

SpineJack Implantable Fracture Reduction System

ICD-10-PCS Code Request

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Vertebral compression fractures: Prevalence

- Osteoporosis is one of the most common bone diseases worldwide that disproportionately affects aging individuals.¹⁻²
- In 2010, approximately **54 million Americans aged 50 years or older** had osteoporosis or low bone mass,³ which resulted in >2 million osteoporotic fragility fractures in that year alone.⁴

It has been estimated
more than 700,000 VCFs
occur each year in the U.S.^{2,5}

About 70,000 of these VCFs
result in hospital admissions
with an average length of stay
of 8 days per patient.⁵

In the first year after a painful
vertebral fracture, patients have
been found to require primary care
services at a rate **14 times greater**
than the general population.⁶

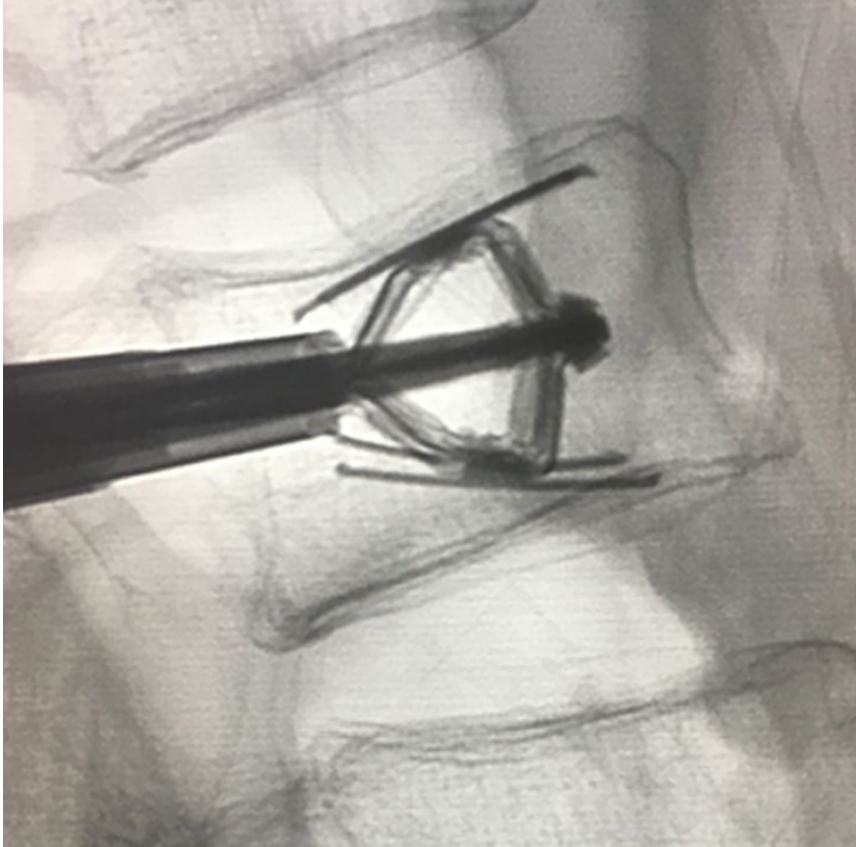
Medical costs attributed to VCFs
in the U.S. **exceeded \$1 billion**
in 2005 and are predicted to
surpass \$1.6 billion by 2025.⁷

Vertebral compression fractures: Disease state

- If vertebral body (VB) collapse is >50% of the initial height, segmental instability will ensue.
- Adjacent levels must support the additional load and this increased strain may lead to subsequent adjacent level fractures (ALFs).
- ALFs are recognized as clinically significant adverse events (AEs) associated with osteoporotic VCFs.⁸⁻⁹
- The estimated incremental medical cost to Medicare of a subsequent fracture over the 180-day period following a new osteoporotic fracture was over \$20,700 (95% confidence interval [CI]: \$19,900 to \$21,800).¹⁰



