Epidemiology and Procedure Burden

Epidemiology of lumbar degenerative conditions and lumbar fusions

- Annually, 266 million patients are diagnosed with low back pain due to lumbar degenerative disease worldwide.¹

- Over 62,000 transforaminal lumbar interbody fusion (TLIF) procedures were estimated to occur in Europe in 2018.²

- The average cost of a lumbar fusion procedure in some European regions is over €10,000.³

- Minimally invasive surgery (MIS) for spinal fusion is increasing for the treatment of lumbar degenerative disease.²

- MIS TLIF is associated with lower morbidity (i.e., blood loss, surgical complications, wound infections, hospital length-of-stay)⁴⁻⁷ and lower total hospital direct costs compared with open TLIF.⁴⁻⁷

High instrument variability and unnecessary instrument use can be an important source of burden in MIS TLIF procedures⁸⁻⁹

- Across surgical specialties many surgical instruments go unused which may be due to ineffectively predicting those necessary to complete a procedure.⁸

- High instrument variability, as well as unnecessary surgical instrument sterilization, packaging, transport, unwrapping, and reorganization drives up cost and carries implications for patient safety.⁹

- In a US study focused primarily on MIS spine procedures, the reduction of unnecessary instrument (and tray) use led to the elimination of over $60,000 in wasted processing of instruments in one year.⁹ A European study estimated the cost of processing reusable instruments as up to €50.43 per tray containing more than 70 items.¹⁰

- Overall, MIS TLIF is a common procedure that can be complex,¹¹ variable in length,¹² and require multiple instruments/instrument passes.¹³

Given this burden, there are opportunities for improvement in MIS TLIF procedures.
The UNLEASH™ Solution helps to streamline and improve the 3 main stages in MIS TLIF*

1 **Discectomy**

**CONCORDE™ Clear**
MIS Discectomy Device
- Optimized for MIS (5 mm diameter)
- Variable cutting tip sizes
- 360° wall suction connection
- Allows visualization of collected disc material
- No capital equipment needed
- Sterile packed single use device

Designed to provide more efficient disc clearing and endplate preparation than using standard discectomy tools.†

2 **Cage Placement**

**PROTI 360°**
Titanium Integrated Technology
- Accelerated osteoconduction and bone matrix formation on the titanium integrated cage surfaces14
- Designed to prevent delamination due to enhanced bonding strength between PEEK and titanium15
  - Greater surface area for osteoblast integration14

Engineered to provide immediate mechanical stability and to promote rapid and long-lasting biological fixation with supporting bone.14-18

3 **Screw Placement**

**VIPER PRIME™**
System
- Advantageous technique for pedicle screw placement
- One-tool screw insertion with cortical fix fenestrated screw thread option
- Single integrated disposable stylet
- Streamlined instrument and implant set

Eliminates the need for guidewires, Jamshidi needles and pedicle preparation instruments which enables surgeons to target pedicles and insert screws in one single instrument pass.19

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* The UNLEASH Solution is indicated for lumbar arthrodesis, transforaminal interbody technique, including discectomy to prepare interspace and insertion of interbody biomechanical device with integral instrumentation for device anchoring.

† Comparative cadaver evaluation (non-clinical testing) where CONCORDE Clear MIS Discectomy Device and traditional discectomy instrumentation were randomized at surgeon and vertebral level.
Clinical Value

1. Discectomy
   - Reduced Instrument Passes When Compared to Standard Discectomy Instruments.*
   - 89% reduction in instrument passes (p<0.001)^10
   - Volumetric Removal
   - Greater Volumetric Removal for Experienced CONCORDE Clear MIS Discectomy Device Users^20
   - The results of a cadaveric study indicated greater volumetric removal with the CONCORDE Clear system.^20

2. Cage Placement
   - Stimulate
   - Osteoblast functions, including bone matrix production, are enhanced on surfaces that are most similar to bone.^14
   - Create
   - Bonding strength approximately twice that of regulatory coating requirement and 30% more compared to other Ti coated PEEK device.15
   - Integrate
   - Favorable environment for bone growth.16

3. Screw Placement
   - The VIPER Prime System was Designed to Improve Guidewire and Workflow Management in the OR.
   - Less Procedure Steps
   - When compared to the Traditional Jamshidi/ Guidewire Technique with VIPER 2.19

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* Note, the results are based on a cadaveric study and may not necessarily be indicative of clinical performance.
^ Devices are MR conditional refer to instructions for use for detailed MR labeling.
The UNLEASH Solution has the potential to improve MIS TLIF procedure efficiency through a reduction in procedure steps and screw placement time.

