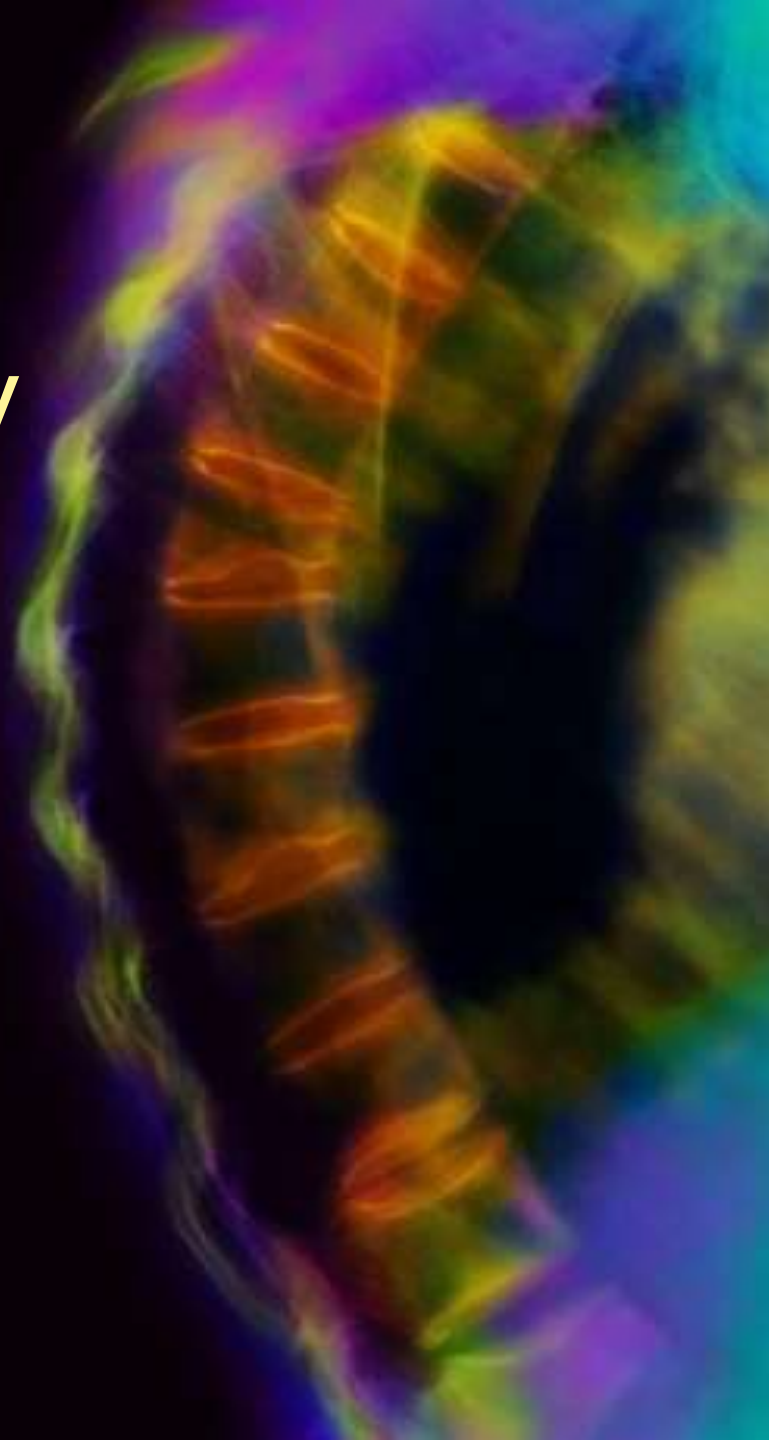
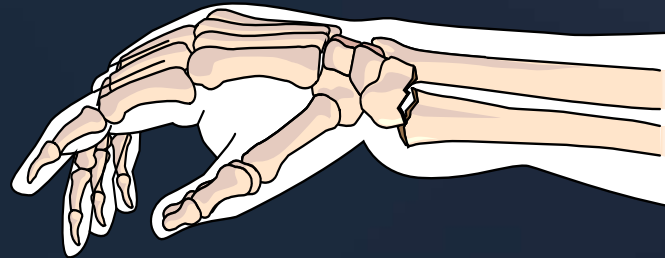


# Vertebral Body Compression Fracture Treatment Options



# ORTHOPEDIC FRACTURE CARE

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**Why have we been content  
to leave the spine in a  
physiologically and  
biomechanically  
compromised condition?**



