

# aprevo<sup>®</sup>

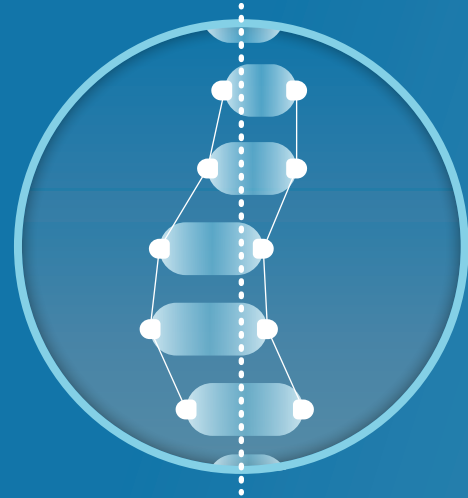
## AI-Enabled 3D Surgical Planning and Patient-Specific Devices



# Challenges in Spinal Fusion Today

## Are Current Lumbar Fusions Sufficient?

Patients have unique anatomical challenges which call for unique solutions.



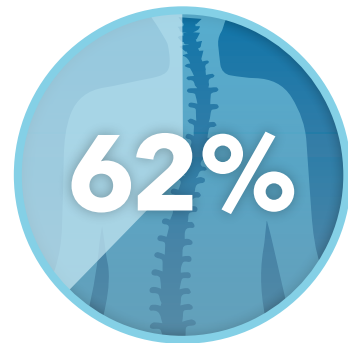
Many patients are left with spinal malalignment, experience complications or require a revision surgery following spinal fusion procedures.<sup>1</sup>

# The aprevo® Technology Platform

An End-to-End Integrated Platform Designed for Better Surgical Results, Reduced Revisions and Improved Long-Term Outcomes

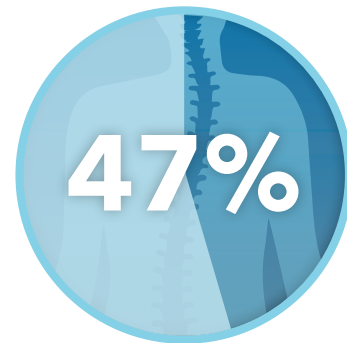


## MALALIGNMENT



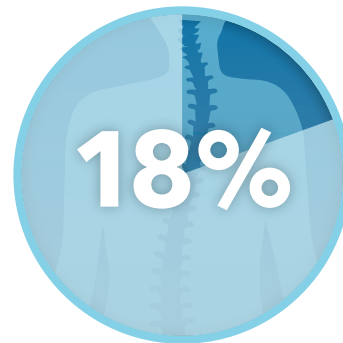
- 62% of patients remained sagittally malaligned after surgery, and 25% of patients remain coronally malaligned after surgery<sup>1</sup>
- For every 1° increase in PI-LL mismatch, the odds of developing adjacent-level disease requiring surgery increased by 40%<sup>2</sup>

## COMPLICATIONS



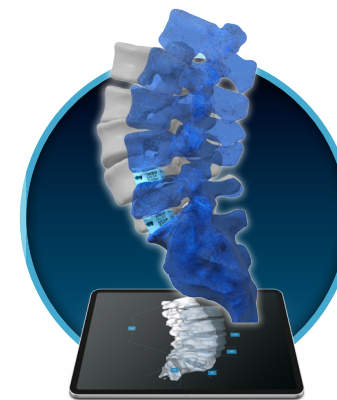
- Implant-related mechanical failure is the most common complication following adult spinal deformity surgery, affecting up to 47% of post-operative patients<sup>3</sup>

## REVISIONS



- 18% of patients undergo revision within four years of spinal deformity surgery<sup>4</sup>
- The 11-year revision rate of lumbar fusion surgery for degenerative spine disorders stands at 20%<sup>5</sup>
- There is a 10x higher probability of revision if sagittal alignment is not achieved during the primary surgery for degenerative conditions<sup>6</sup>

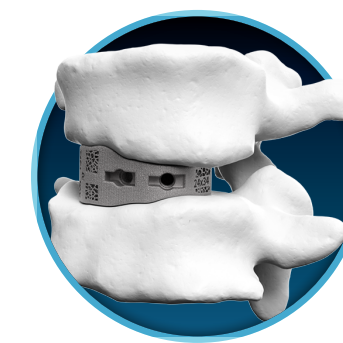
## 1 PRE-OP



myaprevo™

AI-enabled 3D planning and visualization software provides simple and engaging 3D plan visualizations for surgeons. Each patient's personalized plan and associated patient-specific devices are visualized, reviewed and approved through the myaprevo™ App.

