

## Press release

# CUTISS develops world's first machine to produce personalized human skin tissue therapy

- A world-first innovation in tissue engineering and regenerative medicine that can lead to life-saving and life-changing medical treatments for millions of people with severe skin injuries
- Over 11 million people annually suffer from severe burns needing surgery
- Significant milestone in the company's automation program to address scale-up challenges when bio-engineering skin tissues and grafts
- The denovoCast machine has been developed in collaboration with Swiss innovation partner CSEM, with funding from InnoSuisse and EU Horizon 2020

**Switzerland, 24 June 2021** – CUTISS AG, a Swiss clinical-stage life sciences company focused on skin regenerative medicine and tissue engineering, has unveiled the world's first automated machine to produce customized skin tissue grafts for adults and children with severe skin injuries, such as deep burns.

Developed in collaboration with the leading Swiss research center CSEM, the denovoCast machine demonstrates the feasibility of automating the bio-engineered skin manufacturing process, and seeks to revolutionize the current available treatments for severe skin defects.

**Daniela Marino, CEO of CUTISS**, commented: *“Every year over 11 million people suffer from severe burns which require surgery. Skin is our largest organ, so how do you produce enough skin quickly and affordably to treat these patients? Together with our partner CSEM, we used technological solutions to develop the denovoCast machine and automate the production of denovoSkin, our personalized skin tissue treatment.”*

**Vincent Revol, Head Research and Business Development for Life Science Technologies, CSEM**, said: *“Automated manufacturing of cell products in closed systems is a must for all regenerative therapies trying to enter the market today because it reduces dramatically the risk of microbial contamination while ensuring standardized quality and lower production costs. Knowing that our work may impact the lives of millions of patients is a unique source of motivation for the whole team.”*

## **Significant need for patients with severe burns**

When patients suffer from disastrous large and deep burns, the ability to quickly, affordably and consistently provide large quantities of skin grafts is essential. Survival of major burns is closely related to how fast definitive wound closure is achieved. Speeding and scaling up the culturing process of bio-engineered, personalized skin grafts can be a game changer and crucial for saving more lives of patients with major burns, sparing patient healthy skin donor sites. Annually, 11 million patients suffer from severe burns and require skin surgery to restore skin function. The EU and US markets for severe burns is estimated to be over \$2 billion and for burn scar reconstruction is estimated over \$5 billion. The current standard of care – autografting – is often scarce due to donor site shortages, produces skin that is too thin and results in permanent painful, debilitating, disfiguring scars that frequently require follow up corrective surgeries.

## **denovoSkin aiming to transform skin surgery**

The denovoCast machine produces a particular type of skin tissue called denovoSkin, a bio-engineered and personalized dermo-epidermal skin graft developed by CUTISS. It is an innovative process involving the growth of new skin using the body's own tissue as the template. The denovoSkin, which is in Phase IIb clinical trials in the European Union and also accessible on a compassionate use basis, has unique features that promise to surpass any current medical treatment for large and deep skin injuries, with potentially life-saving and life-changing outcomes. It promises to grow with the patient, limit scarring, and drastically reduce the number of follow up corrective surgeries required, particularly in children.

## denovoCast machine greatly improves output and quality of skin tissue

The process for bio-engineering the denovoSkin has so far been manual, lengthy, and requiring a costly clean room, and highly trained personnel. The denovoCast machine automates tissue formation in a fully closed process, requiring no manual intervention. It ensures consistent reproducible quality, enables the simultaneous cultivation of multiple skin grafts, and is expected to reduce production times by more than 30%.

**Vincent Ronfard, Chief Innovation Officer of CUTISS**, remarked: *“By scaling up the production of skin grafts with this ground breaking technology, we can potentially reach many patients in need of life-saving and life-changing treatment. This technology has potential applications for regenerative medicine for other tissues and organs.”*

**Gilles Weder, Team Leader Life Microtechnologies of CSEM**, said: *“Innovation in regenerative medicine is challenging in a highly regulated environment. CSEM and CUTISS bring together the disciplines of biology, engineering and clinical practice to meet this challenge. For denovoCast we validated our approach with patient cells throughout all stages of the development process to ensure a successful transfer from the lab to the clinic.”*

The operational denovoCast machine will now undergo research-grade testing at CUTISS to demonstrate its effectiveness and efficiency in research and clinical settings according to (Good Manufacturing Practice) GMP rules.

➤ Images for denovoCast and denovoSkin can be [accessed here](#).

## Swiss and EU funding for automation program

CUTISS's automation program and the development of the denovoCast were possible thanks to funding from the Swiss Innovation Promotion Agency InnoSuisse and the European Union's Horizon 2020 research and innovation program.

As part of CUTISS's overall automation program, there are two other machines upstream of denovoCast: a cell isolation device (developed by CUTISS) and a cell expansion device (tested by CUTISS). Under the framework of the EU SME instrument H2020 grant program, the cell isolation device and the cell expansion devices were developed and tested in collaboration with innovation service provider Zühlke and healthcare company Terumo, respectively.

### About CUTISS

[CUTISS](#) is a Swiss clinical-stage life sciences company focused on skin regenerative medicine and tissue engineering. It is developing the first personalized and automated skin tissue therapy offering life-saving and life-changing medical treatments for patients with severe skin injuries.

The lead product denovoSkin promises to take skin surgery to the next level and revolutionise current treatments. It is a bio-engineered and personalized dermo-epidermal human skin graft, currently in Phase IIb clinical trials in Switzerland and the European Union, with Orphan Drug Designation for the treatment of burns from Swissmedic, EMA, and FDA.

CUTISS is also developing the world's first machine that can automate the entire production process of the personalized skin graft. The company's knowledge in skin bio-engineering and biology offers several growth opportunities in regenerative medicine.

Established in 2017, the company is a spin-off from University of Zurich (UZH) / University Children's Hospital and a member of the accelerator Wyss Zurich. Headquartered at the Bio-Technopark in Zurich, it won the Top 100 Swiss Startup Award 2020, and has raised about CHF 50 million from private investors, family offices and public bodies.

### About CSEM

[CSEM](#) is a Swiss research and development center active in the fields of precision microfabrication, digitalization, and renewable energy. CSEM builds up the ties between industry and academia. It supports companies as a hub of ingenuity, a center of technological excellence and innovation, and accelerator of the digital transformation.

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