Abstract: The VariLift-L Expandable Interbody Fusion Device has a novel design that was developed to meet the clinical, biomechanical, and anatomic requirements of a stand-alone fusion device, while addressing the known problems with interbody cages and spacers. Device performance has been demonstrated in laboratory testing and validated through clinical experience.

Introduction
For the past several decades, spinal fusion has been the standard of care for the surgical management of a variety of spinal disorders. The constructs for stabilizing the fusion have evolved over the years, including the introduction of interbody cages or spacers which are often used in conjunction with posterior pedicle screw instrumentation. Some problems associated with these devices include:

- Subsidence into the vertebral body
- Anterior or posterior migration
- Limited view of the fusion
- Long, invasive surgical procedure

However, these devices have generated mixed clinical success and a measure of controversy. Some problems associated with these devices include:

To address these problems, a stand-alone intervertebral fusion device should meet at least the requirements listed below.

### Design Criteria for Stand-Alone Intervertebral Devices

1. Support biomechanical loads without supplemental fixation
2. Provide immediate stability
3. Resist subsidence and migration
4. Restore anatomic alignment
5. Minimize exposure and nerve retraction
6. Preserve native anatomy
7. Contain substantial graft volume
8. Provide view of fusion

### VariLift®-L Device Description

The VariLift-L Expandable Interbody Fusion Device was designed to fulfill the design criteria for successful stand-alone interbody fusion. The system consists of titanium-alloy (Ti6Al4V) interbody devices with a novel expansion feature. (Figure 1) The device is cylindrical in shape, with flattened sides, a grooved surface, a hollow inner chamber, and wide fenestrations on each of the four sides.

To implant the device, it is first threaded into the disc space in the unexpanded form. Then, an inner locking expansion washer is advanced anteriorly to spread open the device, expanding it to an angle of 12°. Note that this procedure requires complete disc removal and careful preparation of the endplates to achieve direct contact with bleeding bone.

**Figure 1:** The VariLift-L Expandable Interbody Fusion Device was designed for bilateral placement via the PLIF approach or single device placed via a transverse approach.
VariLift-L Device Evaluation

The design features of the VariLift-L device address each of the 8 requirements for stand-alone interbody fusion, as detailed below.

1. Support loads without supplemental fixation.

The VariLift-L device is manufactured from titanium alloy, a high-performance orthopedic material well-known for its strength and fatigue performance.

Biomechanical device testing was conducted per ASTM Standard F2077-03, “Test Methods for Intervertebral Body Fusion Devices”, including the following test modes:

- Static axial compression
- Static shear compression (Figure 2)
- Dynamic (fatigue) axial compression
- Dynamic (fatigue) torsion

The clinically-relevant, worst-case scenario was tested (i.e. the smallest-size device (11 mm) in the expanded form).

In all lab tests, the devices met or exceeded the performance requirements at loads far exceeding typical physiologic conditions.\textsuperscript{11}

2. Provide immediate stability.

As the VariLift-L device is expanded, the ridges on the superior and inferior surface grip into the vertebral endplates. The wedge shape provides further resistance to motion after placement. The stability of this geometry was verified in laboratory testing (ASTM Draft Standard F-04.25.02.02, “Static Push-out Test Method for Intervertebral Body Fusion Devices”).\textsuperscript{11}

3. Resist subsidence and migration.

The geometry of the VariLift-L device is also intended to avoid subsidence and migration over time.

The device demonstrated sufficient resistance to subsidence in laboratory testing (ASTM F2267-04, “Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device under Static Axial Compression”).\textsuperscript{11}

Additionally, the literature states that a device surface area covering 30% – 40% of the lumbar endplate should withstand normal physiologic loads without subsidence.\textsuperscript{12}

Based on the area of the fifth lumbar vertebra, which is reported to have largest superior endplate surface area (~130 mm\textsuperscript{2})\textsuperscript{13}, the surface area of VariLift-L in contact with the vertebral endplates correlates to a 46% – 82% end-plate coverage.

4. Restore anatomic alignment.

Upon placement and expansion, the VariLift-L device restores disc height and foraminal patency.

Reports in the literature of the total lordosis of the lumbar region range from about 20-70° and represent the sum of the individual angles at each vertebral pair, which range from about 4-20°.\textsuperscript{14,15,16} The 12° posterior-to-anterior angle of the VariLift-L device was selected to provide lordosis while not overstretched the adjacent tissues.

5. Minimize exposure.

The stand-alone VariLift-L PLIF involves a much reduced surgical exposure compared to pedicle screw fixation due to:

- Implant geometry
- Instrument design

The small pre-expanded size of the device eases insertion into a small incision. Additionally, the VariLift-L instruments were designed for a small incision and to reduce retraction to surrounding tissues. For instance, the semi-circular dura-retractor minimizes prolonged retraction against the nerve root and allows mobility within a small incision.

6. Preserve native anatomy.

Reduction of motion at the facet joints has been shown to transfer additional loads to the adjacent discs, possibly accelerating adjacent level disease (ALD).\textsuperscript{27,28}

The VariLift-L PLIF procedure preserves the posterior anatomy, including the motion at the facet joints. The small exposure also results in minimal muscle retraction, which may result in less post-operative pain.

7. Contain substantial graft volume.

The mechanical properties of titanium alloy allow the design to minimize wall thickness, and thus provide a large inner chamber, while meeting the biomechanical demands of a stand-alone device.\textsuperscript{11} Furthermore, the endcap (Figure 1), which is placed after packing the graft chamber, contains and secures the graft material.

8. Provide view of fusion.

The VariLift-L design incorporates large fenestrations on each of its four flattened sides, providing bone-to-graft contact at the superior and caudal surfaces and a radiographic view into the graft chamber from the lateral view. (Figure 4)
Discussion

As detailed above, laboratory testing was used to validate the biomechanical performance of the VariLift-L Expandable Interbody Fusion Device. Notably, these laboratory results are corroborated by clinical experience.

In 2002, Dr. David Attia, the inventor of the device, reported his 5-year results\cite{17, 18, 19}, noting:

- greater than 90% fusion rate
- minimal complications
- 79% of patients had pain reduce from high to low/moderate
- early recovery

A single center, multi-surgeon retrospective study of 638 consecutive patients\cite{20} with up to a 2-year follow-up demonstrated similar findings. Furthermore, radiographic analysis of this series found a 95.9% (612/638) fusion rate with significant (less than 3 mm) device subsidence and migration observed in 3.54% (11/311) and 0.64% (2/311), respectively. Other reports\cite{21, 22} have also verified the viability of the VariLift-L device in stand-alone PLIF use.

The selection of titanium alloy was crucial to the development of the VariLift-L system. The material properties of titanium alloy allow the incorporation of the expandability feature, large fenestrations, and minimal wall thickness to maximize the interior chamber. Furthermore, titanium alloy is well-known for its biocompatibility and for achieving secondary fixation in bone-contacting orthopedic applications\cite{23, 24, 25, 26}.

Conclusions

The VariLift -L Expandable Interbody Fusion System was designed specifically to meet the requirements of stand-alone fusion devices and to address the known problems with intervertebral cages. This system:

- Involves a small incision, minimal retraction, and no impaction
- Offers immediate and long-term stability
- Restores disc space and anatomic alignment
- Provides the strength and biocompatibility of titanium-alloy
- Contains substantial graft volume

This design rationale has been proven in rigorous biomechanical testing and supported by excellent clinical results.
References