Stratamed®

advanced film-forming
wound dressing

A breakthrough in wound healing

Faster healing and early abnormal scar prevention





www.stratamed.com

Heal Better™
Stratpharma
Australia

The importance of wound care

Physicians perform a wide range of complex procedures that require a high level of expertise. Despite adhering to the correct treatment protocols, even with the latest technologies and techniques, certain risk factors remain beyond the physician's control. These include patient's **wound care compliance, infection risk and other wound healing complications, and genetic factors**.[1]

Delayed epithelialisation beyond 10 to 14 days **dramatically increases** the incidence of hypertrophic scarring.[2]

Whether it is a surgical, aesthetic, acute or chronic wound, **proper wound management and early adequate post-procedure care are critical** for achieving the best possible medical and aesthetic outcome, reducing the risk of infection and abnormal scar formation, shortening recovery time, and achieving overall patient satisfaction.[3]

The appearance and side effects of scars can be **improved significantly** if prevention starts immediately after suturing or once a wound has occurred.[4]

Current treatment and challenges



There are many options available for treating different wounds, however, many challenges, such as **antibiotic resistance, infection relapse and the use of non-optimal wound dressings** remain persistent.[5]

The significant negative effect of topical antibiotics on post-operative wounds includes delayed wound healing, allergic contact dermatitis, inflammatory chondritis, anaphylaxis and Stevens–Johnson syndrome.[6]

75% of patients (in the USA), still use over-the-counter petrolatum-based topical antibiotics **without a** doctor's prescription, and **21.6% of them develop contact dermatitis**.[6]

In recent clinical studies, **Stratamed** showed the same efficacy as topical antibiotics* in **preventing infection** following surgical procedures, but **without side effects**.[6,7]

Many **physical wound dressings** are only suitable for wounds on flat surfaces. As a result, these physical wound dressings **do not enable** full surface contact with a lot of wounds (i.e. wounds near joints, on highly contoured areas, deep or tunnelling wounds). The adhesive parts of these dressings have also been shown to cause **allergic reactions** leading to **delays or complications** in the wound healing outcome.[8-11]

The **ideal wound care product** should be transparent, gas-permeable and easy to apply to all wound surfaces. Additionally, it should accelerate the epithelialisation process, reduce symptoms (itchiness, swelling, erythema and pain), prevent infections and the occurrence of abnormal scars.[11]

*Bacitracin Zinc, Neomycin Sulfate, and Polymyxin B Sulfate (Neosporin® Original). | Bacitracin Zinc (Bacitracin®).

Stratamed® – film-forming wound dressing for faster wound healing and early abnormal scar prevention

Stratamed is clinically proven to heal wounds **2 times faster**[13] compared to standard treatment** in burns and **reduce downtime**.[14]

Stratamed allows the **prevention of abnormal scarring** to begin immediately after suturing or once a wound has occurred.

Stratamed is a **viable alternative to topical antibiotics** in the prevention of infections without the risk for contact dermatitis.[6]

One tube of **Stratamed replaces the need for multiple wound care products** such as traditional dressings, hydrogels for moist wound healing and topical antibiotics used for the prevention of infections.

Stratamed is a TGA Registered Class IIa **Medical Device**.



**Standard treatment: silver dressings, collagenases, alginates

Stratamed® indications

Stratamed is an advanced flexible, film-forming wound dressing for the use **immediately** following medical and aesthetic procedures, on acute or chronic wounds and compromised skin surfaces.

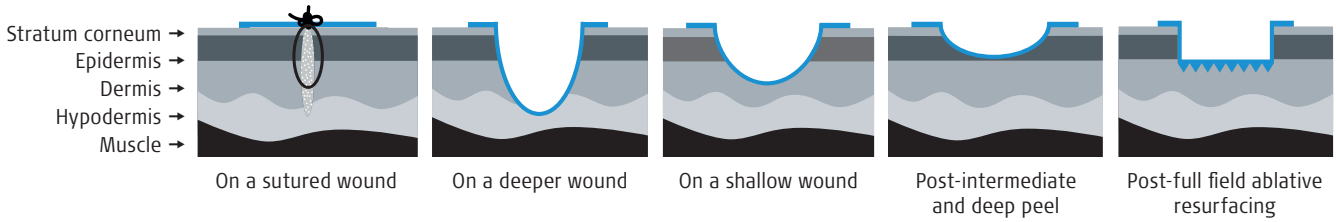
Stratamed has been developed with a special consistency to ensure it remains in **full contact** with the wound bed or damaged surface.

