



A Pioneering Approach to Spinal Stabilisation

Corporate Presentation H1 2020

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Overview



A medical device company focused on disrupting the massive \$7.1B per annum global spinal (vertebrae) stabilisation market

Two flagship ground-breaking, spinal stabilisation devices, Cervi-LOK™ and Faci-LOK™, deliver superior performance and durability and generate significant cost savings

Uniquely provides exceptional and reversible spinal stabilisation without damaging / altering the anatomy, or requiring screws / staples traditionally implanted irreversibly into the spine

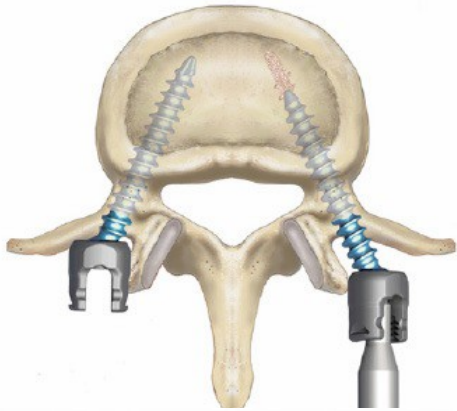
FDA Q-Sub process successfully completed for Faci-LOK™ - FDA approval commencing providing rapid re-valuation potential

Highly experienced management team and advisory board with proven track record in medical device development and roll-out

Pipeline of additional products exploiting the "no screw", "anatomy preservation" approach

Raising up to £3m NEX IPO H1 2020

Current Technology Overview



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

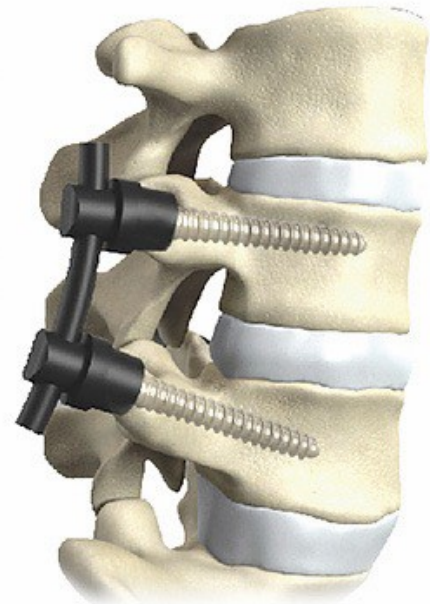
Screws are inserted into the **pedicles of vertebrae**, coupled with rods that extend bilaterally along the spine to stabilise

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™

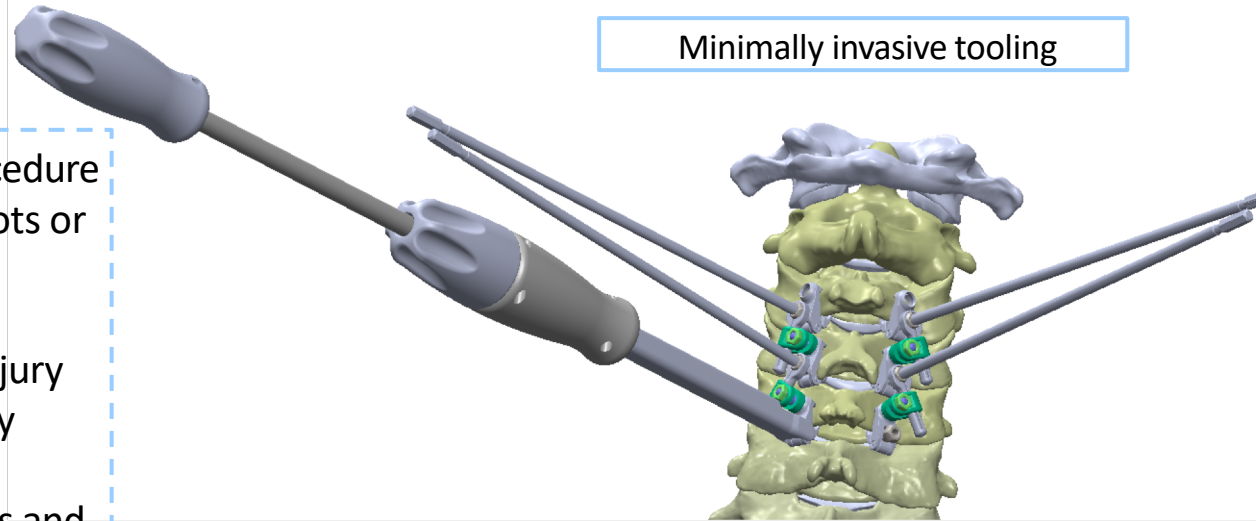
Simple, minimally invasive & minimally intrusive procedure fitted without virtually any exposure of the nerve roots or blood vessels to injury

