

# Sternal Talon for sternal closure in cardiothoracic surgery

Medtech innovation briefing

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## Summary

- The **technology** described in this briefing is the Sternal Talon. It is a device used during surgery to close the sternum after procedures involving a sternotomy.
- The **innovative aspects** are that the talon does not need to be drilled or driven into the bone, holds more securely than wires and can be left in place indefinitely in patients who do not need reoperation. This may allow the patient to return to normal activities sooner.
- The **intended place in therapy** would be as a sternal closure device in people who have had cardiothoracic surgery.
- The **key points from the evidence** summarised in this briefing are from 5 studies (n=233 patients in total), comprising 1 randomised controlled trial and 4 case series. The randomised trial suggested that using Sternal Talon may lead to better outcomes than wire closure, but this was not statistically significant. The case series indicated that Sternal Talon is a safe and effective device in high-risk patients, with a low rate of major complications.
- **Key uncertainties around the technology** are that there is currently very little comparative evidence available.
- The **cost** of Sternal Talon ranges from £479.28 to £689.84 (exclusive of VAT). Commonly 3 Sternal Talons are used per patient, costing from £1,437.84 to £2,069.52. The cost of sternal closure using standard steel wires ranges from £13.06 to £14.42. The **resource impact** would be almost identical to standard care, aside from the cost of the technology.

## The technology

The Sternal Talon (KLS Martin Group) is a rigid fixation device for closing the sternum, or breastbone. It is made of biocompatible titanium alloy and is available in 2 variations: a single talon, which has a single foot plate to sit on each side of the sternum, and a double talon, which has 2 foot plates on each side. The single and double talons come in a range of widths and depths. Each talon is supplied in 2 parts which are inserted separately and a screw and ratchet mechanism is used to connect them.

After choosing the appropriately sized Sternal Talon devices, the surgeon exposes the rib-sternum connection and makes cuts in the intercostal spaces. The feet of the talons do not penetrate the bone, but are hooked over each side of the open sternum into the cuts between paired intercostal spaces. Once in place, the screw is loosened to release the ratchet mechanism and the 2 halves of the talon are then pushed together to the desired width for closing the sternum using a reduction clamp. The screw is then tightened to lock the ratchet mechanism and hold the talon rigid. It can be loosened to unlock the 2 parts if removal or realignment is necessary. Care should be taken to ensure there is proper bone alignment.

Between 1 and 5 Sternal Talons are needed to close a sternum, depending on the patient. Any combination of single or double devices may be used, as deemed appropriate by the clinician. The Sternal Talon devices can be left in place indefinitely, barring any complications or reoperations. Sternal plates or wires can be used to further stabilise the sternum if needed.

Sternal Talons are marked with a 'safe zone' to indicate proper positioning; if the arrow on one foot does not fall in the safe zone of its paired foot, a more appropriately sized device should be used. Surgeons using the device should be careful not to injure the intercostal vessels; if this happens, the Sternal Talons should be removed and the vessel repaired.

Sternal Talon's [instructions for use](#) describe the procedure for emergency removal. Sternal Talons can be removed for emergency re-entry in several ways:

- Turning the screw anticlockwise to the 7 o'clock, open position.
- Cutting the device at the cut points.
- Inserting a flat screwdriver (or similar instrument) into the lock mechanism and manually disengaging the ratchet teeth.

## *The innovation*

Unlike standard care, Sternal Talons do not need to be drilled into the bone. This means that insertion has the potential to be faster than standard practice, because the device hooks over the sternum and has a simple locking mechanism. The Sternal Talon may be more stable than standard wire closure, because it spreads the pressure load across the sternum. This may allow patients to return to normal activities sooner without disrupting sternal healing.

## *Current NHS pathway*

Median sternotomy is a surgical procedure which involves cutting vertically along the length of the sternum, and then opening the sternum by sawing vertically using a reciprocating or oscillating saw. [NHS HES data 2014-15](#) shows that there were 76,307 cardiothoracic procedures, many of which needed median sternotomy and subsequent closure post-procedure. Median sternotomy provides access to the heart, lungs and surrounding structures for other procedures including coronary artery bypass surgery, heart valve replacement and lung volume reduction. After a sternotomy the sternum must be realigned and closed. Sternal closure may also be needed following sternal fractures and sternal reconstruction procedures.

Sternal closure is typically achieved using steel wires to hold the bones in place. The wires are passed through or around each sternal half and then twisted together in front of the sternum, pulling and securing them into position. Different thicknesses of wires and different techniques may be used.

Alternatives to wire closure include metal clips stapled in between each rib, bioabsorbable cords to tie the sternum together (typically used in children) and metal cables or plates that must be screwed directly into the bone.

A repeat sternotomy may be needed in patients who need further cardiothoracic surgery, or in patients who have complications after their original procedure.

