications

- In October 2008, Centers for Medicare and Medicaid Services (CMS), expanded the list of hospital-acquired conditions and now includes surgical site infections and mediastinitis acquired during an inpatient stay following a CABG procedure.\textsuperscript{17} This secondary diagnosis has Medicare and Medicaid payment implications, specifically, these secondary diagnoses are not eligible for additional payment; CMS reimbursement will only cover the primary diagnosis.\textsuperscript{18}

- The National Quality Forum (NQF) has endorsed the risk-adjusted DSWI rate (NQF#0130) as a quality performance measure for patients aged ≥18 years who have undergone CABG and who develop DSWI requiring intervention within 30 postoperative days.\textsuperscript{19} This measure is in use by the U.S. Physician Quality Reporting System (PQRS, measure #165). Physicians who do not participate in the PQRS, or who are unsuccessful in achieving its quality measures, will receive a 2% payment penalty on covered services.\textsuperscript{20} Additionally, data on these events will be publicly reported.\textsuperscript{20}

Potential Cost Savings with Sternal ZIPFIX System

Placing DSWI cost outcomes from LaPar et al in the context of the studies conducted by Stelly et al (2015),\textsuperscript{1,16} shows:

- Compared to wire suture, the use of the Sternal ZIPFIX System could result in a potential cost savings of nearly $450,000 over a 4-year period at a single hospital site.\textsuperscript{1,16}

Introduction and Methods

This value analysis brief summarizes the options for reinforced sternal closure and evaluates the Sternal ZIPFIX System as a reinforced sternal closure device. A Medline search of peer-reviewed studies published between January 2000 through March 2016 that address clinical, economic and biomechanical outcomes associated with sternal fixation after sternotomy using wires, bands and plates was conducted. Conference abstracts from major cardiothoracic organizations were also searched between January 2006 through March 2016. Additional peer-reviewed studies were obtained from citation lists of qualifying studies. Case studies were excluded from review.

* Mechanical test results may not be indicative of clinical performance.
Background

Midline sternotomy provides optimal access to and exposure of the vital organs (heart and lungs), making it the preferred technique for performing surgeries such as CABG, valve repair, open heart, and the repair of trauma-induced sternal fracture. However, sternotomy patients may experience wound healing complications, including sternal instability, wound infections, and mediastinitis (inflammation of the tissues in the mid-chest, or mediastinum) that can result in severe morbidity.

Sternal instability is defined as abnormal breastbone mobility due to fracture, sternocostal separation, or suture disruption of a surgically divided sternum. Sternal instability can result in wound dehiscence – the rupture or splitting of a wound closure – if it occurs within 2 weeks of surgery, as well as late post-operative non-union at approximately 6 weeks. Sternal instability has been associated with complications such as DSWI and mediastinitis.

The incidence of sternal infections following cardiac surgery ranges from 0.5% to 6.4%, and mediastinitis incidence ranges from 1.0% to 2.0%. Mortality rates in patients with sternal wound complications can be high. Mortality due to mediastinitis ranges from 14% to as high as 47%, while mortality due to DSWI ranges from 19% to 29%.

• These complications are more pronounced in patients with multiple comorbid conditions, such as elevated BMI, diabetes, advanced age, and chronic obstructive pulmonary disease (COPD), and can lead to reoperation and increased LOS and mortality.

• Surgeons (N=66) surveyed by a DePuy Synthes Companies-sponsored market research study cited diabetes (73% of surgeons), obesity (71% of surgeons), and age (68% of surgeons) as key risk factors, estimating that the great majority of their open-heart surgery patients (between 70%–77% of patients, depending on the country) are rated as medium or high-risk patients.

• These complications are expected to increase as population aging accelerates and the prevalence of comorbid conditions rises.

Lack of sternal wound closure stability can increase the incidence of complications including dehiscence, infection, mediastinitis, and non-union.
These complications carry a substantial cost burden. For example, the median charge for patients with wound complications was $58,092 (range $16,966 to $408,632), which was 2.8 times the charge for patients with uncomplicated cases.\(^{15}\)

As midline sternotomy remains the preferred method for cardiac surgeries,\(^{1,2}\) and since complications from sternal closure have a considerable effect on both patient health and hospital costs,\(^{3}\) developing more effective sternal closure methods that further reduce the rate of complications is important to improve patient outcomes and reduce costs.