# Fracture Treatment Objectives

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## Four AO principles<sup>1</sup>

- Fracture reduction and fixation to restore anatomical relationships
- Stability by fixation or splintage, as the nature of the fracture and the injury requires
- Preservation of blood supply to soft tissues and bone by careful handling and gentle reduction techniques
- Early and safe mobilization of the part and the patient

\*Arbeitsgemeinschaft Osteosynthesefragen

(English translation: Association for the Study of Internal Fixation - ASIF)

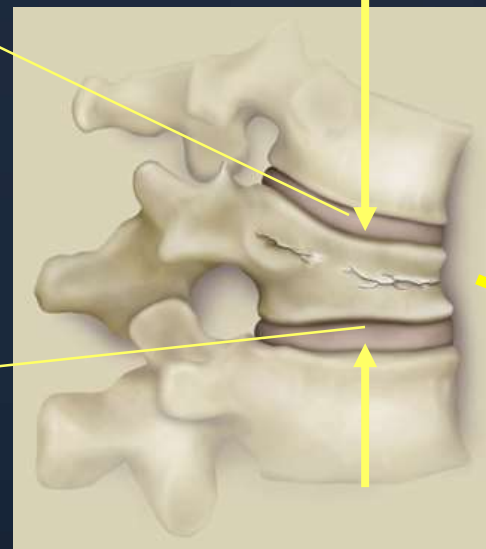
1 Ruedi & Murphy, AO Principles of Fracture Management,  
Thieme, Stuttgart, New York, 2000

# Vertebral Body Compression Fracture (VCF)



Normal

Wedge-shaped

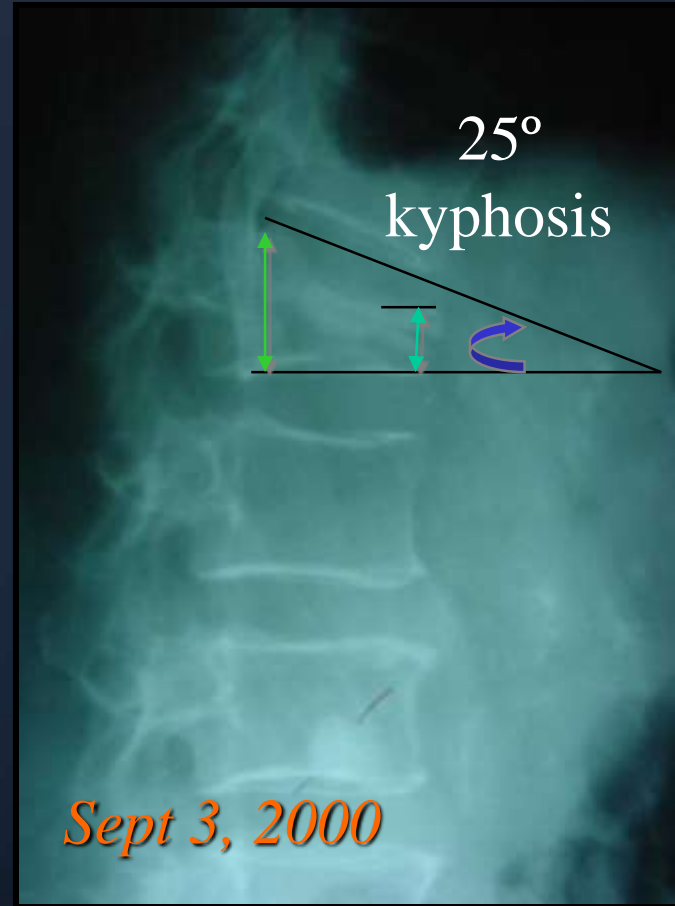
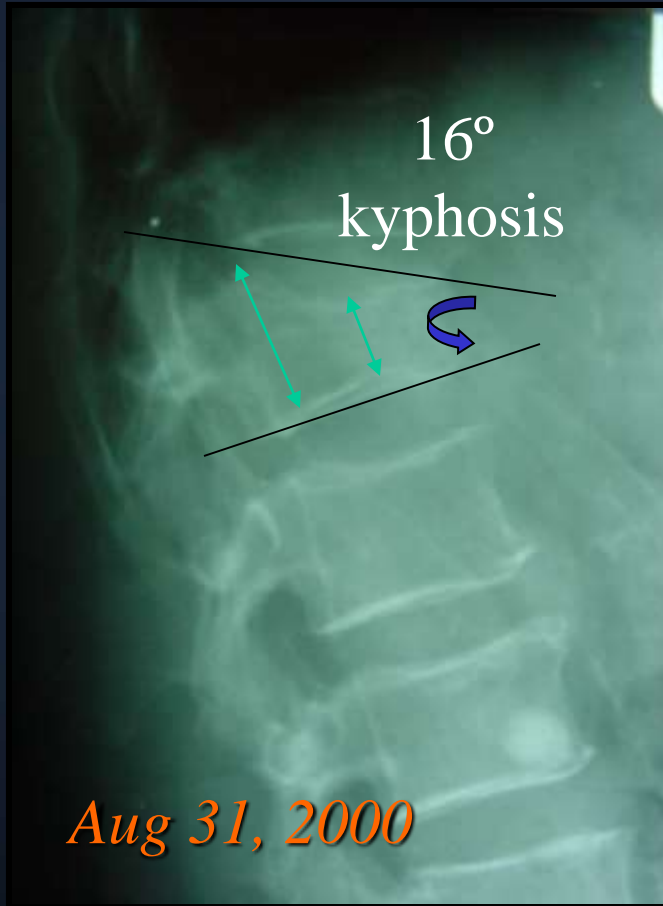


