Brad Culbert

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PROFESSIONAL EXPERIENCE

Consultant, April 2010 - Current
Offering expert witness and consulting services to medical device companies.

- Confidential Company
  - Currently serving as an expert witness for an IPR case before the PTAB.
  - Will be producing a declaration report
- Globus Medical
  - Currently serving as an expert witness for 2 IPR cases before the PTAB.
  - Activities involved producing declaration reports for each IPR and expected to be deposed for each.
- Rapidpulse
  - Currently serving as an expert witness for an IPR case before the PTAB.
  - Activities involved producing a declaration report and deposition for it.
- Walk Vascular/Abbott (Sept 2021 to May 2023)
  - Consulted post-acquisition to assist in the manufacturing and technology transfer to their Temecula, CA facility.
- Globus Medical
  - Served as an expert witness in 7 IPR proceedings before the PTAB.
  - Activities involved producing declaration reports for each IPR and depositions for each.
- Aegis Spine
  - Serving as an expert witness for a trial case.
  - Activities involved producing a declaration report and then subsequently deposed.
  - Case settled prior to going to trial.
- Spinal Elements
  - Served as an expert witness in a PGR proceeding before the PTAB.
  - Activities involved producing a declaration report and then subsequently deposed.
- Incuvate, LLC (Jan 2014 to present)
  - Manage patent portfolio for the various incubator companies (Irvine Neurovascular, Vesatek, Orpheus and Walk Vascular - prior to acquisition by Abbott)
  - Developed new products for peripheral, cardiovascular, neurovascular and spine procedures for the various incubator companies.
  - Obtained 510k and CE Mark on all products developed.
  - Revised design control procedures along with a new quality system for the company to simplify product development.
  - Managed day to day operations (excluding sales & marketing) for all the incubator companies listed above.
  - Performed the role of VP R&D at Walk Vascular which was subsequently sold to Abbott on Sept 1, 2021.
- Intersect Partners (June 2013 to Dec 2013)
  - Market evaluation and plan of two new neurovascular devices (flow diverter system and aspiration catheter)
  - Designed and prototyped a self-expanding covered stent and delivery system for flow diversion around neurovascular aneurysms
  - IP assessment (FTO) and patentability strategy for the new devices

MEDTRONIC EXHIBIT 1003

    - Developed project plans for the above devices
- Ellipse Technologies (Acquired by Nuvasive) (2012-2013)
    - Researched market opportunities for adjustable magnet technology in large spine markets
    - Invented new products with adjustable magnet technologies for spinal applications (patents pending)
    - Designed and prototyped adjustable pedicle screw system
    - Wrote and implemented new design control procedures
    - Developed new surgical instrumentation for the adjustable limb lengthening system
    - Led a team to design and develop an external magnetic control system (electrical mechanical) to remotely adjust implanted magnets for limb lengthening
- Ceterix Orthopaedics (Acquired by Stryker) (2010 to 2011)
    - Participated in raising Series A financing
    - Researched and setup an OEM design and manufacturing company for its continuous suturing device for rotator cuff repair
    - Developed new meniscus repair suturing device from concept to working prototype (patent pending)
- Basin Medical (2010 – 2012)
    - Developed business plan
    - Designed and prototyped tension measuring device for urinary stress incontinence
    - Co-invented new tension device for prolapse repair (patent pending)

CTO & Vice President R&D, Interventional Spine, Inc., May 2000 – March 2010
Irvine, CA (Acquired by Depuy Synthes)
First employee – hired as Director of Engineering, promoted to VP R&D (2001) and CTO (2006)
Triage Medical focused on orthopedic trauma products for small bones and hip fractures. Interventional Spine products applied the core technologies from Triage Medical and developed a series of percutaneous spine procedures. The company was venture backed and had revenue of $1MM per month.

