CUTISS AG

Personalized skin tissue therapy to treat large and deep skin defects

Vision & Mission

We are an innovative, Swiss life-science Clinical Stage Company aiming to provide patients that suffer from large and deep skin defects with the first automate-produced, personalized skin tissue therapy, denovoSkin™ - a safe, effective and accessible therapy for children and adults.

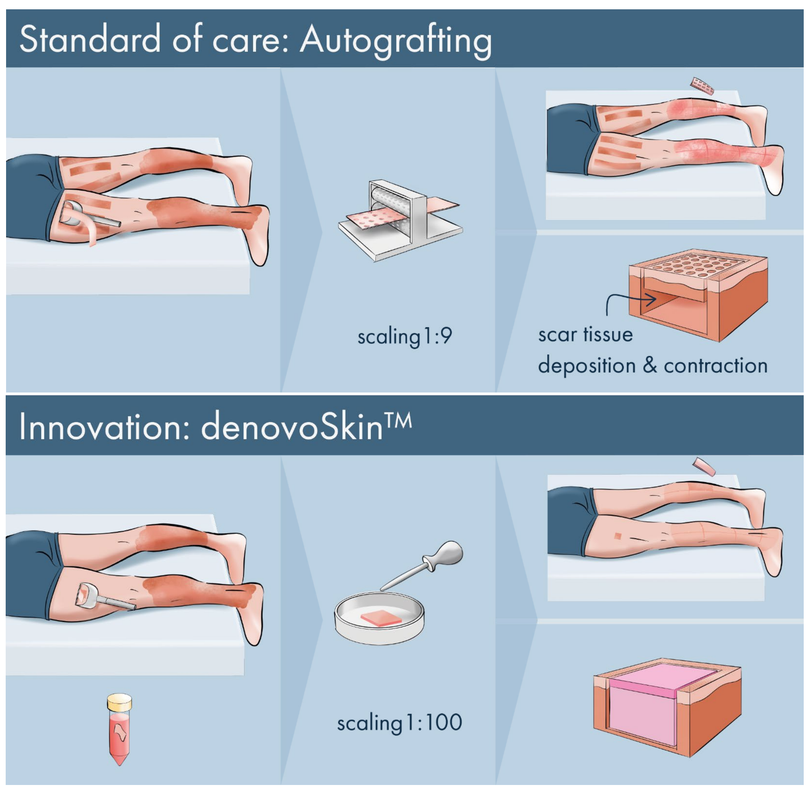
Awards & International Media

Profile

CUTISS is a spin-off (2017) of the University of Zurich (UZH) / University Children's Hospital and is a former member of Wyss Zurich **(technology transfer completed, 2022)**, an accelerator born from the idea of Hansjörg Wyss together with UZH and ETHZ. CUTISS has 40 employees, and its Headquarters at the Bio-Technopark in Zurich-Schlieren with offices, research laboratories, and a Good Manufacturing Practice **(GMP) facility, certified by Swissmedic, Q4 2021.**

Clinical Challenge

Worldwide, millions people suffer from severe, large skin defects that require surgical interventions to restore skin function. Standard of care treatment is often scarce and leaves these patients with permanent, painful, disfiguring and debilitating scars. Scars may impair mobility and growth, require several follow-up surgeries, intense homecare and psychosocial rehabilitation. Standard of care today is meshed autografting: thin sheets of healthy skin from the patient body are harvested (new painful wounds created), meshed (≤1:9), and transplanted on the wounds.