Depressed  
endplate(s)

Spine  
shorter,  
tilted  
forward

Fractured

# Deformity Progression



# VCF Treatment Options

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## Medical Management

- Treatment Protocol
  - Bed rest
  - Narcotic analgesics
  - Braces
- Shortcomings
  - May fail to relieve pain
  - Does not provide long-term functional improvement
  - May exacerbate bone loss
  - Does not attempt to restore the anatomy

# VCF Treatment Options

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## Open Surgical Treatment

- Indication
  - Only if neurologic deficit (very rare, only 0.05%)
  - Instrumented fusion, anterior or posterior
- Shortcomings
  - Invasive
  - Poor outcomes in osteopenic bone

# VCF Treatment Options

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## Vertebroplasty

- Designed to stabilize painful VCFs
- Shortcomings
  - Risk of filler leaks (27-74% reported<sup>1,2,4,5,6,7,8,9,10</sup>)
    - High pressure injection
    - Uncontrolled fill
    - High complication rate (1-20% reported<sup>3,4,5</sup>)
  - Freezes spinal deformity
    - Does not reduce fracture or restore anatomy
    - Not designed to reposition bone

*1 Cortet et al., J Rheum 1999*

*2 Alvarez et al., Eurospine 2001*

*3 Padovani et al., AJNR 1997*

*4 Weill et al., Radiology 1996*

*5 Jensen et al., AJNR 1997*

*6 Cotten et al. Radiology 1996*

*7 Gaughen et al., AJNR 2002*

*8 Grados et al., Rheumatology 2000*

*9 Peh et al., Radiology 2002*

*10 Ryu et al., J Neurosurgery 2002*



# Why Fracture Reduction?

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- What is orthopedic reduction?
  - The restoration, by surgical or manipulative procedures, of a part to its normal anatomical relation<sup>1</sup>
- What is the goal?
  - To produce optimal outcomes with early diagnosis and treatment<sup>2</sup>
  - To accommodate the frail physical status and co-morbidities of geriatric patients<sup>2</sup>

