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Data Driven Surgery

aprevo™ intervertebral body fusion device

ICD-10-PCS Procedure Code Request

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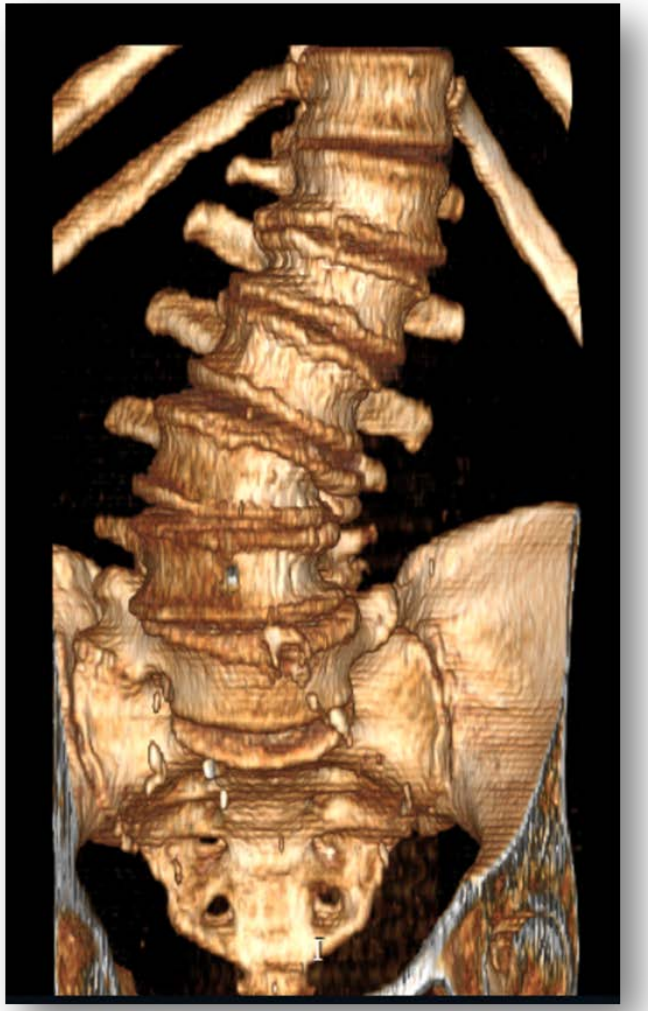
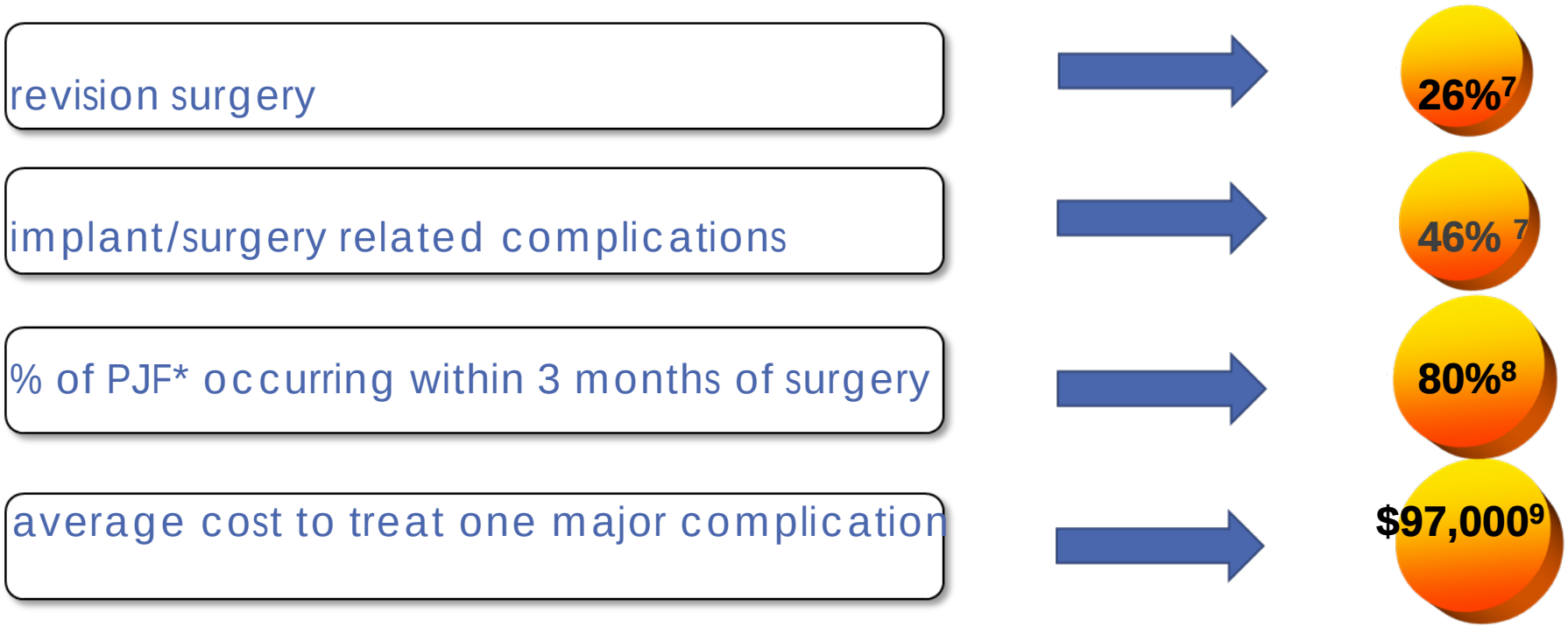
Adult Spinal Deformity (Curvature / Scoliosis)