MEDICAL INDICATIONS/ PROCEDURES

- Surgical incisions and excisions
- Biopsies and ED & C's
- General surgery resulting in sutures (i.e. Mohs surgery, C-section)
- Chronic wounds (i.e. venous, pressure and diabetic ulcers)
- 1st and 2nd degree burns
- Skin barrier damaged by accidents and/or trauma
- Cryosurgery (i.e. for actinic keratosis) and dermabrasion
- Post 5-FU therapy
- Medical tattoo (i.e. post breast reconstruction)
- Inflammatory skin conditions

COSMETIC INDICATIONS/ PROCEDURES

- Laser procedures (full field ablative)
- Platelet Rich Plasma (PRP) therapy
- Chemical peel (intermediate and deep)
- Cosmetic surgery face (i.e. blepharoplasty, lifts, rhinoplasty)
- Cosmetic surgery body (i.e. breast augmentation/ reduction, lifts, abdominoplasty)
- Tattoo removal
- Cosmetic and paramedical tattooing



Why is Stratamed® an innovative product?

FILM-FORMING WOUND DRESSING
Stratamed gel dries to form a thin, flexible wound dressing that ensures full constant contact with the skin.

FASTER RE-EPITHELIALISATION AND REDUCED DOWNTIME
Stratamed promotes a moist healing environment leading to faster re-epithelialisation and reduced downtime.

ABNORMAL SCAR PREVENTION
Stratamed allows the prevention of abnormal scarring to begin immediately post-procedure (before suture removal).

HYDRATION AND GAS PERMEABILITY
Stratamed is semi-occlusive, which allows the skin to breathe and remain hydrated.

SYMPTOMATIC RELIEF
Stratamed provides symptomatic relief from itching, burning sensation and discomfort, reduces redness and discolouration associated with damaged skin.

PROTECTION
Stratamed is bacteriostatic, protects the compromised skin from chemical and microbial invasion, while reducing the risk for contact dermatitis.

SECONDARY DRESSINGS
Stratamed can be used with or without a secondary protective dressing, in combination with other wound care therapies and topical agents.

HARD TO TREAT AREAS
Stratamed is suitable for exposed areas like the face and neck as well as joints and hairy areas without the need for shaving.

NON-REACTIVE
Stratamed is inert, it has no measurable pH, and contains no steroids, alcohol, parabens or fragrances making it suitable for infants, children, people with sensitive skin, during pregnancy and while breastfeeding.

EASY TO USE
Stratamed is easy to apply without the need for removal before re-application and can be used by patients at home.

Stratamed® vs. topical antibiotics

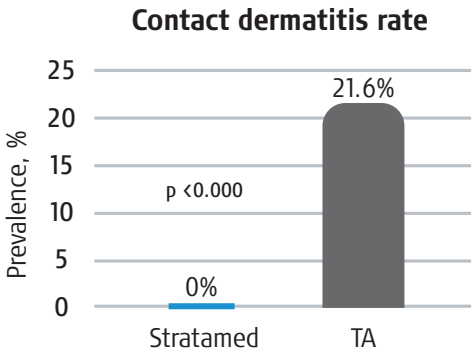
A 231-patient open-label, randomised, single-blinded study was conducted in the USA to compare Stratamed and a topical triple antibiotic ointment (Bacitracin Zinc, Neomycin Sulfate, and Polymyxin B Sulfate, Neosporin® Original) for the infection rate, prevalence of contact dermatitis and healing quality.[6]

Scan to read the published study

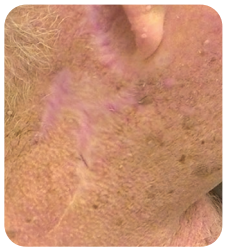
JEADV Journal of the European Academy of Dermatology & Venereology

Benedetto, AV, Staidle, JP, Schoenfeld, J., Benedetto, EA, Benedetto, PX (2021). '**Comparing the use of a novel antibiotic-free film-forming topical wound dressing versus a topical triple antibiotic in dermatologic surgical procedures including Mohs micrographic surgery**', *Journal of the European Academy of Dermatology and Venereology*, 35(1), pp. 247–255.