Complications of median sternotomy include sternal nonunion (when the sternum fails to fuse back together), malunion (when the sternum fuses in a misaligned state), and sternal dehiscence (when the sternum becomes fully separated). The latter of these is often accompanied by mediastinitis, a serious infection of the deep soft tissues. Wound infection is also possible.

## *Population, setting and intended user*

The Sternal Talon is designed to be used in the tertiary-care inpatient setting. It is intended to be used only by suitably qualified surgeons who are experienced in carrying out sternal closure procedures.

The device is indicated for use in most patients having cardiothoracic procedures, although some patients' anatomies may preclude its use. It may be most suitable for people at higher risk of complications such as those with chronic obstructive pulmonary disease, obesity, diabetes and failed primary sternal wire closure.

The manufacturer states that the final decision on patient suitability remains with the surgeon. It is the clinician's responsibility to determine and choose the most appropriate size and configuration of devices.

The device is contraindicated in the following circumstances:

- active or latent infection
- insufficient quantity or quality of bone
- sternal anomalies preventing correct fitting
- severe osteoporosis
- foreign body sensitivity
- allergy or suspected sensitivity to the implant materials
- inflammation in the implant region
- bone tumours in the implant region
- patients who are still growing.

Additional relative contraindications are:

- osteoporosis, osteomalacia or other severe structural bone damage
- parasternal sternotomy with very low sternal width on 1 side

- patients with mental or neurological conditions who are unwilling or unable to follow appropriate postoperative care instructions
- reduced compliance because of drug or alcohol misuse.

Sternal Talon devices should not be bent or modified in any way.

## Costs

### Device costs

Sternal Talon costs between £479.28 and £586.79 for the single-talon version and between £636.07 and £689.84 for the double-talon version, depending on size (excluding VAT).

It should be noted that although Sternal Talon can be used in place of wires, sometimes these wires are used in addition to Sternal Talon for extra stability. Table 1 contains prices based upon the most common configurations of the Sternal Talon device, as used in the studies reported in this briefing. One study ([Levin 2010](#)) specified a configuration using 1 single-talon device and 2 double-talon devices. This cost is presented with and without additional wires, because both are mentioned in the study. Typically, 3 Sternal Talons are used per sternal closure.

Costs are presented as a range, from using all of the smallest to all of the largest devices respectively. Prices in the table were provided by specialist commentators, and this was the lowest cost to add support wires.

**Table 1: Cost of sternal closure using various Sternal Talon configurations**

Description	Cost (min/ max)	Additional information
3 single Sternal Talons	£1,437.84 to £1,760.37	Included studies present 3 Sternal Talons as the most common configuration (60% to 80% of procedures).
3 double Sternal Talons	£1,908.21 to £2,069.52	
2 double Sternal Talons, 1 single Sternal Talon (no wires)	£1,751.42 to £1,966.47	Configuration used in <a href="#">Levin (2010)</a> study, without support wires.

2 double Sternal Talons, 1 single Sternal Talon (with 3 wires)	£1,764.08 to £1,979.13	Configuration used in <a href="#">Levin (2010)</a> study, with 3 wires; the maximum stated in their methodology.
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## Costs of standard care

Costs for standard wire closure were calculated based on information provided by specialist commentators, who specified which and how many wires were used. Prices were taken from the [NHS Supply Chain](#).

- Patients weighing less than 80 kg: 1 pack of Ethicon #5 wires W902 (2 wires, £8.48) and 1 pack of Ethicon #5 wires W905 (1 wire, £4.22). Total cost: £13.06.
- Patients weighing more than 80 kg: 1 pack of Covidien Tyco #7 wires (4 wires, £10.20) and 1 pack of Ethicon #5 W905 (1 wire, £4.22). Total cost: £14.42.

Note that all wires in the above cost example can only be purchased in packs of 12; for example, 12 packs of Ethicon #5 wires cost £101.70 (£8.48 each).

## Resource consequences

The device is currently used in 2 NHS centres.

Any sternal closure device which reduces the need for repeat procedures because of complications may reduce long-term treatment costs.

There are no practical or infrastructure changes associated with implementing Sternal Talon in the current care pathway.

## Regulatory information

Sternal Talon was CE-marked as a class IIb device in November 2007. The extra-small variant was added to the range later, and received a CE mark in June 2008.

A search of the Medicines and Healthcare Products Regulatory Agency website revealed that no manufacturer Field Safety Notices or Medical Device Alerts have been issued for this technology.

## Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

Sternal Talon may be of benefit to patients at higher risk of complications after cardiothoracic surgeries, such as people with obesity, diabetes and chronic obstructive pulmonary disorder. These conditions become more common with older age. Age and disability are protected characteristics under the Equality Act 2010.

## Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the published process and methods statement. This briefing includes the most relevant and best publicly available evidence relating to the clinical and cost effectiveness of the technology. The literature search strategy, evidence selection methods and detailed data extraction tables are available on request by contacting [mibs@nice.org.uk](mailto:mibs@nice.org.uk)

### *Published evidence*

This briefing summarises 5 studies, including a total of 233 patients. The studies consist of 1 randomised trial ([Bennett-Guerrero 2011](#)) and 4 case series ([DeLong 2014](#), [Kumar 2012](#), [Levin 2010](#) and [Muller 2010](#)).

[Bennett-Guerrero \(2011\)](#) randomised 52 patients to either Sternal Talon with wires (n=28) or wires only (n=23). The outcomes trend towards favouring Sternal Talon, but no statistically significant differences were found. [DeLong \(2014\)](#) comprises 24 cases, retrospectively analysed, in patients that had a failed wire closure after sternotomy. The [Kumar \(2012\)](#) poster abstract describes a 188-patient retrospective case series, in patients at high risk for sternotomy complications. The [Levin \(2010\)](#) study was a retrospective case series with 42 high-risk patients across 8 US sites. This study used Sternal Talon alone for closure. The [Muller \(2010\)](#) conference abstract describes a 16-patient case series in high-risk patients, which used Sternal Talon with additional wires for stability, if needed.

Table 2 summarises the clinical evidence as well as its strengths and limitations.

### *Strengths and limitations of the evidence*

Overall, the evidence base for Sternal Talon shows that it can be a safe and effective option for sternal closure, whether used alone or with additional sternal wires for stability. The evidence indicates that this may be most applicable for patients at increased risk of complications, such as people with previous wire-closure failures or patients with obesity, diabetes or chronic obstructive pulmonary disease.

The strengths of the evidence base are that there is 1 randomised trial and some large case series. None of the included studies reported any major complications arising from the use of Sternal Talon.

However, there is very little comparative evidence with standard care. Some of the studies used Sternal Talon alone and some used it with wire closure, and this may have affected the outcomes. The randomised trial was a small pilot study and the authors concluded that a larger follow-on study is needed to improve the evidence base for Sternal Talon. Two of the studies ([Kumar 2012](#) and [Muller 2010](#)) are reported as abstracts, and so details of the studies are limited.

**Table 2: Study overviews**

Study size, design and location	Intervention and comparator(s)	Outcomes	Strengths and limitations
<a href="#">Bennett-Guerrero (2011)</a> 51 patients Randomised controlled trial 2 sites US	Cardiac surgical patients at higher risk of sternal wound complications. Talon n=28 (also with wires). Wires n=23.	Talon patients had a higher percentage of preoperative incentive spirometry than the wire closure patients, lower use of opiates, increased mobility at day 5 post-op, needed fewer days on a ventilator and had a shorter length of stay. None of these outcomes were statistically significant.	Strengths: Robust comparative study design. Limitations: This was a small pilot study funded by manufacturer. One author stated that they received royalties indirectly through sales of the Talon device.



<p><u>DeLong (2014)</u> 24 patients Retrospective case series 2 sites US</p>	<p>Sternal Talon repair for sternal nonunion or acute mediastinitis, or both, after failed sternal wire closure.</p>	<p>Sternal union achieved in all but one case. 16/24 patients had no complications. Subsequent reoperation was needed in 4 cases (1 patient had a haematoma and 3 patients needed Talon device removal – 2 because of infection, 1 because of implant exposure after sternal closure).</p>	<p>Strengths: Demonstration of efficacy in patients with previously failed wire closure. Limitations: This was a small case series with no control group. The study was retrospective, so follow-up was variable between cases and based upon events occurring.</p>
<p><u>Kumar (2012)</u> 188 patients Retrospective case series 1 site US</p>	<p>Patients at high risk for sternotomy complications.</p>	<p>No device-related complications were observed. One postoperative death occurred which was not device-related. Three patients had devices removed after 3 to 6 months because of discharging sinus. Three patients had minor superficial wound problems.</p>	<p>Strengths: The study a large number of case studies. Limitations: The study was retrospective and reported as a poster abstract only, with very few methodological or result details reported.</p>

