FOR IMMEDIATE RELEASE: 2022/02/25

M3, Inc.

"RECELL® Autologous Cell Harvesting Device" Gains Regulatory Approval 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.

About Burns

Burns are classified into three categories according to the depth of injury: first-degree burns, superficial second-degree burns, deep second-degree burns, and third-degree burns (Fig. 1). Extensive or deep burns can cause damage not only to skin tissue but also to major organs of the body, resulting in an extremely poor prognosis for the patient. For such patients, the necrotic tissue is removed and replaced with a graft of healthy skin harvested from the patient in order to both shorten the treatment duration and prevent infection (Fig. 2).

With the above treatment method, healthy donor skin the size of approximately 1/2 to 1/4 of the burn area is required to be harvested. The patient must endure significant consequences such as pain during and after the procedure as well as the risk of extensive scarring (Fig. 3).

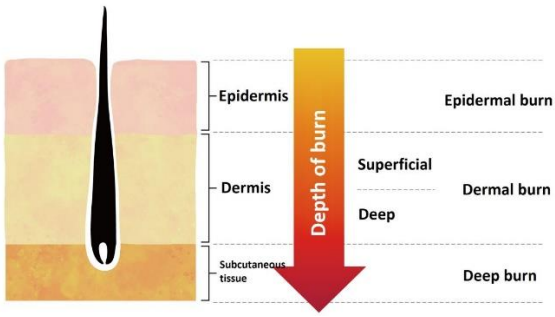

Fig.1) Depth of injury: Third-degree or extensive deep second-degree burns require skin grafting.

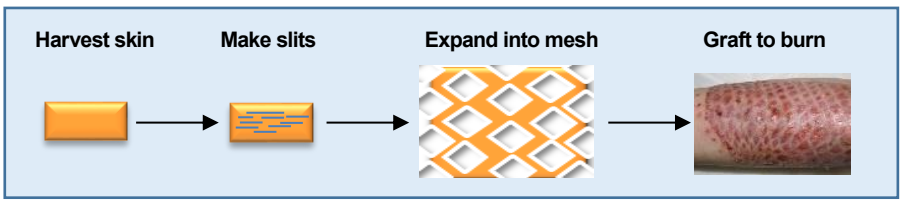

Fig.2) Skin grafting: Several slits are made in the harvested skin and expanded for grafting. A mesh patterned scar may be left after grafting.

Fig.3) Donor site: Harvested area can be severely painful. Scarring and other disfiguring issues may occur.

About RECELL

RECELL is a device which 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. In addition, the suspension can be prepared in about 60 minutes in the operating room utilizing RECELL, allowing for treatment to be initiated sooner upon physician discretion.

RECELL makes it possible to minimize the size of the required donor skin (Fig. 4, 5, 6), 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.

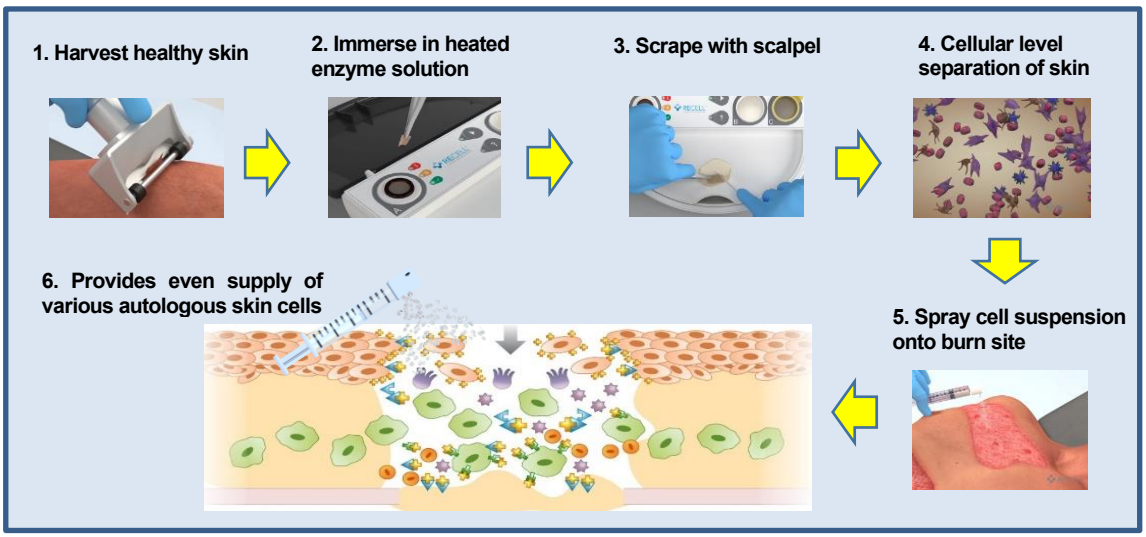

Fig.4) Treatment process using RECELL

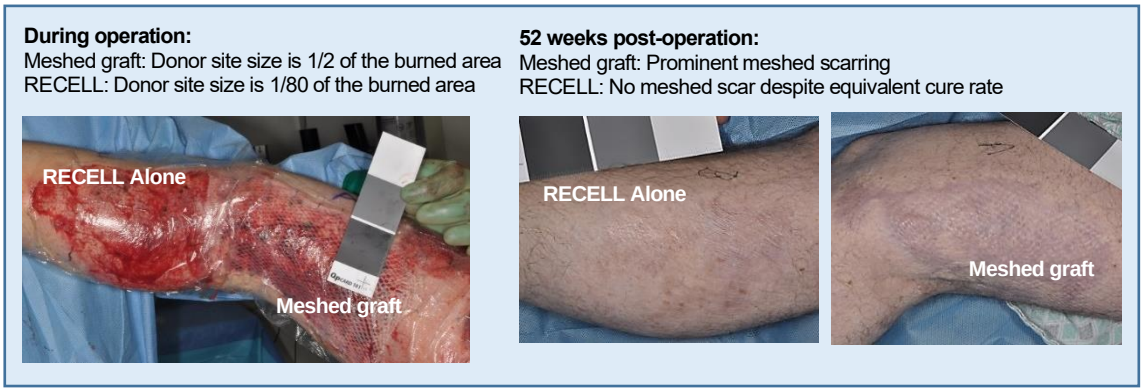

Fig. 5) Case from a U.S. clinical trial: RECELL alone vs. doubled meshed graft in the same patient.
(Photographs courtesy of Kevin Foster, MD, MBA, FACS, Arizona Burn Center, Phoenix, AZ, USA)

Fig. 6) RECELL treatment at the donor site (Courtesy of AVITA MEDICAL, the manufacturer)

In 2015 Taiwan's water park fire accident, provision of RECELL quickly saved the lives of many burn victims. We hope that in the future in Japan as well, prompt treatment with RECELL will contribute as an option for physicians, not only in case of accidents, but also in times of natural disasters or acts of terrorism.

Comment by Tatsuro Tsutsumi, CEO of COSMOTEC

We would like to express our sincere gratitude for the immense cooperation we have received from our fellow collaborators such as medical professionals both domestic and overseas, along with government officials, for introducing this product to Japan. We hope to contribute to the advancement of treatment technologies in the fields of emergency and plastic surgery through this product. In addition, we will continue to strive to contribute to the realization of M3's group mission in the spread of advanced medicine.

■COSMOTEC Overview

Established: December 1992 (a consolidated subsidiary of M3)

Location: Tokyo, Japan

Employees: Approx. 60 (including executives)

CEO: Tatsuro Tsutsumi