

myskin™ is produced by CellTran Ltd for exclusive UK distribution by Autologi,  
the wound healing division of Vernon-Carus Ltd



## Myskin™ information for clinicians



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## Description

**myskin™** is an active wound healing product for application to burns, graft sites, diabetic foot ulcers and chronic wounds as part of a clinical wound management strategy.

**myskin™** is produced according to the Code of Practice for the production of human-derived therapeutic products of the Medicines and Healthcare Products Regulatory Agency (MHRA) (United Kingdom.) The autologous sourcing of cells for each unit of production is unique and the product is produced on an individual need basis.

**myskin™** consists of a medical grade silicone sheet certified for use in human implantation for periods of less than 29 days. This silicone sheet has a specially formulated surface coating of <100 nanometre thickness, deposited by plasma polymerisation of acrylic acid. This coating allows the growth of a layer of proliferative, sub-confluent, autologous keratinocytes cultured under aseptic conditions in vitro. **myskin™** is supplied as a 5cm diameter circular disc of surface area 19.6cm<sup>2</sup>. (Other formats may be supplied after consultation with CellTran.) **myskin™** is individually packaged on a sterile, buffered, serum-free mixture of Dulbecco's Modified Eagle's medium (76%) and Hams F12 medium (23%) in an agar gel form.

Keratinocytes are co-cultured with irradiated murine cells during the production of **myskin**. The murine cells used in production of **myskin** have been tested for the presence of adventitious infections agents. This includes sterility testing for bacterial, fungal and mycoplasma contamination. Murine cells are not present in the final **myskin™** dressing product for application to wounds.

## Clinical experience

The clinical efficacy of **myskin™** to promote wound healing in patients with chronic neuropathic foot ulcers was evaluated in a pilot clinical study. See table 1.

Over 40 patients with chronic wounds have now been treated with Myskin. A pivotal RCT of the application of **myskin** on diabetic foot ulcers has recently ended and results are expected to be published in the first half of 2006.

Six diabetic patients with neuropathic ulcers resistant to conventional therapy were treated with weekly applications of autologous keratinocytes delivered on **myskin** in addition to conventional therapy until wound healing was achieved. The results are summarised in the table below.

Table 1

Patient	Age	Diabetes		Duration of Ulcer(s)	Response to <b>myskin™</b>
		Type	Duration		
1	43	1	22 years	1.4 years 2.3 months 3.4 weeks 4.4 weeks	Decrease in size 10 applications before healing 6 applications before healing Decrease in size after 8 applications (treatment ongoing)
2	56	1	30 years	2 years	8 applications before healing
3	46	1	29 years	16 months	6 applications before healing
4	64	2	12 years	10 months	No response after 24 applications
5	65	2	15 years	2 years	Treatment discontinued after 3 applications due to MRSA infection
6	63	2	19 years	3 months	10 applications before healing

Complete healing was achieved in six out of nine ulcers in six patients, a reduction in ulcer size was achieved in one ulcer and no response was seen in one ulcer. Treatment was discontinued in one patient due to infection. Complete wound healing required between 6 and 17 applications over a period of 6-20 weeks. There were no recurrences in the healed ulcers after a follow-up of 6 months. This study has been published:- M. Moustafa, et al. A new autologous keratinocyte dressing treatment for non-healing diabetic neuropathic foot ulcers. Diabet. Med. 21 (7): 786-789, 2004. (N.B. The prototype product used in the study, TranCell, has subsequently been renamed **myskin™**, but the production process remains unaltered.)

In separate case-by-case studies, patients with a range of non healing wounds were treated with **myskin** and the results are summarised in the table 2 below.

Table 2

Patient	Age	Clinical Condition	Response to <b>myskin™</b>
1	28	Acute burn injury (28% BSA)	Accelerated re-epithelialisation following the application of <b>mySkin™</b> Improved healing following the application of <b>mySkin™</b>
2	9	Acute burn injury (28% BSA)	Accelerated re-epithelialisation following the application of <b>mySkin™</b> Improved healing following the application of <b>mySkin™</b>
3	81	Extensive chronic wounds (8 weeks duration) on both legs following partial skin graft failure after 28% flame burns.	Left leg: 98% healed after 12 applications Right Leg: 78% healed after 12 application.
4	64	Burns injuries to left foot and ankle led to contractures and ankle deformity which resulted in 3 year non healing chronic ulcers. Ulcers recurred despite 3 separate episodes of skin grafting.	Anterior ulcer completely healed after 22 applications while posterior ulcer is healed after 42 applications.
5	83	Chronic ulcers to right leg of more than 60 years duration which developed while the patient was a prisoner of war in World War II. Six episodes of skin grafting failed to achieve permanent wound closure.	Partial healing of both ulcers with general improvement of the wound and the patient's quality of life.
6	44	12 year history of non-healing scalp wounds following initial excision and SSG of full thickness flame burns (15% BSA)	2 Ulcers healed after 2 applications; 2 partially healed after 18 application.
7	82	Non healing pretibial wound (6 week duration) secondary to wound dehiscence following debridement and direct closure of a pretibial laceration. The patient was not considered suitable for further surgical intervention because of a postoperative cardiac event.	Complete wound closure following 7 applications; wound remains healed with 6 month follow up.

