

A Pioneering Approach to Spinal Stabilisation



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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.

Cervi-LOK™ FDA clearance & commercialization during 2021.

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.

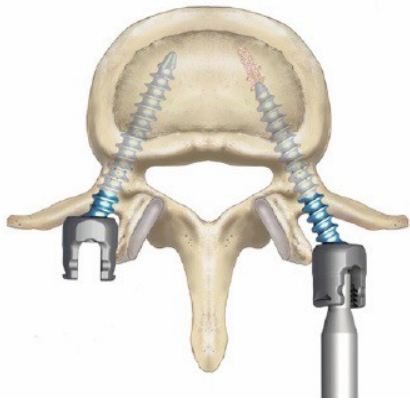


Secure FDA approval for the three initial systems: Cervi-LOK™, GRASP Laminoplasty and Faci-LOK™.



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

Current Technology Overview



Spinal stabilisation technologies and techniques, such as fusion, have not appreciably evolved in over 30 years.

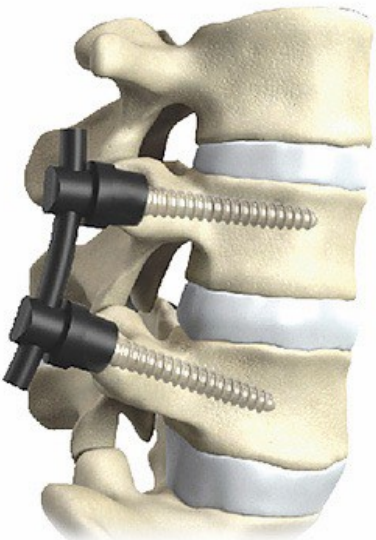
Screws are inserted into the pedicles of vertebrae, coupled with rods that extend bilaterally along the spine to stabilize.

Fusion permanently alters the individual's biomechanics.

Placement of screws requires challenging precision - up to 20% of screws not optimally placed.

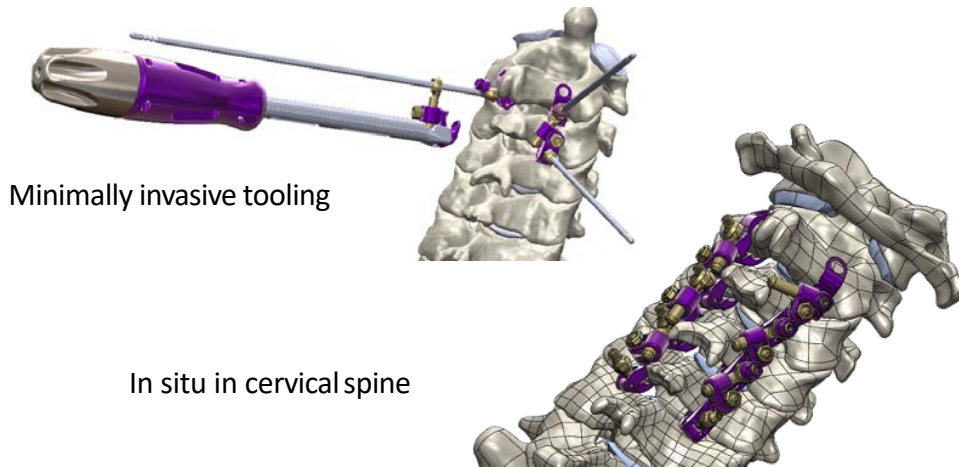
Newer computer assisted placement only reduces incorrect placement to 7%.

Failed back and neck surgery syndrome is very well documented affecting circa 25% of people undergoing surgery^[1].



[1] Thomson S. Failed back surgery syndrome: definition, epidemiology and demographics. Br J Pain. 2013;7:56–59. [\[PMC free article\]](#) [\[PubMed\]](#) [\[Google Scholar\]](#)

