OrthoPediatrics®
Leading Innovation in Pediatric Orthopedics

ApiFix

Positively Changing the Lives of Scoliosis Patients Forever

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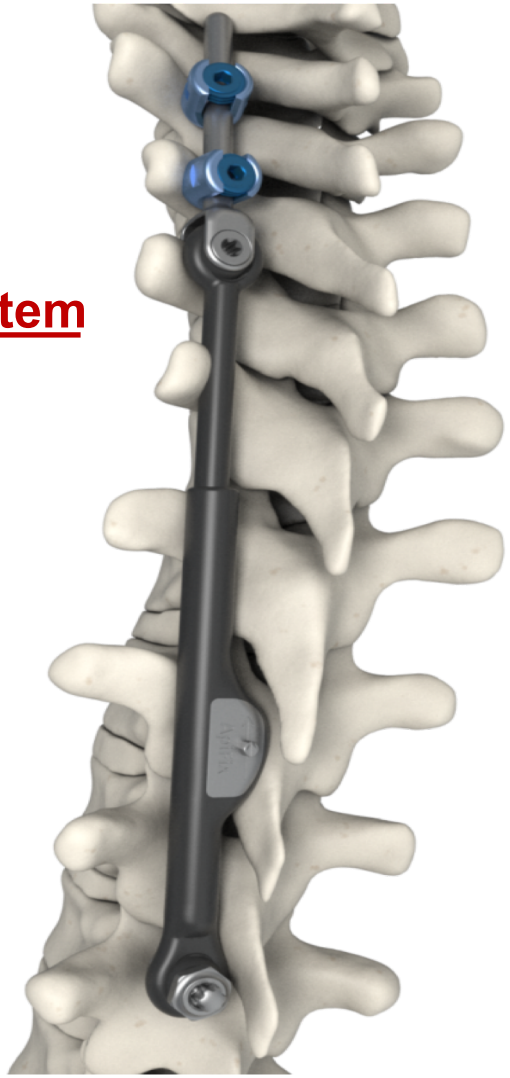
"Posterior (Dynamic) Distraction Device"

- **Posterior Segmental Instrumentation For Correcting Spinal Deformity with 1-level Proximal Fusion**

Minimally Invasive Deformity Correction *(MID-C)* System

- A viable alternative to traditional spinal fusion
- Self-adjusting rod with novel polyaxial joints
- Enables curve correction of the spinal deformity while preserving spinal mobility
- FDA approval (HDE) – August 2019