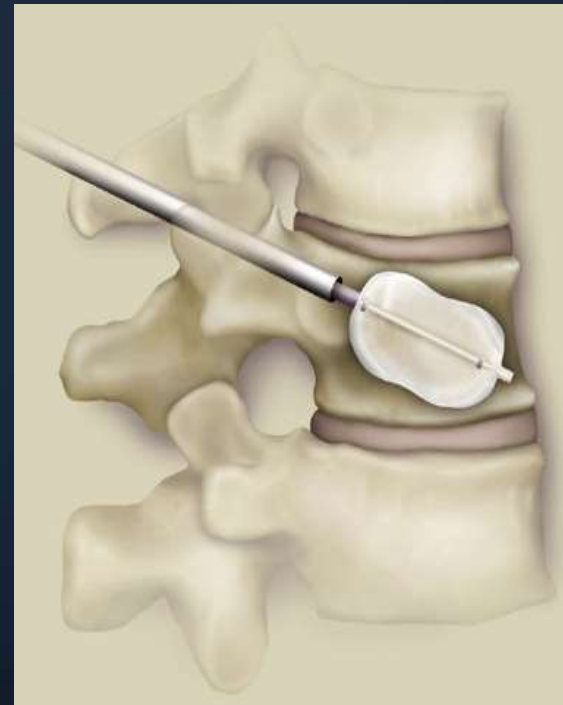
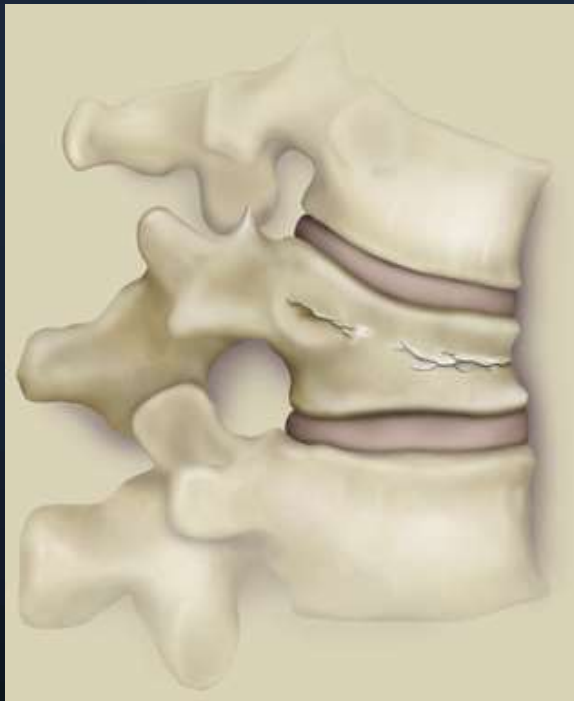
*1 Stedman's Concise Medical Dictionary. 1997. Williams and Wilkins.*

*2 Brakoniecki, Anesthetic Management of the Trauma Patient with Skeletal Injuries, Skeletal Trauma, W.B. Saunders Company, 1998, 1:7:171-172*

# New VCF Treatment Option

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## Minimally Invasive Fracture Reduction