- affects up to **25%** of US adults[1,2] & up to **68%**of elderly[3]
- more than **1.6 million** US adults seek treatment[4]
- impacts health-related quality of life more than arthritis, chronic lung disease, diabetes, and congestive heart failure [5]
- inpatient **surgical treatment is proven to be superior** to conservative care[6]
- surgical realignment involves the use of permanent Interbody Fusion device (IBF) devices to help stabilize the spine and facilitate fusion



Adult Spinal Deformity Surgery Outcomes

High Complication Rates ● Frequent Revision Surgery ● Catastrophic Cost Outliers



*PJF = Proximal Junctional Failure

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What Causes these Complications?

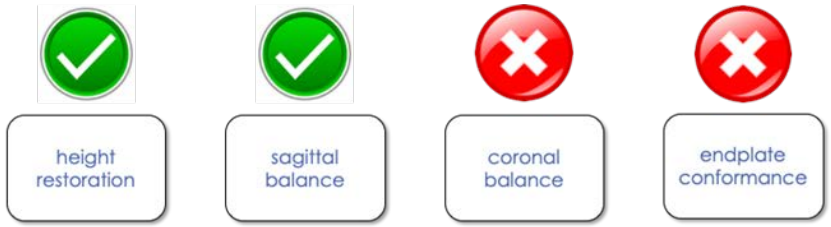
Causes

- overcorrection
- lordotic mismatch
- endplate stress concentration
- poor contact area
- excessive rod loads
- adjacent disc stress

