

TISSUE REPAIR

ICX-SKN



Intercytex

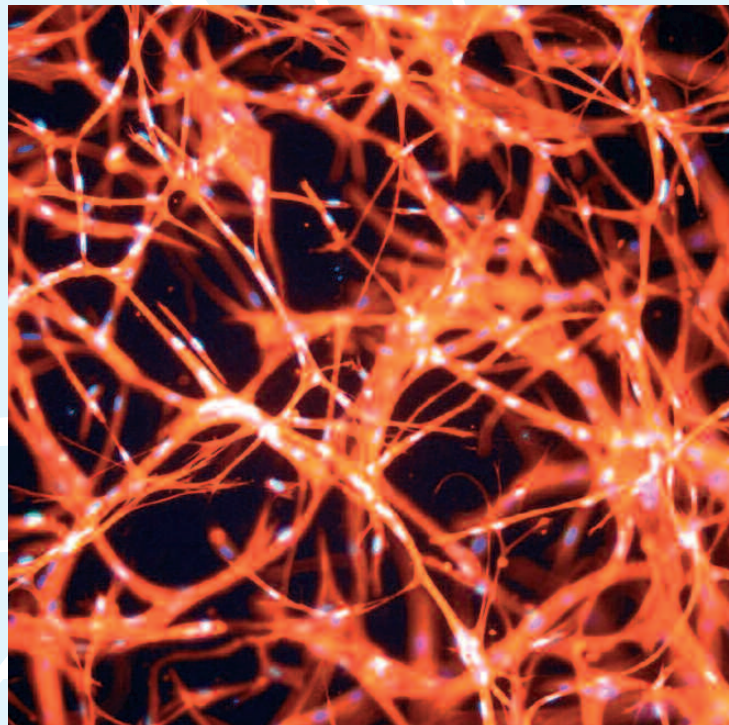
PIPELINE	Pre-clinical	Phase I	Phase II	Phase III	Registration	Launch
ICX-SKN	Grafts					

ICX-SKN is an *allogeneic* skin graft replacement comprising *human dermal fibroblasts* in a strong, stable matrix of collagen, produced by the cells themselves, An additional layer of *human keratinocytes* may be included.

ICX-SKN is designed to be sufficiently robust to be sutured in place, and to possess significant durability providing immediate and long-term closure of acute wounds.

ICX-SKN is intended to be used by surgeons, plastic surgeons and other specialists in hospitals and clinics as a skin graft replacement for acute wounds and burns.

ICX-SKN will be provided in a sealed sterile, flat, foil pack.



Orange flourescent fibroblasts forming a three-dimensional lattice

Key Terms

Allogeneic cells are cells sourced from an unrelated donor.

Human dermal fibroblasts (or HDFs) are the principal cell type found in the dermal layer of human skin where they secrete collagen, the main component of the dermis.

The dermis is a layer of skin just underneath the epidermis that contains sensitive nerve endings, blood vessels and hair follicles.

Allogeneic HDFs are derived from the dermis of normal human skin.

During manufacture of ICX-SKN, HDFs gradually build a dense collagenous meshwork which is largely responsible for the product's tensile properties and high durability.

Human **keratinocytes** are the primary cell types found in the epidermis or the outer layer of skin.

Open-label: a clinical trial in which both participants and investigators know what drug is being tested and what dosages are being used.



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Product sheet

Skin grafting (shown below) is a surgical procedure during which skin is excised from one part of the body and placed over a burn or non-healing wound to permanently replace the damaged or missing skin. In the US, it is estimated that there are 140,000 skin grafts carried out annually as a consequence of trauma, elective or cosmetic surgery*.

Growth of the skin graft market is limited by the availability of donor graft material. If a skin substitute product was available with all the inherent properties of a conventional graft, there would be significant potential for expansion into other woundcare-related indications.



Under standard skin grafting procedures, skin is surgically removed from the patient's body prior to being grafted onto a wound, surgical site or burn. This is traumatic to the patient as further surgical procedures are required additional to the injury already sustained. Furthermore, in the case of severe burns, insufficient donor skin may be available for grafting thus requiring alternative sources – such as ICX-SKN.

ICX-SKN is intended to replace conventional skin grafts generally employed following elective surgery, trauma or cosmetic procedures. Since it is allogeneic, the product can be used "off the shelf", without the additional trauma associated with a conventional donor skin graft.

Clinical and Commercial Development

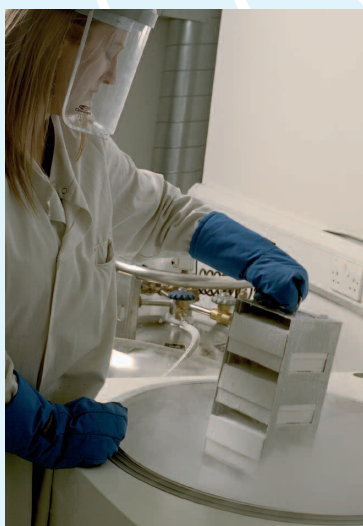
ICX-SKN has recently completed an open-label Phase I trial in the UK. A full-thickness skin sample was excised from the upper arm of six volunteers and replaced with ICX-SKN. The safety and tolerability of the product were determined at one month from the application of ICX-SKN to the wound area. After 28 days both visual and histological analysis showed that in all volunteers, the ICX-SKN grafts were vascularised and overgrown with the hosts' own cells, resulting in a fully integrated skin graft that had closed and healed the wound site.

A Phase IIa efficacy trial will be commenced during the second half of 2007 in larger wounds with a view to generating data

that would enable rapid progress to pivotal trials and granting of a marketing licence.

Intercytex will develop ICX-SKN through all stages of clinical development and registration to launch and plans to appoint appropriate healthcare sales partners for the distribution of ICX-SKN. Intercytex will manufacture ICX-SKN at its GMP manufacturing facilities.

*Source: Krog Associates (Market Research)



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