**Unmet Need**

The current standard for sternal closure remains circlage wire fixation, although cardiac surgeons are the only surgeons who continue to use wire-circlage for bone fixations.\(^{5}\) However, circlage fixation of midline sternotomy under normal physiologic loads can be inadequate and lead to sternal separation. Bacterial contamination in the face of sternal separation and instability can then progress to DSWI and mediastinitis.\(^{5}\)

The merits of increased stability and decreased incidence of non-union, mal-union, and infection have led to paradigm shifts away from wire fixation. By affording greater stability and promoting primary sternal healing, the effective rigid osteosynthesis of the sternum may prevent poststernotomy mediastinitis. Alternative techniques to traditional wiring may reduce the incidence of post-operative complications, such as DSWI, sternal instability, and sternal dehiscence.\(^{5}\)

**Sternal complications such as deep sternal wound infection and mediastinitis cause substantial patient morbidity and place a significant cost burden on hospitals.**\(^{3}\)

**Disadvantages Associated with Trans-sternal Surgical Wires**

To ensure that sternal halves are held together during the healing process following sternotomy, closure typically involves the placement of 5 or more trans-sternal surgical wires approximately 1 cm across each side.\(^{31,32}\)

While stainless steel wires can achieve a good approximation of the sternal halves, they may lack the strength to maintain the two halves in rigid apposition. The wires are placed under significant load during upper limb movement, deep breathing, and coughing, which can lead to displacement and instability.\(^{21}\) Additionally, due to the small surface area of sternal wire, peak loads are focused at concentrated points on the sternum.\(^{33}\) Last, sternal wires are hand-tightened, making it difficult to apply the same amount of tension to each wire. This may result in an uneven load distribution across the length of the sternum.
This leads to the risk of wire cutting into or through the sternum (Figure 1), especially in patients with poor bone quality. If the wires cut into or through the sternum, they may loosen and cause the sternal halves to separate due to the respiratory motion of the chest wall. The loose wires may then cut the sternum into segments. Cut-through can lead to sternal pain or sternal dehiscence, which can lead to complete sternal breakdown, sternal wound infection and mediastinitis.

Traditional closure techniques with stainless steel wires may be limited by insufficient mechanical strength, as well as the risk of wire sutures cutting through the sternum, resulting in construct failure.

The Importance of Maintaining Post-operative Sternal Stability
The goal of reinforced closure is to provide sternal stability by immobilizing the sternal halves during healing while reducing the risk of implant cut-through or fragmentation. Sternal closure stability can be achieved by ensuring that forces are evenly distributed across the sternum by providing higher implant-to-bone contact area and that the sternal halves are rigidly secured and accurately approximated. This reduces the risk of implant cut-through.
• A biomechanical analysis by Krejca et al suggested that, for patients with weaker bone quality, sternal closure techniques that allow for lower peak loads across the sternum should be used to reduce the risk of implant cut-through.33
• Biomechanical reinforcement across the sternum ensures immobility and increases sternal stiffness. This increased stiffness enables the sternum to withstand higher forces and loads, thus improving sternal stability.37
• Poor approximation of the sternal halves can result in increased wound pain.38 Uniform distribution of forces should be achieved without sacrificing closure strength or approximation.33

Figure 2. Importance of Maintaining Sternal Stability During Post-sternotomy Healing23,24,39-41
The Sternal ZIPFIX System

The Sternal ZIPFIX System enables fast sternal closure with consistent tension along a sternotomy of the sternum. The system is flexible, easy to handle and designed for closure strength and stability.

Use 5 ZIPFIX to achieve stable fixation in a full midline sternotomy. ZIPFIX can be used with plates and/or wires or where ZIPFIX insertion is inhibited by patient anatomy. For further information on indications and contraindications please see Sternal ZIPFIX System surgical technique.

Figure 3. A Sternal ZIPFIX System Cable Tie

Figure 4. The Sternal ZIPFIX System
The Sternal ZIPFIX System is made of polyetheretherketone (PEEK), with an attached and removable stainless steel application needle. PEEK provides implant flexibility with mechanical strength and biocompatibility. With an integrated, tension-limiting feature, the Sternal ZIPFIX System Application Instrument allows for consistent tensioning of each Sternal ZIPFIX System implant along the length of the sternum (Figure 5). As a multi-function tool, the Sternal ZIPFIX System Application Instrument allows trimming of the Sternal ZIPFIX System implant after tensioning is complete. As shown in Figure 6, the Sternal ZIPFIX System is over four times wider than single wire and twice as wide as double wires (Sternal ZIPFIX System’s implant body width is 4.2 mm compared to the 0.7-0.9 mm diameter of a single wire), and spreads forces over a larger contact area and a larger implant-bone contact area compared with wires. This may reduce the risk of bone damage. Additionally, the Sternal ZIPFIX System has rounded edges that may reduce soft tissue irritation, and its PEEK material can be cut easily in case of an emergency. Sternal ZIPFIX System bands can be used alone or in conjunction with traditional steel wire closures or other fixation systems.
The Sternal ZIPFIX System is not detectable with x-ray imaging, but can be easily observed via computed tomography scans and other digital imaging techniques (Figure 7).43