Complications

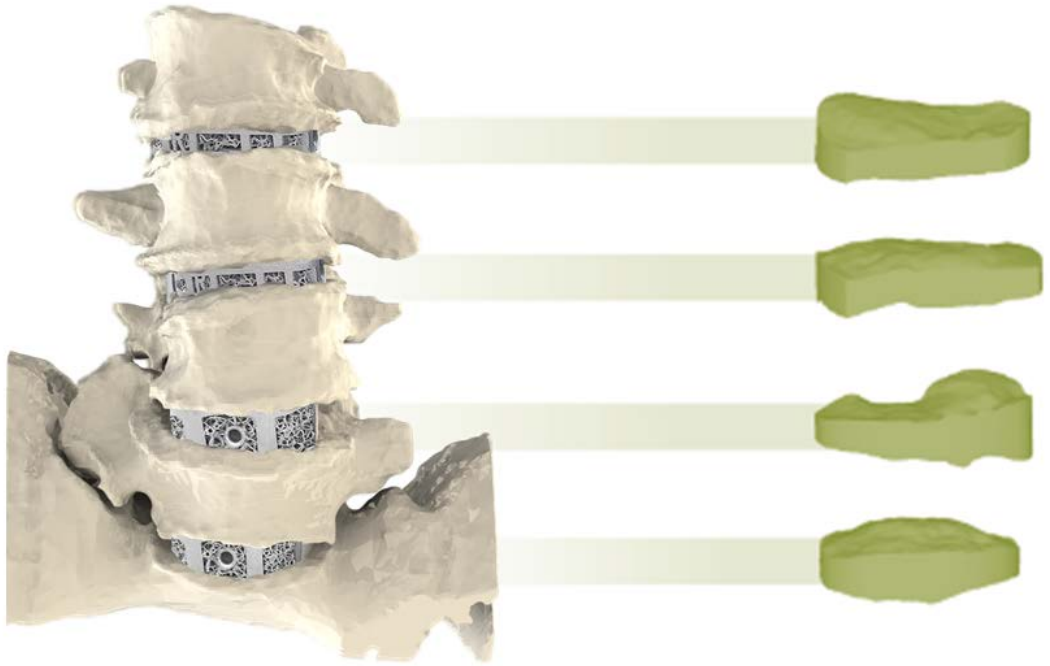
- PJK/PJF
- pseudarthrosis
- adjacent segment disease
- cage subsidence
- rod breakage