- Built and managed an R&D team that took several products from concept to market
- Invented and developed the PercuDyn motion preservation system (IDE underway in the US and currently being sold OUS)
- Invented and developed a new percutaneous access port for spine and other orthopedic applications (currently being used worldwide on all Interventional Spine surgeries for all products)
- Developed and launched the Perpos posterior stabilization system (>$8MM in sales in 2009)
- Submitted the pre-IDE for PercuDyn system and responsible for the biomechanical section of the IDE that was approved by the FDA in 2008
- Performed extensive surgeon training on all products throughout the world
- Developed five orthopedic trauma product lines from concept to market
- Assisted in forming a scientific advisory board of leading surgeons
- Created and implemented the quality system and establishment registration with FDA, European Notified Body and State FDB
- Prepared all 510(k) and CE Mark submissions (first 6 years)
- Participated in venture capital presentations to raise $40MM in financing over three rounds
- Wrote significant portions of the business plans for the financing.
- Built and maintained the IP portfolio - currently hold 20 spine/trauma patents and over 35 pending
- Co-authored 18 published papers and/or abstracts

Sr. R/D Project Manager, EndiCOR Medical, Inc. (Acquired by EV3), Aug. 1998 - May 2000
San Clemente, CA
Endicor Medical was a small venture backed startup company focused on developing percutaneous thrombectomy and atherectomy systems for cardiovascular and neurovascular applications.

- Designed, prototyped and proved animal safety and efficacy of a new version of the X-Sizer thrombectomy system that cuts larger channels through in-stent restenosis (patent issued)
- Developed animal models to satisfy FDA requirements of the safety and efficacy of the X-Sizer thrombectomy system
- Designed, tested and optimized several different cutters for the X-Sizer
- Developed unique test methods to evaluate the performance of the X-Sizer in-vitro
- Designed a new cutting mechanism for a neuro application of the X-Sizer (patent issued)
- Coordinated and attended clinical evaluations of products subsequent to animal safety and efficacy testing
- Led project teams for the above products to transfer to manufacturing

R/D Project Manager, CVD (Now Endologix), Sept 1996 - Aug 1998
Irvine, CA
CVD was a cardiovascular company focused on developing new angioplasty balloons and stents with focal technology. The focal technology was licensed to Guidant Corporation in 1998.

- Designed and transferred to production new PTCA catheters (Guardian OTW, Arc II)
- Designed and transferred to production stent delivery system (Synthesis SDS)
- Performed sterilization validation for the Synthesis SDS
- Performed aging studies for many different products
- Coordinated biocompatibility testing for all the above projects
- Prepared and submitted PMA supplements (Guardian, Arc II)
- Assisted the regulatory department in the preparation and submission of CE Mark dossiers

Angioplasty Product Team Leader, Vas-Cath Inc, (Acquired by C.R. Bard), Oct 1994 - Sept 1996
Mississauga, Ontario, Canada
Vas-Cath was a small privately held company focused on developing and distributing dialysis and angioplasty catheters. They had the number 1 or 2 market share of the angioplasty balloon in all countries in Europe.

- Led a multi-functional team of R&D, manufacturing and quality engineers to continuously improve and maintain the angioplasty catheter product lines
- Designed and validated several new balloon molds and tubing
- Designed apparatus to increase balloon blowing productivity by 40%
- Designed fixtures and performed IQ/OQ and process validations (welders, draw down machines, flaring fixtures, etc.)
- Implemented material change for all balloons on the angioplasty product lines increasing balloon productivity (+50%), burst pressure (+20%) and scratch resistance (+30%)
- Designed single unit packaging for angioplasty catheters
- Performed test method validations for product testing
- Coordinated internal and external efforts to efficiently launch the angioplasty product line into the U.S.

Manufacturing/Project Engineer, Camco Inc. (A division of General Electric), Oct 1992 - Oct 1994
Hamilton, Ontario, Canada
Camco was the largest major appliance manufacturer in Canada.