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

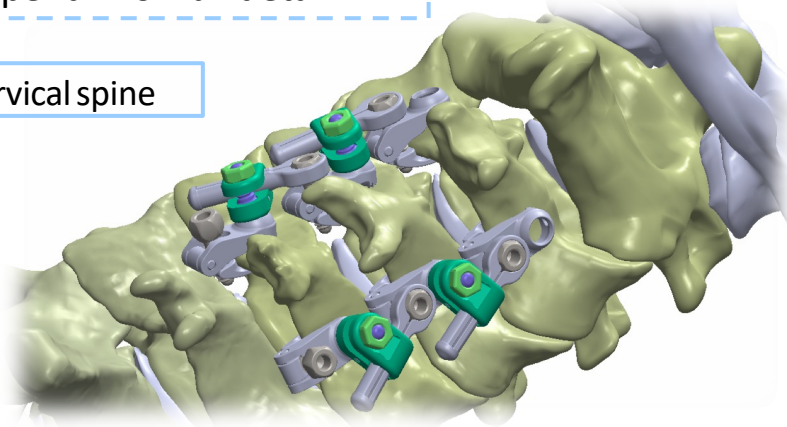
After a series of iterations the entire suite of implants and instruments are now at design freeze

Currently patent pending – see appendix for full detail

Minimally invasive tooling



In situ in cervical spine



Cervi-LOK Cadaver testing Lincotek Lab, Utah

Faci-LOK™

Shares the same inherent design and minimally invasive insertion techniques as Cervi-LOK

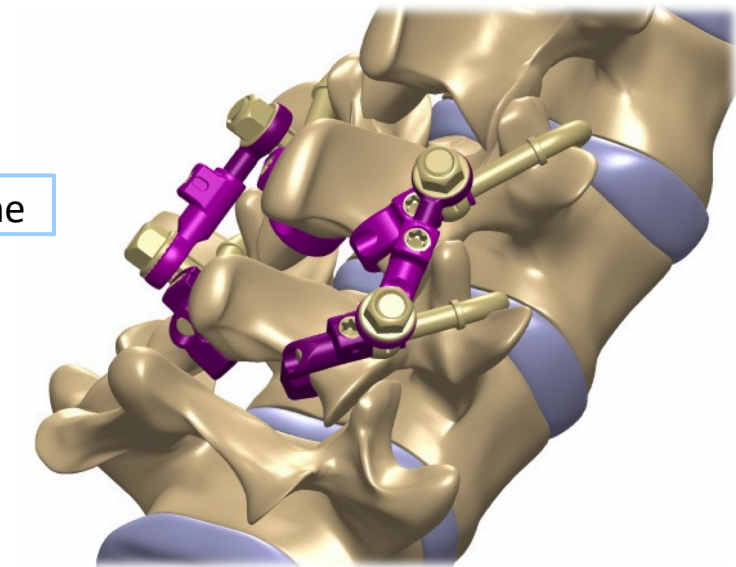
Chances of a profound, deep bone infection are all but eliminated