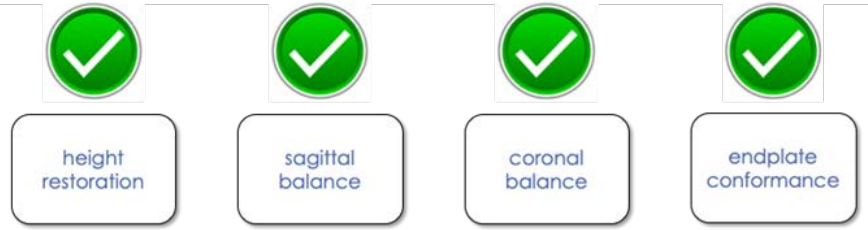
Stock IBF



Stock devices function as off-the-shelf space fillers

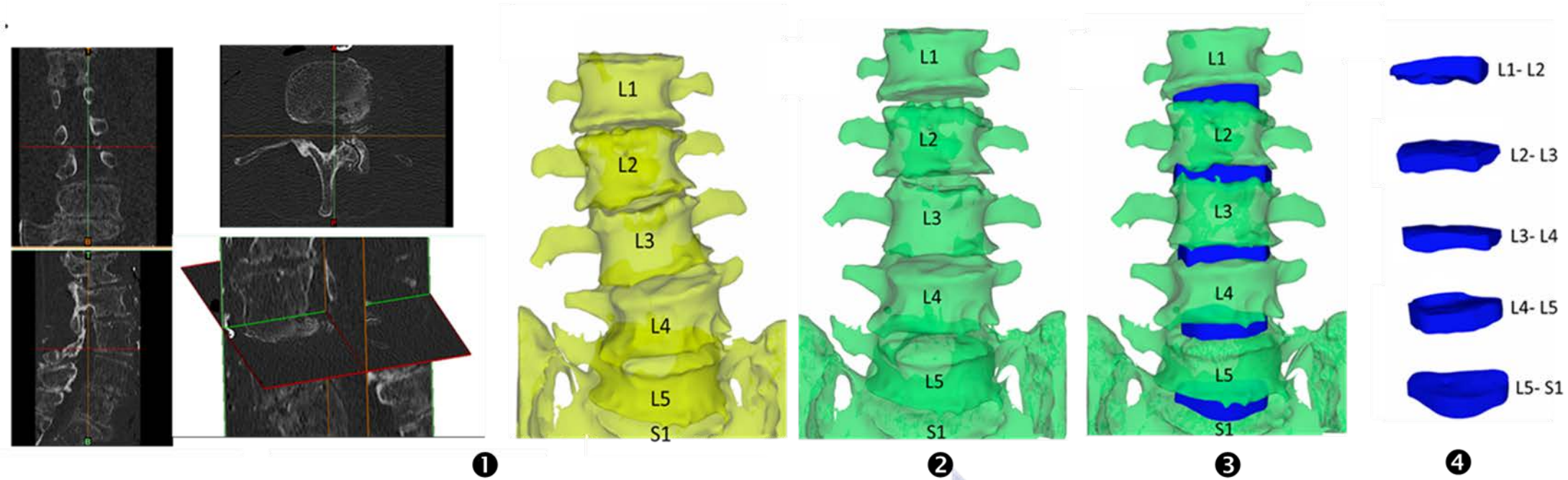
Patient Specific IBF





aprevo™ is personalized to match the planned correction

aprevo™ Patient Specific IBF Devices

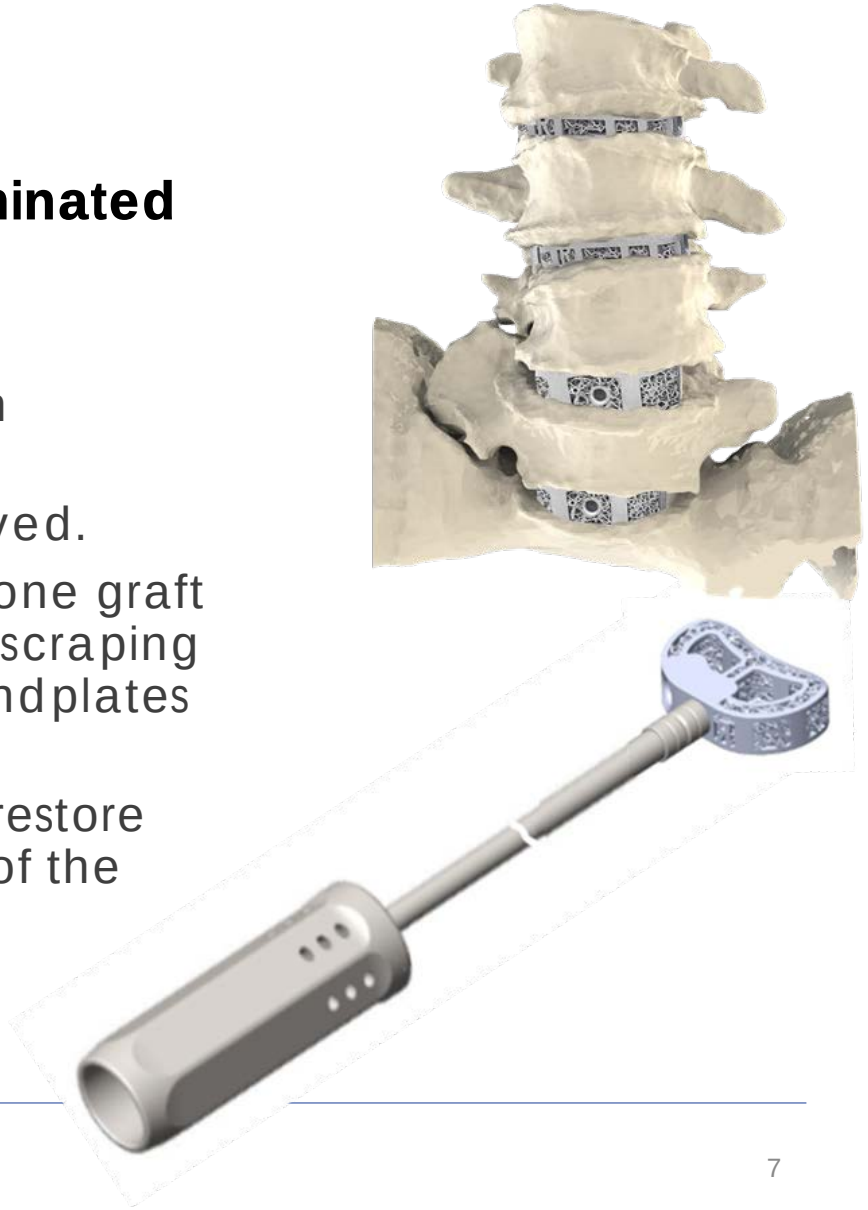


❶ scan → ❷ plan → ❸ design → ❹ 3d print

Procedure Steps

Same Implantation Method as Stock IBF Devices Except Trial-and-Error Fit Process is Eliminated

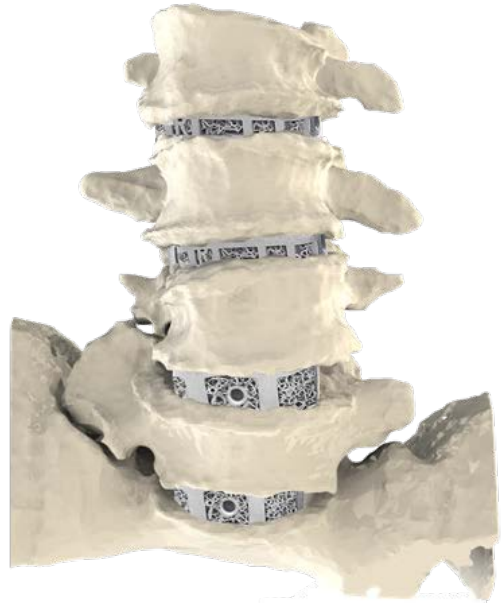
1. Approach may be anterior, lateral or transforaminal/posterior. Standard patient positioning and exposure are used based on approach