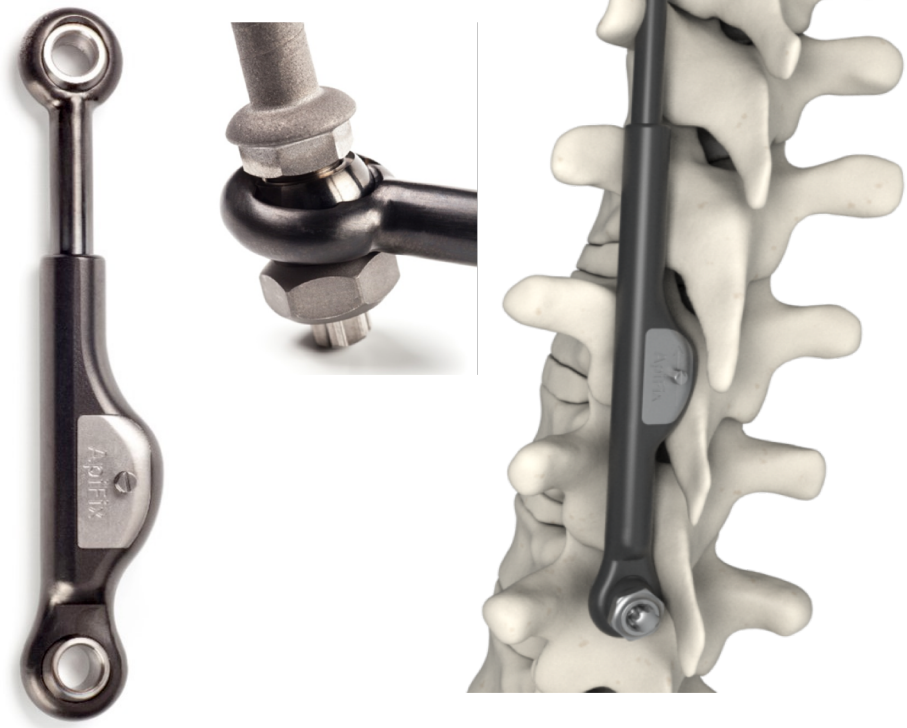
ApiFix MID-C System

Device and Procedure Description

- **Enables Curve Correction of the Spinal Deformity While Preserving Spinal Mobility**
  - Posterior dynamic device
  - Periapical concave distraction

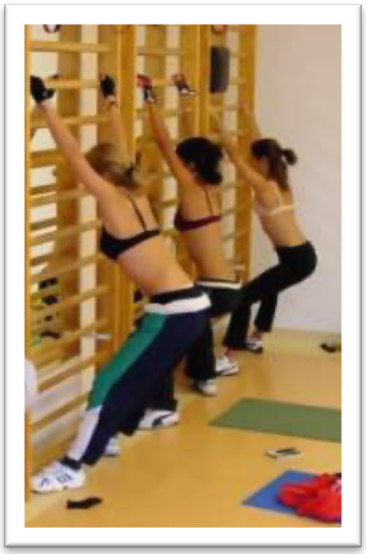
Unique Design Features

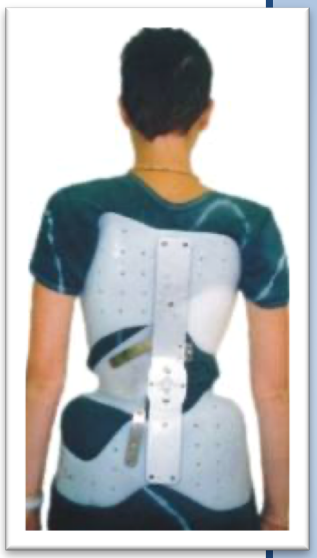
- Self-adjusting, ratcheting rod, unidirectional elongation
- Polyaxial joints allowing 3-D motion
- Enhanced proximal fixation and stability with extender and selective fusion

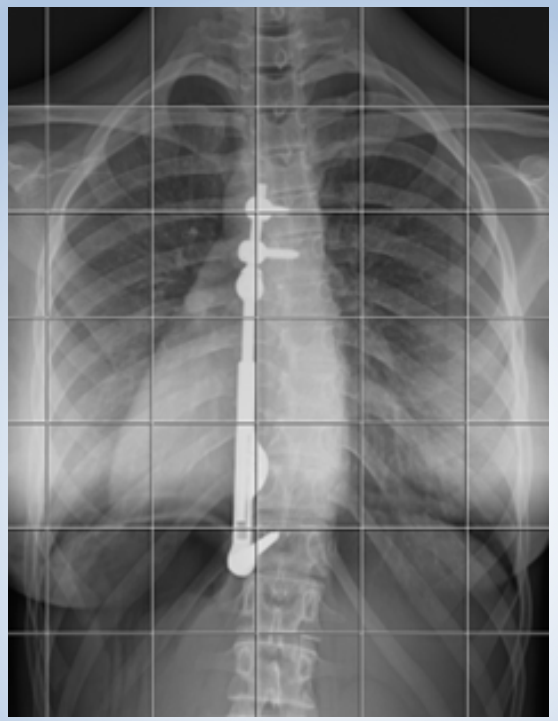


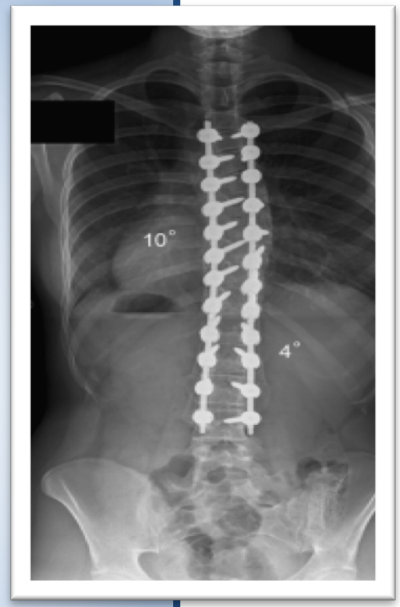
ApiFix MID-C System

A Viable Alternative to Failed Bracing and Traditional Spinal Fusion for the Treatment of Progressive Scoliosis









