

Neovasc Tissue Products

July 2011



Neovasc Inc.



Neovasc Inc. is a medical device company focused on products used to treat heart disease and related conditions

- Founded:** 2000
- Location:** Vancouver, BC, Canada
- Employees:** ~48 full time
- Facility:** 14,000sqft including labs and cleanrooms
- Core Products:** Custom pericardial tissue
Peripatch™ implantable pericardial tissue
Reducer™ for refractory angina
- Listing:** TSX-V (NVC)

Tissue Products Overview



The focus of the **Neovasc Tissue Products Division** is to provide biological tissue materials and associated development and manufacturing services

- Our customers are typically industry partners who private label or incorporate Neovasc biological tissue materials into their own products
- Areas of specialization:
 - Pericardial tissue leaflets for percutaneous aortic and mitral valves
 - Surgical patches for vascular and other applications
 - Tissue for incorporation into specialized vascular devices
- We pride ourselves on being responsive, nimble, and doing whatever it takes to always exceed the expectations of our customers and partners

Neovasc Tissue Product Technologies



- Specially treated pericardial tissue suitable for incorporation into a wide range of implantable devices
- Proprietary treatment process creates implantable, biocompatible tissue that retains physical characteristics of natural tissue
- Initially developed for surgically implantable **heart valve** leaflets and has been demonstrated to meet the biological, mechanical and durability requirements for long-term implantation in heart valve applications
- Adapted for general surgical use as a patch or reinforcement material
- FDA-cleared and CE-marked
- 20+ year implant history



Neovasc Tissue Sources

- We supply pericardial tissue products from the following sources:
 - Bovine** - sourced from Australia and New Zealand (GBR1)
 - Bovine** - sourced from US (GBR3)
 - Equine** - sourced from Canada
 - Porcine** - sourced from Canada
- Our **bovine** pericardial tissue products are generally approved for use in the US and Canada. EDQM Certification of our GBR1 tissue is in place for Europe. CFIA Certification in place for export of our GBR1 tissue to Europe as an intermediate product for incorporation into third party medical devices.
- Our **equine** tissue products are generally approved for use in Europe.
- Our **porcine** tissue products are presently only being used in R&D. CFIA Certification is in place for export to Europe as an intermediate product for incorporation into third party medical devices.

Neovasc Tissue Physical Characteristics

- Typical thickness ranges:

Standard Bovine 0.35 – 0.75 mm (0.014” – 0.030”)

Equine 0.20 – 0.50 mm (0.008” – 0.020”)

Porcine 0.15 – 0.32 mm (0.004” – 0.013”)

- Processed tissue can be provided:

- In a variety of standard sizes
- To desired thickness, uniformity and surface quality
- Precision cut to shape, such as matched valve leaflets
- Geometrically formed to custom 3-D shapes
- Sterile or non-sterile

Neovasc Tissue – Current Customer Applications



1. Minimally invasive aortic heart valve leaflets
2. Minimally invasive mitral heart valve leaflets
3. Specialty heart valve leaflets and components
4. Artificial heart components
5. Covered stent grafts
6. Surgical patches for vascular procedures
7. Surgical patches for general use



Neovasc Heart Valve Leaflet Applications



Neovasc is the world's leading third party supplier of cross-linked pericardial tissue for use in the development of minimally invasive heart valves.



Neovasc Facility and Services



Neovasc has a state-of-the-art development and production facility. In addition to providing our standard tissue products, we work closely with partners to provide solutions specific to their products. These activities include:



- Providing collagen fixed tissue cut or shaped to precise customer specifications
- Providing manufacturing services including precision product assembly, sewing, packaging, inspection, etc.
- Sterilization services, including proprietary liquid chemical sterilant
- Product development services and coordination of design projects
- Verification and validation testing services including valve testing and tissue characterization
- Inventory and supply chain management

Peripatch™ Surgical Patch



Neovasc's Peripatch has significant advantages over synthetic materials for surgical patching or repair applications:

- *Handles like natural tissue*
- *Exceptional tensile and suture retention strength*
- *Does not require special sutures*
- *Reduced suture line bleeding / leakage*



Neovasc markets Peripatch surgical patch products through a growing network of distributors and **strategic partners**: i.e. – Neovasc supplies **LeMaitre Vascular** with their *XenoSure™* Biologic Vascular Patch.

Production Scalability



- Neovasc facility includes a chemistry lab, certified ISO Class 5, 6 & 7 cleanrooms and manufacturing infrastructure for a wide range of tissue and vascular medical devices
- Neovasc maintains excess cleanroom capacity to be able to respond rapidly to the growing needs of our clients



Established and Tested Quality System



- Neovasc is certified to EN ISO 13485:2003 and 22442 compliant
- Neovasc is regulated by US-FDA, Health Canada and European notified bodies and follows all applicable standards and guidelines
- Neovasc's facility and Quality System are audited annually by our notified body (BSI) and have passed multiple audits by industry partners and customers
- Multiple products are approved for sale in the US and Europe that were developed by Neovasc, that comprise or incorporate our tissue, or that are manufactured at our facility
- Neovasc's facility was US-FDA audited in 2008 - passed audit without a single deficiency

All tissue products and associated manufacturing processes are strictly segregated by species and source for quality control purposes.

Neovasc Team



The Neovasc team includes a range of professionals experienced in the development of implantable pericardial tissue technologies and vascular devices. Key members of our team include:

Alexei Marko (CEO) – 16 years experience in the development and commercialization of medical devices, including 11 years focused on vascular field

Brian McPherson (COO) - 15 years experience managing all aspects of medical device manufacture, including biological tissue, stent and catheter products

Randy Lane (Director R&D) – 12 years hands-on experience in the development and manufacture of implantable tissue technologies and engineered tissue heart valves

Mark Pace-Florida (Director of Engineering) – 9 years hands-on experience in pericardial tissue and related product development, including heart valves

David Moffat (Senior Engineer) – 9 years experience in endovascular device development and testing

Paul Geyer (Chairman & Advisor) – 18 years experience in tissue and tissue heart valve development, including role as founder and CEO of Mitroflow International Inc. heart valve company (now a division of the Sorin Group)

Summary



Neovasc provides an unmatched level of service to our tissue product customers

- We are a leading provider of clinically proven implantable pericardial tissue and associated services to the medical device industry
- We have a highly experienced team and state-of-the-art facility that supports all phases of design, development and manufacturing
- We pride ourselves on being responsive, nimble, and doing whatever it takes to always exceed the expectations of our customers and partners



Contact Information



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