2. The discectomy is performed, and endplate cartilage is removed.
3. Endplates preparation must facilitate vascular supply to the bone graft while also maintaining the integrity of the endplate. Excessive scraping of subchondral bone may interfere with the fit between the endplates and must be avoided.
4. Distractors may be used to distract the vertebral segments to restore the disc height, open the neural foramen, and allow delivery of the implant.

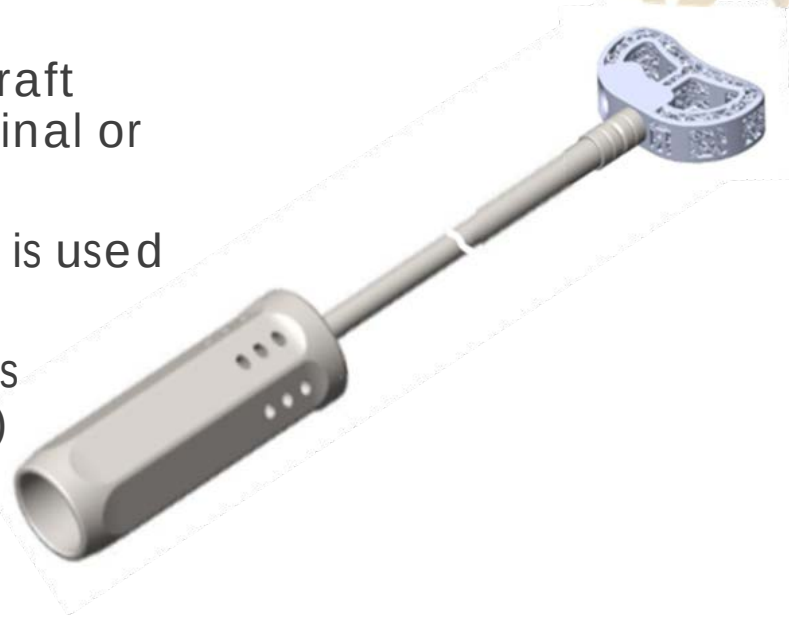


Procedure Steps (cont.)