<p><u>Levin (2010)</u> 42 patients Retrospective case series 8 sites US</p>	<p>Midline sternotomy in high-risk patients, using Sternal Talon.</p>	<p>No wound infections or dehiscence, nonunions, or returns to the operating room were observed. Three deaths occurred which were not device-related. There were no reported problems with computed tomographic scatter or chest roentgenogram visualisation.</p>	<p>Strengths: This was a relatively large case series across 8 sites. Limitations: Reported results are quite brief in this efficacy and safety study. One author stated that they received royalties indirectly through sales of Sternal Talon.</p>
<p><u>Muller (2010)</u> 16 patients Case series 1 site Germany</p>	<p>Primary sternotomy using Sternal Talon for closure (with wires if needed). High-risk patients (obese, patients with diabetes, patients with COPD).</p>	<p>Successful placement of the talons was achieved in all patients. 3 staphylococci infections occurred which were treated successfully. No other complications were reported.</p>	<p>Strengths: the study provided a demonstration of efficacy in patients at high risk of mediastinitis. Limitations: the study was published as a conference abstract and methodological and result details were lacking.</p>

### *Recent and ongoing studies*

- [DRKS00000697](#) – COSTA: Closure of median sternotomy in high-risk patients with the Sternal Talon system. Recruitment: 250 patients. Randomised, international multicentre trial. Status: recruitment and follow-up complete, study closed 02/05/2014.

## Specialist commentator comments

Comments on this technology were invited from clinical experts working in the field. The comments received are individual opinions and do not represent NICE's view.

One of the 3 specialist commentators had used Sternal Talon twice before, 1 had seen but not used it, and the other was not previously aware of it.

### *Innovation*

Two specialist commentators said that Sternal Talon was novel, with one commenting that it is the strongest, or most secure, sternal closure device available. One noted that a 'nitinol clip sternal closure device' is also available, but in their experience this is much weaker than Sternal Talon.

Another specialist commentator said that the design was interesting but not new because other similar devices have previously been proposed.

### *Potential patient impact*

One of the specialist commentators felt that there was a potentially important role for Sternal Talon in secondary sternal closure, whereas the other 2 commentators could not identify any benefitting patient groups based on the current evidence.

One commentator noted that the potential benefits for using Sternal Talon for secondary closure arose from the fact that full dissection of the sternal halves is not needed, and it provides a broader surface area than wires. It may also be more secure in patients with a high body mass index and also reduce the risk of bleeding during recovery. The commentator referenced the [DeLong \(2014\)](#) case series as evidence that Sternal Talon can be used in patients with active mediastinitis. They noted, however, that Sternal Talon may be unsuitable for patients with little or thin subcutaneous tissue overlying the sternum, because it is more bulky than sternal wires. A second commentator echoed this concern that the cosmetic appearance of the Sternal Talon under the skin of the sternum would be unappealing.

One specialist commentator noted that the complication rates reported in the evidence (9 infections and 6 removals out of 233 patients) were higher than expected, and greater than those expected for sternal closure using wires. They were also concerned that Sternal Talon is only in load-bearing contact with the lateral aspects of the sternum, whereas peristernal wires are

in contact with all aspects of the sternum. Also, they felt that figure of 8 wires achieve better 3D-fixation than Sternal Talon.

Two commentators noted a potential benefit of Sternal Talon in people who had postoperative bleeding. One speculated that re-opening the sternum to treat this would be easier with Sternal Talon than with wires. Another stated that the most frequent cause of postoperative bleeding was because of wires puncturing the tissues under the sternum. They felt that the Sternal Talon may reduce this risk as it does not require the use of wires or needles, although noted that there are no data to substantiate this at present.

### *Potential system impact*

Two of the commentators noted a potential negative system impact of Sternal Talon, in that this technology is much more expensive than standard care and as yet does not have any convincing evidence to show patient benefit. No requirements for changes in facilities or infrastructure to adopt this technology were identified.

There may be some staff training needed in order to measure and select the correct size of device, how to place and secure it, and how to remove it in case of any complications.

Two specialists considered that use of Sternal Talon for primary sternal closure is unlikely to be cost saving because it is considerably more expensive than wire closure. One felt that cost savings might be made when using this for secondary closure.

### *General comments*

All of the commentators felt that there was a need for more evidence for Sternal Talon. Specifically, one commentator noted that there is a need for large randomised trials of Sternal Talon compared with simple wires, figure of 8 wires, peristernal and trans-sternal wires. In each of these cases, cost-benefit analyses would be needed.

One commentator noted that standard wire closure already has a low complication and failure rate, particularly in primary sternal closure. Because of this, Sternal Talon may not be of benefit to a large patient population.

### **Specialist commentators**

The following clinicians contributed to this briefing:

- Professor Ulrich von Oppell, Consultant Cardiac Surgeon, University Hospital of Wales, Cardiff & Vale University Health board. Honorary Professor of Cardiothoracic Surgery, University of Cardiff.
- Professor Gianni Angelini, British Heart Foundation Professor of Cardiac Surgery, Bristol Heart Institute, University of Bristol.
- Mr Timothy Locke, Consultant Cardiothoracic Surgeon, Sheffield Teaching Hospitals NHS Foundation Trust.

## Development of this briefing

This briefing was developed for NICE by Cedar. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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