For 2 burns patients, **myskin** facilitated healing of grafted burns wounds. For 5 patients with intractable chronic wounds (with 9 ulcers in total) repeated applications of **myskin** resulted in complete healing in 5/9 ulcers with a major reduction in ulcer size for all other (4/9) ulcers.

This reduction in ulcer size improved the wound conditions for 2 of these patients such that they were then considered suitable for conventional grafting and orthopaedic surgery respectively. This study has been accepted for publication:- N Zhu et al. Treatment of Burns and Chronic Wounds Using a New Cell Transfer Dressing for Delivery of Autologous Keratinocytes European Journal of Plastic Surgery (in press) 2005.

## Indications

**myskin™** is indicated for use on diabetic foot ulcers in standard care for the treatment of neuropathic full-thickness ulcers of at least four weeks duration, which have not responded to conventional treatment.

**myskin™** is indicated for the treatment of burns in place of or in addition to skin grafting. Myskin can be applied over meshed skin grafts. Where skin grafts are taken in the treatment of burns or reconstructive surgery, **myskin™** can be used for re-epithelialisation of graft donor sites.

Use of **myskin™** in venous leg ulcers in combination with standard therapeutic compression bandaging is being evaluated for the treatment of non-infected partial and full-thickness skin ulcers due to venous insufficiency. Myskin™ may also be effective on other non-healing wounds such as pre-tibial lacerations and pressure ulcers.

## Contraindications

**myskin™ is contraindicated for use on:**

1. Those with ischaemic toes or both foot pulses (dorsalis pedis, posterior tibial) impalpable on the affected foot
2. Those who are, or might become, pregnant during the course of the treatment
3. Acute Charcot neuropathic osteoarthropathy
4. Those who have skin conditions which may affect healing (e.g. psoriasis) or are on treatments which may impair wound healing (such as systemic steroids or immunosuppressants)
5. Clinically significant active infection (involving soft tissue or bone), usually characterised as 'critically colonised'.
6. Significant peripheral oedema

### Warnings and Precautions

If the use-by date has passed or the tamper evident seal has been broken, **DO NOT OPEN AND DO NOT USE** the product.

A clinical determination of wound infection should be made based on all of the signs and symptoms of infection.

## Adverse events

Adverse events which occurred at an incidence of greater than 1% in the clinical studies are listed in Table 1: Treatment of one patient was discontinued due to infection with MRSA. This event was not attributed to treatment with **myskin™**.

## Maintaining product effectiveness

**myskin™** has been processed under aseptic conditions and should be handled observing sterile technique. It should be kept in its container on the shipping medium in the sealed bag under controlled temperature (20°C-31°C) until ready for use. **myskin™** should not be refrigerated.

**myskin™** should be placed on the wound bed within 15 minutes of opening the package. Handling before application to the wound site should be minimal. If there is any question that **myskin™** may be contaminated or compromised, it should not be used. **myskin™** should not be used beyond the listed use-by date.

## Use in specific populations

The safety and effectiveness of **myskin™** for pregnant women, have not yet been evaluated. The use of **myskin™** for acute wounds, burns and ulcers caused by pressure are part of ongoing case studies, during which no adverse events have been reported.

## Patient advice

VLU patients should be advised regarding the importance of complying with compression therapy or other treatment, which may be prescribed in conjunction with **myskin™**.

DFU patients should be advised that **myskin™** is used in combination with good ulcer care including off loading, metabolic control and nutrition. Once an ulcer has healed, ulcer prevention practices should be adhered to, including regular medical check ups.

Treatment of Diabetes: **myskin™** does not address the underlying pathophysiology of neuropathic diabetic foot ulcers. Management of the patient's diabetes should be according to standard medical practice.

## Patient screening

In August 2000 the department of health published guidelines relating to microbiological safety of human organs, tissues and cells used in transplantation. In accordance with these guidelines the tissue bank (CellTran) must determine the microbiological risk/status of donors and ensure that their cells are isolated and banked safely.

In order to do this a confidential patient questionnaire must be completed and returned to CellTran along with the biopsy. A blood sample will be taken and tested at an accredited facility for HIV 1 and HIV 2, Hepatitis B and Hepatitis C, Syphilis and HTLV 1, results are held in the patient records at the tissue bank. In fulfilment of the requirement to test for MRSA, swabs will be taken from the wound, mouth and skin at the same time.