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

Confirmation of Patent Allowance received 20/02/2020

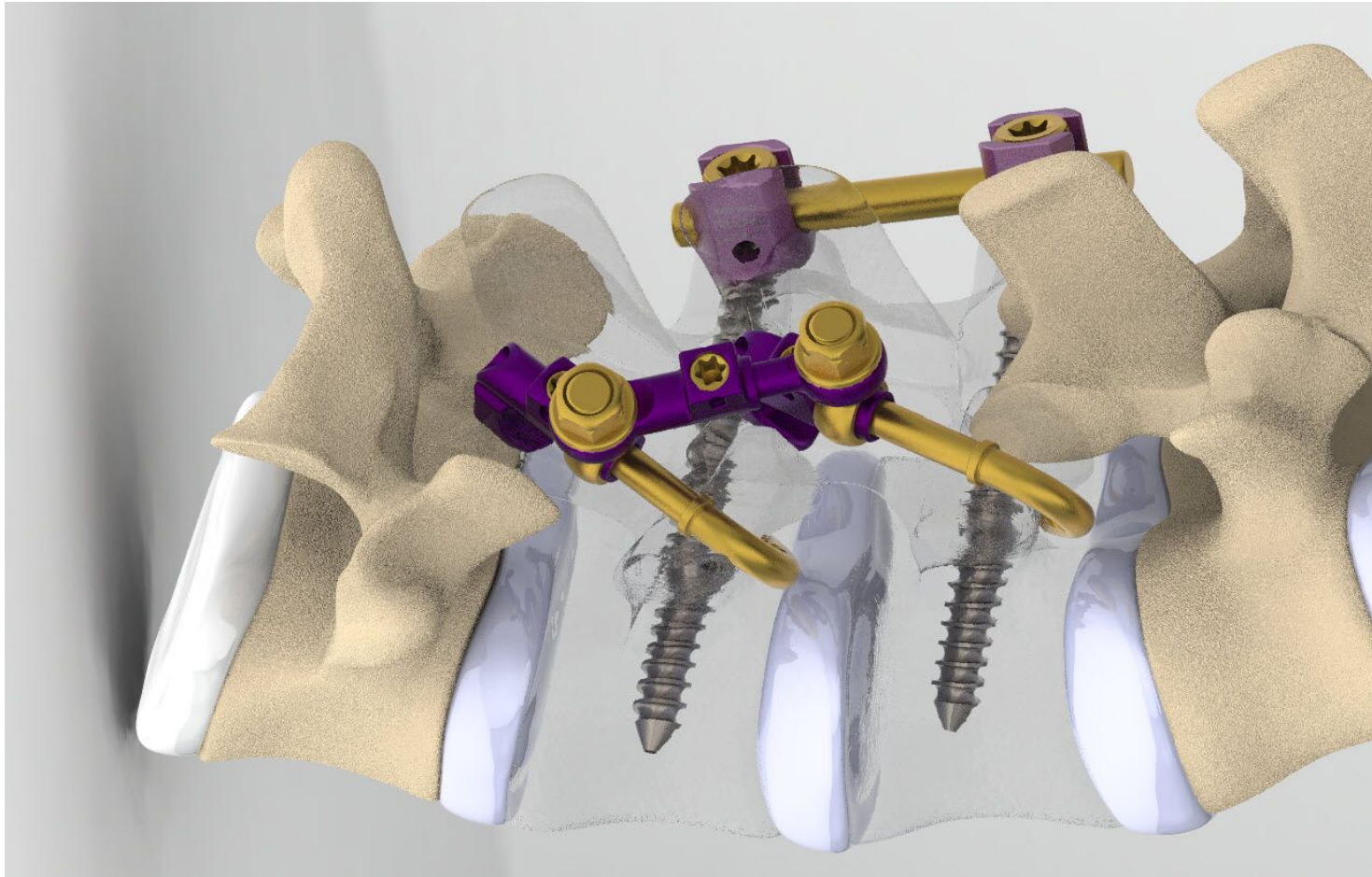


In situ in lumbar spine



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, whilst also mitigating potential injury to nerve roots and other complications of screws
- 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)

The Spinal Fusion Market

Global spinal fusion market estimated at **\$7.1 bn per annum**

Expected to grow at a **CAGR of 5.9%** through 2024 primarily due to:

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

1 million spinal fusions carried out each year -
The US currently accounts for approximately 40% of these

Annually, 30 million Americans will have at least one episode of back pain lasting longer than 6 weeks or more

Market expected to **increase by 50%** over 5- 7 years

Source: MedTech 360 report, 2016

Board & Management Team



Ian Roberts
Group CEO

- 20 years of experience in the medical device sector 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.
- For the past 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.



Peter Houghton
Director of 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. and most recently as principal of a medical distributorship



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.

