SYNFIX® EVOLUTION SYSTEM

Implants and Instruments for Stand-alone Anterior Lumbar Interbody Fusion
SUMMARY

• SYNFIX® Evolution Implants and Instruments: Overview of Features
• Design Rationale
  – Biomechanical Stability
  – Procedural Efficiencies
  – Comprehensive Implant Portfolio
• Surgical Steps
• Triple Aim
• ALIF Evolution Family
• Tips and Tricks
OVERVIEW of FEATURES
SYNFIX EVOLUTION IMPLANTS
SYNFIX EVOLUTION INSTRUMENTS
Evolution SQUID™ Inserter/Distractor Option
INDICATIONS AND CONTRAINDICATIONS

INDICATIONS

The SYNFIX Evolution Secured Spacer 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 spacer 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.

CONTRAINDICATIONS

1. Use of the SYNFIX Evolution is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials (PEEK OPTIMA LT-1, Tantalum, Titanium, Aluminum and/or niobium).

2. Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopaedic implant.

3. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in patients with such conditions must be made by the physician taking into account the risks versus the benefits to the patient.

4. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions. These patients may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.

5. Use of the SYNFIX Evolution is contraindicated when patient anatomy or pathology prevents insertion of all four locking screws.
DESIGN RATIONALE
DESIGN RATIONALE

Biomechanical Stability

Procedural Efficiencies

Comprehensive Implant Portfolio
DESIGN RATIONALE

Biomechanical Stability

Procedural Efficiencies

Comprehensive Implant Portfolio
BIOMECHANICAL STABILITY

Key Features

- PEEK ~ Cortical Bone

18°
BIOMECHANICAL STABILITY*
Compared to $360^\circ$ Fusion

The SYNFIX® LR Implant is equivalent to $360^\circ$ fusion in flexion, extension and lateral bending; superior in axial rotation.¹

¹Cain et al (2005): A new stand-alone ALIF device: Biomechanical comparison with established fixation methods
*Biomechanical test results may not necessarily be indicative of clinical performance
BIOMECHANICAL STABILITY*
Compared to Competitive Products

3 Variable Angle Screws
Medtronic
SOVEREIGN® Interbody Device

Blade Fixation
LDR Spine
ROI-A® ALIF Cage

4 Variable Angle Screws
Centinel Spine
STALIF TT® Cage

The SYNFIX LR Implant demonstrates superior biomechanical stability compared to other stand-alone ALIF products ¹,²

*Biomechanical test results may not necessarily be indicative of clinical performance
BIOMECHANICAL STABILITY

Clinical Outcome

AO principles
Key criterion to promote bone formation and solid fusion

Clinical Experience
SYNFIX LR Implant as effective as 360° fusion in achieving fusion in the management of discogenic back pain over one and two levels.

97.3% fusion rate reported with the SYNFIX LR Implant

DESIGN RATIONALE

Biomechanical Stability

Procedural Efficiencies

Comprehensive Implant Portfolio
PROCEDURAL EFFICIENCIES
Reduced Number of Instrument Passes
PROCEDURAL EFFICIENCIES
Rapid Screw Insertion & Enhanced Design for Surgeon Handling
PROCEDURAL EFFICIENCIES
Minimally Invasive Enabled Anterior Access
Potentially Leading to Reduced Hospital Stay, Blood Loss, Intraoperative Time

1Lammli et al (2014) Stand-alone Anterior Lumbar Interbody Fusion for Degenerative Disc Disease of the Lumbar Spine
DESIGN RATIONALE

Biomechanical Stability

Procedural Efficiencies

Comprehensive Implant Portfolio
**COMPREHENSIVE IMPLANT PORTFOLIO**

<table>
<thead>
<tr>
<th>Footprints</th>
<th>Angles &amp; Heights</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small</td>
<td>6°</td>
</tr>
<tr>
<td>Medium</td>
<td>32mm x 25mm</td>
</tr>
<tr>
<td>Large</td>
<td>36mm x 28mm</td>
</tr>
<tr>
<td>Small Deep</td>
<td>32mm x 28mm</td>
</tr>
<tr>
<td>Medium Deep</td>
<td>36mm x 31mm</td>
</tr>
<tr>
<td>Large Deep</td>
<td>40mm x 34mm</td>
</tr>
</tbody>
</table>

- 6 Footprints
- 4 Angles
- 6 Heights
- 126 Implant Options
COMPREHENSIVE IMPLANT PORTFOLIO
Support Sagittal Restoration & Maximized Graft Volume

Sagittal Restoration is correlated with good clinical outcome\(^1\)

COMPREHENSIVE IMPLANT PORTFOLIO
Reduced Risk of Subsidence

Appropriate choice of cage footprint potentially reduces risk of subsidence.

Asymmetrical anatomic convexity to fit lumbar and lumbosacral endplates.