Figure 7. Images of Wire Sutures Reinforced with the Sternal ZIPFIX System: Figure 7A, X-ray; Figure 7B, Computed Tomography

Images obtained from Elenbaas43
Clinical Studies Evaluating the Sternal ZIPFIX System

Several studies, summarized below, have demonstrated that the Sternal ZIPFIX System compares favorably to conventional wire as a method of sternal closure following sternotomy. Patients receiving the Sternal ZIPFIX System – including those at high risk for complications – show similar or improved complication rates compared with patients undergoing traditional sternal closure with stainless steel wire.\textsuperscript{1,7,8}

Deep Sternal Wound Infection (DSWI)

- In a retrospective chart review, Stelly et al (2015)\textsuperscript{1} compared DSWI outcomes in patients who received cardiothoracic procedures requiring primary or repeat midline sternotomy. Data were reported for 609 patients: 309 received wire suture closure and 300 received the Sternal ZIPFIX System cable-tie system closure in conjunction with wire sutures. Study patients who received the Sternal ZIPFIX system had higher rates of risk factors for DSWI, such as peripheral vascular disease (58 vs. 34, \textit{P}=0.004).
- No patients in the Sternal ZIPFIX System group (0/300) experienced DSWI during study follow-up; in the group that received stainless-steel wire sutures, 8 of 309 patients experienced DSWI (0\% vs 2.6\%, \textit{P}=0.008).\textsuperscript{1}
- The authors concluded that the Sternal ZIPFIX System, used in conjunction with wire sutures, is a simple and reliable system for closure following midline sternotomy, and suggested that the use of Sternal ZIPFIX System may reduce DSWI risk compared to stainless steel wire sutures.\textsuperscript{1}

No patients in the Sternal ZIPFIX System group (0/300) experienced deep sternal wound infections compared with 8 of 309 patients in the stainless-steel wire suture group (0\% vs 2.6\%, \textit{P}=0.008) (Figure 8).\textsuperscript{1}
Percentage of patients with DSWI

Wire Suture Group (n=309)
Sternal ZIPFIX System Group (n=300)

<table>
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<th>1%</th>
<th>1.5%</th>
<th>2%</th>
<th>2.5%</th>
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<tbody>
<tr>
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Figure B. Percentage of Patients with DSWI After Sternal Closure with Wire Suture (n=309) or the Sternal ZIPFIX Cable-tie System used with Wire Sutures (n=300).

- Lage et al (2014) retrospectively reviewed data on patients who underwent cardiac surgery with midline sternotomy. For sternal closure, 948 patients received wires and 238 received the Sternal ZIPFIX System.
- The proportion of patients with BMI >30 kg/m² was significantly higher in the Sternal ZIPFIX System group (27% in the wire group and 66% in the Sternal ZIPFIX System group), and diabetes prevalence was 21% in the wire group and 36% in the Sternal ZIPFIX System group (P<0.001). Other baseline demographics were similar between the groups.
- No significant between-group differences were observed in DSWI occurrence, although DSWI was more likely to necessitate surgical debridement in patients in the wire group (4 out of 5 cases) than the Sternal ZIPFIX System group (2 out of 6 cases).
- Sternal dehiscence occurred in 3 patients in the wire group, necessitating re-operation, but did not occur in any patients in the Sternal ZIPFIX System group.
- Researchers concluded that the use of Sternal ZIPFIX System used in conjunction with wire sutures in high-risk patients resulted in outcomes comparable to that of the use of wires in low-risk patients.

Use of Sternal ZIPFIX System in high-risk patients resulted in outcomes comparable to wire use in low-risk patients.
• Melly et al (2013) conducted a retrospective non-inferiority study comparing 95 patients closed with the Sternal ZIPFIX System vs 498 closed with conventional wires. At the time the Sternal ZIPFIX System was introduced at the authors’ institution, there was an increase in the infection rate, which prompted the authors to research whether infections were related to the device. The investigators found no significant difference in DSWI rates between the groups, with 5 (5%) of the Sternal ZIPFIX System patients and 20 (4%) of the wire-closure patients cl having DSWI infections (P=0.58).

