

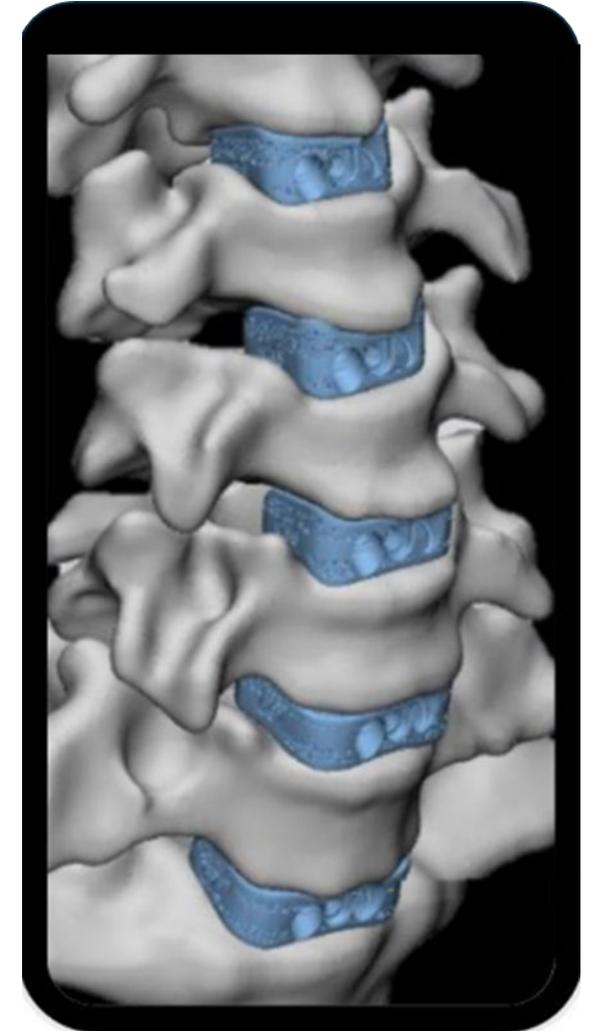


aprevo®-C

**Cervical Spinal Fusion with Custom-Made
Anatomically Designed Interbody Fusion Device**

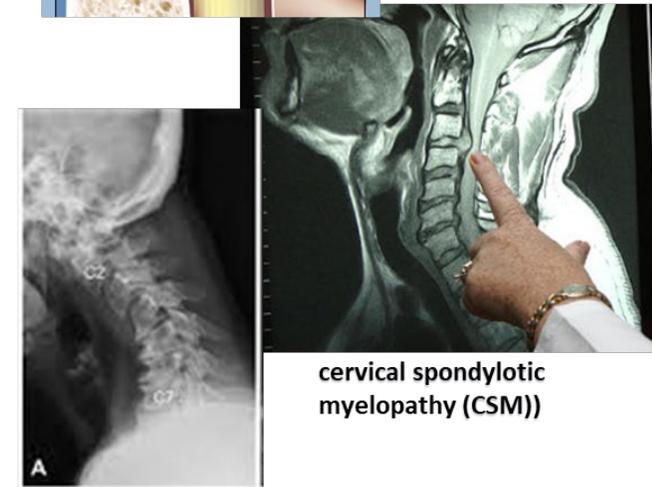
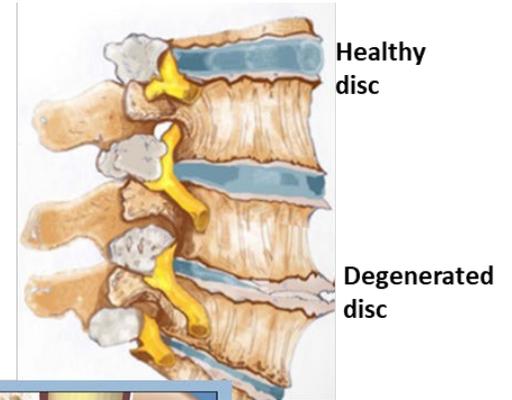
aprevo® Cervical Custom-Made Anatomically Designed Intervertebral Body Fusion Device

1. This device is a cervical intervertebral body fusion implant that is intended to stabilize the cervical spinal column and facilitate fusion between two levels of the cervical spine. It is 3-D printed from titanium.
2. The device is indicated for ACDF (anterior cervical discectomy and fusion) at one or multiple levels of the cervical spine (C2-T1) in patients with the following **degenerative cervical conditions**:
 - cervical disc disease,
 - instability,
 - deformity defined as kyphosis, lordosis, or scoliosis,
 - trauma, including fractures
 - cervical spondylotic myelopathy,
 - spinal stenosis, and
 - failed previous fusion.
3. The ACDF procedure may be performed in an **inpatient** or **outpatient** setting.
4. The fusion procedure and the use of the aprevo® Cervical Custom-Made Anatomically Designed Intervertebral Body Fusion Device is **documented in the surgeon's operative notes**.
5. The device may be used at **one or multiple levels** and is **permanent**.
6. **FDA clearance was received** on November 15, 2024. There has not been clinical use of the device.