Exercise
Curves < 25º

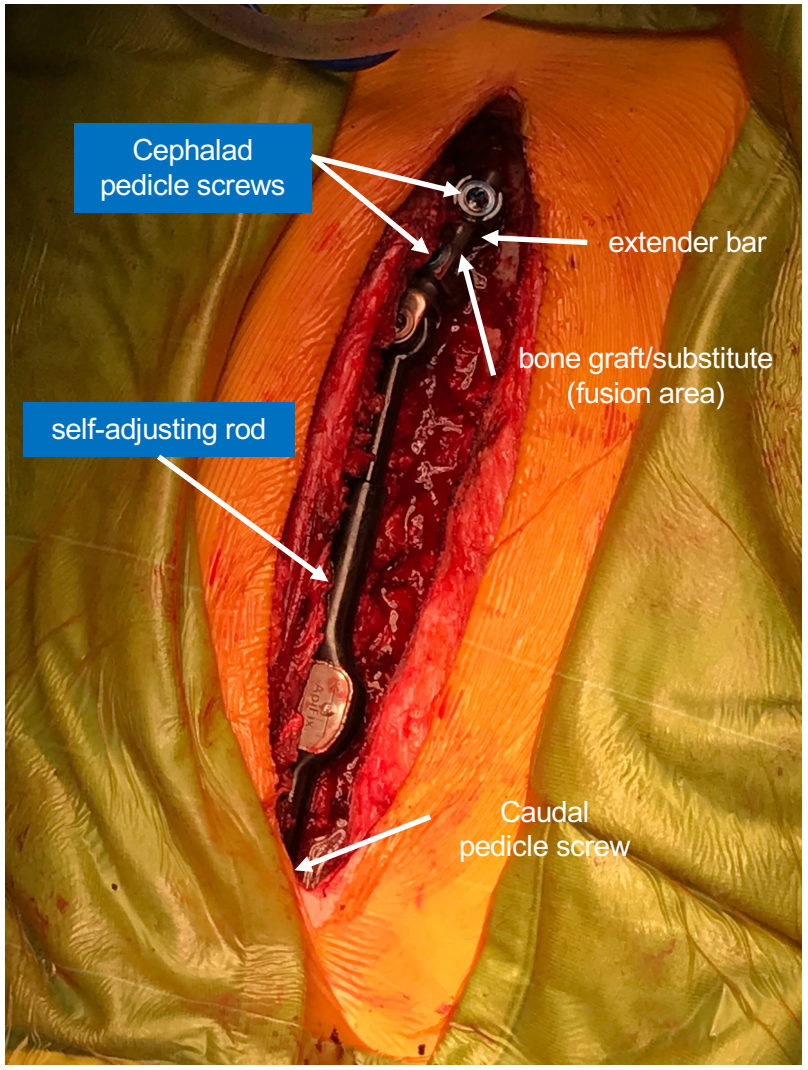
Brace
Curves 25º- 40º

ApiFix System
Curves 35º - 60º

Fusion Surgery
Curves > 50º

Procedural Steps Involved

- Standard posterior midline incision, unilateral exposure
- Placement of **one pedicle screw** caudally
- Placement of **two pedicle screws** cephalad and **1-level fusion with bone graft/bone graft substitute** at this level
- Submuscular placement of **self-adjusting rod** between pedicle screws w/ **extender bar** placed within cephalad pedicle screws (fusion level)
- **Perform intraoperative distraction of unidirectional rod to achieve deformity correction**
- Standard closure technique



- **Inpatient setting only**
- **For treatment of adolescent idiopathic scoliosis (AIS)**