## 2 INTRA-OP



aprevo®

3D correction is built into each aprevo® Interbody Device to help surgeons attain precise correction and predictably achieve the surgical plan. The device is custom-made to map to the unique contours of each patient's anatomy.

## 3 POST-OP



aprevo intelligence

Using personalized analysis, data from each case is used to aid and inform the planning process to enable continuous learning and increased reproducibility.

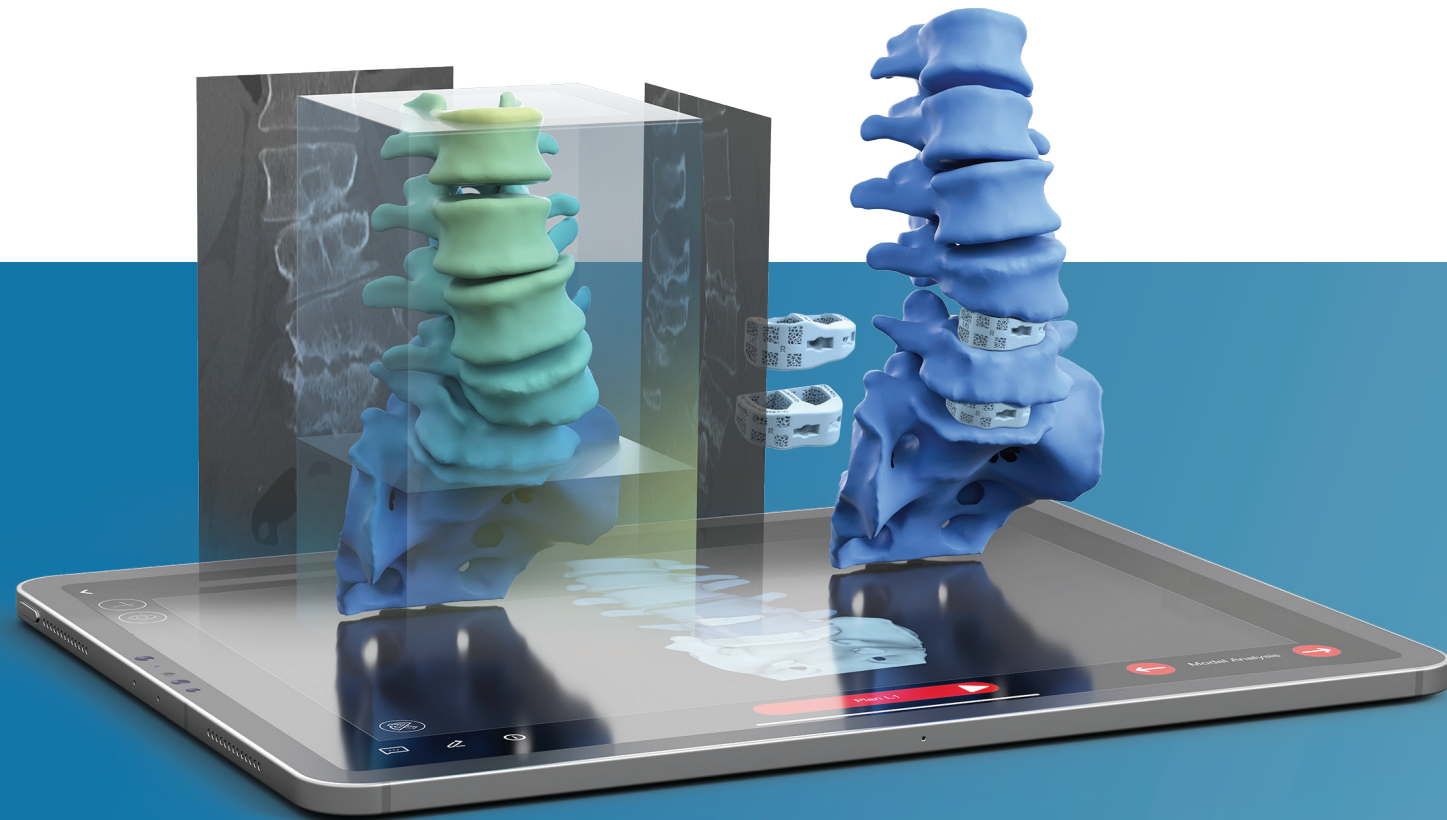




# Pre-Operative Planning Software

## aprevo® Personalized 3D Surgical Planning

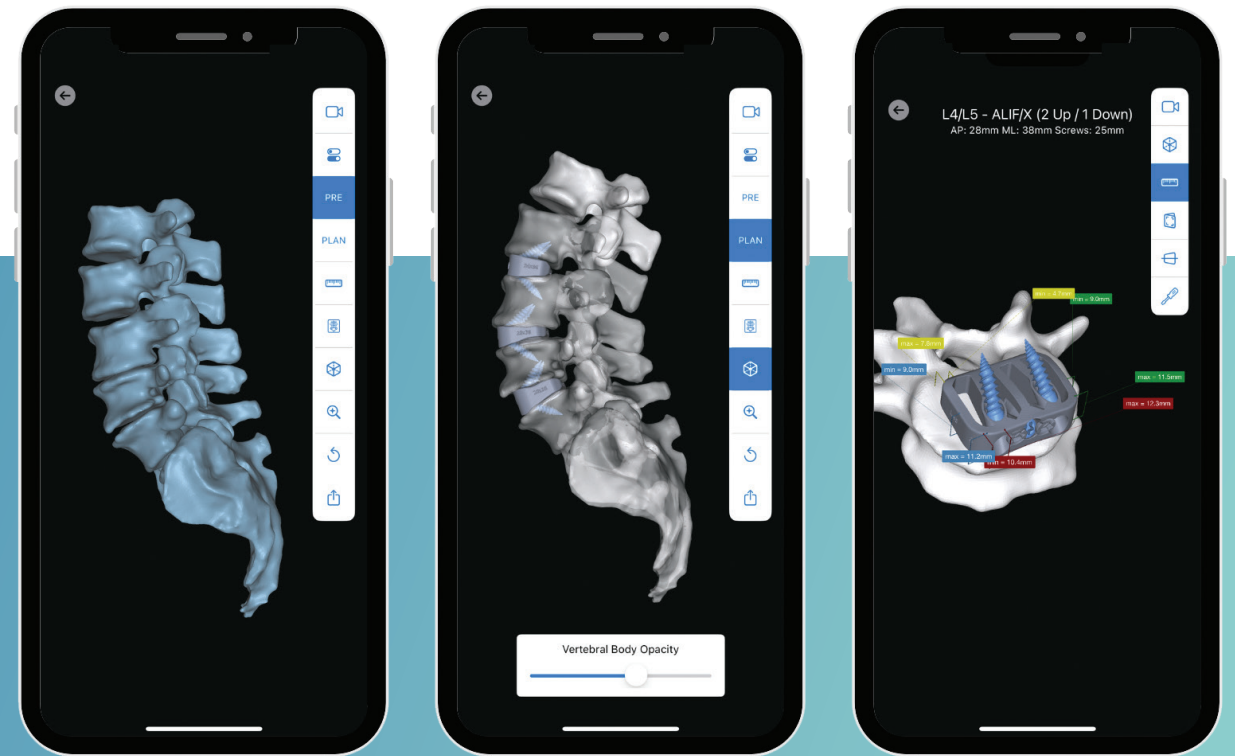
The aprevo® Planning Software combines AI-Enabled segmentation and prior outcomes data to develop personalized surgical plans and devices for each patient.



# Intra-Operative Visualization

## Execute Intra-Operative Precision

Access to the surgical plan aids in the ability to attain precise correction and predictably achieve the desired alignment.

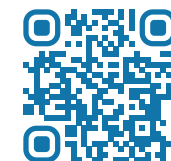


### Comprehensive Insight-Driven Planning

The aprevo® Pre-Operative Planning Software integrates detailed 3D patient data, the latest spinopelvic parameter classifications, normative range targets and real-world post-operative data to inform and enhance pre-operative plans.

# myaprevo™

The myaprevo™ App provides simple and engaging 3D plan visualization for the surgeon. Each patient's personalized plan and associated patient-specific devices are reviewed, visualized and approved through the platform.