Cervi-LOK™

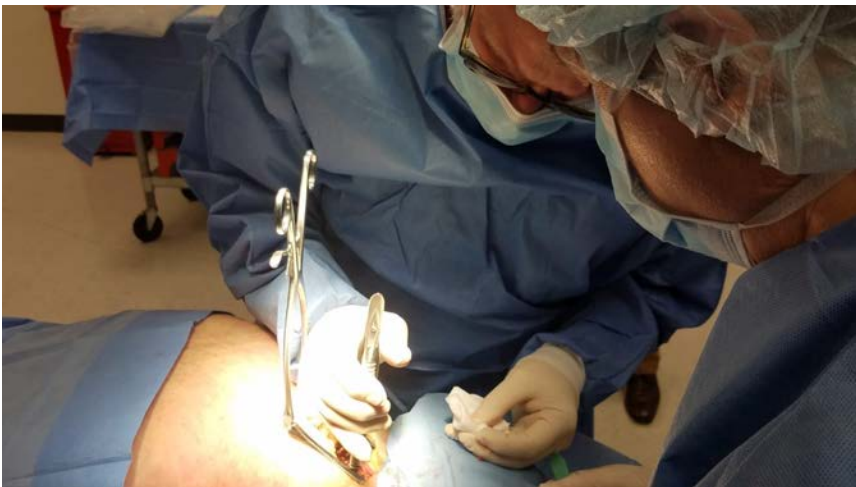


Simple, minimally invasive & minimally intrusive procedure fitted without virtually any exposure of the nerve roots or blood vessels to injury.

Screw free system removes risk of vertebral artery injury which can cause brainstem stroke or nerve root injury.

After a series of iterations the entire suite of implants and instruments are now at design freeze & proceeding to FDA approval.

Patent application 16/206,509 published.



Cervi-LOK Cadaver testing Lincotek Lab, Utah

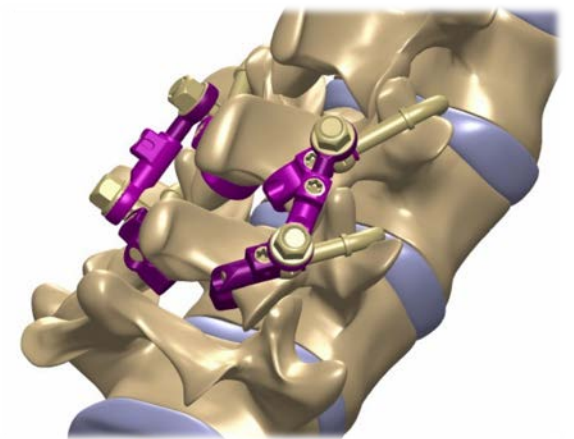
Faci-LOK™

Faci-LOK™ is a minimally invasive, anatomy preserving, thoracolumbar spine stabilisation device for spinal fusion sharing the same inherent design and techniques as Cervi-LOK™.

Chances of a profound, deep bone infection are all but eliminated.

Motion LOK allows the vertebrae to be either compelled towards each other, “compression,” or moved away from each other, “distraction”.

