

# A Pioneering Approach to Spinal Stabilisation

Preserving Nature's Design



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# Overview

- A medical device company developing three pioneering, spinal stabilisation devices, Cervi-LOK™ , GRASP Laminoplasty & Faci-LOK™, deliver superior performance and durability and generate significant cost savings.
- As the multiple advantages of these products become apparent to surgeons, TruSpine will be positioned to create a paradigm shift that will ultimately be disruptive to the \$10.2B global spinal (vertebral) stabilisation market.
- Uniquely provides exceptional and reversible spinal stabilisation without damaging / altering the anatomy, or requiring screws traditionally implanted irreversibly into the spine.
- Following Cervi-LOK™ 510k submission to the FDA in late July, targeting commencement of commercialisation late 2023.
- Highly experienced management team and advisory board with proven track record in medical device development and roll-out.
- Strong IP position including granted Faci-LOK™ US patent.
- Pipeline of additional products exploiting the “no screw”, “anatomy preservation” approach.



# Strategy

Build a leading independent medical devices company that is at the forefront of reshaping the way clinicians approach vertebrae stabilisation and in the process transform how severe back pain is treated



Expand usage into broader settings such as diagnostics



Establish products as the go to solutions for the spinal stabilisation market.



Secure FDA approval for the three initial systems: Cervi-LOK™, GRASP Laminoplasty and Faci-LOK™.



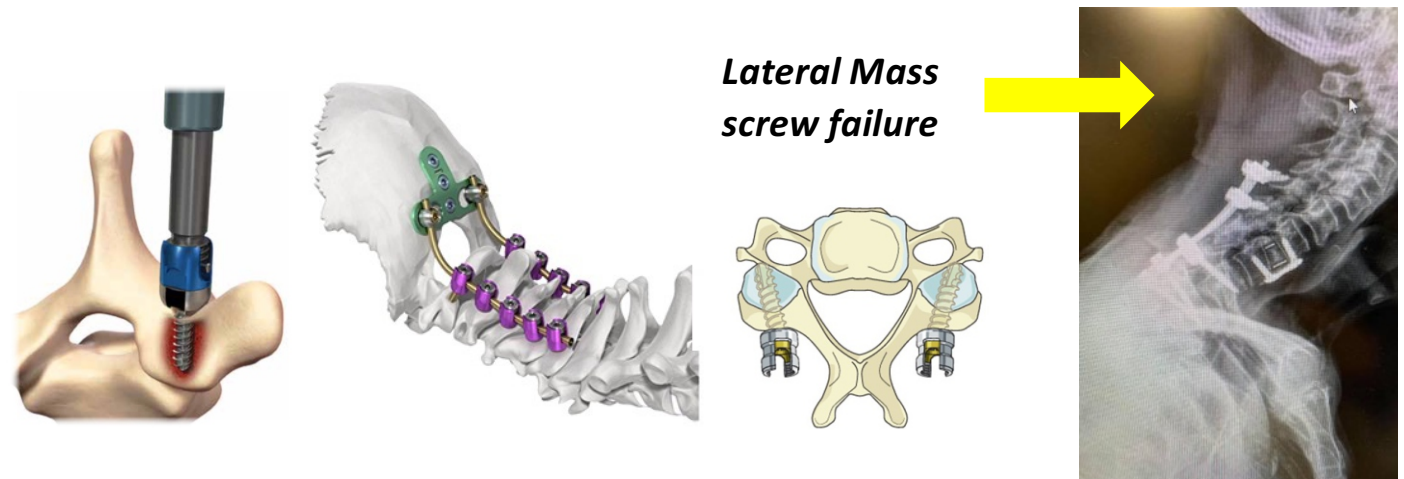
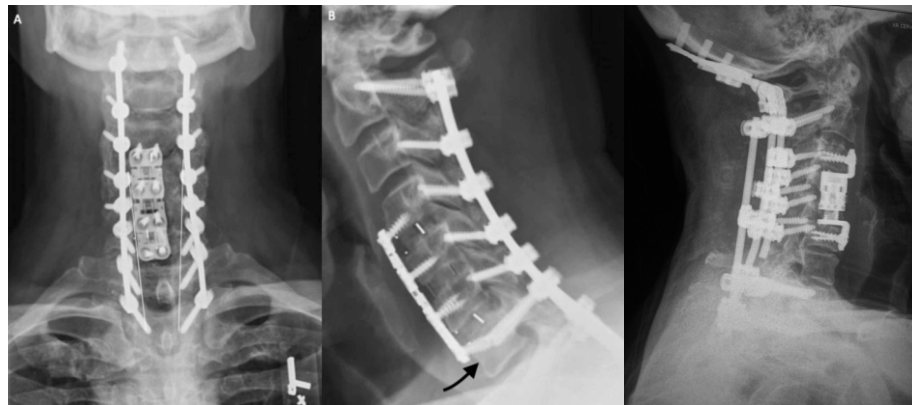
Advance existing pipeline to build a portfolio of complementary products that are minimally intrusive, reversible and preserve the anatomy

