

October 31, 2014

Terumo Announces its Application for the Manufacture and Sales Approval of its Skeletal Myoblast Sheets – To Aim for the World’s First Cardiac Regenerative Therapy

Terumo Corporation (Headquarters: Shibuya-ku, Tokyo, Japan. President: Yutaro Shintaku) filed an application to the Ministry of Health, Labour and Welfare in Japan on October 30 for the manufacture and sales approval of its autologous skeletal myoblast sheets, as “Regenerative Medicinal Products,” for the treatment of severe heart failure due to chronic ischemic heart disease.

If it is approved successfully, the sheets will be the world’s first product to be used as a cardiac regenerative therapy and are expected to become one of the new options in treating heart failure patients.

Terumo has been engaging in R&D activities for a cell sheet based cardiac regenerative therapy since 2007. The company initiated a clinical study at three medical institutions in Japan in 2012 and completed it in 2014. The clinical research of skeletal myoblast sheets, as one of the NEDO* projects, has been advanced by Prof. Yoshiki Sawa, Osaka University. In the “Project to initiate and promote regenerative medicine using cell sheet engineering” led by Prof. Teruo Okano, Tokyo Women’s Medical University, as one of the projects of “Super Special Consortia for Supporting the Development of Cutting-edge Medical Care” (“Tokku”), Terumo has advanced a collaborative research with Osaka University and reached to the clinical study through review for clinical use.

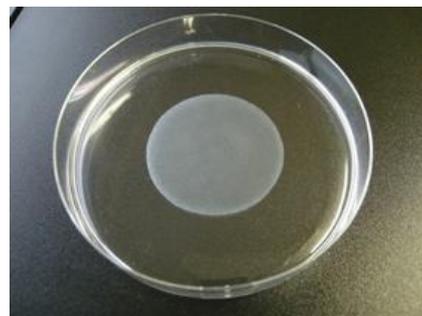
*NEDO: New Energy and Industrial Technology Development Organization

■ Restoring Cardiac Function with Skeletal Myoblast Sheets

Muscle tissues are taken from a patient's thigh and skeletal myoblasts inside them are cultured to produce cell sheets. The condition of severe heart failure is expected to improve by affixing these sheets to cover damaged sites of the patient's heart muscle. The noteworthy feature of this therapy is that there is no risk of adverse reaction as cells are harvested from the patient's own body.



Cell culture at Terumo's facility



Skeletal myoblast sheet

■ **Process to Sheet Transplantation**

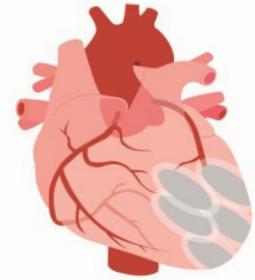
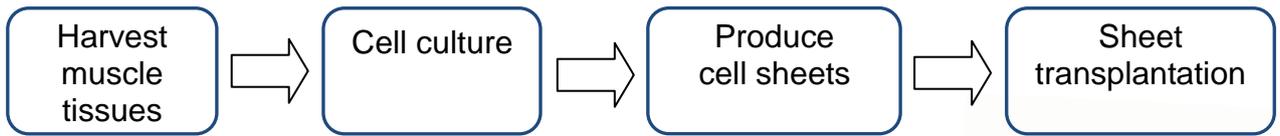


Image of a heart after sheet transplantation

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