US Indications

	United States - IFU
Type of Spinal Deformity	AIS
Curve Classification	Lenke 1, Lenke 5
Curve Magnitude	35° - 60°
Skeletal Maturity	Risser 0 - 5
Sagittal Profile	Kyphosis measured from T5-T12 < 55°
Curve Flexibility	Reduce to ≤30° on lateral bending x-rays

Indications For Use: The ApiFix MID-C System is indicated for use in patients with adolescent idiopathic scoliosis (AIS) for treatment of single curves classified as Lenke 1 (thoracic major curve) or Lenke 5 (thoracolumbar/lumbar major curve), having a Cobb angle of 35 to 60 degrees which reduces to less than or equal to 30 degrees on lateral side-bending radiographs, and thoracic kyphosis less than 55 degrees as measured from T5 to T12. Use of the MID-C System in patients with curves of lower magnitudes (i.e., less than 40 degrees) is based on the risk for curve progression.

Humanitarian Device. Authorized by Federal law for use in the treatment of adolescent idiopathic scoliosis (AIS). The effectiveness of this device for this use has not been demonstrated.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Supporting Information

- **The device is considered permanent**
- **Only one device system is routinely inserted**
  - Note: Device system equals 3 pedicle screws, 1 extender bar (for selective fusion at most proximal level) and 1 self-adjusting rod for deformity correction
- **The procedure involves placement of segmental instrumentation and always performing a 1-level fusion (arthrodesis) proximally with use of bone graft or bone graft substitute**
- **A normally expected rate of device related and non-device related adverse events have occurred without sequela (e.g. infection, screw migration, device failure, etc.)**
  - Current analyses indicate a survival rate at 2.5 years of >90%; failure rates are <3% and re-operation rates for any reason whatsoever are ~8.5%.