- The average total MIS TLIF procedure time is close to 2 hours,\(^4,21\) with high variability in procedure time components.\(^2\)
- A study of discectomy and fusion patients demonstrated that prolonged anaesthesia time significantly increased the likelihood of overall complications (Odds Ratio (OR) = 2.71, p < 0.05), venous thromboembolism (OR = 2.69, p < 0.05), length of stay (OR = 3.61, p < 0.0001), and return to the operating room (OR = 2.92, p < 0.01).\(^22\)

**Discectomy**

The CONCORDE Clear System demonstrated a 76% reduction in discectomy time when compared to traditional discectomy tools in a cadaveric ethnography study (14.96 min vs. 3.64 min, p<0.001).\(^21\)

**Screw Placement**

The VIPER Prime™ System demonstrated a 47% decrease in mean time for preparation, tapping and screw insertion (PTS) when compared to the VIPER 2® MIS Spine System (22.22 min vs. 11.85 min, p<0.001).\(^23\)

Combined, the UNLEASH Solution may provide procedural time savings in both discectomy and screw placement. A reduction in procedure time may help reduce anaesthesia time. Additionally, the UNLEASH Solution enables a reduction in instrument trays in the OR compared to current product offerings.\(^°†\)

\(^*\) Note, the results are based on a cadaveric study and may not necessarily be indicative of clinical performance.

\(^\wedge\) Instrument trays are counted as each individual tray/level within an instrument set.

\(^\circ\) The UNLEASH Solution includes CONCORDE Clear MIS Discectomy Device (0 trays), the CONDUIT EIT System (1 tray), and the VIPER Prime System (1 tray).

\(^\dagger\) Current product offerings include Standard Discectomy Instruments (1 tray), CONCORDE Bullet System (2 trays), and the VIPER® 2 MIS System (3 trays).
## Economic Value

**Time saved from reduced instrument passes can lead to reduced OR costs**

<table>
<thead>
<tr>
<th></th>
<th>Control Time (Min)^</th>
<th>UNLEASH Component Time (Min)</th>
<th>Time Savings (Min)</th>
<th>Potential Cost Savings†</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Discectomy</strong>&lt;sup&gt;§&lt;/sup&gt; (cadaveric)*</td>
<td>14.96</td>
<td>3.64</td>
<td>11.32</td>
<td>€192</td>
</tr>
<tr>
<td><strong>PTS</strong>&lt;sup&gt;°&lt;/sup&gt;</td>
<td>22.22</td>
<td>11.85</td>
<td>10.37</td>
<td>€176</td>
</tr>
</tbody>
</table>

^ Control consists of current product offerings of Standard Discectomy Instruments (1 tray), CONCORDE Bullet System (2 trays), and the VIPER® 2 MIS System (3 trays).
* Study size =18 (9 cases per group). Time savings were statistically significant (p<0.001). Cadaveric results may not necessarily be indicative of clinical performance.
° Study size = 29 (14 control, 15 experiment). Time savings were statistically significant (p<0.001).
† Assumes an OR cost per minute of €14.70 (average based on data from Italy, Germany, the Netherlands, and the UK<sup>14-23</sup>) and an anaesthesia cost per minute of €2.25.<sup>33</sup> All cost values were inflated to 2019 currency prices and converted to EUR.<sup>24,25</sup> Value of savings was derived by multiplying cost per minute (€14.70 + €2.25) by time saved (11.32 minutes for Discectomy and 10.37 minutes for PTS)<sup>24</sup>.33

**Time saved from reduced instrument passes can also lead to reduced sterilization or reprocessing costs:**

- Several studies suggest that reductions in instruments/surgical trays<sup>†</sup> result in reduced sterilization/reprocessing costs.<sup>8,9,34-37</sup>
- On average, the UNLEASH Solution is associated with 4 fewer trays<sup>†</sup> when compared with traditional product offerings, and leads to an estimated annual savings of €10,086 in sterilization costs when assuming 50 procedures per year at a given institution and a cost of approximately €50 per instrument tray<sup>§</sup> processed/sterilized.