Same Implantation Method as Stock IBF Devices Except Trial-and-Error Fit Process is Eliminated

5. Three *aprevo* implants are provided for each level: a nominal size, which matches the surgical plan requirements; a size that is 1mm smaller in superior/inferior height; and a size that is 2mm larger in superior/inferior height.
6. The smallest device is attached to inserter, packed with bone graft and seated into position. If additional height is desired, the nominal or large size is used.
7. Once an implant has been placed, A/P and lateral fluoroscopy is used to confirm that the final position is appropriate.
8. Supplemental fixation, such as posterior pedicle screws with rods should be used. Hyperlordotic anterior IBF devices (≥20° lordosis) must be used with at least anterior supplemental fixation.
9. The use of *aprevo* is normally dictated into the procedure section of the provider/operative note in the medical record.

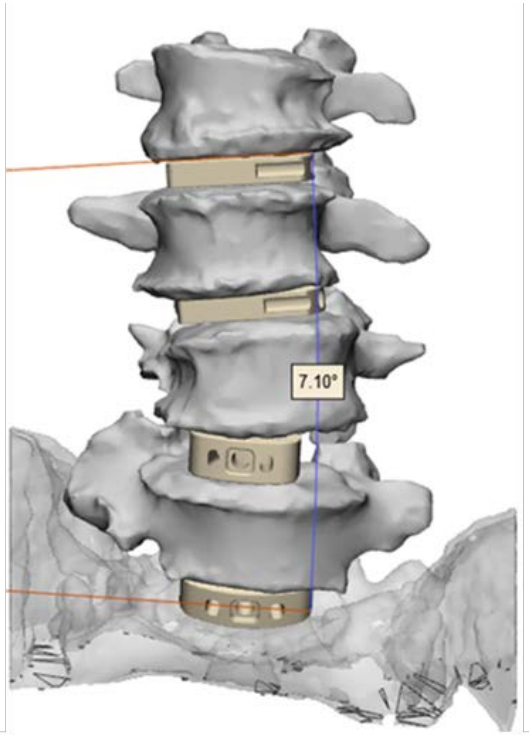




Achieve Targeted Alignment

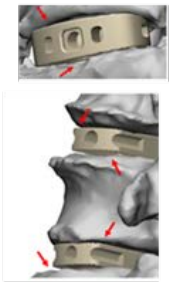
Stock Devices†

- missed targeted coronal correction by **7.1°**
- under corrected lordosis by **18.5°**
- produced **11.9**mm overcorrection of posterior height

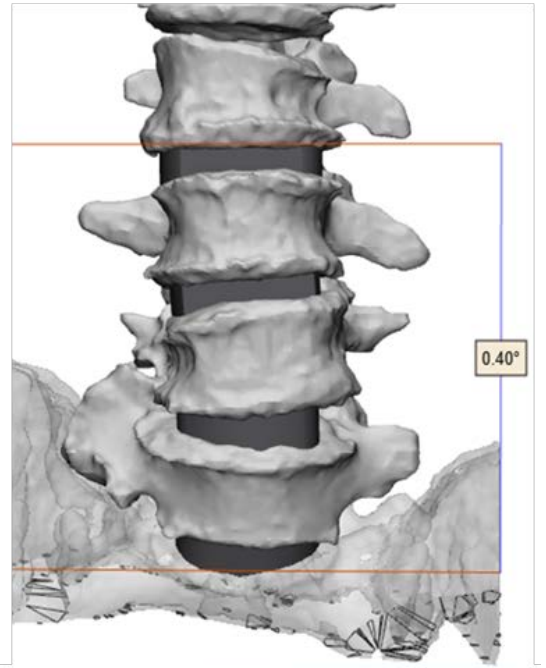


	Targeted correction	Stock IB	Δ
Posterior height (mm)	100	111.9	11.9
Lordotic angle (°)	56	37.5	-18.5
Coronal angle (°)	0	7.1	7.1

Stock devices do not have an anatomical interface. Arrows identify areas of **point contact** which altered alignment and increased disc height from the targeted correction.



