**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; ⁵; 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

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

2. CAGE PLACEMENT
   - PROTI 360° Titanium Integrated Technology
     - Accelerated osteoconduction and bone matrix formation on the titanium integrated cage surfaces
     - Designed to prevent delamination due to enhanced bonding strength between PEEK and titanium
     - Greater surface area for osteoblast integration

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

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

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

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.

† 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.
**Reduced Instrument Passes**

When compared to standard discectomy instruments,* 89% reduction in instrument passes (p<0.001).\(^{20}\)

Greater Volumetric Removal

**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.\(^{20,*}\)

**STIMULATE**

Osteoblast functions, including bone matrix production, are enhanced on surfaces that are most similar to bone.\(^{14}\)

Greater Volumetric Removal

**CREATE**

Bonding strength approximately twice that of regulatory coating requirement and 30% more compared to other Ti coated PEEK devices.\(^{15}\)

**INTEGRATE**

Favorable environment for bone growth.\(^{16}\)

*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.
**PROCEDURE Efficiency**

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, with high variability in procedure time components.
- 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).

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**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).

**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).

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**Graphs:**
- **DISCECTOMY:** The CONCORDE Clear System demonstrated a 76% reduction in discectomy time (p<0.001).  
  - Mean Time (Min): 14.96 min (Control, n=9) vs. 3.64 min (Concorde Clear, n=9)

- **SCREW PLACEMENT:** The VIPER PRIME System demonstrated a 47% decrease in mean time for preparation, tapping and screw insertion (PTS).  
  - Mean Time (Min): 22.22 min (Control, n=14) vs. 11.85 min (VIPER Prime System, n=15)

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**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.**

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*Note, the results are based on a cadaveric study and may not necessarily be indicative of clinical performance.  
Instrument trays are counted as each individual tray/level within an instrument set.  
The UNLEASH Solution includes CONCORDE Clear MIS Discectomy Device (0 trays), the PROTI 360° Titanium Integrated Technology (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).
ECONOMIC Value

Time saved from reduced instrument passes can potentially 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>Discectomy (cadaveric)°</td>
<td>14.96</td>
<td>3.64</td>
<td>11.32</td>
<td>€192</td>
</tr>
<tr>
<td>PTS²⁴</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.
 Assummes an OR cost per minute of €14.70 (average based on data from Italy, Germany, the Netherlands, and the UK) and an anaesthesia cost per minute of €2.25. All cost values were inflated to 2019 currency prices and converted to EUR. 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).

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

- Several studies suggest that reductions in instruments/surgical trays result in reduced sterilization/reprocessing costs.⁸,⁹,³⁴-³⁷
- On average, the UNLEASH Solution is associated with 4 fewer trays 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 processed/sterilized.

### Model Parameters Opportunities

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

* The UNLEASH Solution includes CONCORDE Clear MIS Discectomy Device (0 trays), the PROTI 360° Titanium Integrated Technology (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).
¹ Instrument trays are counted as each individual tray/level within an instrument set.
² Assumption based on the procedural volume of a mid-sized hospital.
³ All cost values were inflated to 2019 currency prices and converted to EUR. Value of savings was derived by multiplying the sterilizing and packaging cost per instrument tray (€50.43°) 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° x 4 fewer trays = €10,086).
EARTHWARDS® Recognition

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

The UNLEASH Solution includes VIPER PRIME System, an Earthwards® 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 2 System, the VIPER PRIME System Is Associated With51:

<table>
<thead>
<tr>
<th>REDUCTION*</th>
<th>REDUCTION*</th>
<th>LESS ENERGY*</th>
<th>LESS WATER*</th>
</tr>
</thead>
<tbody>
<tr>
<td>In Materials (Excluding Packaging)</td>
<td>In Primary Packaging</td>
<td>Used To Sterilize And Disinfect Instruments</td>
<td>Used To Sterilize And Disinfect Instruments</td>
</tr>
<tr>
<td>69%</td>
<td>47%</td>
<td>67%</td>
<td>67%</td>
</tr>
</tbody>
</table>

* Earthwards® is the Johnson & Johnson approach for developing innovative and more sustainable products.
* Reduction are in comparison to the existing VIPER 2 system.
REFERENCES

19. VIPER PRIME System Internal Data on File. ADAPTIV SEA 103327910. Note: VIPER Prime System eliminates the following steps when compared to the VIPER 2 MIS Spine System: Insert Jamshidi needle, insert guidewire, remove Jamshidi needle, insert tap, remove tap, start screw, and remove guidewire.
50. VIPER PRIME System Internal Earthwards® Data on File. ADAPTIV SEA 103339245.
51. VIPER PRIME System Internal Earthwards® Data on File. ADAPTIV SEA 103339245.