FOR IMMEDIATE RELEASE: 2022/9/1

M3, Inc.

"RECELL® Autologous Cell Harvesting Device" Insurance Coverage Begins in Japan
~ Medical Device for Acute Burns and Donor Sites ~

M3, Inc. (Headquarters: Tokyo, Japan; CEO: Itaru Tanimura; URL: https://corporate.m3.com/; “M3” below) has announced that its subsidiary COSMOTEC Co., Ltd. (Headquaters: Tokyo, Japan; CEO: Tatsuro Tsusumi; “COSMOTEC” below) gained approval of "RECELL® Autologous Cell Harvesting Device" (“RECELL” below), a medical device for acute burns and donor sites, for manufacturing and marketing in Japan on February 17, 2022, is now covered by insurance as of today.

RECELL is the first medical device that the M3 Group has marketed as its own product and has carried out the entire process from seed development to insurance coverage. In the future, in addition to its own products, the M3 Group will accelerate its efforts to expand its presence as a partner in the launch strategies of new technologies and products from domestic and foreign medical device manufacturers and ventures in Japan.

【Summary of marketing approval and insurance coverage for RECELL 】

Brand name：RECELL Autologous cell harvesting and non-cultured cell suspension preparation kit
Generic name： Kits for autologous skin cell transplantation
Medical device approval number： 30400BZX00039000
Class classification： Highly controlled medical devices Class III
Insurance reimbursement category： C2 (New features and technologies)
Insurance reimbursement price： RECELL1920： 897,000 yen / RECELL640： 836,000 yen
∗For use, please review RECELL's notes on material price calculation.
Intended use/Method of use：

This product is a medical device intended to produce a non-cultured cell suspension from skin fragments taken from patients and to promote wound healing in acute burns and skin grafts. The Central Social Insurance Medical Council has also published documents on this matter.

【About RECELL】

RECELL is a medical device used in burn cases, mainly for deep degree II and III burns. It can separate harvested skin on a cellular level to produce an autologous cell suspension, requiring donor skin of only 1/80 times the size of the burn area. By directly spraying this suspension onto the burn site, it allows the cells necessary for skin formation, such as keratinocytes, pigment cells,

and fibroblasts, to grow evenly under homogeneous physiological conditions.

RECELL makes it possible to minimize the size of the required donor skin, while providing the same treatment outcome (epithelization) as standard skin grafting. It can also be applied to the donor site, which leads to better results in accelerating wound healing. In addition, the suspension can be prepared in about 30 to 60 minutes in the operating room utilizing RECELL, allowing for treatment to be initiated sooner upon doctor discretion.