Patent Grant date 23 June 2020 - U.S. Patent number 10,687,866



In situ in lumbar spine

Faci-LOK™ vs Current Technology

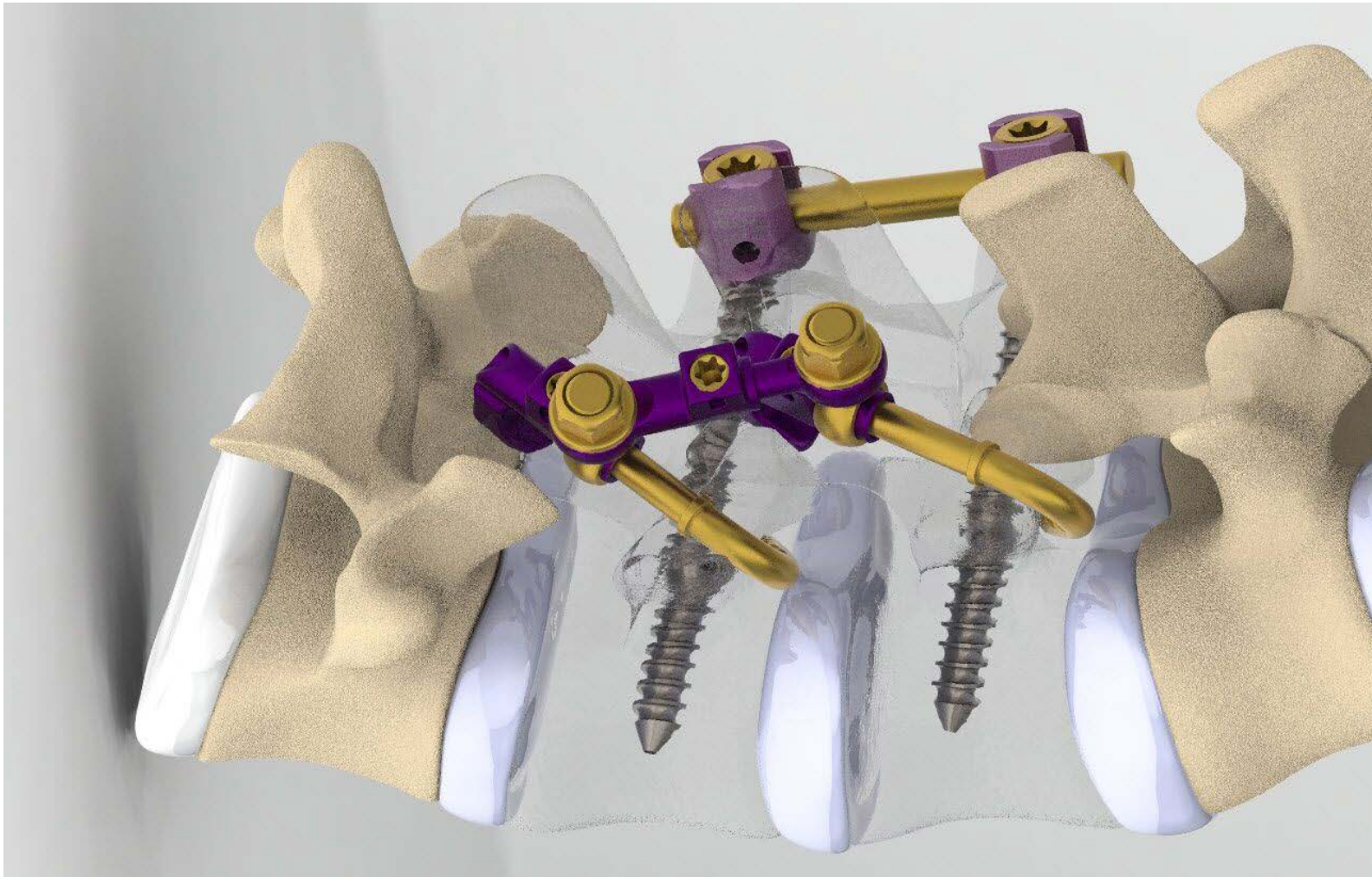


Diagram represents Faci-LOK™ on one side of the vertebrae and traditional approach on the other.

Cervi-LOK™ & Faci-LOK™: Benefits

- 1** Will be the least invasive and lowest risk of any system on the market, mitigating injury to vascular structures, nerve roots and other complications

- 2** Fully reversible and can be removed without having altered the anatomy. Significantly reduced chance of developing a deep bone infection.

- 3** Represents a significant cost saving and reduced surgery time. Conservative estimates are that the surgery time should be reduced by 50%.

- 4** Reduce the amount of exposure to radiation for patient, surgeon and staff.

- 5** Considerable diagnostic potential which could truly revolutionise the current practice of spinal surgery, as well as offering significant therapeutic benefits.

- 6** Both devices' lab tests confirmed significantly greater pull out strength and did not fail on cycle testing (traditional approaches with screws fail after c. 500k cycles).

GRASP Laminoplasty System



The GRASP Laminoplasty system does not require the use of any screws, thereby avoiding damage to the bony anatomy with respect to its fixation and anchoring.

The system "grasps," the laminae using the Cervi-LOK™ anchor, and connected to this unique technology, is able to expand the bony spinal canal, relieving pressure on the spinal cord.

One of the first systems that would allow surgeons to preoperatively plan the extent of decompression.

First laminoplasty system that could stabilise multiple levels; therefore, it would provide unprecedented options to surgeons, thus providing a total solution from a single provider, using common componentry.

