



Press Contact:
Elise B. Hamann
The Allied Group
p. 401-946-6100 x. 3171
ebhamann@thealliedgrp.com

Technical Contact:
Art Burghouwt
Concordia Medical
p. 401-828-1100 x118
aburghouwt@concordiamedical.com

FOR IMMEDIATE RELEASE

Concordia Medical's New BIOFELT™ Tissue Engineering Scaffolds Contribute to the Growing Field of Regenerative Medicine

***BIOFELT is an integral part of revolutionary approach to developing replacement
tissues for damaged or diseased organs***

Coventry, R.I., February 13, 2008—Concordia Medical, www.concordiamedical.com, an innovator in specialty fiber based medical implants and scaffolds for regenerative medicine, announces the first clinical uses of BIOFELT™, a unique non-woven biomaterial which can readily be absorbed by the human body. Two of Concordia's medical device customers have separately received approvals to proceed with human clinical uses of products based on BIOFELT in the urological and dental implant markets.



BIOFELT, a bioabsorbable polymer fiber scaffold that is highly porous, soft and flexible, biocompatible and enables human cells to grow into its 3D interconnected pores so that new natural tissue can be formed to replace and/or repair damaged human tissues. BIOFELT has been used in numerous leading biomedical research laboratories around the world for various advanced tissue engineering applications in the field of regenerative medicine.

Concordia Medical's development relationships currently include Dr. Laura Niklason at Yale University, Dr. John Mayer at Children's Hospital Boston/Harvard Medical Center, Dr. Roy Aaron at Brown University/Lifespan, Dr. Anthony Atala at Wake Forest University, as well as at other leading research institutions in the United States, Europe and Asia. Pre-clinical applications include cardiovascular tissue regeneration for arteries and heart valves and orthopedic tissue regeneration of cartilage.

-more-

BIOFELT describes a range of absorbable 3D non-woven felt scaffolds that have successfully demonstrated the ability to rapidly grow cells and form organized 3D tissue structures. The main benefits of Concordia Medical's non-woven felt process over woven and knit structures are the high porosity factor (>97%) and excellent flexibility and softness.

Concordia Medical's BIOFELT is produced from medical grade polyglycolic acid (PGA) and poly-L lactic acid (PLLA) and can be formed into various size sheets, discs, and tubes. Thicknesses can be specified from 0.3 to 7 mm and the bulk density from 30 to 300 mg/cc. Finished scaffolds are scoured, vacuum-sealed in moisture barrier foil pouches and packed with desiccant.

Concordia Medical also produces custom orders of BIOFELT made from other polymers such as co-polymers of PGA, PLLA, PLC, and TMC, or fiber blends of various absorbable polymers, and customer supplied resins and fibers. Additionally, Concordia Medical can produce felts that contain woven and/or knit scrims to achieve additional strength, while maintaining the advantage of high porosity values afforded by the non-woven component.

"The field of regenerative medicine is evolving at a rapid and exciting pace," commented Art Burghouwt, Executive Vice President of Concordia Medical. "BIOFELT has been instrumental in helping key thought leaders accelerate their research in transforming the treatment of human disease and providing innovative new therapies."

According to a US Department of Health and Human Services report 2020: A New Vision, "Regenerative medicine empowers doctors with the ability to replace damaged tissue in patients with healthy organic tissue that is accepted and functions like (and in some cases, is) the body's own."

Dr. Laura Niklason, Yale University, Associate Professor of Anesthesiology and Biomedical Engineering and co-founder of Humacyte, Inc., a newly established company focused on tissue engineering based in North Carolina, has used Concordia Medical's BIOFELT to culture arteries by taking the felt and forming it into a tubular-shape the size of the target artery that is to be grown.

Dr. Niklason seeds the BIOFELT in a sterile environment with vascular cells to lay down proteins and collagen. While the BIOFELT degrades, the cells simultaneously grow so that at the end of a 6-8 week period, healthy tissue and cells have grown and replaced the synthetic material ready to be placed in the host's body.

"Concordia really is at the forefront," stated Dr. Niklason, "I know of no other company that can tailor the bio-specs of the fibers to any desired space and diameter. No other industrial partner in the country could step up and tackle our research goals. As far as I'm concerned, they are the only game in town."

While today's bypass procedure consists of a doctor stripping a several foot long vein from the patient's leg from which the "best" pieces are sewn into the arteries and the rest discarded, Dr. Niklason has been able to take a biopsy of less than an inch from the patient, and grow 6-10 vessels/arteries 5" in length; enough to do a complete heart bypass on a human.

Concordia's involvement in tissue engineering scaffolds is a direct extension of the work done by Dr. Robert Langer's laboratory at Massachusetts Institute of Technology (MIT) and Albany International Research Company starting in 1986. These scaffolds were developed from absorbable polymers utilizing extensive textile processing expertise to create non-woven substrates for tissue engineering. Concordia purchased the assets related to producing these scaffolds from Albany International Research Company in early 2005, established a controlled manufacturing environment, applied expanded engineering controls and quality control initiatives, and then initiated the BIOFELT brand of non-woven scaffolds.

"Concordia has executed complex projects in the high tech fiber world," stated Dr. Robert Valentini, MD PhD, Brown University and CEO of Myomics, Inc., a company focused on the discovery and screening of compounds to treat neuromuscular disease and minimize muscle adverse effects. "Concordia is now also known in the medical circle for its innovation and operational execution."

###

Concordia Medical is an innovator in specialty fiber based medical implants and scaffolds for regenerative medicine. With extensive experience in the development and GMP manufacture of biomedical implants, which consist of bioresorbable and/or non-resorbable fibers for tissue-engineering applications, Concordia Medical is working with academic research partners and medical device industry leaders to develop the next generation of medical implants. The company recently announced expanded uses of its newest product line, BIOFELT™, a versatile bioresorbable polymer scaffold that can be used in PMA devices for tissue engineering and cell-seeding, as well as 510(k) medical implant applications. BIOFELT facilitates the growth and proliferation of cells and autologous tissues in vitro and in vivo. Headquartered in Coventry, Rhode Island, Concordia Medical is ISO 13485:2003 certified for medical device design and manufacturing. For more information, please call Art Burghouwt at 401-828-1100 x118 or visit www.concordiamedical.com