- Stratamed, as an antibiotic-free gel, **is a viable alternative** to triple antibiotic (TA) or any other petrolatum-based product, with or without antibiotics.
- Stratamed is **as effective as TA** in preventing infections without the risk for contact dermatitis.
- Stratamed promotes **faster healing, reduced erythema and improves the quality of newly formed tissue.**



Clinical results

	Immediately post Tx	After 7 days of Tx	After 7 months of Tx
Stratamed Stratamed is bacteriostatic			
Triple antibiotic ointment (Bacitracin Zinc, Neomycin Sulfate, and Polymyxin B Sulfate, Neosporin® Original)			

A 19-patient randomised, single-blinded, split-scalp trial was conducted in the USA to compare Stratamed and topical antibiotic (Bacitracin Zinc, Bacitracin®) assessing the edema, erythema, crusting, healing response and outcome preference following FUE (Follicular Unit Extraction) hair transplantation.[7]

Scan to read the published study

AESTHETIC SURGERY JOURNAL OPEN FORUM

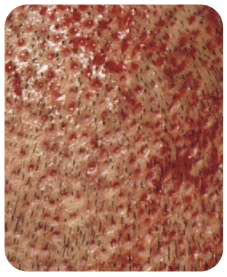
James, IB, Turer, DM, DiBernardo, BE (2022). **'Comparison of a Novel Silicone Gel Wound Dressing vs Bacitracin After Follicular Unit Extraction Hair Transplantation'**, *Aesthetic Surgery Journal Open Forum*, 4, pp. 1–8.

- Stratamed **avoids concerns of promoting bacterial resistance** or significantly **altering the skin microbiome**.
- **Faster healing response** was observed **as early as day 1** in the Stratamed group.
- Stratamed is as **effective as topical antibiotics** in reducing the inflammation (edema, erythema and crusting).

After 1 day post-procedure



Stratamed



Antibiotic

Clinical Results: Burns



Start of treatment with Stratamed



After 6 days of treatment with Stratamed

- Stratamed showed **no secondary wound infection or allergic reactions**.
- Stratamed **had a lower incidence of both pain and pruritus** compared to standard treatment.

Lucattelli, E., Cipriani, F., Pascone, C., Di Lonardo, A. (2021). 'Non-Healing Burn Wound Treatment With A Sterile Silicone Gel', *Annals of Burns and Fire Disasters*, 34(1), pp. 53–57.

* Standard treatment: silver dressings, collagenases, alginates

Burn with delayed re-epithelialisation – leg[13]

Stratamed **speeds up the healing process – 2 times faster wound healing** compared to standard treatment.*

The mean to achieve 95% re-epithelialisation were 5,4 days in the Stratamed group vs. 12,5 days in the standard treatment group.



Start of treatment with Stratamed



After 7 days of treatment with Stratamed



After 18 days of treatment with Stratamed

Second-degree burn – face[15]

A 6-year-old boy sustained a second-degree burn on the face.

Hospital Municipal de Quemados, Buenos Aires, Argentina



Start of treatment with Stratamed



After 6 days of treatment with Stratamed

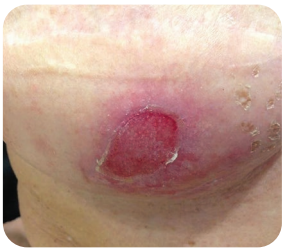


After 9 days of treatment with Stratamed

Second-degree burn – foot[15]

A 2-year-old boy sustained a second-degree burn on the right foot.

Hospital Municipal de Quemados, Buenos Aires, Argentina.



Start of treatment with Stratamed



After 11 days of treatment with Stratamed



After 36 days of treatment with Stratamed

Second-degree burn – breast[16]

A 75-year-old woman sustained a 5 × 4 cm uninfected second-degree burn on the right breast.