- Developed an efficient process to incorporate a sub-assembly line onto a main refrigeration line using just-in-time strategy that resulted in an annual company savings of $300,000
- Successfully coordinated an implemented a $500,000 project that introduced a new product to market
- Led a team to implement predictable manufacturing to several key processes of the plant to conform to ISO 9000

- Designed work and test stations for the refrigeration assembly line
- Developed, redesigned and tested polyurethane foam molds and fixtures for new refrigeration product

EDUCATION

2001, MBA from California State University, Fullerton
1992, BASc. in Metals and Materials Engineering from University of British Columbia

List of US Patents:

US8105382B2 Intervertebral implant

US8568481B2 Intervertebral implant

US10390963B2 Intervertebral implant

US10398566B2 Intervertebral implant

US10583015B2 Intervertebral implant

US11273050B2 Intervertebral implant

US11432942B2 Intervertebral implant

US11497618B2 Intervertebral implant

US10265101B2 Adjustable magnetic devices and methods of using same

US11123107B2 Adjustable magnetic devices and methods of using same

US6951561B2 Spinal stabilization device

US7648523B2 Method and apparatus for spinal stabilization

US9028533B2 Method and apparatus for spinal stabilization

US9226758B2 Method and apparatus for spinal stabilization

US9445826B2 Method and apparatus for spinal stabilization

US9962189B2 Method and apparatus for spinal stabilization

US10639074B2 Method and apparatus for spinal stabilization

US10667844B2 Method and apparatus for spinal stabilization

US8945190B2 Method and apparatus for spinal fixation

US9101411B2 Method and apparatus for spinal fixation

US9387313B2 Telescopic Percutaneous Tissue Dilation Systems and Related Methods

US10293147B2 Telescopic percutaneous tissue dilation systems and related methods

US8551094B2 Distal bone anchors for bone fixation with secondary compression

US7326211B2 Deployment tool for distal bone anchors with secondary compression

US7686807B2 Tool for bone fixation device

US6890333B2 Method and apparatus for bone fixation with secondary compression

US8715284B2 Method and apparatus for bone fixation with secondary compression

US9408648B2 Method and apparatus for bone fixation with secondary compression

US10349991B2 Method and apparatus for bone fixation with secondary compression

US7070601B2 Locking plate for bone anchors

US7175625B2 Soft tissue anchor and method of using same

US6648890B2 Bone fixation system with radially extendable anchor

US6632224B2 Bone fixation system

US7008428B2 Bone fixation system

US6942668B2 Proximal anchors for bone fixation system

US9861354B2 Meniscus repair

US11013510B2 Meniscus repair

US10758222B2 Meniscus repair

US8579926B2 Plaque removal device with rotatable cutting element

US7842055B2 Neuro thrombectomy catheter

US7235088B2 Neuro thrombectomy catheter

US6482217B1 Neuro thrombectomy catheter

US11490909B2 Systems and methods for removal of blood and thrombotic material

US10716583B2 Systems and methods for removal of blood and thrombotic material

US11490909B2 Systems and methods for removal of blood and thrombotic material

US9883877B2 Systems and methods for removal of blood and thrombotic material

US10716583 Systems and methods for removal of blood and thrombotic material

US10492805B2 Systems and methods for thrombolysis and delivery of an agent

US11510689B2 Systems and methods for thrombolysis and delivery of an agent

US10492805B2 Systems and methods for thrombolysis and delivery of an agent

US10716583B2 Systems and methods for thrombolysis and delivery of an agent

US10561440B2 Systems and methods for manipulating medical devices

US11497507B2 Systems and methods for closing portions of body tissue

US9248221B2 Aspiration monitoring system and method

US9895473B2 Aspiration monitoring system and method

US10603415B2 Aspiration monitoring system and method

US10702292B2 Aspiration monitoring system and method

US10226263B2 Aspiration monitoring system and method

US11051832B2 Aspiration monitoring system and method

US9433427B2 Systems and methods for management of thrombosis

US9913936B2 Systems and methods for management of thrombosis

US10192230B2 Systems and methods for management of thrombosis

US10922704B2 Systems and methods for management of thrombosis

US11540847 Systems and methods for management of thrombosis

US10716880B2 Systems and methods for aspiration and monitoring

List of Publications:

Mechanical characteristics of the new BONE-LOK bi-cortical internal fixation device

- November 2003
- The Journal of foot and ankle surgery: official publication of the American College of Foot and Ankle Surgeons 42(6):344-9

DOI:10.1053/j.jfas.2003.09.003

Mechanical and structural characteristics of the new BONE-LOK cortical-cancellous internal fixation device

- February 2003
- The Journal of foot and ankle surgery: official publication of the American College of Foot and Ankle Surgeons 42(1):15-20

DOI:10.1053/jfas.2003.50000