# The Problem

Spinal stabilisation technologies and techniques, such as fusion, have not appreciably evolved in over 30 years. Screws are inserted into the pedicles of vertebrae, coupled with rods that extend bilaterally along the spine for stabilisation. Fusion permanently alters the individual's biomechanics.

Placement of screws requires challenging precision - up to 20% of screws are not optimally placed. Newer computer-assisted placement only reduces incorrect placement to 7%.

Failed back and neck surgery syndrome is very well documented, affecting circa 25% of people undergoing surgery.



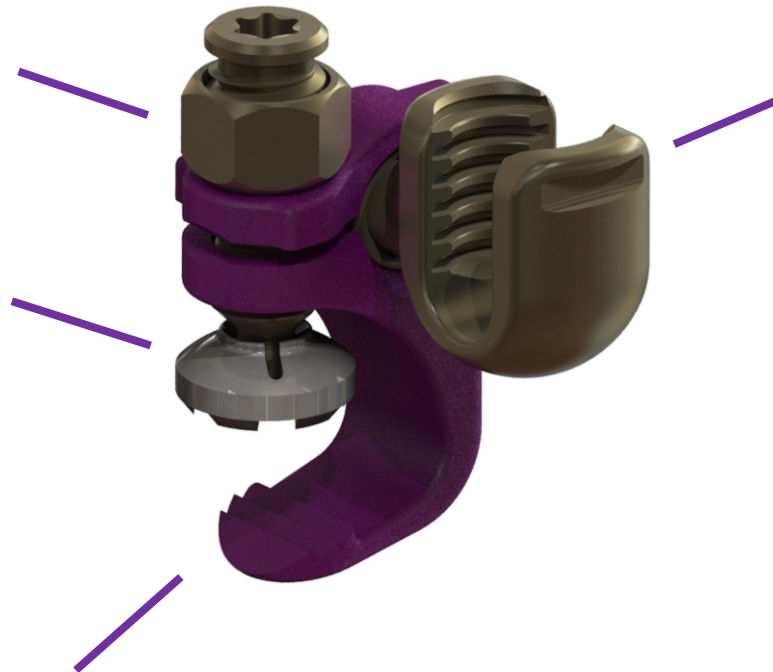
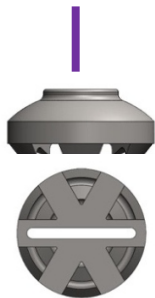
# The Solution – Cervi-LOK

Innovating and revolutionizing the posterior spine stabilization market

Clamp secured by lock nut to lock tulip and implant

Footplate driven by inner actuation screw to secure implant to posterior and sub laminar surface

Footplate Clamping Mechanism



Tulip to capture 3.5mm rod and set screw with 6 degrees of freedom (polyaxiality) for easier rod placement

- 3 implant sizes – Small, Medium, and Large
- Left and Right side specific

Serrated teeth on tongue of implant for extra security and resistance to pull off on sublaminar surface



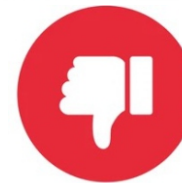
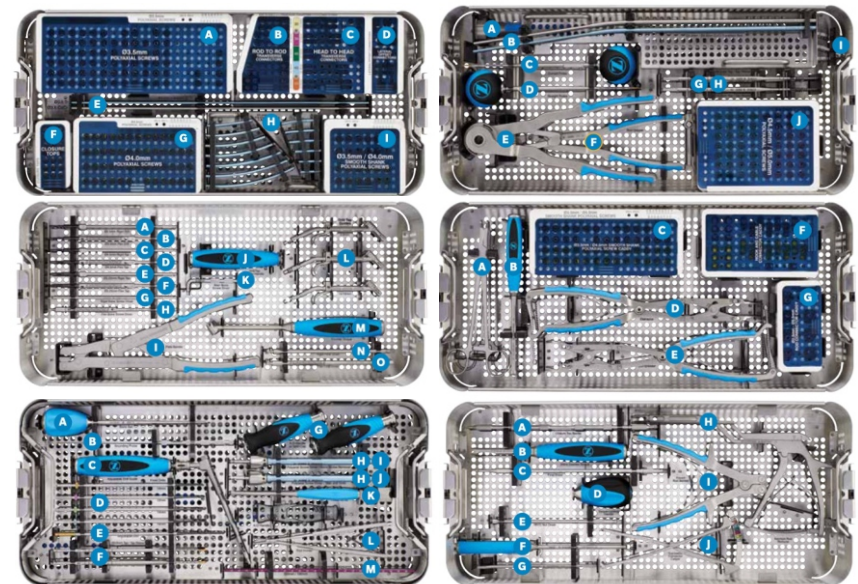
# The Solution – Cervi-Lok