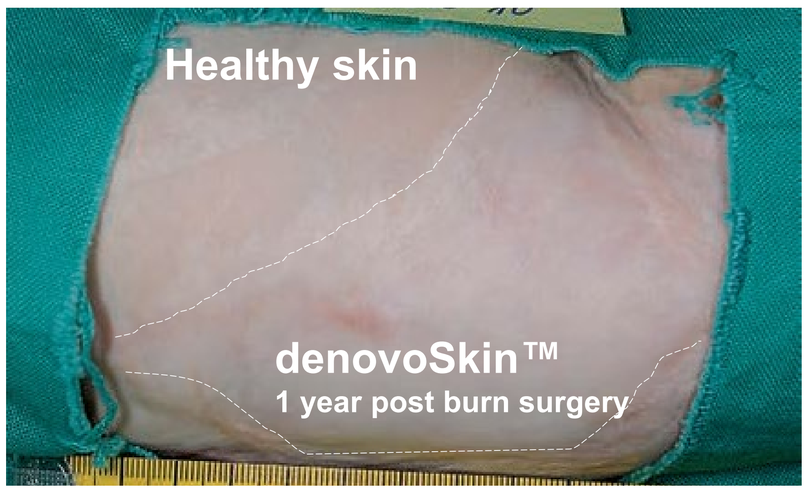


Our Solution

After many years of research, CUTISS can now bio-engineer denovoSkin™ a personalized dermo-epidermal skin graft. Starting off from a stamp-sized piece of healthy patient's skin, denovoSkin™ is created in large quantities (≥1:100) with a thick, bi-layer, robust structure. Because of its intrinsic characteristics, denovoSkin™ is expected to be mechanically stable and result in a minimally scarring outcome after transplantation onto the patient's wounds.

Current Manufacturing Process

Skin is composed by two main layers: Epidermis and Dermis. To bio-engineer denovoSkin™, patient's epidermal and dermal cells are isolated in our GMP facility from a thin, small biopsy. The cells are expanded separately in vitro in 2D, and thereafter used in combination with a compressed hydrogel to create a personalized dermo-epidermal 3D skin graft. denovoSkin™ is then transplanted on the patient's wounds. The current manual process takes 3-4 weeks with a shelf life of >48h. Tests are ongoing to optimize logistics.



Development Stage

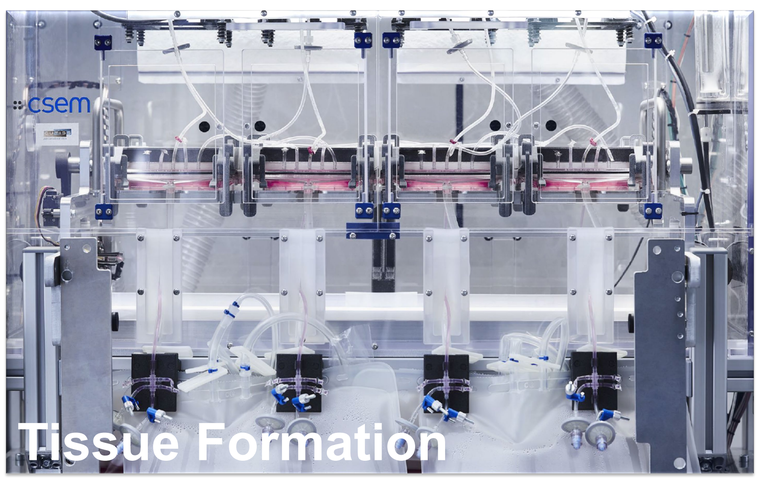
Phase I safety trial for denovoSkin™ is completed with 5 years follow up. denovoSkin™ received the Orphan Drug Designation for the treatment of burns by Swissmedic, EMA, and US FDA. It is currently tested in three European multi-centric Phase II efficacy clinical studies (NCT03227146, NCT03229564, NCT03394612). Acute (burn) and elective adult and pediatric patients (e.g. scar reconstruction, etc.) are enrolled (After the 2020 stop, **>10 patients enrolled in 2021**). **Burn compassionate patients, incl. a neonate (2021), were treated** with promising results

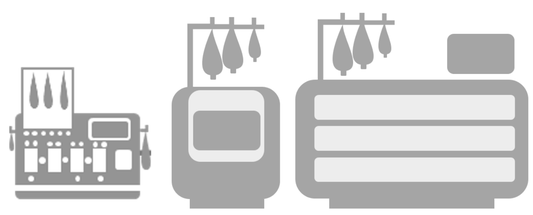
Main Clinical Publications-Links

Meuli M. et al., Plast Reconstr Surg. 2019 July
Moiemen N. et al., Burns open 2021 July
Schiestl C. et al., Burns open 2021 July
Zamparelli M. et al., in preparation
https://www.youtube.com/watch?v=fVlL9Hjojtk

Automated Manufacturing

Skin is our largest organ. The bio-engineering of personalized skin tissue therapy faces scale-up challenges. We work on the translation of the current manual process into an automated, fully closed one. **Three automates were developed (2021)** in collaboration with Zühlke Engineering and CSEM, supported by EU and Swiss grants: cell isolation, expansion and tissue formation. Automated denovoSkin™ production, first-in-class, is expected to decrease manufacturing costs and time, ensure robustness of the process and allow for de-centralization. Importantly, the developed automates could also represent a platform for the engineering of other cells and tissue, beyond skin.