The Spinal Fusion 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

Source: Maia Research Analysis

FDA Clearance Process

- ▼
▼ Q-Sub process with the FDA completed for Faci-LOK™
Cervi-Lok™ proceeding through 510(k) approval pathway
- ▼
▼ Lincotek medical providing design, testing & validation for all final products and instrumentation.
- ▼
▼ Emergo engaged to manage FDA submissions and clearance process.
- ▼
▼ Engage with specialist medical device testing facility E-Core (University of Toledo, co-directed by Vijay Goel, PH.D.) and OrthoKinetic Testing Technologies, LLC., founded and run by Lisa Ferrera PhD.
- ▼
▼ Both products eligible for 510 (k) approval thereby eliminating the need for clinical trials. Cervi-LOK™ 510 (k) FDA clearance during H1 2021.



Bringing Products to Market

Initial focus is to:



Optimise the surgical approach and specialised instrumentation with input from Key Opinion Leaders (KOLs), our medical advisory board and the target market



Develop network of KOL's in the USA Europe and Asia



Market products to the spinal surgical community - conferences, white papers, and via KOLs



Collect and present comprehensive patient data through surgery, recovery and aftercare initially in US, India/Far East

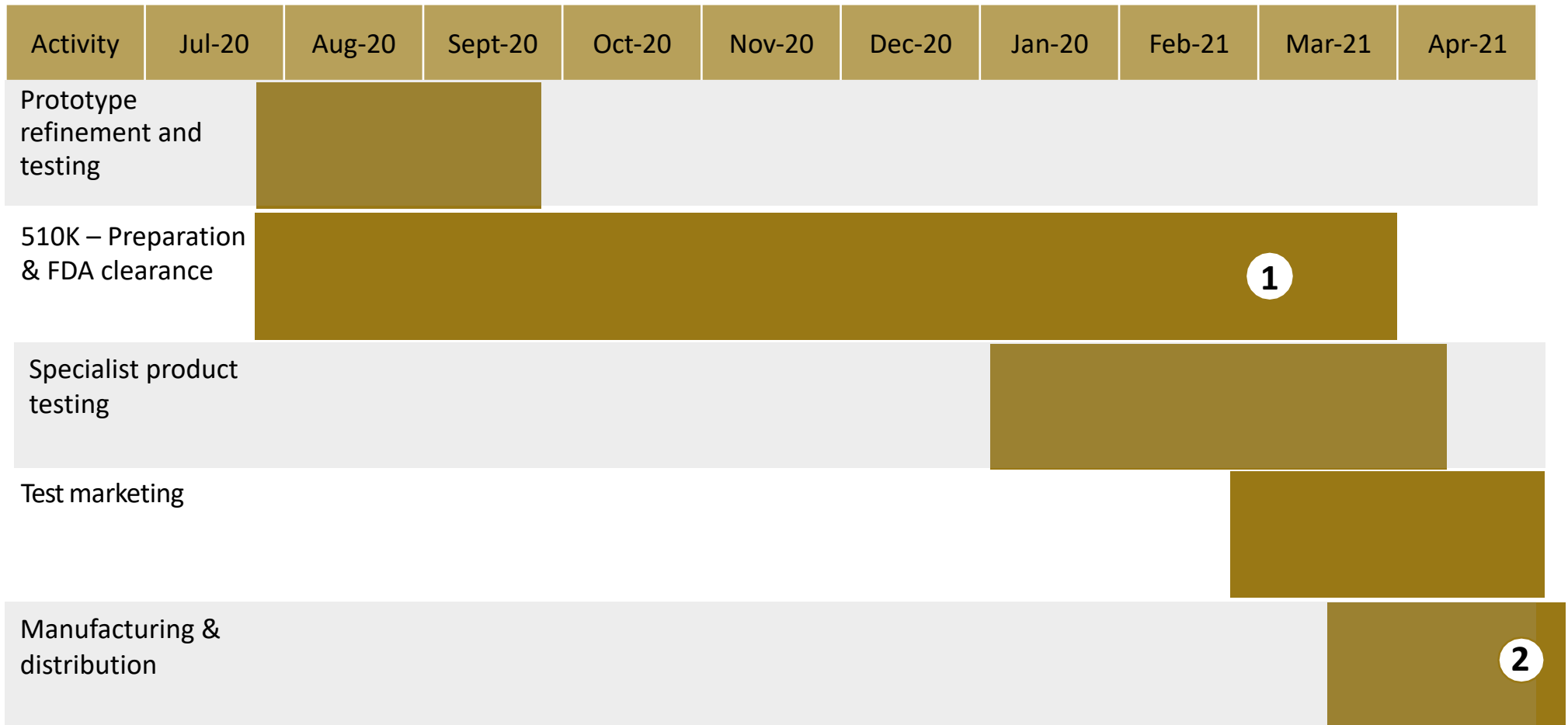


Data will be used by sales teams located strategically across the US (i.e. east coast, mid- west and west coast) to drive take-up by surgeons, hospitals, and surgeries



