

# PrintBio Receives FDA Clearance for 3DMatrix DynaFlex™, Adding Uniflex™ Technology to its First Product, 3DMatrix™

3DMatrix DynaFlex™ incorporates PrintBio's proprietary Uniflex™ unidirectional flexible mesh technology

MIAMI BEACH, FL, UNITED STATES, May 27, 2025 /EINPresswire.com/ --<u>PrintBio</u>, Inc. today announced U.S. Food and Drug Administration (FDA) 510(k) clearance of 3DMatrix DynaFlex<sup>™</sup> ("DynaFlex"), which



incorporates PrintBio's proprietary Uniflex<sup>™</sup> unidirectional flexible mesh technology into the Company's initial product, 3DMatrix<sup>™</sup> Surgical Mesh, the first 3D-printed resorbable surgical mesh which received FDA 510(k) clearance less than one year ago.

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This integrated design and manufacturing advance brings an unprecedented level of design flexibility, enabling innovative solutions limited only by the surgeon's imagination" *Dr. Kevin Slawin, Founder and CEO*  DynaFlex is approved for use in the reinforcement of soft tissue where weakness exists in patients undergoing plastic and reconstructive surgery.

PrintBio, Inc., is the only clinical-stage regenerative medicine company solving medical challenges with custom-engineered 3D-bioprinted living implants. Leveraging their first-in-human clinical experience with 3Dbioprinted and implanted living tissues, PrintBio is developing an array of biocompatible products, beginning with 3DMatrix<sup>™</sup>, a 3D-printed bioresorbable surgical mesh, utilizing its proprietary technologies.

"PrintBio has developed the first 510(k)-cleared 3D printed resorbable surgical mesh. This integrated design and manufacturing advance brings an unprecedented level of design flexibility, enabling innovative solutions limited only by the surgeon's imagination," said Dr. Kevin Slawin, formerly an experienced oncologic open and robotic surgeon, and now the Chairman and CEO of PrintBio, Inc. DynaFlex, PrintBio's second 510(k)-cleared surgical mesh product, delivers on the innovation promise. Uniflex Technology allows for directional compliance that enables the

surgeon to provide tissue support in one direction and still allow physiologic compliance in the orthogonal direction.

"Being innovative and 'first' is not new to the PrintBio team, which was also the first and only group allowed by FDA to implant a 3D-printed living implant in a patient, an event <u>covered at the time on the front page of the NYTimes</u>," Slawin added.

PrintBio is relentlessly pursuing its commitment to rapid innovation, developing novel mesh designs that offer unique solutions to meet surgeon and market needs. Ongoing efforts include:

- New product extensions broadening the scope of our mesh product's size, thickness, flexibility, and shape

- New mesh designs that offer differential and directional load bearing options depending on the clinical setting

#### About 3DMatrix Dynaflex

3DMatrix<sup>™</sup> DynaFlex (DynaFlex<sup>™</sup>) is a single-use, fully absorbable, colorless, non-woven, 3Dprinted, macroporous, polymeric surgical mesh made entirely of uncolored and undyed polydioxanone (PDO) monofilament, which may reduce infection and minimize biofilm formation compared to products manufactured using a woven or braided filament. DynaFlex<sup>™</sup> is indicated for use in surgical repair or reinforcement of soft tissue. DynaFlex<sup>™</sup> acts as a mechanical support to soft tissues and provides a scaffold for tissue ingrowth. It is designed to fully degrade over six to seven months. 3DMatrix<sup>™</sup> provides temporary mechanical support and stabilization during the healing process. The mesh is designed, like physiological tissues (e.g., muscle, fascia), to be stronger in the load bearing than in the orthogonal direction to provide mechanical support and stability where needed and flexibility to accommodate movement when not, allowing the body to heal properly and comfortably.

DynaFlex<sup>™</sup> is initially provided in three sizes, 6 cm x 5.5 cm, 6 cm x 14.5 cm, 5 cm x 17.5 cm that can be cut to the desired shape and size for each specific application at the time of use. DynaFlex<sup>™</sup> is intended to be used by prescription only in a healthcare facility or hospital.

## About PrintBio, Inc.

PrintBio, Inc. (https://printbio.com), is the only clinical and commercial stage regenerative medicine company solving medical challenges with custom-engineered 3D-printed products, including living implants (clinical stage). Leveraging their first-in-human clinical experience with 3D-bioprinted and implanted living tissues, PrintBio is developing an array of biocompatible products, beginning with 3DMatrix<sup>™</sup>, and 3DMatrix DynaFlex, 3D-printed bioresorbable surgical meshes utilizing its proprietary technologies (commercial stage). It also offers a non GMP research-grade collagen, ColVivo<sup>™</sup>, a collagen bio-ink and solution-form collagen that can be used for translational research purposes. PrintBio's facility is located on the Queens side of the Queens-Midtown Tunnel, in Long Island City, Queens, and houses the world's first clinical-grade manufacturing facility for living bioprinted implants and related materials.

## About Rapha Capital Management, LLC

Rapha Capital Management, LLC is an investment advisory firm focused on making strategic investments in early stage, non-public biotechnology companies, through special purpose, joint venture entities (SPVs), which it manages. Rapha Capital was founded by its President, Kevin Slawin, M.D., a successful and experienced oncologic and robotic surgeon focusing now on disruptive healthcare technologies. Previously, he was the founder of Bellicum Pharmaceuticals, Inc., the very first CAR-T cell company, which he took public in 2014 with a \$55 million crossover Series C and a successful \$161 million IPO in December 2014. After leaving Bellicum, he founded Rapha Capital Management, LLC (https://raphacap.com), which offers alternative asset management services to Rapha's fifteen SPVs, Rapha Capital Investment I to XV, LLC, as well as to its private equity fund, Rapha Capital PE Life Sciences Fund VI, which is the current vehicle for all investments managed by Rapha Capital Management. Rapha Capital Investment XIV, LLC is the SPV that owns and controls PrintBio, Inc.

For more information about Rapha Capital Management, email info@raphacapital.com or visit <u>https://raphacap.com</u>

Certain information set forth in this press release may constitute "forward-looking statements" under applicable securities laws. There are a number of factors that could cause actual results or outcomes to differ materially from those addressed in such forward-looking statements. Thus, forward-looking statements are provided only as an opportunity to understand management's beliefs and opinions in respect to the company's future prospects.

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