



CUTISS Announces First Reconstructive Surgery under Compassionate Use and First U.S. Patient Treated with denovoSkin™

denovoSkin™, the autologous, bio-engineered dermo-epidermal skin graft developed by CUTISS AG, offers a potential viable alternative in both burn and reconstructive skin surgery to improve patients' quality of life and alleviate the shortage of donor sites.

Pediatric patient underwent reconstructive skin surgery for the resolution of burn scars and contractures, with promising outcomes at 3-months post-grafting.

This marks the first use of denovoSkin™ in the U.S. and the first use of denovoSkin™ in compassionate reconstructive surgery.

Boston, MA and Switzerland, 10 October 2024 – [CUTISS AG](#), a life sciences company at the forefront of tissue engineering therapy and regenerative medicine, announced the first ever grafting of denovoSkin™, its autologous, bio-engineered dermo-epidermal skin graft, in a compassionate reconstructive procedure, with the patient also being the first ever U.S. case for the company. The procedure was authorized by the U.S. Food & Drug Administration (FDA) under single patient Investigational New Drug (IND) application and performed by the surgical team at Massachusetts General Hospital (MGH). The four-year-old patient suffered from complex scarring and contractures after the resolution of deep burn wounds affecting 90% of his body, and lacked other therapeutic reconstructive options. Following two denovoSkin™ grafting procedures, the patient is recovering well at MGH. A third procedure is being planned.

Dr. Daniela Marino, CEO of CUTISS, said: *“We are honored to collaborate with Massachusetts General Hospital. This procedure represents more than just an application of technology – it’s about offering solutions where options are limited and highlights the impact of collaboration between top institutions and innovative emerging companies. At CUTISS, we are dedicated to advancing treatments that can make a real difference in patients’ lives. While the journey is ongoing, we continue to explore the application of denovoSkin™ in burns and reconstructive surgery challenges.*

In 2023, more than 20,000 burn patients were reported in the U.S., with 10% experiencing large burns affecting more than 20% of their body area¹. As climate change drives temperatures higher, burn injuries have been reported with increasing frequency². Most burns occur in private residences, but also represent an important injury burden in combat³ and other high-risk professions. Today’s standard of care in burn and reconstructive skin surgery is autografting: the harvesting of the patient’s own healthy skin and its grafting onto the patient’s wounds. Autografting often leads to scars that necessitate maintenance and may require follow-up surgeries. In patients with drastically limited donor sites to provide healthy tissue, other wound closure options are available in the U.S., such as cultured epithelial autografts (CEA).

Jeremy Goverman M.D., Massachusetts General Hospital, stated: *“A large burn that covers most of the patient’s body area requires a significant amount of reconstruction and typically there is very limited healthy skin to use for the traditional autografting process. While the current commercially available CEA for initial wound closure can be lifesaving, it consists of just the upper layer of the skin which limits*

¹ <https://ameriburn.org/wp-content/uploads/2024/08/2024-bisr-3.pdf>

² <https://valleywisehealth.org/arizonas-2023-extreme-heat-wave-led-to-record-number-of-burn-injuries/>

³ <https://pubmed.ncbi.nlm.nih.gov/35400523/>

growth over time and causes increased scarring. Furthermore, it is very thin, difficult to work with, and shrinks significantly while it heals. Grafting advancements that feature full thickness, with an epidermis and dermis, that help the skin to look and behave more like normal skin, will mean better outcomes for patients.”

denovoSkin™ is a personalized, bi-layer graft bio-engineered from a small, thin biopsy of the patient’s healthy skin. Its bi-layer dermo-epidermal structure aims to significantly reduce the need for harvesting healthy donor sites and enables improved functional outcomes and enhanced quality of life for patients. CUTISS’ proprietary tissue engineering technology seeks to change the status quo in skin surgery, addressing the limitations of current approaches.

Rob Sheridan M.D., Chief of Staff at Shriners Children’s Hospital Boston, commented: *“A durable, permanent, high-quality, full-thickness skin replacement that does not require large donor sites would transform acute and reconstructive burn care, and may be particularly beneficial for younger patients who grow over time and often require extensive follow-up procedures. These advancements have remained an elusive goal despite decades of work, and we are very hopeful that this effort will succeed.”*

denovoSkin™, manufactured at CUTISS’ facilities in Switzerland, is the company’s lead product and has so far been grafted on over 60 patients (from neonates to adults) as part of the ongoing clinical trials in Europe, as well as on a compassionate use basis.

Today’s announcement follows the successful Phase I five-year readout of denovoSkin™ published in the [Journal of Burn Care & Research](#) in 2024, the [successful Phase II one-year readout in burns](#), and the [positive Phase II interim readout in reconstructive surgery](#). CUTISS is transitioning towards Phase III trials of denovoSkin™ in Europe.

About CUTISS AG

Established in 2017, CUTISS is at the forefront of tissue engineering therapy and regenerative medicine. Our lead product, denovoSkin™, a bio-engineered, personalized skin graft, promises to transform skin surgery. Currently transitioning to phase III clinical trials in Europe, denovoSkin™ has received Orphan Drug Designation from Swissmedic, the European Medicines Agency (EMA), and the US FDA for the treatment of burns.

Moreover, CUTISS is pioneering the development of the world’s first automated platform for large-scale skin tissue production, advancing breakthrough programs in skin pigmentation restoration and expanding the horizons of tissue engineering. For more information: www.cutiss.com.

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