Dr. Cubiró, Hospital de la Santa Creu I Sant Pau, Barcelona, Spain

Clinical Results: Chronic Wounds



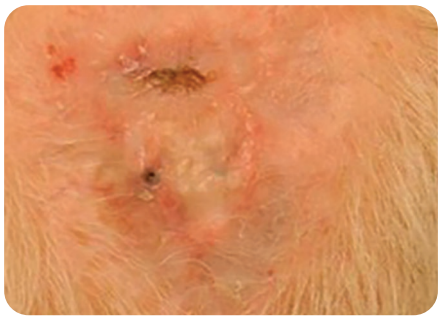
4 months after surgery, start of treatment with Stratamed[17]



After 7 days of treatment with Stratamed



2 years after surgery, start of treatment with Stratamed[17]



After 5 weeks of treatment with Stratamed

"We believe that this gel was a major reason why all patients had improvement and healing of their scalp wounds after a prolonged period of nonhealing."

"Stratamed for our patients uses the unique properties of film-forming gels in a formulation that may be ideal for these wounds."

Prof. Anthony Benedetto, MD, DO, FACP, Philadelphia, USA

Monk, E., et al. (2014). 'Successful Treatment of Nonhealing Scalp Wounds Using a Silicone Gel', *Dermatologic Surgery*, 40(1), pp. 76–79.



Start of treatment with Stratamed[11]



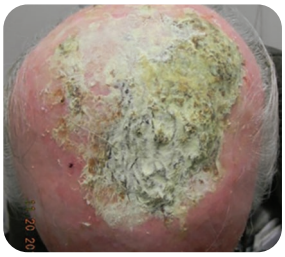
After 7 days of treatment with Stratamed



After 6 weeks of treatment with Stratamed

- Stratamed on chronic wounds provides an effective "healing boost" to biologically inactive granulation tissue inducing reepithelialisation even after only 1 week of treatment.
- Stratamed is effective for challenging persistent ulcerative lesions secondary to surgery followed by partial thickness skin grafts.

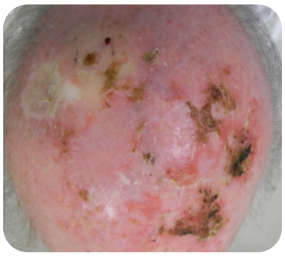
Marini, L et al. (2017). 'Importance of Scar Prevention and Treatment – An Approach From Wound Care Principles, *Dermatologic Surgery*, 43, S85–S90.



Before treatment with Stratamed[17]



Immediately after debridement of the large crust. Start of treatment with Stratamed



After 2 weeks of treatment with Stratamed

- Stratamed prevents tissue maceration to the wound's surrounding skin, allowing less frequent dressing changes, although secondary dressings were not required in any of the published cases.

Uva, L., et al. (2015). 'Erosive pustular dermatosis successfully treated with a novel silicone gel', *International Journal of Dermatology*, 55(1), pp. 89–91.

Clinical Results: Other Indications



Start of treatment with Stratamed



After 15 days of treatment with Stratamed



After 40 days of treatment with Stratamed



After 78 days of treatment with Stratamed



After 90 days of treatment with Stratamed

Pressure Ulcer – Sacral[19]

26-year-old male with grade 3 sacral pressure lesion caused by prolonged hospitalisation. History of grade II obesity.

Wound size: 12 × 8 cm

Healing time expectation was 1,5–3 years with the treatment* used before start of Stratamed application.

After 7 days of treatment the reduction of exudation and the acceleration of the wound edges approximation were identified.

After 90 days of treatment the pressure ulcer was healed and the patient was discharged.

Nurse Vanessa Neckel, Brazil

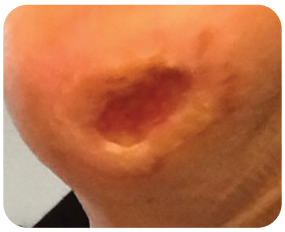
* Initial treatment: hydrogel and hydrofibers with alginate, collagenase with chloramphenicol ointment, sunflower oil with fatty acids.