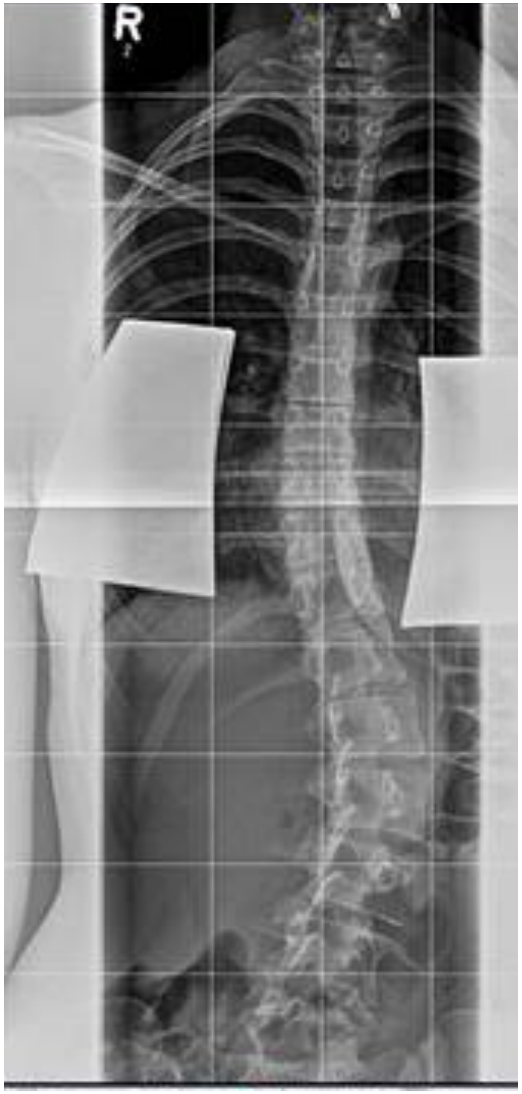
Supporting Information

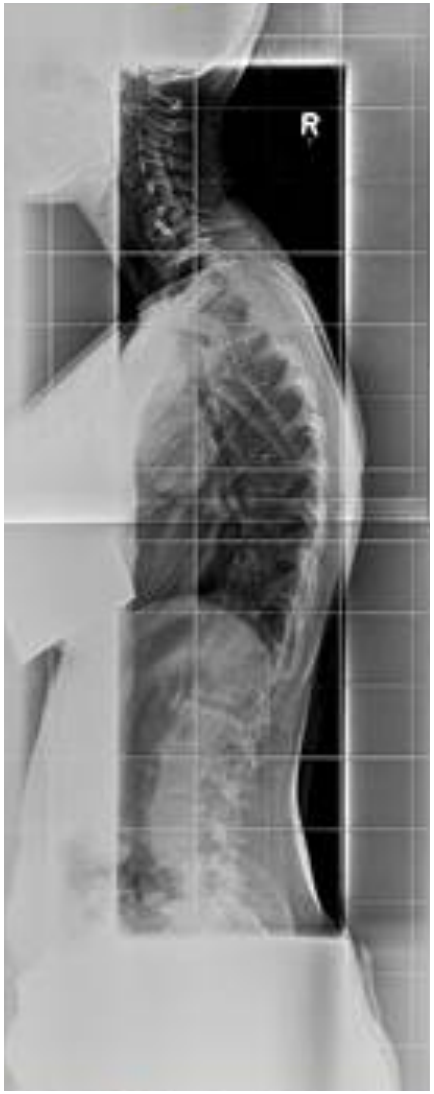
- **A description of the procedure(s) performed including use of the device/technology (*MID-C System*) will be recorded in the physician's post-operative notes and part of the patient's medical record**

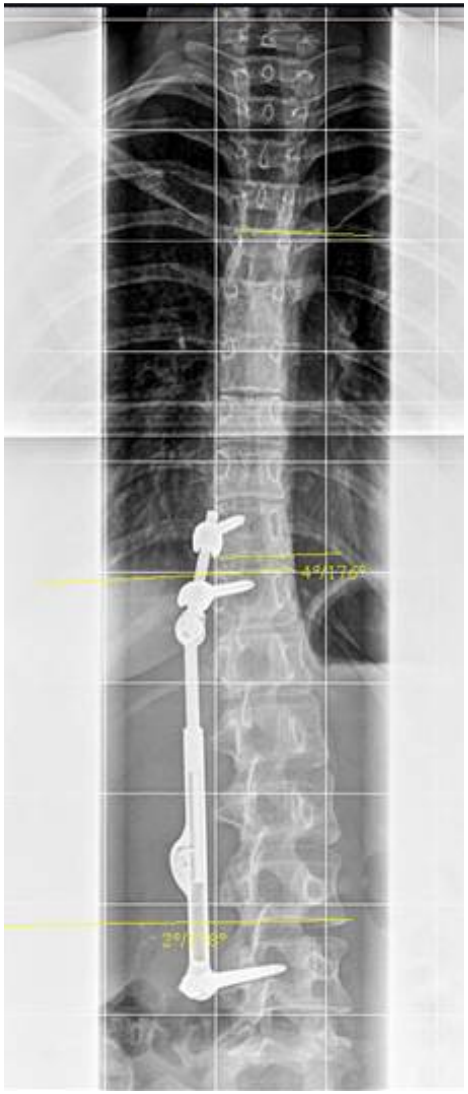
- **Different naming conventions for the device/technology or procedure include:**
  - ApiFix Procedure
  - Minimally Invasive Deformity Correction (MID-C)
  - Posterior Distraction Device
  - Posterior Dynamic Deformity Correction
  - Posterior Dynamic Distraction Device
  - Posterior Dynamic Spinal Stabilization

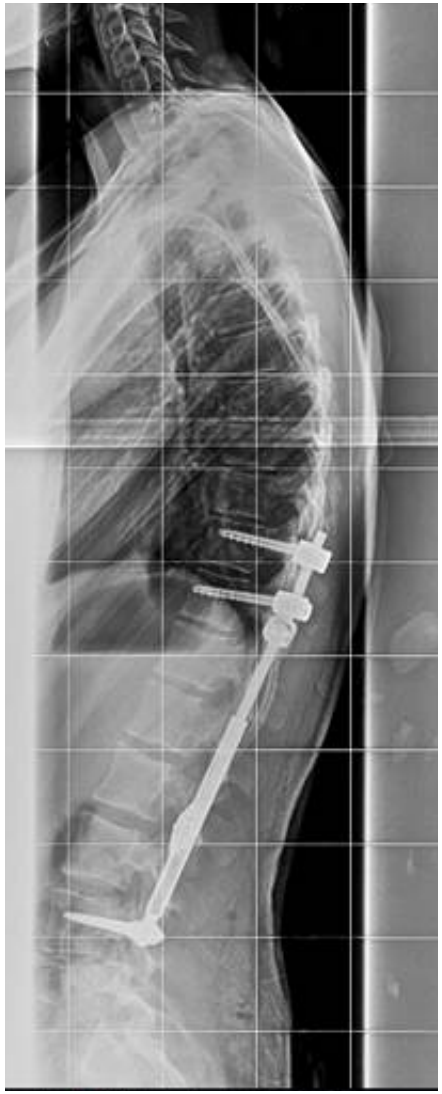
Case Study (281)