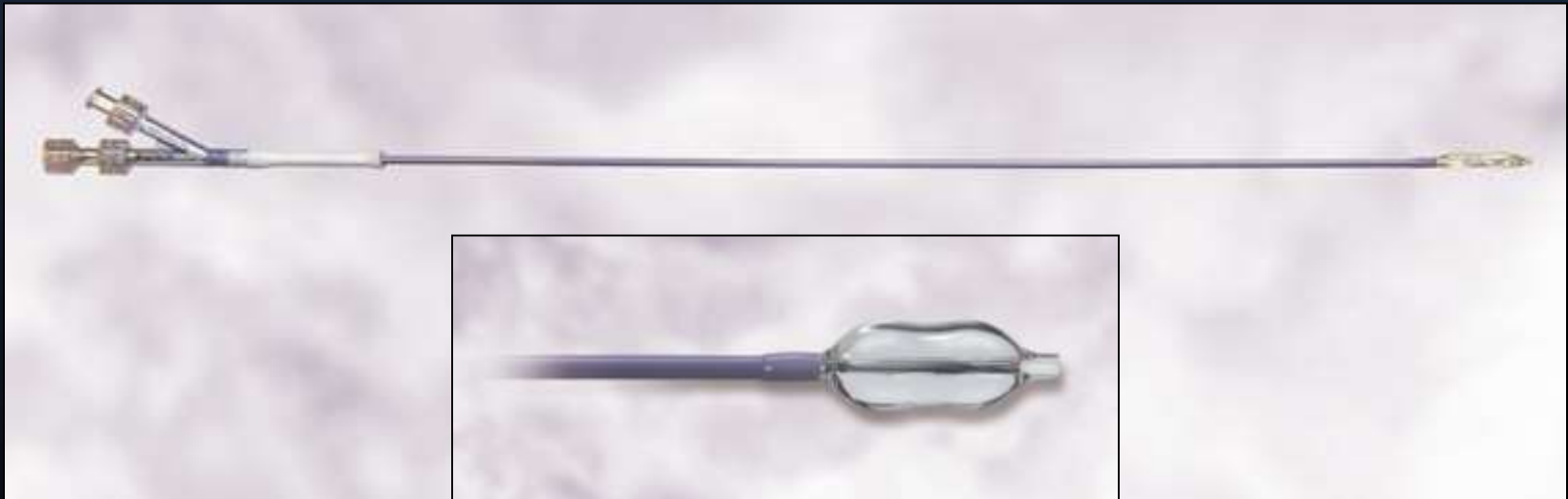


# Minimally Invasive Fracture Reduction

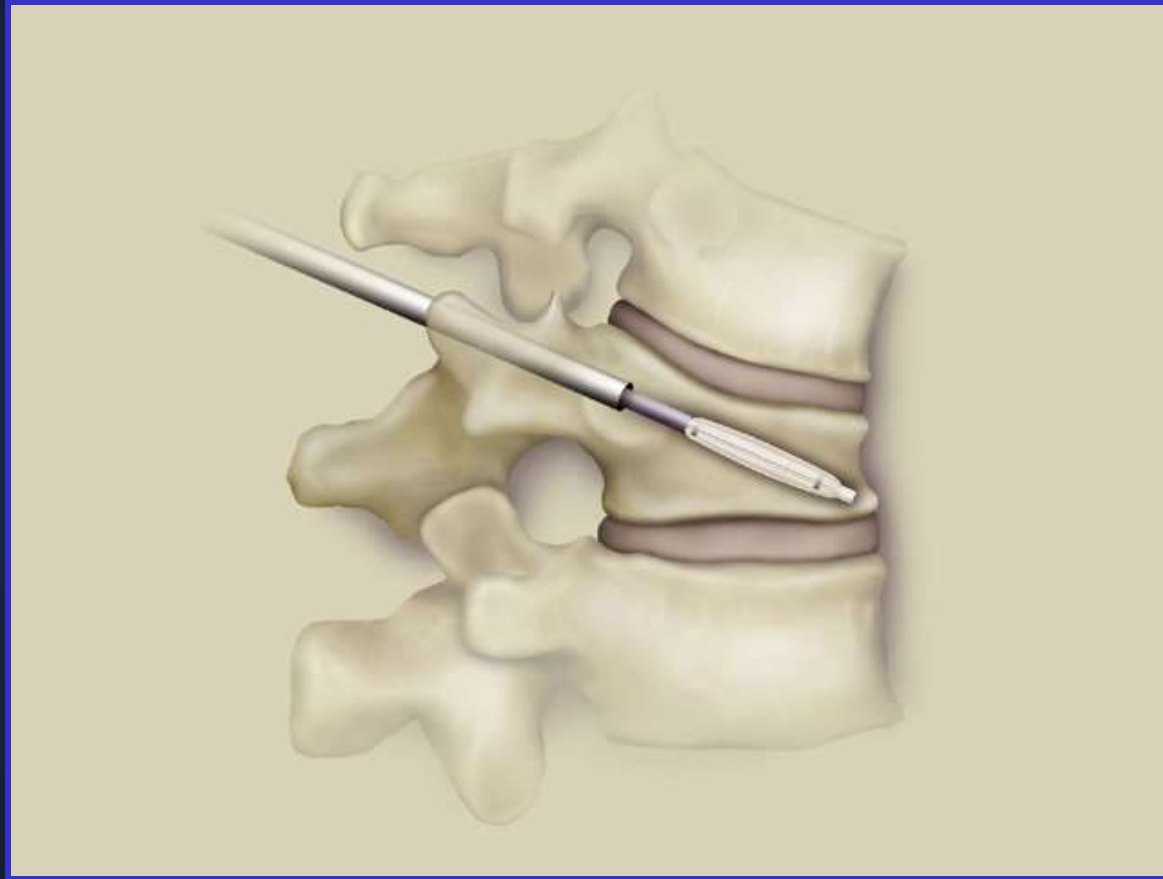
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## KyphX® Inflatable Bone Tamp (IBT)

For use as a conventional bone tamp for the reduction of fractures and/or creation of a void in cancellous bone in the spine, hand, tibia, radius and calcaneus.