Start of treatment with Stratamed



After 18 days of treatment with Stratamed



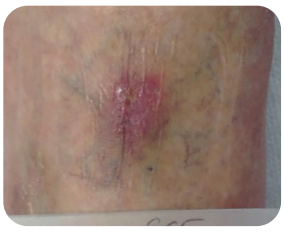
After 31 days of treatment with Stratamed

DFS (Diabetic Foot Syndrome)[20]

Madrid, Spain



Start of treatment with Stratamed



After 14 days of treatment with Stratamed



After 21 days of treatment with Stratamed

Ulcus Cruris Syndrome (severe)[21]

Lower leg, >90 days open

Dr. Strohal, Federal Academic Teaching Hospital, Feldkirch, Austria



Start of treatment with Stratamed



After 7 days of treatment with Stratamed

Full thickness donor site wound[22]

Data on file, Stratpharma AG.

Clinical Results: Surgeries



Start of treatment with Stratamed



After 10 days of treatment with Stratamed



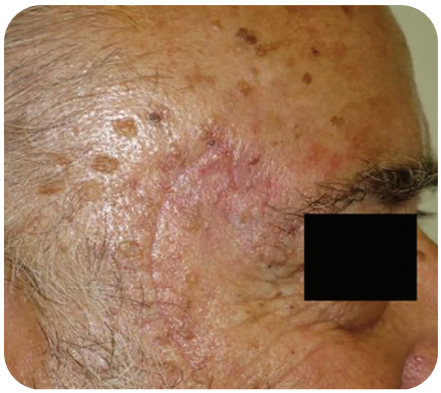
After 1 month of treatment with Stratamed

BCC (Basal Cell Carcinoma) – head[16]

Dr. Cubiró, Hospital de la Santa Creu I Sant Pau, Barcelona, Spain



Start of treatment with Stratamed



After 2 months of treatment with Stratamed

SCC (Squamous Cell Carcinoma) – head[16]

Surgical excision and skin flap reconstruction. Pre-diabetic patient.

Dr. Cubiró, Hospital de la Santa Creu I Sant Pau, Barcelona, Spain



Start of treatment with Stratamed

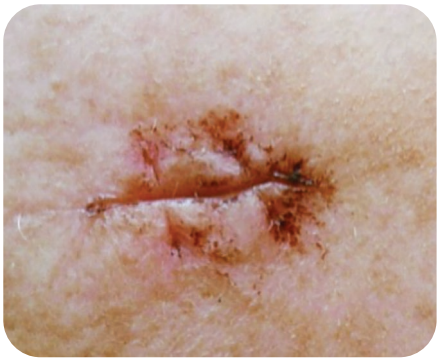


After 2 months of treatment with Stratamed

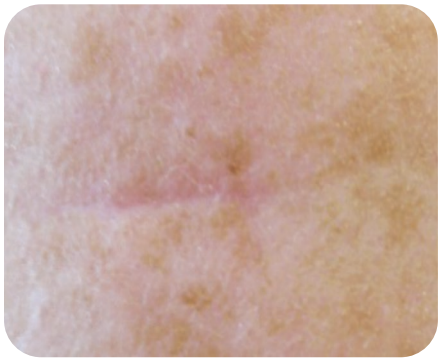
Mohs surgery – lip[23]

Surgical excision on the upper lip.

Data on file, Stratpharma AG



Start of treatment with Stratamed



After 8 weeks of treatment with Stratamed

Linear incision – head[14]

Dr. Sandhofer, Linz, Austria

Clinical Results: Aesthetic Procedures

Clinical Results: Aesthetic Procedures



Before procedure



Post-procedure, start of treatment with Stratamed



After 7 days of treatment with Stratamed

Laser Resurfacing (acne scars)[14]

Treatment with Stratamed in combination with Thermage® and CO_2 fractional laser resurfacing.

Dr. Sandhofer, Linz, Austria



Before procedure



During procedure and start of treatment with Stratamed



After 10 weeks of treatment with Stratamed

Hypertrophic scar post thorax surgery[14]

Treatment with Stratamed in combination with CO_2 / Mosaic fractional laser resurfacing and radiofrequency.

Dr. Sandhofer, Linz, Austria



Start of treatment with Stratamed



After 5 months of treatment with Stratamed

Hypertrophic scar post reduction mammoplasty[14]

Stratamed in combination with CO_2 laser.