INTRA-OP Continued

# aprevo® Personalized Devices

## 3D Correction is Built Into Each aprevo® Personalized Interbody Device

Utilizing patient data and advanced digital technologies, surgical plans are tailored to each surgeon's preferences and each patient's unique needs. Each patient receives a "made for you" device, ensuring that their personalized treatment extends seamlessly into the operating room.

### A Precision Fit Designed to Optimize Surgical Outcomes

**aprevo® Lateral LLIF**

**aprevo® Transforaminal TLIF-O | TLIF-C**

**aprevo® Anterior ALIF | ALIF-X**

Porous titanium surface lattice designed to promote bone on-growth and in-growth

# Personalized Devices vs. Stock Implants

## The aprevo® Platform Offers Surgeons Customized Surgical Planning Solutions and Uniquely Crafted Personalized Devices Designed to Achieve Better Surgical Outcomes Compared to Traditional Stock Devices

aprevo® Personalized Devices deliver a precise fit tailored to each patient's unique anatomy. Data shows that end-plate matched devices significantly increase surface contact area<sup>7</sup> and reduce posterior rod stress.<sup>8</sup> Unlike stock implants, aprevo® Devices correct in all planes, incorporating both coronal and sagittal alignment to help surgeons achieve their planned alignment with greater precision.

### aprevo® Clinical Data

#### Predictable Intervertebral Alignment:

82% of 365 Personalized aprevo® Interbody Levels achieved targeted alignment within 5°<sup>9</sup>

#### Improved Bone Graft Contact:

94% average aprevo® Device to vertebral endplate contact at 1-year follow-up on CT<sup>10</sup>

#### Subsidence Mitigation:

96% of Personalized aprevo® Levels with zero subsidence at 1-year follow-up on CT<sup>10</sup>

#### Improved Alignment Restoration in Degenerative Cases:

52% increase in alignment restoration of preoperatively malaligned patients with degenerative conditions using aprevo®<sup>11</sup>

#### Improved Alignment in Complex Adult Deformity:

42% improvement in achieving targeted PI-LL within 5° compared to stock implants<sup>12</sup>

#### Reduced Rate of Revisions:

<2% rate of revision surgery for mechanical complications in adult spinal deformity patients from the multi-center COMPASS Registry<sup>13</sup>

#### Endplate-Matched Implants Have Shown:

**28%**

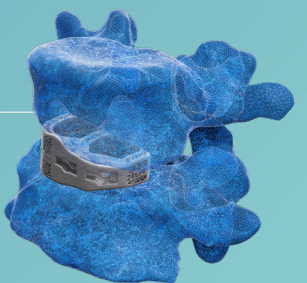
decrease in posterior rod stress<sup>8</sup>

**50x**

increase in contact area<sup>7</sup>

**30x**

reduction in stress concentration on the endplate<sup>7</sup>





# aprevo<sup>®</sup> intelligence

## Achieve the Plan With aprevo<sup>®</sup>

aprevo<sup>®</sup> intelligence provides the surgeon with confirmation of achieved alignment through post-operative analysis and usage reports.



# Driven by Data

## Continuous Learning

A continuous feedback loop powered by personalized analysis examines performance to enhance reproducibility and integrated learning. By leveraging post-operative insights, surgeons can utilize outcomes data to achieve greater precision and predictability.



**Data Collection** 6

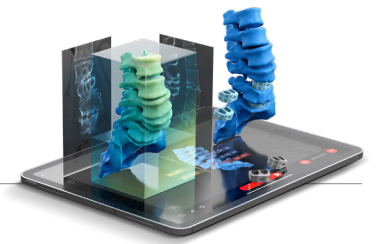
Post-operative radiographs are collected by Carlsmed<sup>®</sup>. This imaging data is analyzed, and a detailed aprevo<sup>®</sup> intelligence case report is generated, reflecting pre-operative, planned and post-operative alignment parameters.

**aprevo<sup>®</sup> intelligence** 7

Ongoing data collection and analysis fuel the planning algorithm by identifying areas for improvement. By leveraging these post-operative insights, surgeon preferences are fine-tuned to streamline the planning process and facilitate precision performance.