Grow sales teams and/or enter into JVs to expand product outreach and customer base

Timeline to Market - Cervi-LOK™



510K PATHWAY CONFIRMED BY FDA

1 FDA Approval

2 MARKET READY

Board of Directors



Ian Roberts - Group CEO

- 25 years of experience covering marketing, sales, manufacturing and distribution.
- Former European Director with Stryker Orthopaedics responsible for spine and trauma.
- Established Hospira UK & Ireland operations and lead the development of two manufacturing facilities.
- Last 8 years has been advising investors on alternative investments in life sciences with specific focus on med tech.



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.



Martin Armstrong - Non-Exec Chair.

- Wide commercial experience at executive level across a number of market sectors, including roles as chairman.
- Senior senior partner of Accountancy and Corporate Insolvency company Turpin Barker and Armstrong, has a wealth of experience in accountancy, audit and strategic financial planning, as well as turnaround and corporate insolvency.



Annabel Schild - Non-Exec Director

- Seasoned entrepreneur, having invested in multiple companies in finance, technology and hospitality over the last 31 years.
- Portfolio of investments has given her the experience and knowledge to detect prime companies with an excellent story.
- Supporter of many UK children’s charities, including the Anne Frank Trust (a UK education charity).

Inventor & Chief Technology Consultant



Professor Boehm with saw bone saw bone testing with traditional pedicle screw

Professor Frank H. Boehm Jr., MD

Professor F. Boehm, MD is the inventor of the TruSpine products and a technical consultant

Professor of Neuroanatomy and Neurophysiology -
Combined University of Malta and Lugano (2018-present)

A pre-eminent figure in the spinal surgery field and a medical doctor who has performed over 2,000 neurosurgical procedures and published numerous articles and original research papers on spinal surgery

Chief designer of TruSpine products, historically has sold spine IP to major spinal instrumentation companies

Awarded 15 patents

Previous inventions won the Frost & Sullivan award, considered the highest award in spinal technology, for best new spine technology

Management Team



Peter Houghton - Sales & Marketing

- 25 years of experience in the medical device field holding an array of leadership positions within the orthopaedic, clinical neuroscience, vascular, and biologic markets
- Previously with Arrow International and part of the sales leadership team at Codman (a Johnson & Johnson company), his first introduction to neurosciences and the spine market
- For the past 12 years, he has been working with industry leaders Medtronic Spine & Biologics, innovators K2M, Inc.



Janice Stone - Regulatory & Quality Affairs

- 30 years of experience in both the delivery and administrative sides of the health care system
- Former Administrative Director, Ms Stone was in charge of more than 40 FTE's across several clinical and diagnostic service lines for more than 15 years
- Trained facilitator in Total Quality Management/Total Quality Improvement activity, Customer Service / Patient Experience Initiatives and is also a trained ISO Auditor.

Medical Advisory Board



Richard A. Bassin. MD. F.A.C.

- Trained General and Vascular surgeon, Former Director of ER – Mount Sinai Hospital, New York, NY.
- Technical advisor to Oppenheimer Funds & Goldman Sachs regarding medical tech investments.



Mark Smith MD.

- Board certified Neurosurgeon.
- VP of Business Development and Medical Director - Kelyniam Global Inc.
- Former Associate Professor of Neurosurgery, Upstate Medical Centre, Syracuse, NY
- Former Chief of Biomedical Engineering - University of Maryland Shock Trauma Center.



Leon Liem MD.

- Board certified Neurosurgeon
- Director of the Hawaiian Neurosurgical Group
- Adjuvant Professor of Neurosurgery, University of Hawaii
- Preeminent Neurosurgeon in Hawaii – leading efforts to unify and improve Neurosurgical care throughout the Hawaiian island chain.
- Previously Neurosurgery Section Head, United States Army.



William Lavelle MD.

