

Neovasc Tissue Products

November 2009



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:** 40 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

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 incorporate Neovasc biological tissue materials into their own products.
- Areas of specialization:
 - Pericardial tissue leaflets for 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. Neovasc's GBR1 sourced bovine tissue has received EDQM certification facilitating incorporation into products intended for the European market.
- Our **equine** tissue products are generally approved for use in Europe.
- Our **porcine** tissue products are presently only being used in R&D.

Neovasc Tissue Physical Characteristics



Typical thickness range:

| | |
|-------------------------|----------------------------------|
| Ultrathin Bovine | 0.20 - 0.30 mm (0.008" - 0.012") |
| Standard Bovine | 0.40 - 0.75 mm (0.016" - 0.030") |
| Equine | 0.20 - 0.50 mm (0.008" - 0.020") |
| Porcine | 0.10 - 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 3rd party supplier of crosslinked leaflet material for use in the development of minimally invasive heart valves.



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.

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

Production Scalability



- Neovasc facility includes 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 facility and Quality System are audited annually by our notified bodies (TUV/BSI).
- 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 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 10 years focused on vascular field

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

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

Randy Lane (Biological Tissue Project Manager) – 12 years hands-on experience in the development and manufacture of implantable tissue technologies and engineered tissue heart valves

Amir Miller (VP, New Technologies) – 9 years experience in vascular stent and catheter design

Fabio De Pasquale (Director, Regulatory Affairs) – 20 years experience in quality systems and regulatory affairs, during which, he has obtained medical regulatory approvals for over 50 different medical devices

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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