• Total infection rate was 6.1% over the 12 months including both superficial wound infections and deep sternal infections, with a total of 36 diagnosed sternal infections (5 in the Sternal ZIPFIX System group and 31 in the conventional wire group). The use of Sternal ZIPFIX System did not show significant influence on ‘overall’ infection (odds ratio: 0.067, confidence interval: 0.04–9.16, P = 0.72).

Sternal Stability and Sternal Dehiscence

In the study by Lage et al (2014) described above, sternal dehiscence occurred in 3 patients in the wire group (n=548), necessitating re-operation, but did not occur in any Sternal ZIPFIX System patients (n=235).

Melly et al (2013) conducted a retrospective descriptive and comparative study of 95 Sternal ZIPFIX System patients and 498 conventional wire patients. They found no sternal instability in the Sternal ZIPFIX System group and 4 patients with sternal instability in the conventional wire group.

Petzina et al (2012) described their experience using the Sternal ZIPFIX System for primary sternal closure in 20 consecutive patients who were operated on for CABG or CABG with aortic valve replacement. Mean patient age was 78 and 70.5 years for females and males, respectively, while mean BMI was 28.5 kg/m² for females and 28.7 kg/m² for males. All primary sternal closures using the Sternal ZIPFIX System were successful; 11 patients received Sternal ZIPFIX System alone, while 9 patients also received steel wires. The researchers concluded that the Sternal ZIPFIX System was a safe and easy to use sternal closure system, suitable for patients at high risk for sternal wound complications.

Zielezinski et al (2012) described their experience using the Sternal ZIPFIX System in 31 patients for primary sternal fixation following mid-sternotomy for cardiac surgery, with the goal of reducing sternal dehiscence. Mean patient age was 68 years, with 40% of the sample older than 75 years. Patients had substantial comorbidities: 37% had diabetes and 30% had COPD; additionally, 87% of patients were obese (defined by investigators as BMI >25 kg/m²) and 13% had malignant obesity (BMI >40kg/m²). In this study, secondary wound dehiscence occurred in 2 patients, both due to marginal transection of the sternum. The researchers concluded that the use of Sternal ZIPFIX System may reduce the incidence of sternal dehiscence after mid sternotomy in high-risk patients.
The Sternal ZIPFIX System In High-risk Patients

Patients with multiple comorbid conditions, such as elevated BMI, diabetes, advanced age, and COPD, are at higher risk for experiencing sternal wound complications. The prevalence of these conditions is increasing worldwide, emphasizing the importance of sternal fixation methods that can be safely and effectively used in these populations. Findings from multiple studies suggest that the Sternal ZIPFIX System may benefit high-risk midline sternotomy patients.

Studies by Stelly et al (2015), Lage et al (2014), Petzina et al (2012), and Zielezinski et al (2012), described previously, and Klotz et al (2013) included high-risk patients who received the Sternal ZIPFIX System. Results from these studies showed that use of the Sternal ZIPFIX System in high-risk patients was comparable to that of use of wires in low-risk patients: high-risk patients receiving the Sternal ZIPFIX System experienced no DSWI compared to wire patients with lower rates of risk factors, or similar rates of complications were observed between the two groups. Petzina (2012) and Zielezinski (2012) also concluded that the Sternal ZIPFIX System was suitable to use in high-risk patients.

Findings from multiple studies suggest that the Sternal ZIPFIX System may benefit high-risk midline sternotomy patients.
Patients who received the Sternal ZIPFIX System had a significantly higher baseline prevalence of obesity (66% vs 27%) and diabetes (36% vs 21%) compared to wire closure patients. Despite this, Sternal ZIPFIX System in high-risk patients resulted in outcomes comparable to that of the use of wires in low-risk patients.\(^7\)

• Stelly et al reported that patients who received the Sternal ZIPFIX System had higher rates of risk factors for DSWI (including peripheral vascular disease, diabetes, and COPD). However, no Sternal ZIPFIX System patients (0%) experienced DSWI, whereas 8 wire suture group patients (2.6%) had DSWI complications.\(^1\)