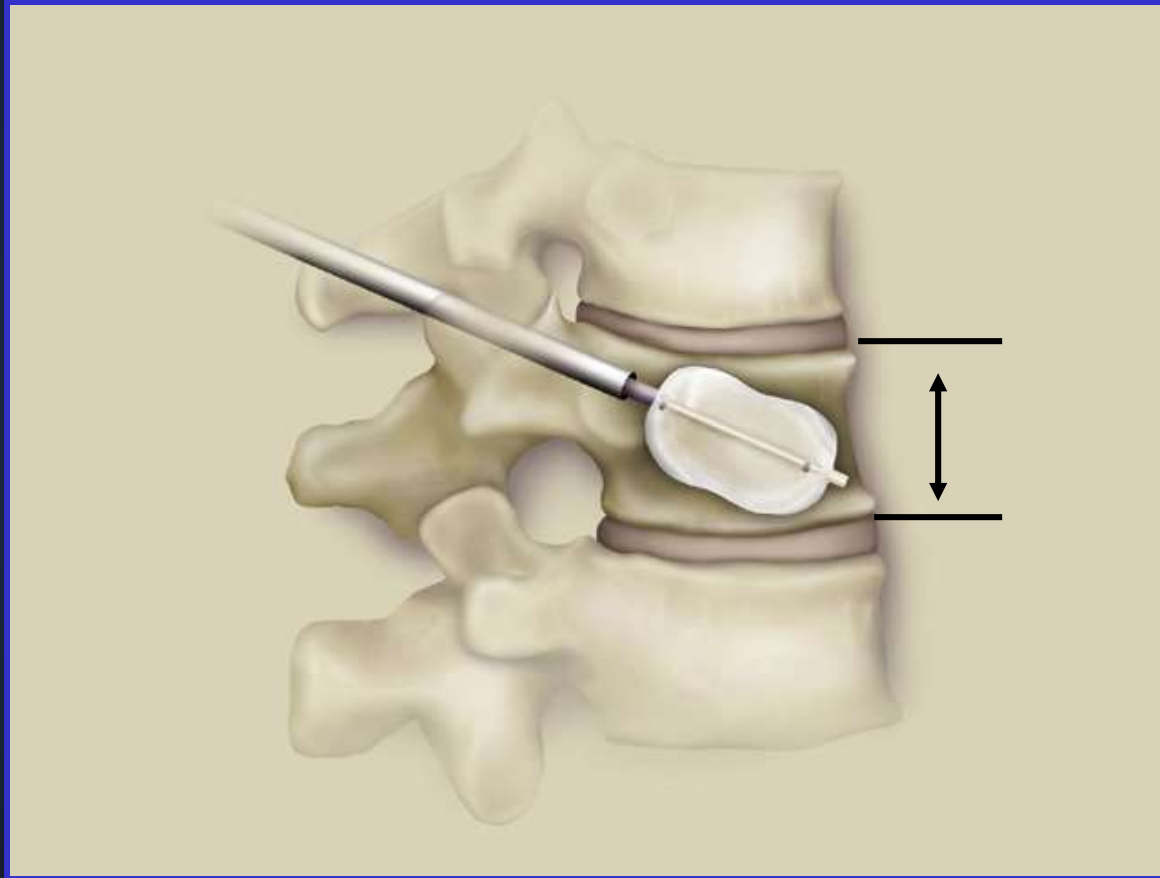


# KyphX<sup>®</sup> Introducer Tool Kit



Allows precise, minimally invasive access to the vertebral body and provides a working channel

# KyphX<sup>®</sup> IBT Inflation



Reduces the fracture, compacts the bone,  
and may elevate the endplates

# KyphX<sup>®</sup> IBT Removal



Leaves a defined cavity within the  
vertebral body

# Minimally Invasive Fracture Reduction

## *Clinical Experience*

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- Over 3 years of orthopedic fracture reduction
- As of June 30, 2002
  - Fractures reduced > 22,000
  - Patients > 17,000

# Minimally Invasive Fracture Reduction

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KyphX<sup>®</sup> Inflatable Bone Tamp has  
been developed for patients with  
symptomatic VCFs



# Possible causes of VCFs

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- Primary osteoporosis
- Secondary osteoporosis
  - Drug-induced (corticosteroids, tobacco, barbituates, heparin)
  - Endocrine (hyperparathyroidism, diabetes)
  - Miscellaneous (renal failure, COPD, rheumatoid arthritis, hepatic disease or transplant)

# Possible causes of VCFs

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- Osteolytic lesions
  - Multiple Myeloma
  - Bone metastases
  - Paget's disease
- Trauma
  - 1/2 of all trauma cases are misclassified

# Summary



- The general goal for fracture treatment is restoration of anatomy and early return to function
- Conventional therapy not always effective
- KyphX<sup>®</sup> IBT is a new option for VCFs designed to:
  - reduce the fracture
  - move cancellous bone (elevate endplates)
  - create void inside vertebral body
- As with hip fracture surgery, early diagnosis and intervention are important for fracture reduction

# THANK YOU!

KyphX Inflatable Bone Tamps are intended to be used as conventional bone tamps for the reduction of fractures and/or creation of a void in cancellous bone in the spine, hand, tibia, radius and calcaneus.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. See device Instructions for Use for complete indications, precautions, and method of use.

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