The Health Impact of Severe Cervical Spondylosis

1. While 85% of individuals over the age of 60 show some radiographic evidence of cervical spondylotic (degenerative) changes, the vast majority are asymptomatic or successfully treated with conservative care.¹
2. More severe patients typically present with symptoms of pain (radiculopathy) or motor-function loss (myelopathy). Typical diagnoses include fractures, degenerative disc disease, spinal canal narrowing (stenosis), or structural deformity. Consequently, nerve roots and/or the spinal cord may be compressed and/or injured causing the associated symptoms.
3. Degenerative spinal conditions are associated with pain, physical disabilities and mental disabilities, as well as decreases in health-related patient quality of life.
 - Cervical Spondylotic Myelopathy (CSM) affects quality of life to an extent greater than diabetes or cancer.²
 - Adult Cervical Spinal Deformity (ACSD) impacts health related quality of life comparable to the bottom 25th percentile of blindness, emphysema, renal failure, and stroke.³
4. Anterior Cervical Discectomy and Fusion (ACDF) procedures are reserved to treat severe cases that do not improve with conservative treatment.



Adult cervical spinal deformity (ACSD)

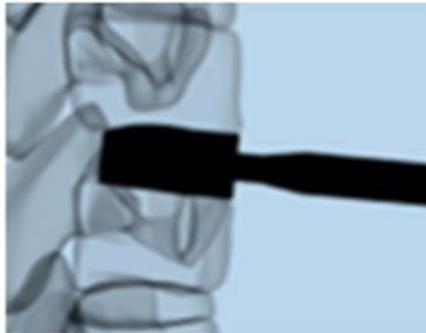
1. Kuo DT, Tadi P. Stat Pearls Publishing; 2025 Jan-Available from: <https://www.ncbi.nlm.nih.gov/books/NBK551557/>
2. Oh, Taemin et al. World neurosurgery vol. 106 (2017): 699-706. doi:10.1016/j.wneu.2016.12.124
3. Smith, Justin S et al. Neurosurgery vol. 80,5 (2017): 716-725. doi:10.1093/neuros/nyx028

FDA Breakthrough Device Designation

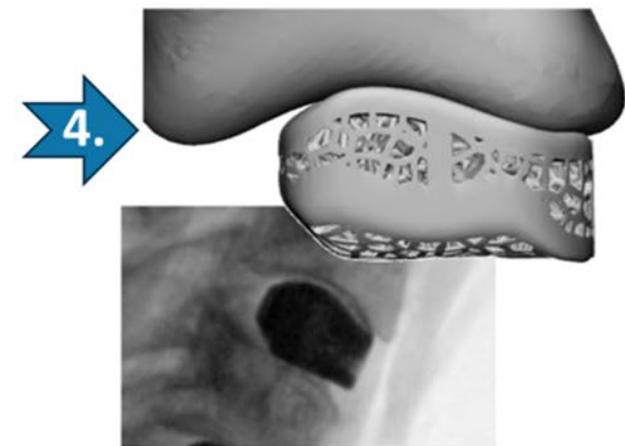
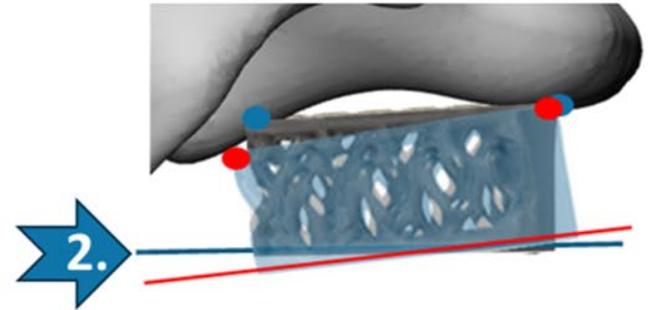
the aprevo[®] cervical devices are expected to improve the standard of care in cervical fusion surgery.



1. Achieving appropriate cervical curvature (lordosis) improves clinical outcomes and reduces the risk of requiring additional surgery due to failure of the adjacent level or recurrence of symptoms.
2. However, achieving optimal alignment is challenging. This is because the bony anatomy of the cervical vertebral endplate is different for every patient. Off-the-shelf devices do not fit the anatomy of the patient, and this can cause unpredictable angles and poor surgical outcomes.