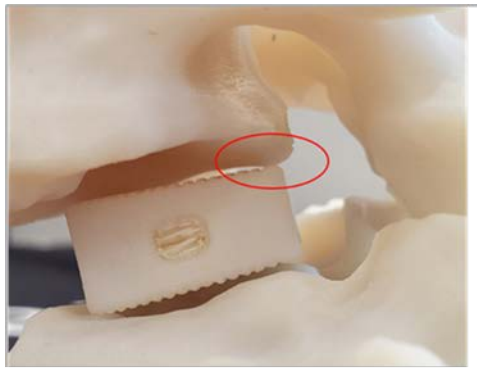
aprevo Personalized to Match the Surgical Plan

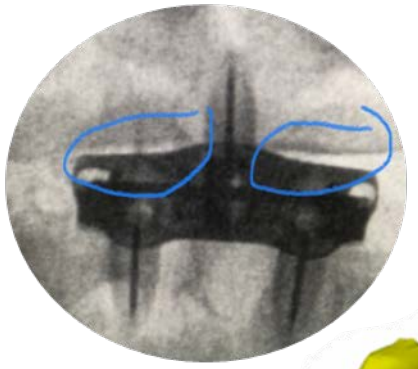


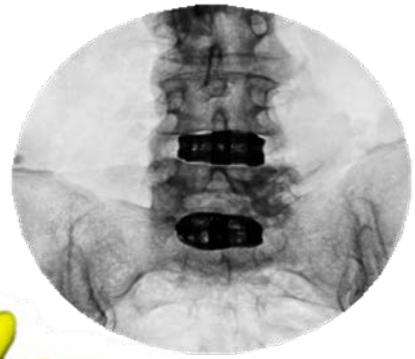
- coronal angle correction to within **0.4°**
- lordosis correction to within **0.5°**
- posterior height to within **0.2mm**

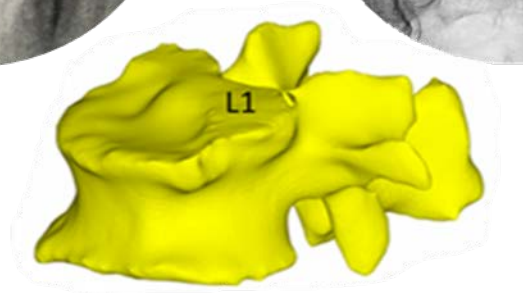
	Targeted correction	*aprevo* personalized device	Δ
Posterior height (mm)	100	100.0	0.2
Lordotic angle (°)	56	56.5	0.5
Coronal angle (°)	0	0.4	0.4

Anatomical Interfacing









- **28%** decrease in posterior rod stress [10]
- **50x** increase in contact area [11]
- **30x** reduction in stress concentration [11]
- **45%** more effective contact [12]
- ↓ stress increase inside the adjacent disc and facets [13]
- ↓ postop subsidence (clinical data) [14]
- ↓ severity of subsidence-related pain (clinical data) [14]

anatomical interfacing can reduce the likelihood of:

- **PJK/PJF**
- **pseudarthrosis**
- **adjacent segment disease**
- **cage subsidence**
- **rod breakage**

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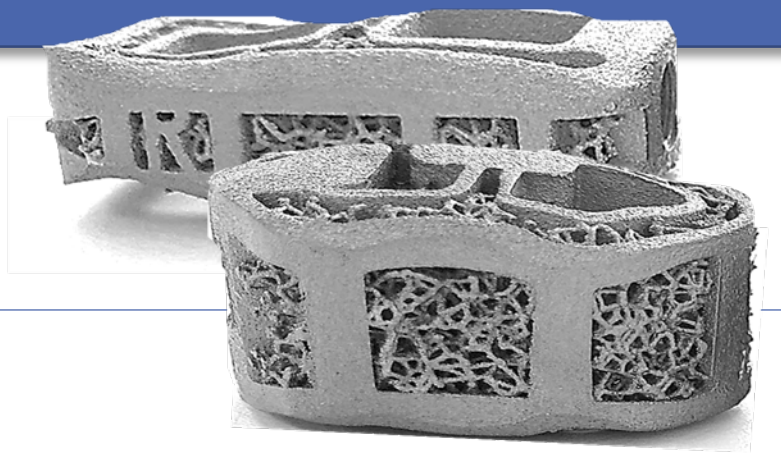
Regulatory

