



Stratatech

Excellence in Regenerative Medicine

Introducing StrataTest[®]
Human Skin Model

StrataTest[®] Human Skin Model

PRODUCT FEATURES

- Biological characteristics of human skin
- Enhanced, high-quality *in vitro* testing model yields better prediction of *in vivo* biological response.
- Proprietary NIKS[®] human keratinocytes provide a fully-stratified, multi-layered human skin substitute in each test well
- NIKS[®] cells demonstrated to be pathogen-free and non-tumorigenic
- Highly-reproducible, accurate and cost-effective measurement of the *in vitro* response to chemicals and compounds
- Supplied in a readily-available, easy-to-use 24-well test format

A full-thickness human skin equivalent for toxicity testing

The StrataTest[®] human skin model is the superior, cost-effective solution for *in vitro* consumer product testing, drug discovery and toxicity screening. Composed of both an epidermis and a dermis, StrataTest[®] displays the same physical, chemical and histological characteristics of human skin. It is supplied in a readily-available, easy-to-use 24-well test format.

Many of today's animal and cell-based toxicity testing models are burdened by significant accuracy, reproducibility, cost and ethical concerns. The 27-country European Union, for example, has banned the sale of animal-tested cosmetic and consumer products. The unique characteristics of StrataTest[®] provide not only an enhanced, high-quality *in vitro* testing model, they enable better prediction of *in vivo* biological response than standard, two-dimensional, mono layer cultures.

StrataTest[®] was developed under the same standards as the company's flagship StrataGraft[®] human skin substitute, which recently was evaluated in a human clinical safety trial.

Both products are manufactured using Stratatech's proprietary NIKS[®] human keratinocytes. NIKS[®] cells, which have been demonstrated to be pathogen-free and non-tumorigenic, provide a fully-stratified, multi-layered human skin substitute in every well of the StrataTest[®] test plate. The tissue grows precisely as new human skin does, fully replicating its structure and function. Unlike cultured human keratinocytes from other sources, the uniquely uniform NIKS[®] cells can be grown indefinitely in the laboratory, resulting in less batch-to-batch variability.

The StrataTest[®] human skin model offers consistent cell sourcing and quality, coupled with the faithful reproduction of native human skin. These characteristics provide customers with a highly-reproducible, accurate and cost-effective measurement of the *in vitro* response to a broad range of chemicals, compounds and other potential toxins.



References

Cellular response to environmental stress

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In vitro model for cell biology research

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Normal growth and differentiation in a spontaneously immortalized near-diploid human keratinocyte cell line, NIKS. Allen-Hoffmann BL, Schlosser SJ, Ivarie CA, Sattler CA, Meisner LF, O'Connor SL. *Journal of Investigative Dermatology* 2000 Mar 114(3):444-55.

Clinical evaluation of NIKS®-based tissue

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Characterization of genetically-modified NIKS® tissue

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STRATATEST® IN VITRO HUMAN SKIN MODEL

- A superior, cost-effective *in vitro* solution
- Better prediction of *in vivo* response
- Clinically-tested quality

FEATURES & SPECIFICATIONS

- Full thickness, multi-layered living human skin tissue
- Biological characteristics of native human skin
- Epidermal compartment: NIKS® keratinocyte progenitors
- Dermal compartment: Normal human dermal fibroblasts
- Epidermal barrier function comparable to native skin
- Cultivated in serum-free media
- Readily-available, easy-to-use 24-well format
- 0.6 cm² / skin tissue

APPLICATIONS

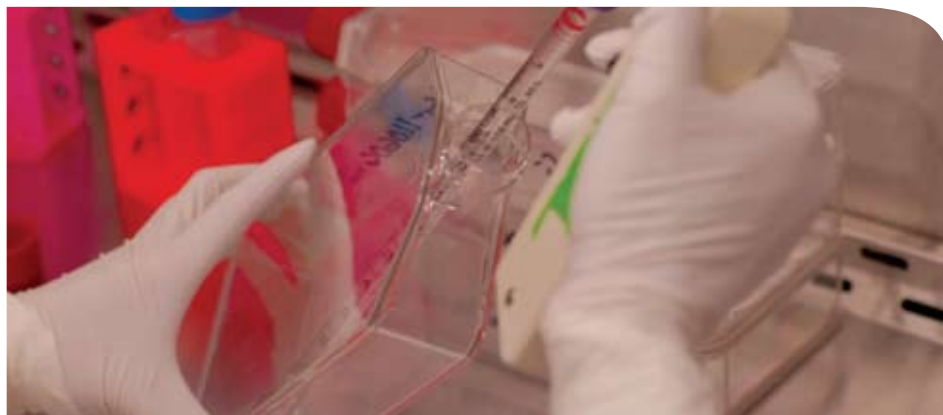
- Monitor cellular response to environmental stress
- Evaluate cellular response to chemical insult
- Useful *in vitro* model for cell biology research

CELL SOURCE: NIKS® CELL LINE

- Keratinocyte progenitors
- Consistent cell source
- Non-tumorigenic
- Pathogen-free

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CORPORATE HIGHLIGHTS

- Founded in 2000, focused on the commercialization of novel skin substitute products
- Flagship StrataGraft® tissue is a second-generation cell-based, tissue-engineered skin substitute
- Successful completion in 2008 of a clinical safety trial of StrataGraft® tissue
- Valuable product pipeline of additional, next-generation products
- Suite of ExpressGraft® products that overproduce natural, human wound-healing factors

Company Profile

Stratatech is a regenerative medicine company focused on the commercialization of novel skin substitute products for therapeutic and research uses. The company was founded in 2000 to commercialize an extraordinary discovery made at the University of Wisconsin-Madison. The discovery of the NIKS® cells – a human keratinocyte cell line that produces living tissue nearly identical to native human skin – has the potential to revolutionize wound care.

Keratinocytes are the cells that make up approximately 90 percent of the epidermis, the outer layer of human skin. NIKS® keratinocytes are a consistent source of pathogen-free, non-tumor-producing, long-lived adult progenitor cells. These cells faithfully reproduce normal human skin tissue architecture and barrier function when cultured appropriately.

The company's StrataGraft® tissue is a second-generation cell-based, tissue-engineered skin substitute that exhibits natural human skin structure and function. Stratatech in 2008 successfully completed a clinical safety trial of StrataGraft® tissue for temporary skin replacement prior to autografting. The company anticipates initiating additional safety and efficacy clinical trials of the tissue with expanded indications, including the treatment of diabetic foot ulcers.

The company markets a smaller, 24-well testing format of this tissue as StrataTest®. StrataTest® can be used by pharmaceutical, biotechnology and consumer goods companies to test the toxicity of new chemicals and compounds.

The company's valuable product pipeline, based on its patented NIKS® human keratinocytes, is comprised of additional, next-generation skin substitute products. These pipeline products include a suite of ExpressGraft® skin substitute products that overproduce natural, human wound-healing factors. These natural factors were selected because they are known to reduce infection, improve blood flow to the wound and increase the rate of healing with reduced scarring.

All of Stratatech's unique products are manufactured using the company's proprietary NIKS® human keratinocytes. Stratatech has exclusive, worldwide commercialization rights in all fields of use to the original NIKS® cell line patent issued to the Wisconsin Alumni Research Foundation (WARF) and to six subsequent NIKS® cell-line-related patents filed by WARF. In addition, Stratatech has nine issued and numerous pending patents related to this core technology.

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