

SYNFIX® EVOLUTION SECURED SPACER SYSTEM

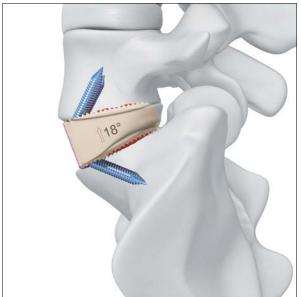
Biomechanical Stability that Stands-Alone



Introducing

SYNFIX® EVOLUTION SYSTEM for STAND-ALONE ANTERIOR LUMBAR INTERBODY FUSION (ALIF)





PROVEN PERFORMANCE, ENHANCED DESIGN.

The SYNFIX® Evolution System continues the legacy built by the biomechanical stability and proven performance of SYNFIX® LR Implant combined with the enhanced design elements of SYNCAGE® Evolution Implant.^{1,2} The system delivers an enhanced design for clinical handling and procedural efficiencies, and an improved implant offering with expanded lordotic, height and footprint options for varied patient anatomies (126 implant options).

SYNFIX® Evolution Implant for Stand-Alone ALIF

An all-In-one option

- 1. Allows insertion via a minimally invasive tissue-sparing approach
- 2. Provides a biomechanically stable environment to support fusion
- 3. Increases procedural efficiencies

- 4. Improves clinical handling
- 5. Enables restoration of segmental anatomy
- 6. Permits a more rapid return to normal activity⁶

WHERE BIOMECHANICAL STABILITY STANDS ALONE!

INDICATIONS FOR USE

The SYNFIX® Evolution Secured Cage System is a stand-alone anterior interbody fusion device indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). The interior of the cage component of the SYNFIX Evolution can be packed with autograft.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.



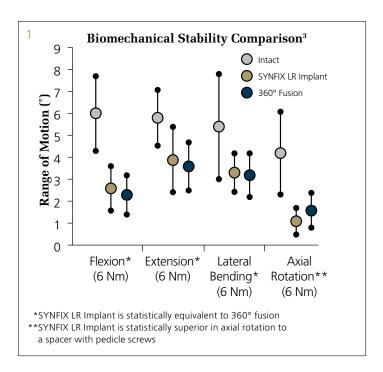
You Need

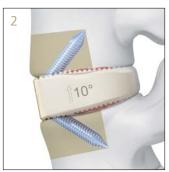
BIOMECHANICAL STABILITY*

We Deliver

- Demonstrates biomechanical stability equivalent to a cage with pedicle screws through SYNFIX® Implant technology. (Figure 1).3
- Superior biomechanical stability compared to other standalone ALIF implants with SYNFIX Implant technology.^{4,5}

Provided by an integrated titanium plate with four diverging locking screws – this forms a fixed angle construct creating a wedge of bone which acts as an anchor to potentially prevent fixation failure (Figure 2, 3).







You Need

INCREASED PROCEDURAL EFFICIENCIES

We Deliver

- Rapid screw advancement "Double lead screw" (Figure 4).
- Reduced instrumentation steps "One instrument for cage and guided screw insertion" (Figure 5).
- Secured screw attachment to driver "thread lock sleeve" (Figure 6).
- Alleviate U-joint driver soft tissue entanglement "protection sleeve" (Figure 6).







You Need

SUPPORTING CLINICAL EVIDENCE

We Deliver

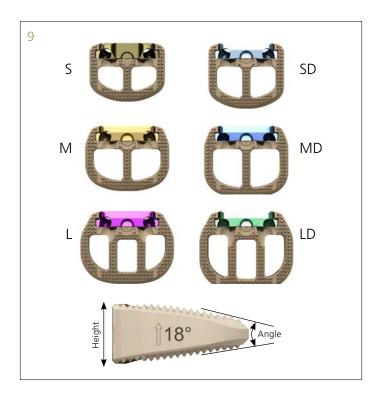
- Over 20,000 implant insertions with SYNFIX Spacer technology since inception.
- Stand-alone fusion as effective as 360° fusion in the management of discogenic or mechanical back pain over one and two levels (Figure 7, 8).^{1,2}
- Supports Anterior MIS approach shown to reduce:6
 - · Intraoperative procedural time
 - · Patient blood loss
 - · Length of Hospital Stay

You Need

BROAD IMPLANT OFFERINGS



- Optimized fit and fill of the disc space with comprehensive implant portfolio (Figure 9).
 - · 126 implant sizes
 - · 6 footprints
 - · 6 heights
 - · 4 angles
- Anatomic implant endplate geometry.
- Enhanced lumen design to maximize graft volume (Figure 10).





References

- 1. Clinical and radiological outcomes of stand-alone anterior lumbar interbody fusion used to treat discogenic pain: Two year results of the SynFix-LR device. Ardern, D W, et al. Adelaide, South Australia: ISSLS Department of Orthopaedics of Trauma, Royal Adelaide Hospital & St. Andrews Hospital, 2008.
- 2. Anterior stand-alone fusion revisited: a prospective clinical X-ray and CT investigation. Siepe, C J, et al. 2015, Eur Spine, S. 24:838–851.
- 3. A new stand-alone anterior lumbar interbody fusion device: Biomechanical comparison with established fixation techniques. Cain, C MJ, et al. 23, s.l.: Lippincott Williams & Wilkins, Inc, 2005, Spine, Bd. 30, S. 2631-2636.
- 4. Biomechanical comparison of two different concepts for stand-alone anterior lumbar interbody fusion. Schleicher, P, et al. 2008, Eur Spine, Bd. 17, S. 1757–1765.
- 5. Biomechanical comparison of stand-alone anterior lumbar interbody fusion devices with secured fixation: Four-screw locking plate vs Three-screw variable angle vs. blade fixation. Freeman, A, et al. Las Vegas, USA: s.n., 2016. ISASS.
- 6. Stand-alone Anterior Lumbar Interbody Fusion for Degenerative Disc Disease of the Lumbar Spine. Lammli, John, et al. 15, 2014, Spine, Bd. 39, S. 894 901.
- *Biomechanical test results may not necessarily be indicative of clinical performance

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