## Cervi-LOK™ Instrumentation



*Instruments are single use and sterile packed*

## Standard Lateral Mass Screw Instrumentation



*Instruments need to be sterilized by hospital which is costly*

# Surgical Risk Comparison – Cervi-Lok

Surgical Risks Comparison	Cervi-LOK	Pedicle Screws
Non invasion of vertebrae	Yes ✓	No ✗
Reduced Risk of nerve injury	Yes ✓	No ✗
Preserve patient bone anatomy	Yes ✓	No ✗
Reversible Procedure	Yes ✓	No ✗
Reduced surgery time and anesthesia	Yes ✓	No ✗
Superior Pull-out Strength	Yes ✓	No ✗
Ability to modify device position post placement	Yes ✓	Limited
Significant reduction in x-ray exposure	Yes ✓	No ✗



# Cervi-LOK vs Lateral Mass Screws

- Across a literature search on Posterior Cervical Stabilization procedure times (lateral mass screws), the mean operative time across the 13 included articles was 146.8 minutes and ranged from 77.4 minutes to 240.0 minutes.
- Cadaver Labs conducted and timed to evaluate Cervi-LOK procedure times





Date	Method	Incision Time	Procedure Time	Closing Time	Total Time
7/1/21	Utah 2 Surgeons	18 min	38 min	8 min	64 min
2/3/22	SYR 1 Surgeon	15 min	47 min	10 min	72 min
2/3/22	SYR 2 Surgeons	15 min	17 min	10 min	42 min

- Significant time savings with Cervi-LOK vs Lateral Mass Screws

# Value Proposition & ValueBased Medicine

**Preserving Nature’s Design:** TruSpine is innovating and revolutionizing the posterior spine stabilization market in developing **minimally intrusive technology** and minimal disposable and sterile instrumentation that will create **costs savings** in sterilization departments, operating room time, cost, and efficiency while adding tremendous **value** for all stakeholders in the healthcare ecosystem including hospitals, payers, spine surgeons, and ultimately the patient.

Today, very few spine companies are investing in innovative ways to stabilize the posterior spine.

			
<ul style="list-style-type: none"> <li>✓ Better posterior stabilization</li> <li>✓ Reduced OR Time</li> <li>✓ Surgical efficiency and turn over</li> <li>✓ Reduced complications</li> <li>✓ Reduced instrumentation</li> <li>✓ Reduced fluoro and no navigation/robotics needed</li> <li>✓ Happy patients due to minimal incision and less intrusiveness</li> <li>✓ No burned bridges</li> </ul>	<ul style="list-style-type: none"> <li>✓ More spine procedure output</li> <li>✓ Increased \$\$\$</li> <li>✓ Reduced sterilization costs</li> <li>✓ Better patient satisfaction</li> <li>✓ No navigation/robotics required</li> <li>✓ Increased employee satisfaction</li> </ul>	<ul style="list-style-type: none"> <li>✓ Reduced costs per surgery</li> <li>✓ Recognition on utilizing superior technology</li> <li>✓ Increased \$\$\$</li> <li>✓ Marketing opportunity for hospital / payor</li> <li>✓ Increased patients treated</li> <li>✓ Optimal outcomes</li> </ul>	<ul style="list-style-type: none"> <li>✓ Better patient satisfaction</li> <li>✓ Quicker recovery due to no trauma to tissue/bone</li> <li>✓ Anatomy preserved</li> <li>✓ Less pain</li> <li>✓ Less opioids/narcotics</li> <li>✓ Less blood loss and length of stay</li> <li>✓ Same day release in some instances</li> </ul>