Age	Risser	Cobb	LB	F/U 1-year
15	4	40°	10°	3°





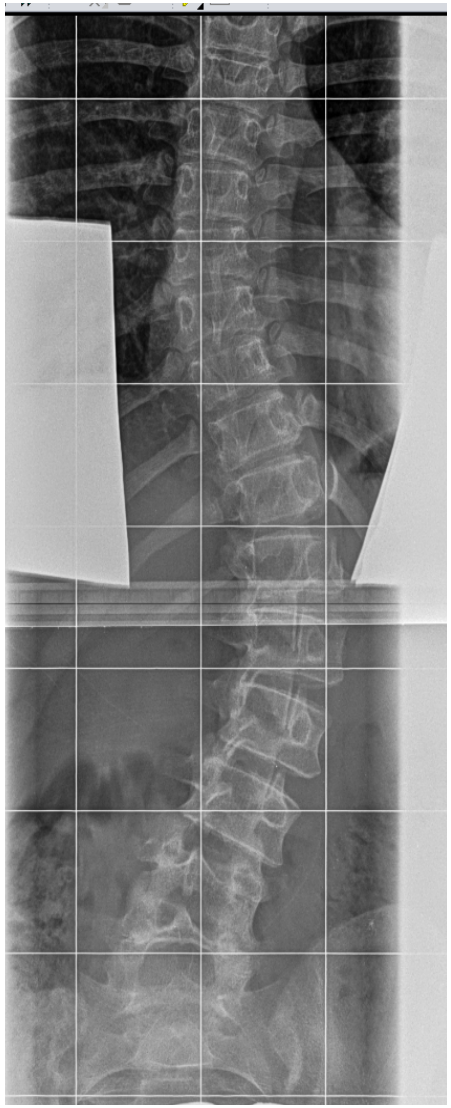


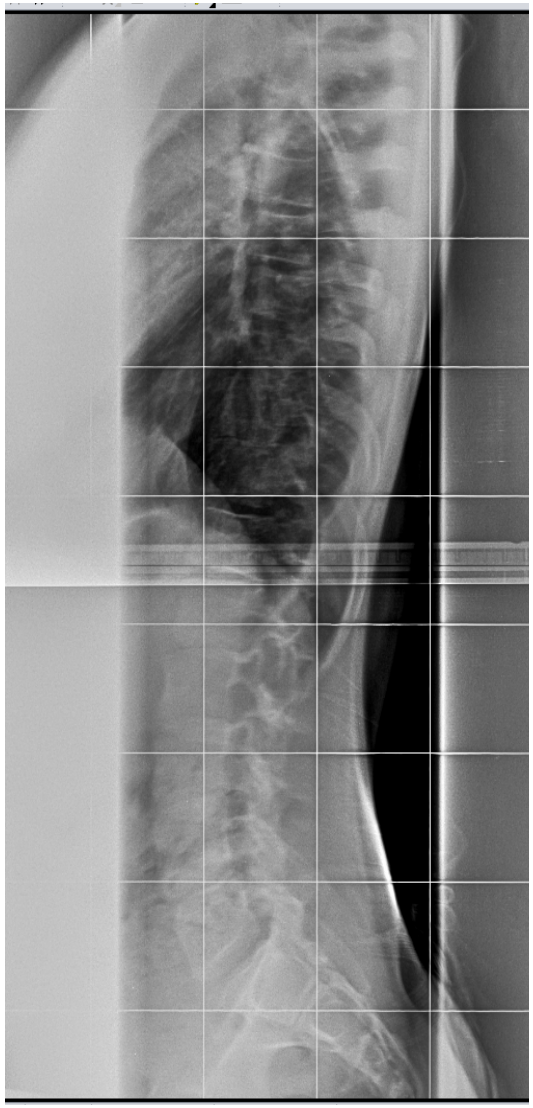


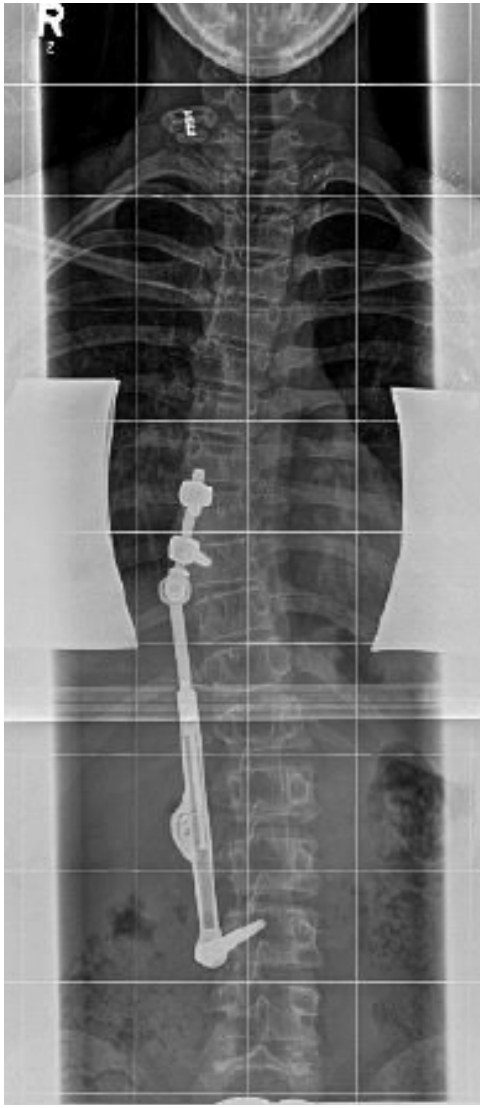
Case Study (286)

