NEWS RELEASE

Industry-Academia Collaborated Microstructure Spine-Fusing Device Now Covered Under Japanese National Health Insurance

Tokyo, Japan, June 1, 2021 --- Teijin Nakashima Medical Co., Ltd., a Teijin Group company that develops, manufactures and distributes artificial joints, spinal devices and trauma devices, announced today that its 3D printed interbody spacer, a special microstructure spine-fusing cage that the company developed with support from Tokyo Medical and Dental University (TMDU) and Japan Agency for Medical Research and Development (AMED), as one of the Medical Research and Development Programs Focused on Technology Transfer: Strategic Promotion of Innovative Research and Development (S-Innovation), has been accepted for reimbursement under Japan national health insurance program as of today following the manufacture and sales approval that the device received in this April.

This 3D printed interbody spacer is a spinal cage for treating spinal conditions such as herniated discs and spondylolisthesis. By fusing it with the vertebral bone, it can replace a surgically removed intervertebral disc to maintain proper height between the vertebral bodies.

In order to obtain better fusion, the 3D printed interbody spacer designed a special microstructure for the contact surface between the spinal cage and the vertebral bone. The microstructure incorporates the metal additive manufacturing technology that is implemented with a 3D printer. As bone orientation is induced to inside the device, excellent bone fusion can be expected in the early stage of implantation without the use of autogenous bone filling in the cage.

The special microstructure is designed as a tertiary structure to realize induction of bone orientation based on the Bone Quality Evaluation Index Focusing on the Orientation of Bone Tissue proposed by Prof. Takayoshi Nakano, Graduate School of Engineering, Osaka University. Also, Teijin Nakashima Medical accumulated efficacy assessment
data by non-clinical studies including animal experiments and repeatedly improved the design of the device under advice based on clinical observations by Dr. Manabu Ito, Medical Director, National Hospital Organization Hokkaido Medical Center.

Teijin Nakashima Medical will manufacture and sell the 3D printed interbody spacer after July 2021. Going forward, Teijin Nakashima will explore the possibility to apply the technology established through this product development to other spinal devices or artificial joint products with the cooperation of AMED and other organizations participating in this project.

Existing spinal cages require collecting a patient's own bone as autologous bone and using it to fill in the cavity of the cage to ensure sufficient bone fusion. To reduce the patient's pain and physician's burden associated with this procedure, there has been a strong demand for an alternative procedure.

In response, Prof. Takao Hanawa, Institute of Biomaterials and Bioengineering, Tokyo Medical and Dental University (TMDU), launched in 2012 a joint research project to investigate possible new devices, including materials for suitable new alloys, methods for creating functional surfaces and new manufacturing processes. The research was an industry-academia collaboration involving Osaka University, Tohoku University, Hokkaido University, Hokkaido Medical Center and Teijin Nakashima Medical with the support from AMED's Medical Research and Development Programs Focused on Technology Transfer: Strategic Promotion of Innovative Research and Development.

The device eventually developed under the project, the 3D printed interbody spacer was evaluated for its efficacy and safety and finally approved for manufacture and sale by the Ministry of Health, Labor and Welfare this past April 9.

About the Teijin Group
Teijin (TSE: 3401) is a technology-driven global group offering advanced solutions in the fields of environmental value; safety, security and disaster mitigation; and demographic change and increased health consciousness. Originally established as Japan's first rayon manufacturer in 1918, Teijin has evolved into a unique enterprise encompassing three core business domains: high-performance materials including aramid, carbon fibers and composites, and also resin and plastic processing, films, polyester fibers and products converting; healthcare including pharmaceuticals and home healthcare equipment for bone/joint, respiratory and cardiovascular/metabolic diseases, nursing care and pre-symptomatic healthcare; and IT including B2B solutions for medical, corporate and public systems as well as packaged software and B2C online services for digital entertainment. Deeply committed to its stakeholders, as expressed in the brand statement “Human Chemistry, Human Solutions”, Teijin aims to be a company that supports the society of the future. The group comprises more than 170 companies and employs some 20,000 people across 20 countries worldwide. Teijin posted consolidated sales of JPY 836.5 billion (USD 7.7 billion) and total assets of JPY 1,036.4 billion (USD 9.5 billion) in the fiscal year that ended on March 31, 2021.

Please visit www.teijin.com
About Japan Agency for Medical Research and Development (AMED)
AMED was established in April 2015 to catalyze the process of medical innovation and overcome the barriers between sectors, connecting talented individuals to accelerate medical research and development. Since then, significant gains in the fight against many diseases have been made.

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