# Global Market

Global spinal fusion market estimated at **\$10.2bn per annum**

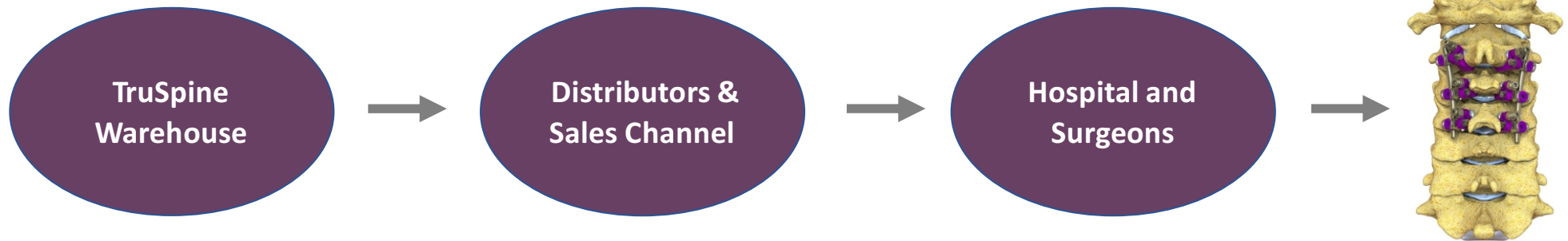
Expected to grow at a **CAGR of 3.1%** through 2026 primarily due to:

- Emerging markets
- Ageing global populations
- Increase in obesity
- Increasing awareness of treatment options

**1.6 million** spinal fusions carried out each year -  
The US currently accounts for approximately 54% of these

Nearly 65 million Americans report a recent episode of back pain. Health care costs and indirect costs due to back pain are over \$12 billion per year.

# Business Model



The Cervi-LOK System will be a game changer and disruptor to the spine market giving all distributors a SOLID solution in fusing the posterior cervical spine. As increased revenues are generated, TruSpine will expand its distribution sales channel to handle uptake of the procedure.

## Key Partners



# Commercialisation Timetable

	Q4 FY23	Q1 FY24	Q2 FY24	Q3 FY24	Q4 FY24	Q1 FY25	Q2 FY25	Q3 FY25	Q4 FY25	Q1 FY26	Q2 FY26	Q3 FY26	Q4 FY26	Q1 FY27	Q2 FY27
<b>US Commercial Launch</b>															
<b>Clinical Data Collection</b>															
<b>EU Regulatory Perperation</b>															
<b>EU Clearance and Cervi-Lok Launch</b>															

2024



2025



2026



# Summary



*Cervi-LOK Cadaver testing Lincotek Lab, Utah*

- Cervi-Lok device 510K to be lodged imminently
  - All device testing complete
  - Instrumentation & packaging complete
  - Packaging undergoing sterilisation and age testing validation
  - FDA 510k lodgement following completion of testing & validation
  - Following Cervi-LOK™ 510k submission to the FDA in late July, targeting commencement of commercialisation late 2023.
- Spartan Medical investment distribution agreement significant product validation and allows rapid go to market for Ceri-Lok post FDA
- Multiple patented products to follow on including Faci –Lok (lumber spine) & GRASP Laminoplasty.
- EIS & VCT compliant investment.

# Board of Directors



**Laurence Strauss - CEO**

- Laurence Strauss started his career in 1986 on the Stock Exchange as a Blue Button on the Market floor and built up a successful private client Broking Business working for the likes of “Allied Provincial” and “Elders Finance.”
- In 1992 Laurence chose to leave the City, taking a directorship with a small M&E contracting business quadrupling the Company’s size in 3 years. From there he was headhunted by a shop fitting business where again he oversaw a large expansion program overseeing over 200 staff and £100m T/O.
- More recently Laurence has been advising private clients on stock investments and floatation’s, he was first introduced to TruSpine Technologies Plc as a fundraiser for the Company’s IPO.



**Norman Lott - Group CFO**

- Experienced international CFO with considerable PLC experience, having held multiple roles in AIM listed companies on the London Stock Exchange
- Member of the Institute of Chartered Accountants in the UK having qualified in 1980
- Aside from his experience as CFO he has also held other senior management roles including that of CEO; he also has relevant experience in this sector



**Dr Tim Evans - Non-Exec Director**

- Apothecary to Her Majesty and the Royal Households of London since 2005
- Qualified 1979, Westminster Hospital Medical School
- Awarded with an LVO to his services by HM The Queen 2016
- He is a Trustee and UK Board member of Mothers2Mothers, a charity providing healthcare service to 8 countries in sub Saharan Africa



**Nik Patel Non Exec Director**

- Practicing Consultant Neurosurgeon & Honorary Senior Clinical Lecturer at the Institute of Clinical Neurosciences (University of Bristol) since his appointment in 2005
- Trained in medicine at Charing Cross & Westminster Medical School, & in neurosciences at University College London; in 1991, he gained a First-Class Honours Degree in Neurosciences & in 1994 graduated in Medicine with Distinction in Pathology from University of London
- His basic surgical training was completed at Oxford University & his neurosurgical training was completed at Frenchay hospital, University of Bristol, where he was appointed Consultant Neurosurgeon in 2005