Janice Stone
Regulatory
Manager

- 30 years of experience in both the delivery and administrative sides of the health care system. As an Administrative Director she was in charge of more than 40 FTE's across several clinical and diagnostic service lines for over 15 years.
- She is a trained facilitator in TQM/TQI activity, as well as Customer Service/Patient Experience Initiatives and is also a trained ISO Auditor. She has also chaired numerous committees charged with the design and implementation of key programs within the hospital system.

Advisory Board



Dr Tim Evans

- Apothecary to Her Majesty and the Royal Household since 2005
- Qualified 1979, Westminster Hospital Medical School
- Awarded with an LVO to his services by HM The Queen 2016



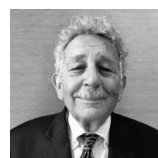
Abdallah Raweh

- Cardiovascular Surgeon – London/UK
- Vice Rector Ludes University Lugano – Switzerland
- Director of London Core Review Cardiothoracic Surgery Course for the Arab Countries



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.



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 regarding medical tech investments.



Mark Smith MD.

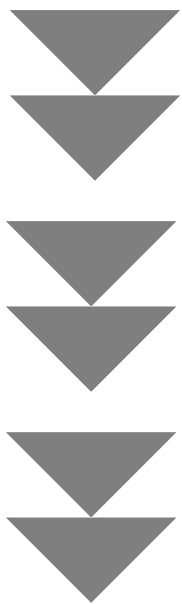
- Board certified Neurosurgeon.
- Former Associate Professor of Neurosurgery, Upstate Medical Center, Syracuse, NY



Charles Kime MD.

- Board certified Orthopaedic Spine Surgeon.
- Spine Fellowship at the World-Famous Texas Back Institute.
- Orthopaedic Associates of Harvard, P.C. Spine Surgeon at a level 1 Trauma centre including resident training and over 5000 surgical procedures.
- University of Connecticut School of medicine, clinical instructor of Orthopaedic Surgery

FDA Clearance Process



Q-Sub process with the FDA completed for Faci-LOK™, - submitted for Cervi-Lok™ currently working towards a 510(k) approval for both

Lincotek medical engaged to complete design, testing and initial product build

Emergo engaged to progress FDA approval process

Engage with specialist medical device testing facility E-Core (University of Toledo, co-directed by Vijay Goel, PH.D.). Compile data to satisfy FDA requirements.

Both products eligible for 510 (k) approval thereby eliminating the need for clinical trials. Faci-LOK™ expected to gain 510 (k) approval within 9 -12 months of IPO.

EMERGO  GROUP

Global medical device/regulatory/registration partner
for FDA approval process

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



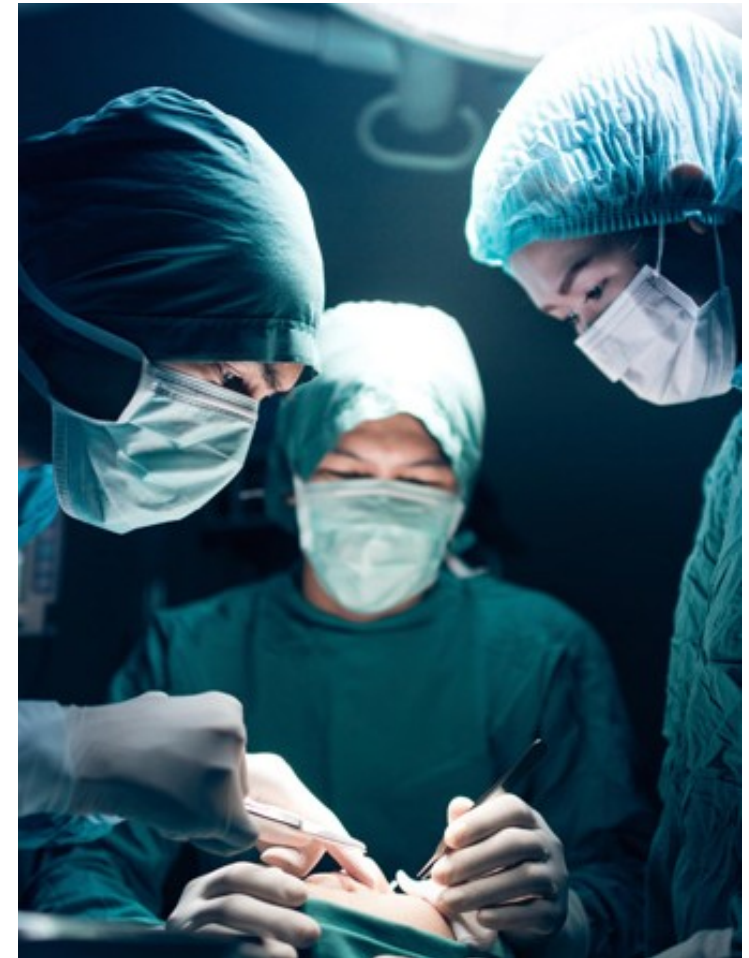
Data will be used by sales teams located strategically across the US (i.e. east coast, mid-west and west coast) to drive take-up by surgeons, hospitals, and surgeries