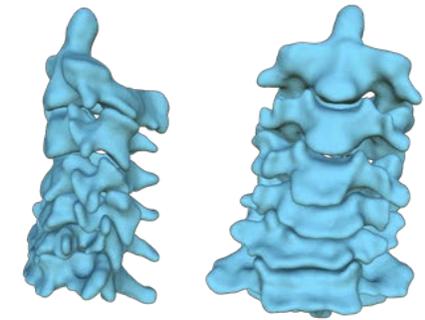
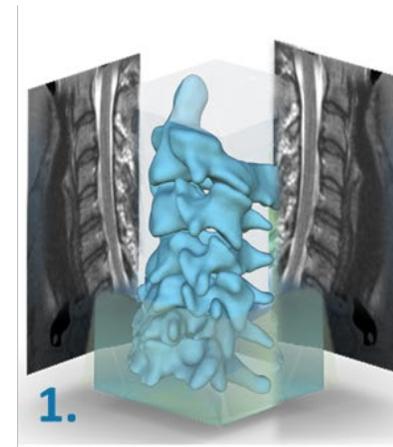


3. To improve fit, surgeons frequently burr away surface irregularities on the endplate, however removing just 1mm of bone significantly weakens the endplate, which can allow a sinking of the interbody device into the bony surface (subsidence), causing pain and loss of alignment.
4. Custom-made anatomically designed cervical interbody devices are created to match the precise alignment needs of each patient and to fit the irregular surface of their bone.

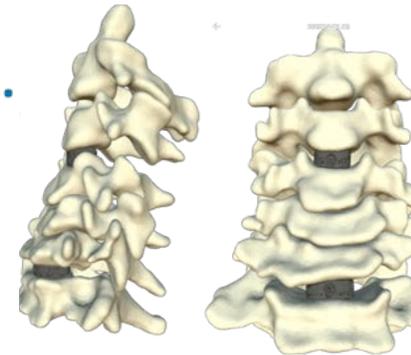


The Design Process

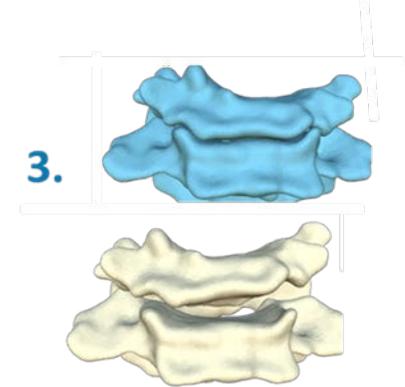
1. Patient imaging is used to create a virtual 3-dimensional cervical spine model using AI enabled software. Each vertebral body is individually segmented, and the endplate anatomy is topographically mapped.
2. The clinician's treatment and alignment goals for the patient are translated to a surgical plan in which the vertebral bodies adjacent to the disc spaces being treated are positioned to achieve these goals.
3. The negative space arising between the vertebral endplates is mapped to define the geometry of the device and achieve the desired spinal alignment.
4. The superior and inferior device surfaces are matched to the bony topography of the endplates.
5. The implants will be 3D printed from titanium alloy. Carlsmed creates the personalized surgical plan and fabricates the matching patient specific devices in approximately two weeks.