### Model Parameters

<table>
<thead>
<tr>
<th>Model Parameters Opportunities</th>
<th>UNLEASH Solution&lt;sup&gt;†&lt;/sup&gt;</th>
<th>Comparison of current product offerings&lt;sup&gt;†&lt;/sup&gt;</th>
<th>Procedure Savings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Trays&lt;sup&gt;†&lt;/sup&gt;</td>
<td>2 Trays&lt;sup&gt;†&lt;/sup&gt;</td>
<td>6 Trays&lt;sup&gt;†&lt;/sup&gt;</td>
<td>4 Trays&lt;sup&gt;†&lt;/sup&gt;</td>
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<td></td>
<td></td>
<td>Procedures per year</td>
<td>50&lt;sup&gt;†&lt;/sup&gt;</td>
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<tr>
<td></td>
<td></td>
<td>Cost per instrument tray&lt;sup&gt;§&lt;/sup&gt; processed/sterilised</td>
<td>€50.43&lt;sup&gt;†&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Potential annual reprocessing cost-saving</td>
<td>€10,086&lt;sup&gt;Δ&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>* The UNLEASH Solution includes CONCORDE Clear MIS Discectomy Device (0 trays), the CONDUIT EIT System (1 tray), and the VIPER Prime System (1 tray).
† Current product offerings include Standard Discectomy Instruments (1 tray), CONCORDE Bullet System (2 trays), and the VIPER® 2 MIS System (3 trays).
‡ Instrument trays are counted as each individual tray/level within an instrument set.
§ Assumption based on the procedural volume of a mid-sized hospital.
△ All cost values were inflated to 2019 currency prices and converted to EUR.<sup>24,25</sup>
Δ Value of savings was derived by multiplying the sterilizing and packaging cost per instrument tray (€50.43<sup>†</sup>) by the assumption of 50 procedures per year at a given institution by the number of instrument trays lowered with the UNLEASH Solution (50 procedures x €50.43<sup>†</sup> x 4 fewer trays = €10,086).
There is a need to develop more sustainable surgical practices that improve environmental performance

- The need for improving environmental effects of healthcare has been increasingly discussed in the published literature.\textsuperscript{38-44}
- Hospitals are significant contributors to natural resource depletion and environmental impact.\textsuperscript{40,44} For instance, steam sterilization in hospitals is an energy and water intensive process.\textsuperscript{39}
- With the recent push towards sustainability, the operating room has been identified as an opportunity for environmentally conscious interventions.\textsuperscript{45,46}
- An important part of the environmental footprint of hospitals relates to use of medical devices.\textsuperscript{40,47}
- Several recent studies have reported on opportunities for improvement in sustainability measures, including more efficient hospital sterilization, and reduced unnecessary instrumentation.\textsuperscript{38,48,49}

The UNLEASH Solution includes VIPER PRIME™ System, an Earthwards\textsuperscript{®} recognized product

- The Earthwards approach is Johnson & Johnson’s continuous improvement process that is used to support the development of more environmentally sustainable products.

As Compared To The Existing VIPER\textsuperscript{®} 2 System, the VIPER PRIME™ System Is Associated With:\textsuperscript{50}:

- **Reduction**\textsuperscript{*} In Primary Packaging
  - 69%
- **Reduction**\textsuperscript{*} In Materials (Excluding Packaging)
  - 47%
- **Less Energy**\textsuperscript{*} Used To Sterilize And Disinfect Instruments
  - 67%
- **Less Water**\textsuperscript{*} Used To Sterilize And Disinfect Instruments
  - 67%

\textsuperscript{*} Earthwards\textsuperscript{®} is the Johnson & Johnson approach for developing innovative and more sustainable products.

\textsuperscript{*} Reduction are in comparison to the existing VIPER 2 system.\textsuperscript{50}
For recognized manufacturer, refer to product label.

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Please refer to the instructions for use for a complete list of indications, contraindications, warnings and precautions.