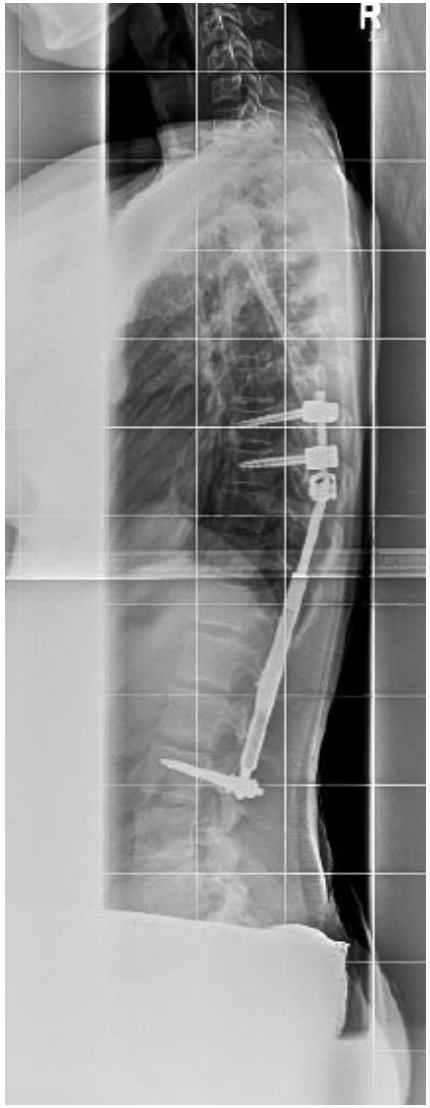
ApiFix

Age	Risser	Cobb	LB	F/U 1-year
13	0	50°	6°	14°









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September 8, 2020

ICD-10 Coordination and Maintenance Committee Meeting