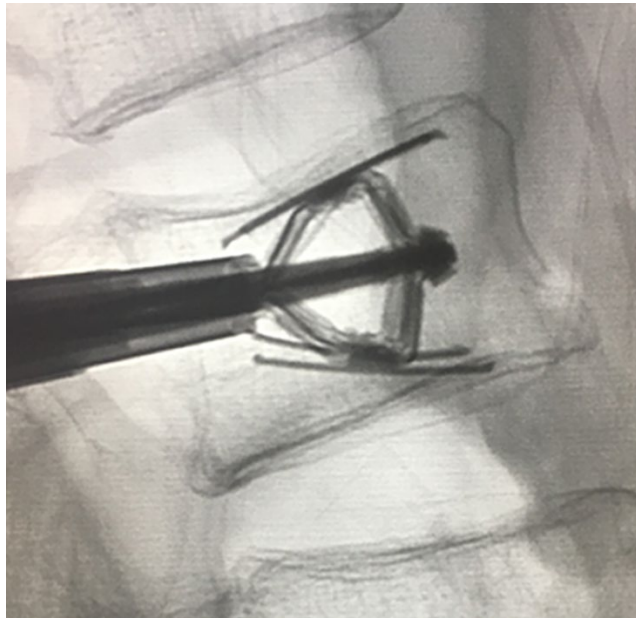
Vertebral compression fractures: Treatment



- When evaluating treatment options for osteoporotic VCFs, one of the **main goals of treatment is to restore the load bearing bone fracture to its normal height** and stabilize the mechanics of the spine by transferring the adjacent level pressure loads across the entire fractured vertebra.
- **In this way, the intraspinal disc pressure is restored and the risk of subsequent adjacent level fractures is reduced.**¹¹

SpineJack system: What is it?

Implantable fracture reduction system



Indicated for use in the reduction of painful osteoporotic vertebral compression fractures (VCFs).



The SpineJack system is intended to be used with Stryker's VertaPlex or VertaPlex High Viscosity (HV) bone cement.¹²⁻¹³



Cleared August 2018
(K181262)



NTAP application
submitted
October, 2019

SpineJack system: What is it? (continued)

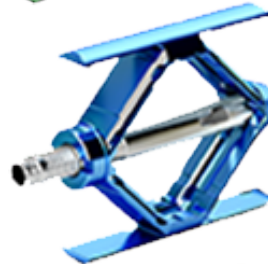
Includes two cylindrical implants constructed from titanium-6 aluminum-4 vanadium (Ti6Al4V)



Three sizes available:



5.8mm



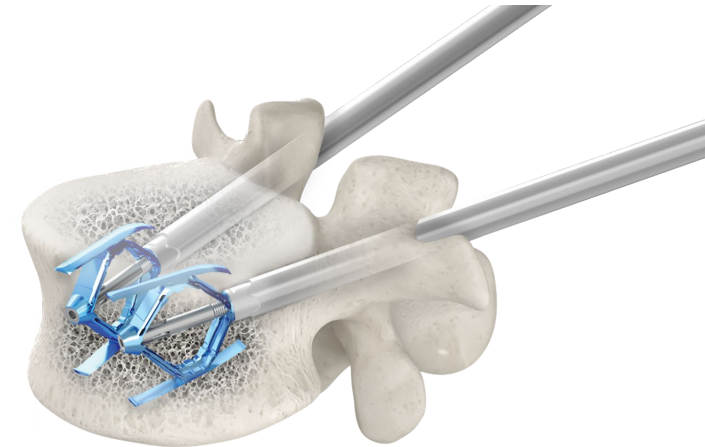
5.0mm



4.2mm

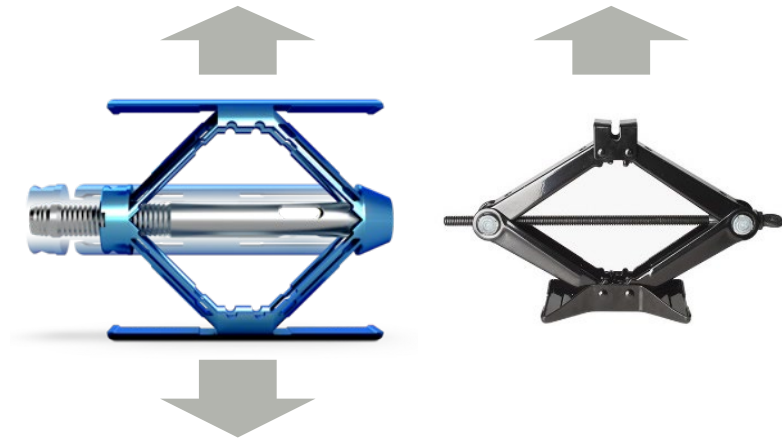
Implant size selection is based on the internal cortical diameter of the pedicle of the affected VB.

The use of two implants is recommended to treat a fractured VB.¹³



Multiple VBs can also be treated in the same operative procedure.

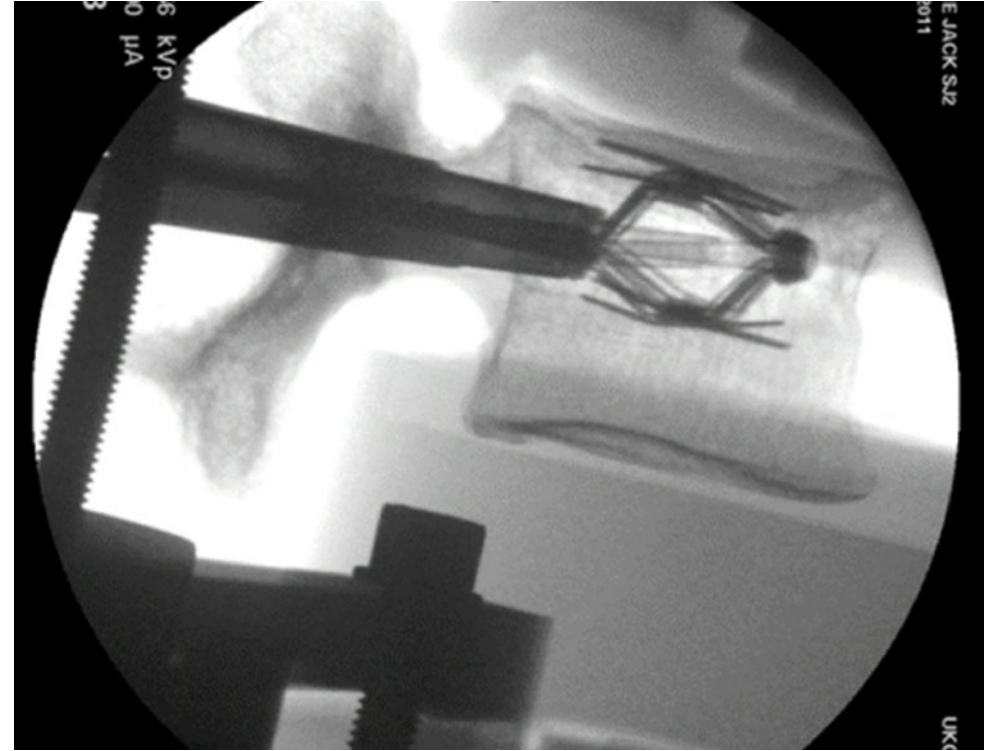
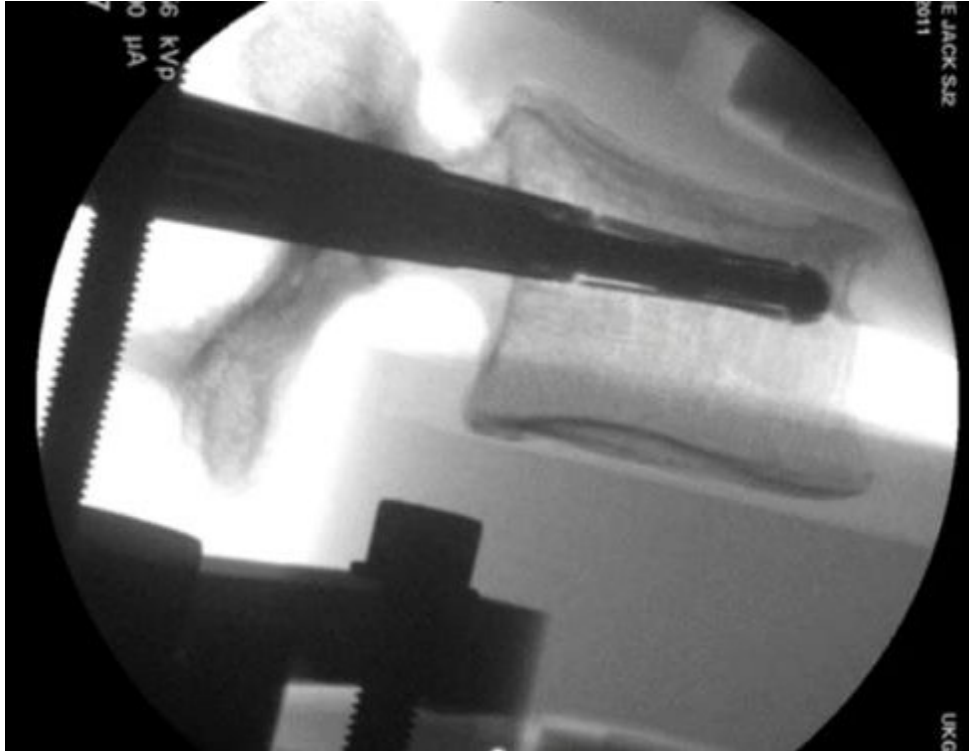
SpineJack system: How does it work?