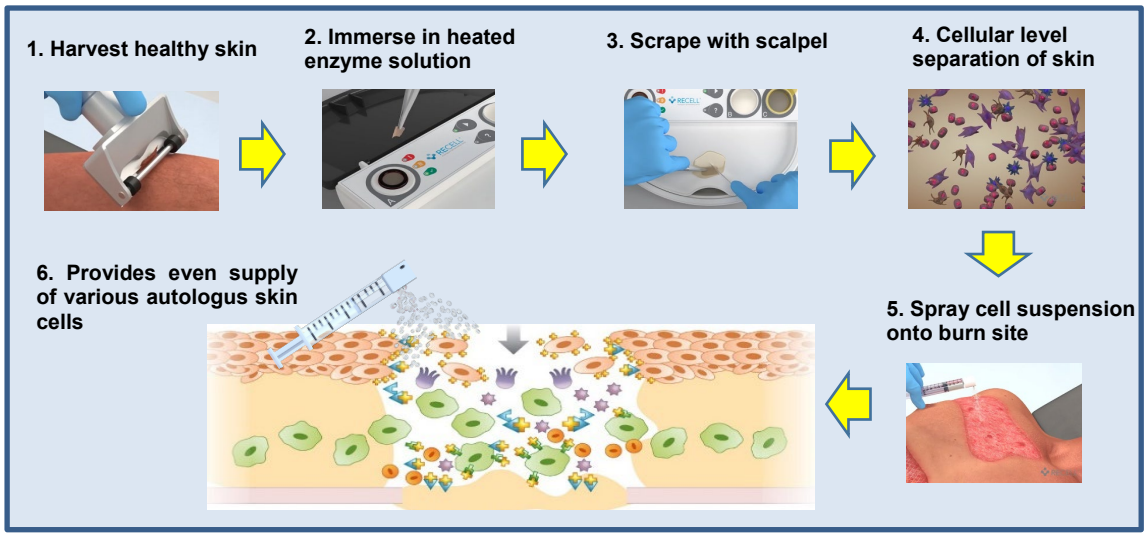

Figure 1：Treatment process using RECELL.

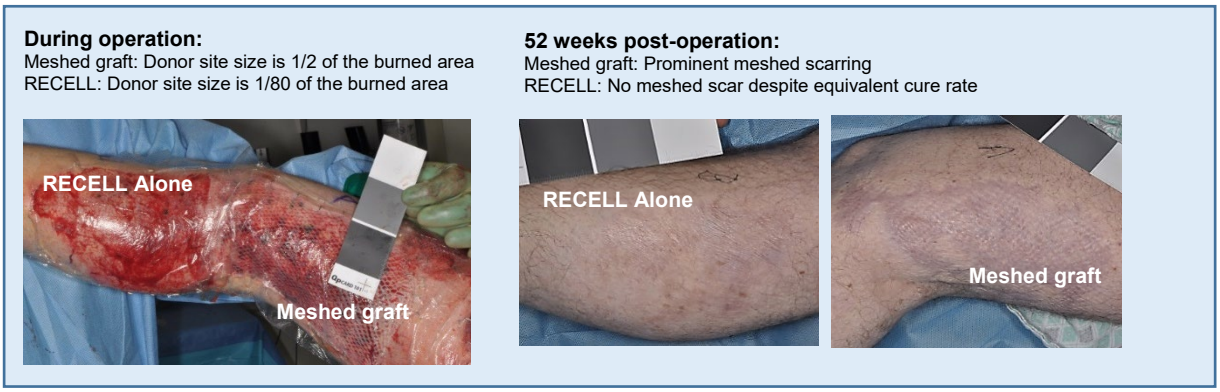

Fig. 2) Case from a U.S. clinical trial: RECELL alone vs. doubled meshed graft in the same patient.
(Photographs courtesy of Kevin Foster, MD, MBA, FACS, Arizona Burn Center, Phoenix, AZ, USA)

Fig. 3) RECELL treatment at the donor site (Courtesy of AVITA MEDICAL, the manufacturer)

Comment by Tatsuro Tsutsumi, CEO of COSMOTEC.

RECELL is the first medical device to be marketed as an in-house product by the M3 Group, which handles the entire process from seed development to insurance coverage. The process of bringing the product to market involves a wide range of steps, including the development of product seeds, the formation of partnerships using capital alliances, obtaining regulatory approval, obtaining insurance reimbursement, e-promotion and the implementation of distribution processes. The product has been launched as a result of the skills and know-how possessed by each company across divisions and group companies within the M3 Group, and also as a result of the generous support of doctors from related academic societies.

We will continue to contribute to saving the lives of as many patients with burns as possible and returning them to their daily lives as soon as possible through this product. We will also combine the Group's capabilities to support the launch strategies of new technologies and products in Japan, not only our own products, but also those of domestic and foreign medical device manufacturers and ventures.

Comment by Avita Medical CEO Dr. Mike Perry

We are very pleased that the Japanese Ministry of Health, Labour and Welfare has granted marketing approval under favourable conditions. We look forward to continuing to work with our valued partner, Cosmotec, in promoting RECELL in the Japanese market.

■COSMOTEC Overview

Established: December 1992

Location: Tokyo, Japan

CEO: Tatsuro Tsutsumi

Business Type：Type 1 medical device manufacturing and sales business (Cardiac Surgery, General Surgery, Sales of medical equipment mainly for endovascular treatment / Sales of general medical equipment and hospital equipment）