## How **myskin™** is supplied

**myskin™** is supplied sealed in a screw top container with 5% CO2/air atmosphere and agarose nutrient medium, ready for single use. To maintain cell viability, **myskin™** should be kept in its container at 20°C-31°C until use. **myskin™** is supplied as a circular disk approximately 50 mm in diameter and 0.75 mm thick. **myskin™** is produced in aseptic conditions but is not terminally sterilised. Sterility tests are carried out prior to despatch of **myskin™**, full retrospective sterility test results are available 72h after **myskin** has been despatched. **myskin™** must be used within 3 days of receipt. A use-by date is indicated on the inner packaging.

## How **myskin™** works

**myskin™** comprises a flexible medical-grade silicone backing sheet coated with a chemically controlled film in a process called plasma polymerisation. This film allows the rapid growth of keratinocytes while the silicone provides a supporting layer allowing **myskin™** to be handled easily in the clinic.

Once cultured, **myskin™** is applied so that cells are in contact with the wound bed. The polymer film is engineered to promote cell growth and subsequent release when triggered by exposure to the wound.

**myskin™** works by supplying cells which provide wound cover as well as by stimulating re-epithelialisation. The cells on **myskin™** are viable and proliferative at the time of application to the wound. The cells survive the harsh biochemical environment of the wound and can act to reverse the condition of the wound.

**myskin™** is covered by Patent Numbers WO0078928, AU776839, NZ516064, ZA200110319, and Registered Trade Mark 2361797.

## How to use **myskin™**

**myskin™** is to be applied at weekly intervals according to a delivery schedule prearranged with CellTran. **myskin™** is to be used within a hospital or primary care clinic environment, until healing of the wound is achieved. Wounds are dressed with **myskin™** for 3-4 days followed by 3-4 days with standard absorbent dressing. During the time the **myskin™** dressing is not in place other Vernon-Carus Autologi wound management products can be used if deemed appropriate.

CellTran's clinical data to date suggest that a maximum of 12 applications is sufficient for wound healing. In exceptional cases more applications may be required. A single biopsy is sufficient to provide enough cells for approximately 20 applications. A cell stock will be cryogenically preserved by CellTran to allow for repeat orders up to 6 months from receipt of initial biopsy without the requirement for a repeat biopsy.

The biopsy is taken by a trained medical professional from non-burnt skin, using a skin graft knife. Optimum biopsy size is 2x2 cm<sup>2</sup>. A larger biopsy will generally produce a higher yield and thereby reduce the lead time for production of **myskin™**. The biopsy should be a split skin biopsy of a thickness which includes the dermal/epidermal junction, and as a guide would be 0.5 mm to 0.8 mm thick. Size and thickness of biopsy is critical to number of dressings that can be produced and to the lead time for delivery. For further information on the biopsy requirements for **myskin** treatment, see the separate sheet MS003 Myskin Biopsy Guidelines.

It is vital that the biopsy site is prepared thoroughly by washing, followed by wiping with an antiseptic product. Bacterial, fungal or viral

contamination present on a biopsy or in the saline solution used to ship it to CellTran, may hamper or preclude the production of **myskin™**.

The biopsy is delivered to CellTran, where keratinocytes are isolated and cell stocks are prepared and cryopreserved. **Myskin** is then produced from secondary cultures of autologous keratinocytes. **myskin™** can be delivered 7 days after receipt of biopsy (a longer lead time will be required for a large number of dressings).

## Clinical application of **myskin™**

1. Following cleaning and debridement, the wound should be given a saline wash to remove any remnants of iodine or actives from the wound.
2. **myskin™ IS DIRECTIONAL AND MUST BE APPLIED WITH THE CORRECT SURFACE IN CONTACT WITH THE WOUND.** The wound contact surface of **myskin™** is in contact with the agar shipping media. Use sterile forceps to apply **myskin™** dressings to the wound.
3. Avoid movement of **myskin™** once it has been applied to the wound. Avoid overlapping of **myskin™** dressings on the wound.
4. Cover **myskin™** and adjacent wound area with GEL FX or similar dressing according to exudate control requirements, followed by a gauze wrap.
5. Do not use Acticoat™ or similar antibacterial products to cover the **myskin™** discs as such products reduce keratinocyte viability and thereby reduce the efficacy of **myskin™**.
6. Discard any **myskin™** dressings where aseptic conditions may have been compromised during application.

Do not wash the wound for 2-3 days, this will allow the cells to 'take' on the wound. Upon dressing change, carefully remove **myskin™** dressings and discard as clinical waste.

Treat all empty packaging as clinical waste for incineration.

The above application process is repeated weekly until the wound has healed.