- Board certified Neurosurgeon.
- Wilkes University, Wilkes-Barre, PA, BS Biochemistry, Minor Physics, 1998
- Former Associate Professor of Neurosurgery, Upstate Medical Centre, Syracuse, NY
- Education Committee, SUNY Upstate Medical University, Syracuse, NY 2009-present
- Innovasis- Scientific Advisory Board

Investor Information



AQUIS TICKER

TSP

Current Ordinary Shares

87,778,967

Options (exercisable @ 36p)

Up to 10% of issued

Major Shareholders*

LCS Trust	22.7%
Directors /management/advisors	25%

Advisors

Auditors	PKF
Solicitors	Hill Dickinson
Broker	WH Ireland
Investor Relations	Walbrook PR

Investment Case



- HMRC approved for EIS & VCT
- Revolutionary products to transform \$US10.2 billion spinal devices market
- Minimally invasive, minimally intrusive reversible and safer spinal stabilisation technology
- Cervi-LOK™ FDA approval and commercialisation 2021
- Strong IP with granted US patent & multiple pending patents
- 8 spinal start-ups acquired last 7 months Dec – June 20

Appendix - Historical Acquisitions in the Spinal Sector

Ⓢ - Indicates Start-up

May2020

- Ⓢ Illuminoss is acquired by HealthpointCapital for undisclosed

Apr2020

- Ⓢ Flower Orthopedics is acquired by Conventus Orthopaedics [for undisclosed](#).
- Ⓢ Apifix with Non-Fusion Scoliosis Technology is acquired by OrthoPediatrics [for \\$37M up front](#).

Feb2020

- Ⓢ EOS Imaging is acquired by Alphatec Spine [for \\$122M cash, stock and debt](#)
- Ⓢ Fitbone Limb Lengthening System (Wittenstein SE) is acquired by Orthofix undisclosed

Jan2020

- RTI Surgical OEM business is acquired by Montagu [for \\$490M](#)
- Arthrocare is acquired by Anika Therapeutics [for \\$100M](#)
- Ⓢ Parcus Medical is acquired by Anika Therapeutics [for \\$95M](#)

Dec2019

- Ⓢ Verb Surgical is acquired by J&J [for undisclosed](#)
- Ⓢ IntraFuse is acquired by Conventus Orthopaedics [for undisclosed](#)

Nov2019

Oct2019

- Ⓢ Mobium Imaging is acquired by Stryker [for \\$500M](#)

May2019

- Vertiflex is acquired by Boston Scientific [for \\$465M](#)

Apr2019

- Ⓢ Titan Spine is acquired by Medtronic [for \\$470M](#)

Jan 2019

- Ⓢ Renovis Surgical Technologies is acquired by Kyocera [for undisclosed](#)

Nov 2018

- Ⓢ Response Ortho acquired by WishBone Medical [for undisclosed](#)
- Ⓢ Paradigm Spine is acquired by RTI Surgical [for \\$300M \(7.5 X sales\)](#)

Sep 2018

- Mazor Robotics is acquired by Medtronic [for \\$1.6B \(13.5 X sales last year\)](#)
- Ⓢ Invuity is acquired by Stryker for [\\$190M \(4.9 X sales\)](#)
- Ⓢ Vertera Spine acquired by NuVasive [for undisclosed](#)

Aug 2018

- K2M is acquired by Stryker [for \\$1.6B in a stock purchase at \(5.2 X sales\)](#)
- Ⓢ EIT is acquired by DePuy Synthes [for undisclosed in Germany](#)
- Ⓢ Surgimap is acquired by Globus Medical [for undisclosed](#)

July 2018

- Thortex and Millennium Surgical acquired by Aalign Technologies [for undisclosed](#)

June 2018

- Ⓢ Sentio nerve location technology for spine acquired by J&J DePuy Synthes [for undisclosed](#).

May 2018

- Ⓢ 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 In'Tech Medical [for undisclosed](#)

Apr 2018

- JRI Orthopaedics (UK) is acquired by AK Medical (China) for \$24M

Mar 2018

- Skeletal Kinetics is acquired by Orthofic [for \\$105M \(7 X sales\)](#)
- Ⓢ SafeOp is acquired by AlphaTec Spine [for \\$27M cash plus stock](#)

Feb 2018

- Ⓢ Orthotaxy, a French software-enabled surgery startup, is acquired by J&J DePuy [for undisclosed](#)

Appendix - Patents & IP Protection Status

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

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