• Lage et al (2014) found that, despite having a higher rate of patients with BMI >30 kg/m\(^2\) and diabetes in the Sternal ZIPFIX System group compared to wire closure patients, rates of postoperative complications were similar (4%) in both groups. The authors concluded that the use of Sternal ZIPFIX System in high-risk patients resulted in outcomes comparable to that of the use of wires in low-risk patients.\(^7\)

• Both Petzina et al (2012) and Zielinszki et al (2012) concluded that the Sternal ZIPFIX system was suitable for use in patients at high risk for sternal wound complications.\(^9,10\)

• Klotz et al (2013) described their experience using the Sternal ZIPFIX System in 16 severely obese patients (BMI >33 kg/m\(^2\)) who underwent CABG or valve surgery. A majority of the sample had risk factors for complications, including diabetes (69%) and being an active smoker (56%). Investigators reported that the time required to use the Sternal ZIPFIX System was similar to conventional wire sternal closure. For the 16 patients receiving the Sternal ZIPFIX System, the average intensive care unit stay was 2.1 days. Wound dehiscence occurred in 2 patients, both requiring vacuum assisted closure-therapy. Researchers did not observe sternal instability in any patients. They concluded that the Sternal ZIPFIX System is a fast and easy closure technique, does not extend procedure time, and facilitates a secure sternal closure in severely obese patients.\(^11\)
Biomechanical Evaluations Performed by DePuy Synthes

Biomechanical evaluations also demonstrate that the Sternal ZIPFIX System provides higher resistance to fatigue failure than a USP 5 single wire and construct strength. Mechanical tests comparing the Sternal ZIPFIX System’s resistance to cut-through to that of stainless steel wires showed that the Sternal ZIPFIX System can resist a greater load before cut-through occurs. In a market research survey conducted by DePuy Synthes Companies, 56% (37/66) of surgeons cited less wire breakage and 50% (33/66) cited less cut-through as the top unmet needs related to wire closure.

Fatigue Failure

In a biomechanical study using stainless steel pins to simulate the sternum, the strength of the Sternal ZIPFIX System (5 implants) was compared to a combination configuration (3 Sternal ZIPFIX System implants and 2 stainless steel wires) and a stainless steel wire construct (8 wires) by loading it cyclically in tension until failure. A maximum load to reach 500,000 cycles (>3 weeks of healing) was measured for each configuration.

- The Sternal ZIPFIX System construct had a higher resistance to fatigue failure, measured as yield load (N), compared to the combination configuration and the stainless steel wire construct (1500N, 800N, 350N, respectively; Figure 9).

* Mechanical test results may not be indicative of clinical performance.
Fatigue Load
Another biomechanical study compared the Sternal ZIPFIX System to a United States Pharmacopeia (USP) 5 single stainless steel wire and a USP 6 double stainless steel wire. Fatigue life was assessed, measured as the number of cycles survived by each construct at a fixed load.\textsuperscript{13,47}

- Under conditions that simulated maximal load during coughing (300N), the Sternal ZIPFIX System could withstand over 1 million cycles (equivalent to more than 6 weeks of bone healing).\textsuperscript{13,47}
- This was substantially higher than the single USP 5 stainless steel wire (148,071 cycles, equivalent to 7.3 days) and the USP 6 double stainless steel wire (321,701 cycles, 15.8 days; Figure 10).\textsuperscript{13,47}

The ZIPFIX has larger implant-to-bone contact area compared to stainless steel wire to reduce risk of bone cut-through\textsuperscript{6}.

Figure 10. Fatigue Load of Sternal ZIPFIX System vs Stainless Steel Wire (In Cycles Survived At 300N)\textsuperscript{13,47}

Mechanical test results may not be indicative of clinical performance.
Cut-Through
Another mechanical test used a model that simulated poor-quality bone to compare the resistance to cut-through of the Sternal ZIPFIX System implant to that of USP 5 Stainless Steel Wire and USP 6 Stainless Steel Double Wire.\textsuperscript{13,14}

• The mean yield load for the Sternal ZIPFIX System implant was significantly higher than the USP 5 Stainless Steel Wire or the USP 6 Stainless Steel Double Wire (184N ± 7.0, 52N ± 5.3, and 83N ± 7.8 respectively, $P<0.05$; Figure 11).\textsuperscript{13,14}

• This suggests that, compared to stainless steel wire, the Sternal ZIPFIX System can resist a greater load before bone cut-through occurs.\textsuperscript{13,14}