# The aprevo® Workflow: A Seamless End-to-End Platform

aprevo®



## REFERENCES

1. Moal B, Schwab F, Ames CP, et al. Radiographic outcomes of adult spinal deformity correction: A critical analysis of variability and failures across deformity patterns. *Spine Deform.* 2014 May;2(3):219-225. doi: 10.1016/j.jspd.2014.01.003
2. Tempel Z, Gandhoke G, Bolinger B, et al. The influence of pelvic incidence and lumbar lordosis mismatch on development of symptomatic adjacent level disease following single-level transforaminal lumbar interbody fusion. *Neurosurgery* 80:880-886, 2017. doi: 10.1093/neuros/nyw073
3. Ha AS, Hong DY, Coury JR, et al. Partial intraoperative global alignment and proportion scores do not reliably predict postoperative mechanical failure in adult spinal deformity surgery. *Global Spine J.* 2021;11(7):1046-1053. doi: 10.1177/2192568220935438
4. Glassman SD, Dimar JR 2nd, Carreon LY. Revision rate after adult deformity surgery. *Spine Deform.* 2015;3(2):199-203. doi:10.1016/j.jspd.2014.08.005
5. Martin BI, Mirza SK, Comstock BA, Gray DT, Kreuter W, Deyo RA. Reoperation rates following lumbar spine surgery and the influence of spinal fusion procedures. *Spine (Phila Pa 1976).* 2007;32(3):382-387. doi:10.1097/01.brs.0000254104.55716.46
6. Rothenfluh D, Mueller D, Rotherfluh E, Min K. Pelvic incidence-lumbar lordosis mismatch predisposes to adjacent segment disease after lumbar spinal fusion. *Eur Spine J.* 2015; 24(6):1251-1258. doi: 10.1007/s00586-014-3454-0
7. Patel R. Does patient-specific implant design reduce subsidence risk in lumbar interbody fusion? A bottom-up analysis of methods to reduce vertebral endplate stress. University of Colorado Denver, 2018.
8. Chatham LS, Patel VV, Yakacki CM, Dana Carpenter R. Interbody spacer material properties and design conformity for reducing subsidence during lumbar interbody fusion. *J Biomech Eng.* 2017;139(5):0510051-0510058. doi: 10.1115/1.4036312
9. Sadrameli SS, Blaskiewicz DJ, Asghar J, et al. Predictability in achieving target intervertebral lordosis using personalized interbody implants. *Int J Spine Surg.* 2024;18(S1):S16-S23. doi: 10.14444/8637
10. Ames C, Smith J, Nicolau R. Tomographic assessment of fusion rate, implant-endplate contact area, subsidence, and alignment with lumbar personalized interbody implants at one-year follow-up. *Int J of Spine Surg.* 2024; 18(S1):S41-S49. doi.org/10.14444/8640
11. Asghar J, Patel AI, Osorio JA, et al. Mismatch between pelvic incidence and lumbar lordosis after personalized interbody fusion: The importance of preoperative planning and alignment in degenerative spine diseases. *Int J Spine Surg.* 2024;18(S1):S24-S31. doi:10.14444/8638
12. Smith JS, Mundis GM, Osorio JA, et al. Analysis of personalized interbody implants in the surgical treatment of adult spinal deformity. *Global Spine J.* doi:10.1177/21925682231216926
13. Kent RS, Ames CP, Asghar J, et al. Radiographic alignment in deformity patients treated with personalized interbody devices: early experience from the COMPASS registry. *Int J Spine Surg.* 2024;18(S1):S6-S15. doi:10.14444/8636



Learn more at: [www.carlsmed.com](http://www.carlsmed.com)



## CT Scan

Patient-specific CT scans and imaging are used to create a precise 3D model of the spine, providing a detailed foundation for personalized surgical planning.



## 3D Plan & Design

aprevo® AI-Enabled Software helps surgeons create surgical plans with precise alignment and desired corrections. Based on the plan, patient-specific devices are designed to fit the patient's unique anatomy.



## Manufacture

The patient's aprevo® Devices are 3D-printed after the surgical plan and device designs are approved by the surgeon.



## Device Delivery

The patient's personalized devices are delivered sterile and ready for implantation during surgery.



## Data Intelligence

The patient's post-operative images are measured and analyzed to refine future surgical plans and improve precision through continuous learning.