1Michaela et al (2008) Footprint mismatch in lumbar total disc arthroplasty
COMPREHENSIVE IMPLANT PORTFOLIO

Screws

- Blunt tip
- Dual lead Cortical thread
- Fine tip

20 mm, 25 mm and 30 mm lengths available
SURGICAL STEPS
SURGICAL STEPS

Access

Discectomy

Distraction

Trialing
SURGICAL STEPS

Implant Preparation

Cage Insertion

Option A: Aiming Device

Option B: Evolution SQUID™ Inserter
SURGICAL STEPS

Pilot Hole Creation

Screw Insertion

Final Tightening

Screw Preparation
SURGICAL STEPS

Screw Removal

Cage Removal
TRIPLE AIM
TRIPLE AIM
Strategic Fit of the SYNFIX Evolution System

Increased procedural efficiencies targeting less OR time and reduced hospital stay

Primary biomechanical stability is a key AO principle for successful fusion

Comprehensive implant portfolio delivers solutions for a wide range of patient anatomies
EVOLUTION FAMILY
ALIF EVOLUTION FAMILY

SYNCAGE® Evolution

- PEEK cages
- Anterior and anterolateral access option
- Additional fixation required
- SYNCAGE® Evolution Trials and Rasp
- Evolution Trial Spacer and Implant Holder

SYNFRAME® Access and Retractor System
- Proprep
- Implant options (footprint, angle, heights)
- Implant convexities
- Evolution SQUID Inserter/Distractor (Push blocks are system specific)
- Exposure to closure

SYNFIX Evolution

- PEEK cage with Titanium locking plate and screws
- Anterior access option
- Stand-alone
- SYNFIX Evolution Trials
- Aiming Device Holder
- SYNFIX Evolution Trial Implant Holder
TIPS AND TRICKS
AIMING DEVICE ASSEMBLY

- The Coupling uses the same T15 drive feature as the SYNFIX Evolution Screwdriver.
- The Coupling is not self-retaining.
- The Aiming Device cannot be assembled to the Aiming Device Holder if the Coupling is fully inserted. Therefore make sure the Coupling is removed prior to assembling the Aiming Device to the Holder.
AIMING DEVICE ASSEMBLY

- It is recommended that the scrub tech removes the Coupling prior to passing the Aiming Device Holder to the surgeon. This will minimize inadvertant release of the implant as well as prevent impaction on the Coupling Screw.
- The Aiming Device Holder can be impacted for implant insertion. Remove the Coupling first!
- 17/19 Aiming Device is a 2 screw Aiming Device, due to the distance between the cranial and caudal holes on the implant. Rotation of the aiming device is necessary.
SYNFIX EVOLUTION SCREWDRIVER OPTIONS

• U-joint
• Thread Lock Sleeve (sterile, single use)

• U-joint
• Self retaining

• Straight
• Self retaining
PROTECTION SLEEVE ASSEMBLY

- For all U-jointed SYNFIX Evolution Instruments
- Slide the Protection sleeve, with the arrow pointing to the handle end
- The Protection Sleeve has a pre-angulation of 35° to facilitate insertion into the Aiming Device and provides additional positional memory of the joint
THREAD LOCK SLEEVE ASSEMBLY

- Ensure the arrow on the Thread Lock Sleeve is pointing towards the Screwdriver handle.

- Thread the Thread Lock Sleeve all the way down on the Screwdriver tip.

  Note: The Thread Lock Sleeve will float freely on the Screwdriver tip.
SCREW LOADING WITH THREAD LOCK SLEEVE

- Place a screw in the screw Loading Station with the tip down (1)
- Keep Loading Station and Screwdriver in the vertical position
- Engage the screw with the Screwdriver tip (2)
- Ensure the lobes of the Thread Lock Sleeve are mating with the loading station. It may be necessary to advance the Sleeve using your finger to engage the screw. (2)
- Use visual aids to ensure the Thread Lock Sleeve is completely down (3)
- Turn the Screwdriver counter-clockwise until the sleeve is fully seated on the screw head (two-finger tight) (3)
SCREW INSERTION

- Attach Aiming device
  - Optionally detachable Aiming Device Holder
    (It is recommended to have one screw inserted before detaching the holder)
- Create pilot hole with awl
- Screw insertion
  - Start with the S1 screw in case of L5-S1 segment
  - Align the screw with bore in aiming device
  - Lobes of Thread Lock Sleeve dock and Thread Lock Sleeve automatically detaches
  - Angulation of the U-Joint can make driving the screw challenging, so try and keep the U-Joint as straight as possible.
- In case you want to remove a screw use one of the Self Retaining Screwdrivers
Following complete screw insertion, the screw has to be final tightened with the Torque Limiting Handle.

- **Option 1** Insert the screw with a Straight Handle for ergonomics and then once all screws are inserted switch to the Torque Limiting Handle in combination with one of the Self Retaining Screwdrivers (1) (2).

- **Option 2** Insert and final tighten the screw in one step using the Torque Limiting Handle (2).
FINAL TIGHTENING

- During final tightening the **U-joint should be as straight as possible** to ensure good torque transmission from the handle to the screw.
- **Do not cross the Screwdriver over the Aiming Device Holder**
- Use the **Soft Tissue Retractor** to retract soft tissue, so you can reduce U-joint angulation
- Use the **lip designed on the Aiming Device** to find solid support for the soft tissue retractor
20°
30°
40°
50°
60°

Crossing the streams
70°

Crossing the streams