500 – 1000 N

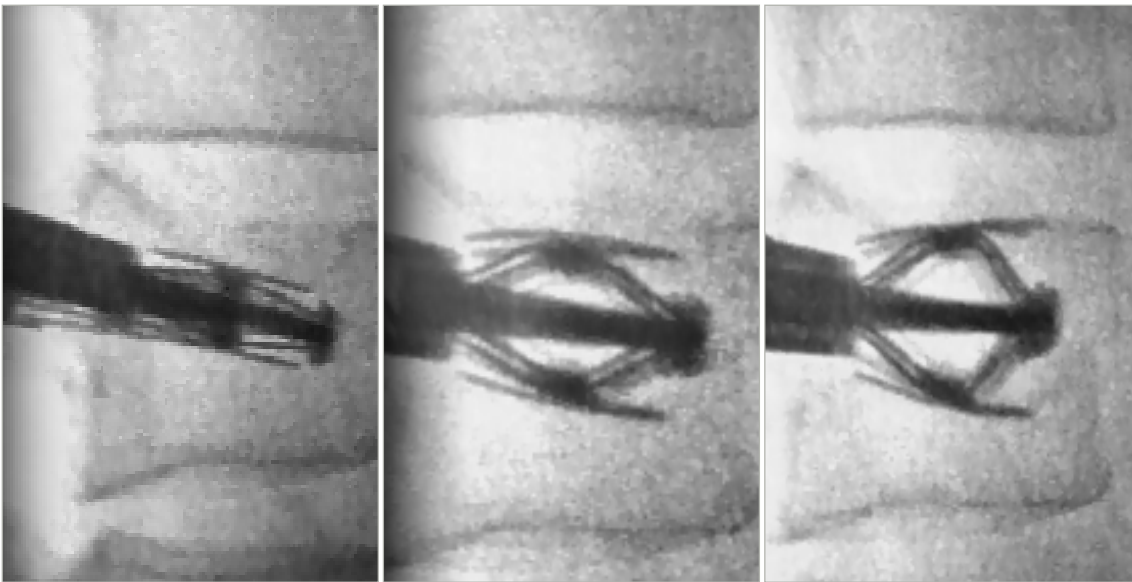
- SpineJack implant exerts lifting pressure on the fracture that may be likened to the action of a scissor car jack.
- Following the insertion of the implant into the VB, it is progressively expanded through actuation of an implant tube that pulls the two ends of the implant towards each other.
- The longitudinal compression on the implant causes it to open in a craniocaudal direction.¹⁴⁻¹⁵
- The force generated by the bilateral SpineJack implants varies according to implant size, ranging from 500-1000 Newtons for fracture reduction and superior endplate lift.
- The SpineJack implant provides symmetric, broad load support under the fractured endplate and spinal column.¹⁶