# Appendix – Acquisitions in the Spinal Sector

- **May 2020**
- (S) Illuminoss is acquired by Healthpoint Capital for undisclosed
- **Apr 2020**
- (S) Flower Orthopedics is acquired by Conventus Orthopaedics [for undisclosed](#).
- (S) Apifix with Non-Fusion Scoliosis Technology is acquired by OrthoPediatrics [for \\$37M up front](#).
- **Feb 2020**
- (S) EOS Imaging is acquired by Alphatec Spine [for \\$122M cash, stock and debt](#)
- (S) Fitbone Limb Lengthening System (Wittenstein SE) is acquired by Orthofix [undisclosed](#)
- **Jan 2020**
- RTI Surgical OEM business is acquired by Montagu [for \\$490M](#)
- Arthrocare is acquired by Anika Therapeutics [for \\$100M](#)
- (S) Parcus Medical is acquired by Anika Therapeutics [for \\$95M](#)
- **Dec 2019**
- (S) Verb Surgical is acquired by J&J [for undisclosed](#)
- (S) IntraFuse is acquired by Conventus Orthopaedics [for undisclosed](#)
- Nov 2019
- **Oct 2019**
- (S) Mobium Imaging is acquired by Stryker [for \\$500M](#)
- **May 2019**
- Vertiflex is acquired by Boston Scientific [for \\$465M](#)
- **Apr 2019**
- (S) Titan Spine is acquired by Medtronic [for \\$470M](#)
- **Jan 2019**
- (S) Renovis Surgical Technologies is acquired by Kyocera [for undisclosed](#)
- **Nov 2018**
- (S) Response Ortho acquired by WishBone Medical [for undisclosed](#)
- (S) Paradigm Spine is acquired by RTI Surgical [for \\$300M \(7.5 X sales\)](#)
- **Sep 2018**
- Mazor Robotics is acquired by Medtronic [for \\$1.6B \(13.5 X sales last year\)](#)
- (S) Invuity is acquired by Stryker [for \\$190M \(4.9 X sales\)](#)
- (S) Vertera Spine acquired by NuVasive [for undisclosed](#)
- **Aug 2018**
- K2M is acquired by Stryker [for \\$1.6B in a stock purchase at \(5.2 X sales\)](#)
- (S) EIT is acquired by DePuy Synthes [for undisclosed in Germany](#)
- (S) Surgimap is acquired by Globus Medical [for undisclosed](#)
- **July 2018**
- Thortex and Millennium Surgical acquired by AVALIGN Technologies [for undisclosed](#)
- **June 2018**
- (S) Sentio nerve location technology for spine acquired by J&J DePuy Synthes [for undisclosed](#).
- **May 2018**
- (S) Expanding Orthopedics is acquired by CoreLink [for undisclosed](#)
- Corin Orthopaedics is acquired by Permira, an EU private equity group [for undisclosed](#)
- Bradshaw Medical is acquired by InTech Medical [for undisclosed](#)
- **Apr 2018**
- JRI Orthopaedics (UK) is acquired by AK Medical (China) [for \\$24M](#)
- **Mar 2018**
- Skeletal Kinetics is acquired by Orthofix [for \\$105M \(7 X sales\)](#)
- (S) SafeOp is acquired by AlphaTec Spine [for \\$27M cash plus stock](#)
- **Feb 2018**
- (S) Orthotaxy, a French software-enabled surgery startup, is acquired by J&J DePuy [for undisclosed](#)



# Appendix - Patents

- Faci-LOK
  - Provisional application filed 12 January 2015 - # 62/102,581
  - Non-Provisional PCT (International) filed 12 January 2016 # US2016/013,030
  - US Utility application # 15/646,615 filed 11 July 2017
  - Application published on USPTO website on 9 November 2017 US Pub # 2017/0319,238. Individual countries will be designated later in 2018.
  - **Patent Grant date 23 June 2020 - U.S. Patent number 10,687,866**
  
- Cervi-LOK
  - US Utility application # 16/206509
  - "CIP" - Continuation-In-Part filed on 30 November 2017 - assigned Provisional Number # 62/592,819
  - Clarification on claims from USPTO in May 2019
  - Multiple international applications currently being filed including the EU and China.
  
- GRASP Laminoplasty
  - Non-Provisional application filed on April 12, 2020
  - Provisional patent application filed 12 April 2019 - # 62/833,330
  - Non-Provisional application to be filed in June 2019