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

Achievements & Recent Developments

- Cervi-LOK™ development completed
- Faci-LOK™ development
 - patent allowance confirmed 20.20.2020
 - recorded 445N in pull-out strength when tested - 35% higher than current technology
- Pipeline of complementary products in development
- Selected as one of the '20 Best European MedTech Companies' from over 250 nominations (TechTour Health Summit, Lausanne, 2017)
- HMRC EIS pre-approval granted
- Appointment of Queen's Apothecary as advisor
- Ongoing negotiations with complementary spinal technology companies, including a company that would feature use of technology in concert with a stem cell regenerating system.



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



Secure FDA approval for two initial systems: Cervi-LOK™ and Faci-LOK™



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

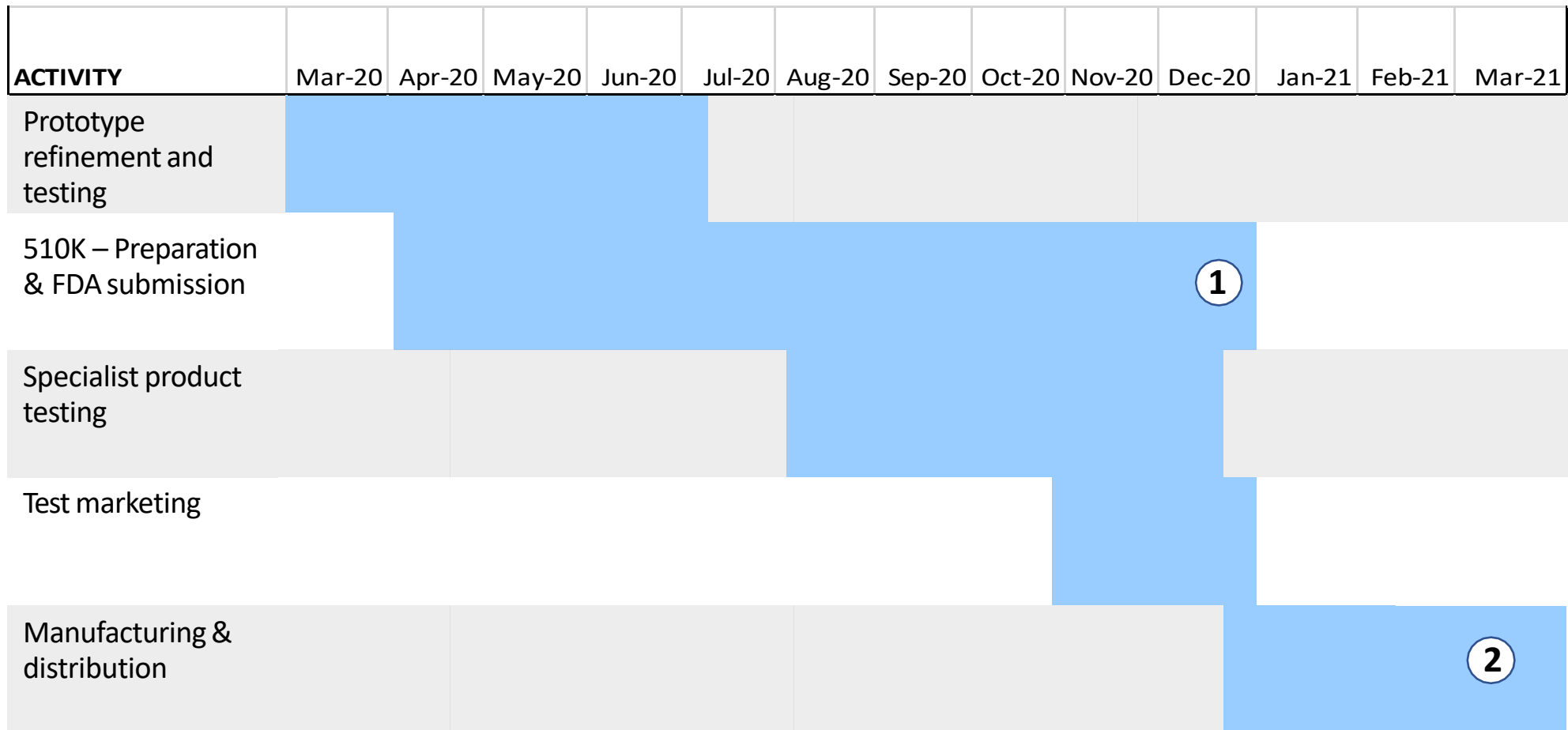


