

Press Release

www.ime-electrospinning.com

IME Medical Electrospinning helps shape the first standard on fiber-based medical scaffolds, published by ASTM International

Waalre, The Netherlands, 27 May 2021 – [IME Medical Electrospinning](http://www.ime-electrospinning.com), global leader in fiber-based solutions for the medical industry, today announces the publication of the first standard for fiber-based medical scaffolds published by international standards organization ASTM, which it helped create. The standard was co-authored by IME's CTO Ramon Solberg and will guide the design and manufacture of fiber-based medical products used to improve patient care.

F3510-21 - Standard Guide for Characterizing Fiber-Based Constructs for Tissue-Engineered Medical Products

The need for standardization of fiber-based scaffolds was identified in 2019, during the 'Workshop on the characterization of fiber-based scaffolds: Challenges, progress, and future directions'¹. This workshop was initiated by a consortium of industry leaders such as Medtronic, academic institutes, non-profit organisations, and governmental bodies. Following the conclusions of the consortium, a workgroup was formed, facilitated by the American National Institute of Standards and Technology, NIST, to develop an ASTM Standard, in which IME took an active role. This published standard now provides important guidance for the development and production of reproducible, high-quality nanofiber-based medical devices, with the goal of improving patients' health and safety.

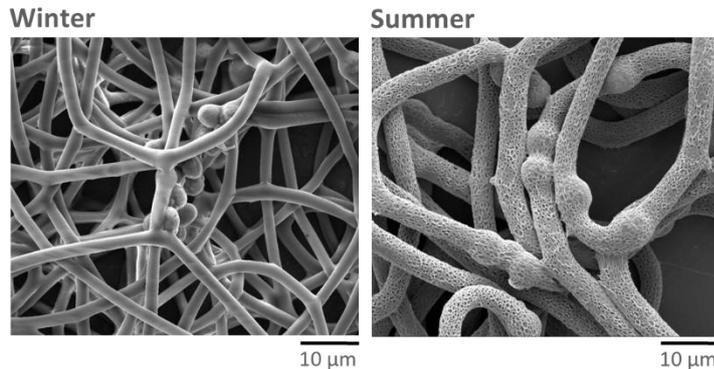
IME sets the standard with its technology

Since its establishment in 2008, IME has pioneered advanced solutions for the precise control and scalable production of fiber-based medical scaffolds. Optimizing fiber and scaffold properties such as fiber diameter, porosity, and mesh thickness is vital for the intended functionality of these scaffolds. If left uncontrolled, fluctuations in environmental parameters, like temperature and humidity, can greatly influence scaffold properties, leading to inconsistencies in the final product. Within the ASTM standard, the precise control of environmental parameters is a central tenant of guidance for producing highly consistent fiber-based products, with therapeutic safety and efficacy in mind.

With the MediSpin™XL, IME's industrial production platform for fiber-based scaffolds, the company has already incorporated a wide variety of technical solutions to meet the highest standards for industrial production of fiber-based scaffolds. The platform therefore includes innovative

¹ Garcia, L., Soliman, S., Francis, M. P., Yaszemski, M. J., Doshi, J., Simon Jr, C. G., & Robinson-Zeigler, R. (2020). Workshop on the characterization of fiber-based scaffolds: Challenges, progress, and future directions. *Journal of Biomedical Materials Research Part B: Applied Biomaterials*, 108(5), 2063-2072.

technologies, protected by multiple patent families, such as rigorous climate control, in process thickness measurement and in-line quality monitoring systems to ensure a consistent end-product.



Seasonal variations in climate have a dramatic effect on the consistency of fiber-based scaffolds, depicted in these images. Advanced climate control facilitates the reproducible production of homogeneous nanofibers, independent of season or time of the day – Photo by Ramon Solberg, Founder & CTO of IME Medical Electrospinning

Judith Heikoop, Chief Executive Officer at IME Medical Electrospinning, says:

“Having been on the forefront of developing standards in medical electrospinning, ensuring safe, scalable and reproducible scaffolds for medical devices and drug delivery solutions, we applaud the introduction of these new standard by NIST and ASTM. This will help to further advance ground-breaking solutions and bring them to patients as fast and efficient as possible. And we’re very proud that the contribution to the technological innovations in the field by our founder and CTO Ramon Solberg, were instrumental in these new standard.”

Ramon Solberg, Chief Technology Officer at IME Medical Electrospinning, adds:

“I’m very proud to have been part of a great team of field experts, led by NIST, to contribute to these new US standard. Obviously it will become the blueprint for further worldwide standards in our industry and will certainly help advancing large-scale manufacturing of reproducible and scalable fiber-based scaffolds. These wonderful pieces of art will substantially transform the medical device market for a wide variety of medical applications and thus revolutionize tissue engineering.”

=== E N D S ===

About Medical Electrospinning

Applying specific polymers, IME’s advanced equipment creates fiber-based medical device solutions that mimic the natural human extracellular matrix in nanometer and micrometer format for implants and membranes in the human body. Human cells recognize these artificial matrices (scaffolds) as the body’s own, facilitating the repair of the damaged tissue for heart valves, blood vessels, nerves, tendons, skin and bone etc. This is in contrast to implants and membranes of traditional structures, which are seen as foreign and therefore can lead to scar tissue or rejection phenomena. The MediSpin™ XL platform has been developed specifically for MedTech industrial manufacturing of medical devices and is now also suitable for pharmaceutical drug delivery applications and ensures firm control over the crucial parameters of the electrospinning process, leading to reproducible and consistent end-products.

About NIST

The National Institute for Standards and Technology (NIST) is part of the U.S. Department of Commerce and founded in 1901. NIST is a unique federal agency with a broad mission to promote U.S. innovations and industrial competitiveness by advancing scientific measurements, standards and technology in a way that enhances economic security and improves our quality of life. NIST provides these measurements and standards to a broad range of products and services that rely on technology, from the smallest of nano-technologies to the largest and most complex of human-made creations.

For more info, please visit www.nist.gov

About ASTM

Founded in 1898, ASTM International is one of the world's largest international standards developing organizations. ASTM International develops and delivers international voluntary consensus standards that are used to improve product quality, enhance safety, facilitate market access and trade. The company delivers the test methods, specifications, guides, and practices that support industries and government worldwide.

For more info, please visit www.astm.org

About IME Medical Electrospinning

For over ten years, IME Medical Electrospinning has been a leading player in the field of developing and implementing electrospinning processes and equipment for the manufacturing of medical devices for (regenerative) medicine and drug delivery. Electrospinning is a flexible process for producing extremely thin fibers and structures that have excellent properties to help regenerate human tissue. IME Medical Electrospinning has developed a unique set of innovations in electrospinning technology for reproducible and scalable production of electrospun material under tightly controlled conditions required for the MedTech and Pharma market. Customers and scientific partners include the MedTech and Pharma industry, scientists and health institutions.

More information available at www.ime-electrospinning.com

For further inquiries:

IME Medical Electrospinning, Waalre, The Netherlands

Judith Heikoop M.Sc. Ph.D.

T: +31 40 28 27 956

E: j.heikoop@ime-electrospinning.com

For media:

LifeSpring Life Sciences Communication, Amsterdam

Léon Melens

T: +31 6 538 16 427

E: lmelens@lifelsspring.nl