• This increased resistance may be attributable to a larger implant-to-bone interface due to the width of the Sternal ZIPFIX System – specifically, the load on the sternum at the implant-to-bone interface distributes over this larger area and reduces stress at the interface.\textsuperscript{13,14}

• Revision surgery is frequently necessary when cut-through occurs; reductions in reoperations may reduce the economic burden associated with sternal closure.\textsuperscript{48}

Figure 11. Implant Cut-through Yield Load (N) For the Sternal ZIPFIX System vs. Stainless Steel Wire\textsuperscript{13,14}

Mechanical test results may not be indicative of clinical performance.
Economic Evaluations of Sternal Closure and Complications

Reimbursement and Quality Implications
• The Inpatient Prospective Payment System FY 2009 final rule included sternal wound complications in the expanded list of hospital-acquired conditions. As of October 1, 2008 surgical site infections and mediastinitis acquired during an inpatient stay following a CABG procedures have Medicare and Medicaid payment implications. Specifically, these secondary diagnoses are not eligible for additional payment; CMS reimbursement will only cover the primary diagnosis.
• The National Quality Forum (NQF) has endorsed the risk-adjusted DSWI rate (NQF#0130) as a quality performance measure for patients aged ≥18 years who have undergone CABG and who develop DSWI requiring intervention within 30 postoperative days. This measure is in use by the U.S. PQRS (measure #165). Physicians who do not participate in the PQRS, or who are unsuccessful in achieving its quality measures, will receive a 2% payment penalty on covered services. Additionally, data on these events will be publicly reported.

Economic Implications
Cost analyses have demonstrated that sternal wound complications have a substantial effect on both healthcare costs and hospital LOS.
• In a study of 55 patients diagnosed with post-sternotomy DSWI between January 2009 and September 2012, Chan et al (2016) found that mean hospital stay was 54.2 days. This stay was significantly longer for patients with DSWI and secondary sternal wound infection (69 days versus 48 days for patients without secondary infection, P=0.04).
• A retrospective study (2000) compared costs for patients who underwent CABG and subsequently did or did not develop deep chest infections. Over the first year, patients who developed infections incurred an additional $20,000 in costs and 20 additional hospital days.
• In a cost analysis of 65,534 patients undergoing CABG, LaPar et al (2013) found that postoperative complications were significantly associated with increased hospital LOS and total hospital costs.
• Patients with CABG or CABG + aortic valve replacement (AVR) and no DSWI complications had a hospital LOS of 4 to 10 days.
• In patients with DSWI complications, hospital LOS ranged from 5 to 44 days. Costs for DSWI in CABG or CABG + AVR patients increased from $10,261 to $90,256.
• Incidence of any postoperative complication was correlated with adjusted incremental costs of approximately $15,000. Increased incremental costs associated with DSWI were $56,003.
Potential Cost Savings with Sternal ZIPFIX System

Placing these DSWI cost outcomes obtained from LaPar et al (2013)\textsuperscript{16} in the context of the study conducted by Stelly et al (2015),\textsuperscript{1} shows the potential for substantial cost savings with use of the Sternal ZIPFIX System compared to wire suture. In this study, 309 patients received wire suture closure and 300 received the Sternal ZIPFIX System in conjunction with wire sutures.

- No Sternal ZIPFIX System patients (0.0\%) experienced DSWI; 2.6\% of stainless-steel wire suture patients experienced DSWI.\textsuperscript{1}
- Compared to wire suture, use of the Sternal ZIPFIX System may result in a potential cost savings of nearly $450,000 over a 4-year period at a single hospital site.\textsuperscript{1,16}

Conclusion

Midline sternotomy is the preferred technique for many cardiac surgeries and for the repair of trauma-induced sternal fracture. Substantial data indicate that the Sternal ZIPFIX System provides improved construct strength and resistance to cut-through following sternotomy when compared to traditional wire. The Sternal ZIPFIX System spreads force over a greater contact area, which helps to maintain sternal stability. Sternal instability and cut-through have been demonstrated to increase the risk of post-sternotomy complications, such as DSWI and sternal dehiscence, which in turn result in increased mortality, hospital costs, and LOS. The Sternal ZIPFIX System performs as well as or better than traditional wire closures in reducing the risk of DSWI, sternal dehiscence, and sternal instability, and performs well in patients with comorbid conditions such as obesity, diabetes, and advanced age, who are at higher risk of sternal closure complications.
References


6. DePuy Synthes Sternal ZIPFIX System Surgical Technique (DSEM/CMF/0914/0039 09/14)