Expand usage of Cervi-LOK™ and Faci-LOK™ into broader settings such as diagnostics



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

Timeline to Market – Cervi -LOK



510K PATHWAY CONFIRMED BY FDA

① FDA CLEARANCE

② MARKET READY

Investment Case

Revolutionary products to transform spinal stabilisation market

Minimally invasive, minimally intrusive reversible and safer spinal stabilisation technology

Significant cost savings for surgeons, patients and insurers

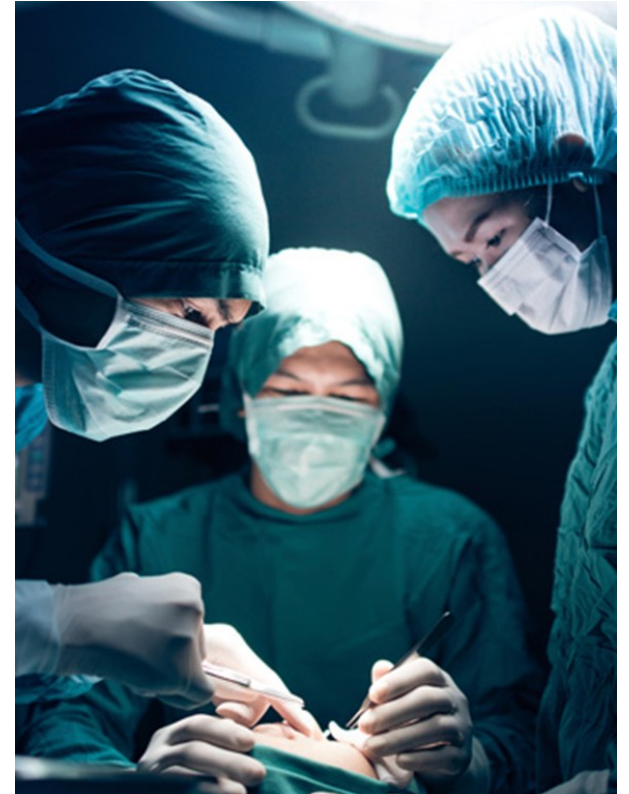
FDA approval commencing providing rapid re-valuation potential

US\$7.1 billion spinal market and growing

Defined rollout strategy in place to commercialisation

Additional pipeline of products in development

Management team with a track record of delivery



Appendix



Patents and 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 Allowance Confirmed 20 Feb 2020 – Patent issue in process.