SpineJack system: How does it work? (continued)



SpineJack system: How is it used?

- Percutaneously implanted into a collapsed VB under fluoroscopic guidance.¹³
- Once in place, the implants are expanded to mechanically restore VB height and maintain the restoration.



- The implants remain in place secured by polymethylmethacrylate (PMMA) bone cement, which stabilize the restoration, provide pain relief and improve patient mobility.

SAKOS level 1 clinical evidence

The SAKOS trial was a prospective, multicenter, randomized, comparative clinical study that compared the safety and effectiveness of two VCF reduction techniques: the SpineJack system and the KyphX Xpander inflatable bone tamp (balloon kyphoplasty).¹⁷

N=141

- 68 SpineJack system
- 73 Balloon kyphoplasty (BKP)
- 82% (116 of 141) of patients were Medicare age 65 or older

SpineJack system: Substantial clinical improvement

The clinical outcomes of the SpineJack (SJ) system demonstrate a substantial clinical improvement in treating osteoporotic VCFs compared to BKP.¹⁷

Superior mid-vertebral height restoration

- Significantly greater midline VB height restoration with SJ system at 6 and 12 months

6 mo. p= 0.0246

12 mo. p= 0.0035

Significantly fewer adjacent level fractures

- Reduction in clinically significant AEs
 - BKP compared to the SJ system had more than double the rate of ALFs

12.9% v. 27.3%

p= 0.043

- Fewer hospital and physician visits
- Decrease in future interventions

Greater pain score reduction

- Less pain medication usage including opioid analgesics at 5 days after surgery (SJ group 7.4% vs. BKP group 21.9%)
- Decreased pain intensity vs. baseline more pronounced in the SJ group at 1 and 6 months

1 mo. p= 0.029

6 mo. p= 0.021

Clinical outcomes: Durability

- Over the 3-year follow-up period in a single-center study by Noriega et al, VB height restoration and kyphosis correction was better with SJ system compared to balloon kyphoplasty.¹⁸
- VB height restoration/kyphotic correction was still evident at **36 months** with SJ system, which included:

A greater mean
correction of anterior
VB height
($p = 0.007$)

Greater midline
VB height
($p = 0.034$)

Larger correction
of the VB angle
($p = 0.003$)

Summary

- It has been estimated more than 700,000 vertebral compression fractures occur each year in the U.S.^{2,5}
- **ALFs are recognized as clinically significant adverse events associated with osteoporotic vertebral compression fractures.**⁸⁻⁹
- **The SpineJack system provides substantial clinical improvement compared to balloon kyphoplasty.**¹⁷
 - Superior mid-vertebral body height restoration
 - Significantly fewer adjacent level fractures, which leads to reduced physician visits and future hospitalizations
 - Greater pain score reduction
- **Current ICD-10-PCS codes do not uniquely identify the use of SpineJack system, and do not allow for accurate reporting and outcome-tracking when treating osteoporotic vertebral compression fractures**

Disclaimer

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Appendix

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