Market for denovoSkin™

Global total addressable market (TAM) for Autografts (Skin Grafts) is USD 7.5bn in 2023, with 13.5% CAGR *(Marketresearchfuture).* TAM for autografting in burns is USD 1.5bn in 2023, with 6.9% CAGR *(Grandreviewresearch).* It is CUTISS' ambition to generate first sales for burns with manual production in EU. Automation would then gradually replace the manual process and allow geographic expansion.

Competitive Landscape

As of today, there is no direct competitive technology on the market. Large and deep skin defects are treated by meshed autografting. In severe burns, autografting can be combined with acellular dermal templates (e.g. Integra®), epidermal sheets (e.g. Epicel®), or cell spray (e.g. ReCell®). An allogeneic bi-layer graft was recently approved in US for second degree burns (Stratagraft®). An autologous bi-layer graft technology is in development in Canada. denovoSkin™ possesses unique features that promise permanent wound closure and improved patient's quality of life, while replacing autografting in the treatment of burns and other reconstructive indications.

Intellectual Property

Trade secret of production process and:

<u>Patents Exclusively licence by UZH</u>

- Method for compression (2013), WO 2014/207251. Granted EU, US and others.
- Tissue graft (2014), WO 2016/015754. **Granted US (2021)** and others.

<u>Patents owned by CUTISS</u>

- Automation family (2019/2020), Filed and in national phase.

Pigmentation

Homogeneous pigmentation provides UV light protection and aesthetic satisfaction, indeed:

- Autografting results into dyspigmented scars
- denovoSkin™ is de-pigmented
- 1% of world population suffers from pigmentation disorders (e.g. Vitiligo, TAM USD 1.6bn in 2023)

With strong KOL support, CUTISS is working on medical device solutions, at point-of-care:

- **2022 - Exclusive license for Viticell® CE marked device** IBSA
  - Manual device to restore pigmentation using patient's cells-
- Automated device to restore pigmentation - in development.
  - First French grant secured - via CUTISS French subsidiary-

Series B3 Financing Round OPEN

To date, 48MCHF were raised (dilutive and non). Main investors: University of Zurich + NF = UZH Life Sciences Fund, GIULIANI, Zürcher Kantonalbank, THE WYSS FOUNDATION

A Series B1 and B2 Financing Round were closed in 2020 with 27MCHF. **A Series B3 Financing Round is now OPEN to secure <u>additional financing</u> <u>≤</u>17MCHF in Q2-2022** in support of the, already significant, acceleration of execution after the COVID19 pandemic. Main use of proceedings:

- Completion of clinical enrollment
- GMP manufacturing scale-up
- Automated GraftBox™ for culture and transport
- Pigmentation launch with Viticell®

Management Team

- **Daniela Marino,** Dr.
  Chief Executive Officer and Co-Founder
- **Fabienne Hartmann-Fritsch**, Dr.
  Chief Clinical Officer and Co-Founder
- **Vincent Ronfard**, Dr.
  Chief Innovation Officer
- **Kathi L. Mujynya**,
  Chief Operation Officer
- **Peter Harboe-Schmidt,**
  Chief Financial Officer

Board of Directors

- **Martin Meuli**, Prof. Dr. med.
  Chairman, Medical Advisor and Co-Founder
- **Daniela Marino**, Dr.
  CEO and Co-Founder
- **Ernst Reichmann**, Prof. Dr.
  Scientific Advisor and Co-Founder
- **Giammaria Giuliani**,
  Investor
- **Gerard Ber**
  Independent board member

Contact

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