Cervi-LOK

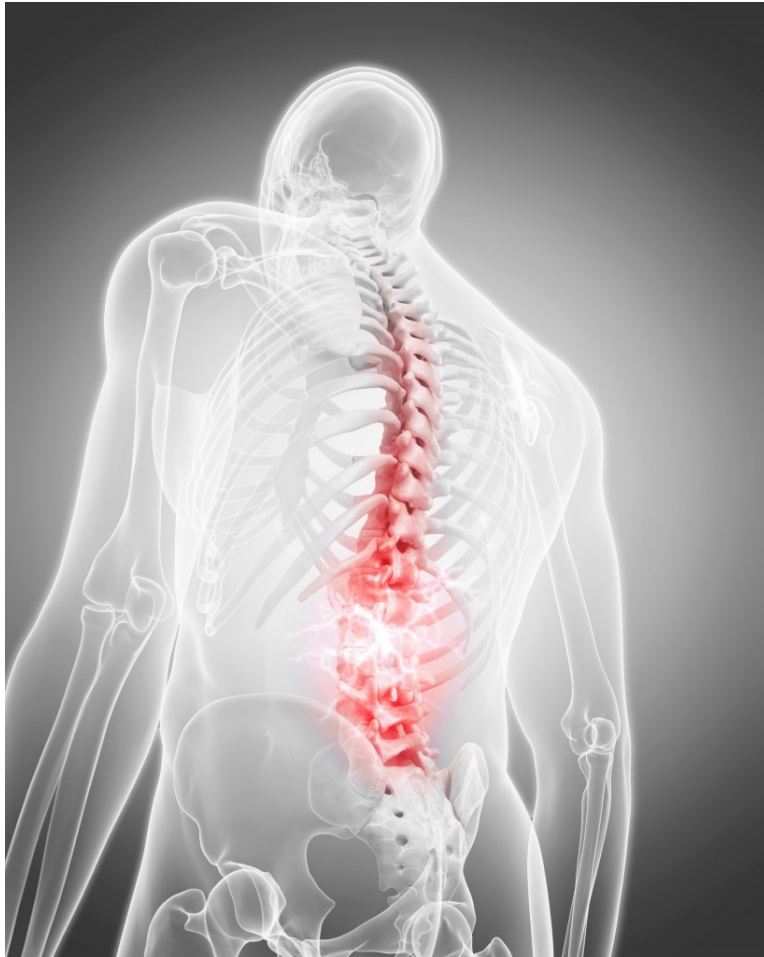
- Cervi-LOK included within the original Faci-LOK application
- "CIP" - Continuation-In-Part filed on 30 November 2017 - assigned Provisional Number # 62/592,819
- Clarification on claims from USPTO in May 2019

Multiple international applications currently being filed including the EU and China.

GRASP Laminoplasty

- Provisional patent application filed 12 April 2019 - # 62/833,330
- Non-Provisional application to be filed in June 2019

Pipeline of Products



The **GRASP Laminoplasty system** combines the anchor designed for the Cervi-FAS with another unique technology to provide a laminoplasty, a procedure used to treat cervical stenosis

The **OP-LOK C** for use in patients who have undergone a cervical Laminectomy

The **OP-LOK L** for use in the lumbar and lower thoracic spine, again in patients who have undergone laminectomy

The **VascuGraft system** to provide vascularised bone graft substrate in establishing a spinal fusion

The **FaciFUSION** endoscopically establishes a facet fusion graft in concert with a Faci-LOK.

The **Faci-PARS** to address spondylolysis, a defect in the lamina which is seen in 6-9% of all adolescents, and perhaps much higher in teens with significant back pain

The Inventor

- Professor F. Boehm, MD is the inventor of the TruSpine products and a technical consultant
- 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 12 patents
- **Previous inventions won the Frost & Sullivan award, considered the highest award in spinal technology, for best new spine technology**



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

Historical Acquisitions in the Spinal Sector

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)

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
- Amedica's spine business is acquired by CTL Medical for less than \$10M
- Ⓢ Surgimap is acquired by Globus Medical for undisclosed
- Ⓢ Maxim Surgical is acquired by Fuse Medical for \$3M in a stock transaction

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

Sept 2018

- Ⓢ Vertera Spine acquired by NuVasive 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.

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

Sept 2017

- Ⓢ Vertera Spine acquired by NuVasive for undisclosed

July 2017

- Thortex and Millennium Surgical acquired by Aalign Technologies for undisclosed

June 2017

- Ⓢ Sentio nerve location technology for spine acquired by J&J DePuy Synthes for undisclosed.

Jan 2017

- Ⓢ Zyga Technologies is acquired by RTI Surgical for \$35M (8.8 X sales)