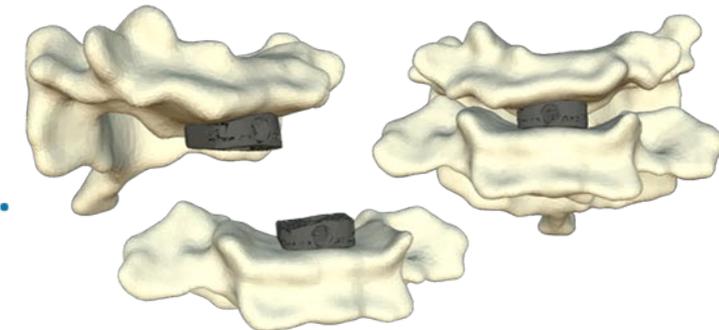
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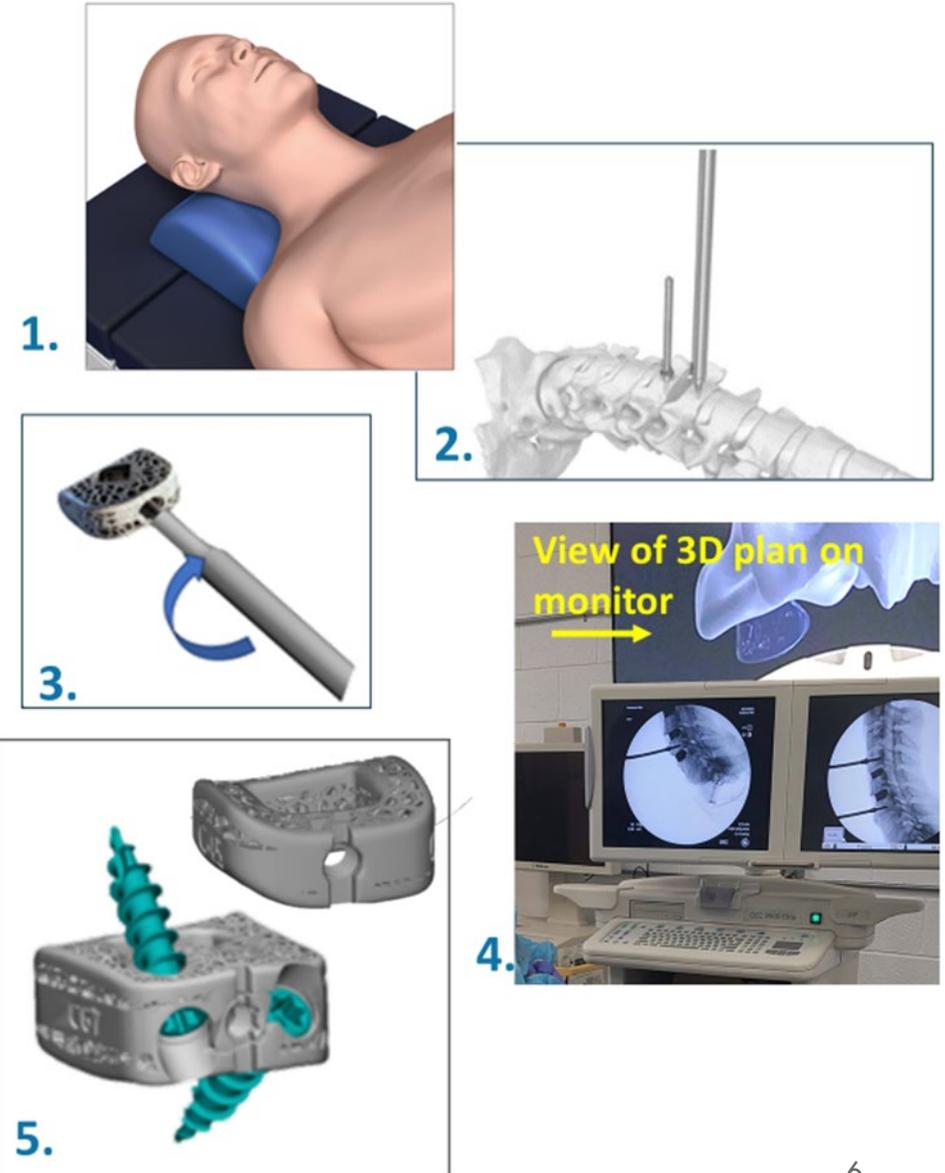
4.



Procedure Steps

Same Implantation Method as Stock Interbody Fusion Devices Except the Trial-and-Error Fit Process is Eliminated

1. An anterior approach is used.
2. After the discectomy and decompression are performed, the disc space is carefully prepared for the interbody fusion device. Subchondral bone on the vertebral endplate is preserved to optimize the fit between the patient-specific aprevo[®] cervical device and the bony endplates.
3. The aprevo device is attached to the inserter and placed into the disc space. Two height options are provided for each treated level.
4. To aid in achieving the appropriate implant position, the surgeon may compare the position of each implant in the A/P and lateral views, as seen on intraoperative fluoroscopy, to the targeted position in the 3D plan.
5. The aprevo[®] personalized cervical interbody devices are available with and without integrated screw fixation. When used with the integrated fixation screws, the device may be used as a standalone, however, when used without the integrated screw fixation, supplemental fixation (such as an anterior plate with screws) is required.
6. Cervical interbody devices are considered permanent, however, if removal is required, the process is identical to the use of stock devices.



Documentation

- Documentation of the implantation of the aprevo® cervical device can be found in the operative report of the patient’s medical record

Procedural Naming Conventions

- aprevo® cervical intervertebral body fusion device (anterior column)
- aprevo® cervical interbody device
- Custom-made anatomically designed CERVICAL interbody device

Relevant joints:

- Cervical Vertebral Joint
- Fusion of 2 or more Cervical Vertebral Joints
- Fusion of Cervicothoracic Vertebral Joint

Relevant approaches to anterior column

- Anterior Open
- Anterior Percutaneous
- Anterior Percutaneous endoscopic



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The aprevo[®] **Clinical Goal**

**Reduce implant
related complications and revisions
through
improved surgical outcomes.**



Thank you