Breakthrough Device Designation : July 2020
FDA cleared : December 2020
(additional configurations pending FDA clearance)
First clinical use : Q1 2021

Intended to stabilize the lumbar spinal column and facilitate fusion at one or more vertebral levels of the lumbar spine with FDA cleared supplemental fixation .Indicated for use as an adjunct to fusion at one or more levels of the lumbar spine in patients having an ODI >40 and diagnosed with severe symptomatic adult spinal deformity (ASD) conditions. These patients should have had six months of non-operative treatment. The devices are intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. These implants may be implanted via a variety of open or minimally invasive approaches. These approaches may include anterior lumbar interbody fusion or lateral lumbar interbody fusion.

aprevo™ patient-specific intervertebral body fusion devices have never been the subject of a recall by the FDA or an adverse event in the United States.



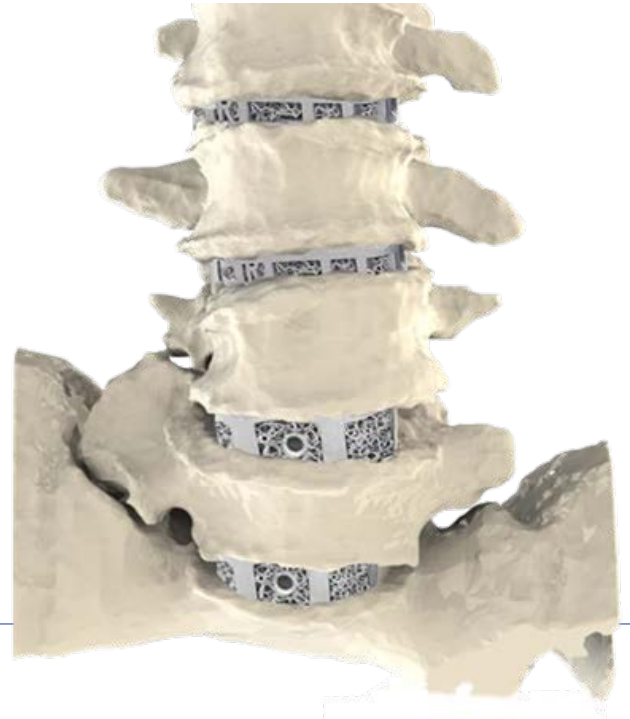
Procedural Naming Conventions

Existing ICD-10-PCS codes identify only generic, non-patient-specific IBF devices. The existing codes do not identify patient-specific devices such as aprevo™, and do not allow for accurate reporting and outcomes-tracking when utilizing this device.

aprevo™ intervertebral body fusion device

Relevant joints:
- Thoracolumbar vertebral joint
- Lumbar vertebral joint
- Lumbar vertebral joints, 2 or more
- Lumbosacral joint

Relevant approaches:
- Open
- Percutaneous
- Percutaneous



Summary

- *aprevo* has been cleared by the FDA as a device and has been granted Breakthrough designation.
- *aprevo* devices allow the surgeons to tailor the deformity correction to the individual needs of the patient.
- *Aprevo* meets specific alignment goals for each patient to improve outcomes, reduce complications, and contribute to greater patient satisfaction.
- *aprevo* will be used in conjunction with spine procedure codes, but those procedure codes cannot presently appropriately identify a patient-specific intervertebral body fusion device.

References

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Thank you