Dr. Sandhofer, Linz, Austria



Start of treatment with Stratamed



After 11 days of treatment with Stratamed

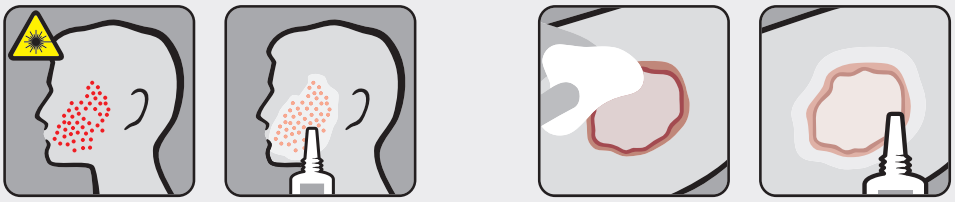
IPL (Intense Pulse Light Therapy) – arm[24]

Sydney, Australia

How to apply Stratamed®?

- Ensure that the affected skin or wound is clean.
- Gently pat dry as much excess exudate or wound fluid from the area as possible prior to gel application.

On damaged or broken skin not requiring a secondary dressing:



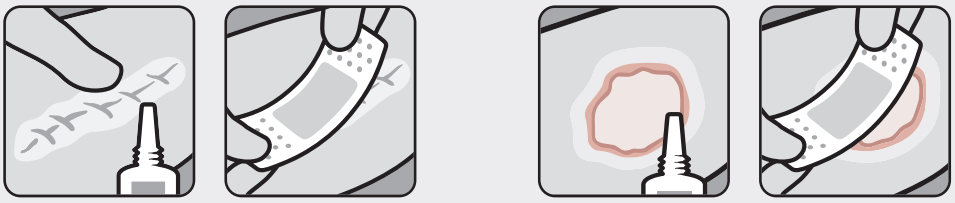
Apply a **very thin layer** of Stratamed to the affected area and **allow the gel to dry**.

When applied correctly to the affected areas, Stratamed should be dry in **5–6 minutes**. If it takes longer to dry you have probably applied too much. Gently remove the excess with a clean tissue or gauze and allow the drying process to continue.

Stratamed should be applied **once daily, or twice daily** to exposed areas or as advised by the physician.

Once dry, Stratamed may be covered by sunscreen, cosmetics, pressure garments or casts.

On damaged skin or wounds requiring a secondary dressing:



Apply a **thin layer** of Stratamed then cover with the secondary dressing. **Drying is not necessary**.

Stratamed should be re-applied **when changing the dressing or checking the wound progress**, or as advised by the physician.

Additional directions

- For best results, Stratamed should be maintained in **continuous contact** with the skin (24 hours a day / 7 days a week). Stratamed may be re-applied **more often** to ensure constant contact with the skin, or to reduce symptoms.
- If Stratamed has been removed by washing, it should be reapplied.
- Stratamed can be applied **directly** to the wound using the finger, cotton bud, etc.
- Stratamed **will not absorb** exudate or wound fluid. The film formed by Stratamed will not prevent the fluid from escaping from the wound.
- Stratamed **does not need to be rubbed in or massaged**, as it does not penetrate below the level of stratum corneum and will not enhance its effect.
- Stratamed may be used in combination with absorbent dressings. Apply Stratamed directly to the wound or to the contact side of the secondary dressing.
- Applying Stratamed on the wound edges will help prevent maceration.
- Stratamed may stain clothing if not completely dry. If staining occurs, dry cleaning should be able to remove it without damaging the fabric.

Stratamed® and other products

Stratamed **should not be applied over topical medications** unless advised by the physician.

IMPORTANT:
Because Stratamed is semi-occlusive:

- Stratamed may enhance the effect of an active ingredient if Stratamed is applied over the active ingredient.
- Stratamed may prevent or reduce absorption of active ingredients if they are applied over Stratamed.

How much Stratamed® do I need?

Stratamed is an advanced formulation which requires **substantially less product** per application than typical moisturising creams or gels.





Stratamed 5g
is enough to treat a 2–4 cm linear incision twice per day for over 90 days



Stratamed 10g
is enough to treat a 5–8 cm linear incision twice per day for over 90 days



Stratamed 20g
is enough to treat a 10–12 cm linear incision twice per day for over 90 days or an area of 6 × 12 cm twice per day for over 60 days



Stratamed 50g
is enough to treat an area of 12 × 15 cm twice per day for over 60 days

Recommended duration of treatment

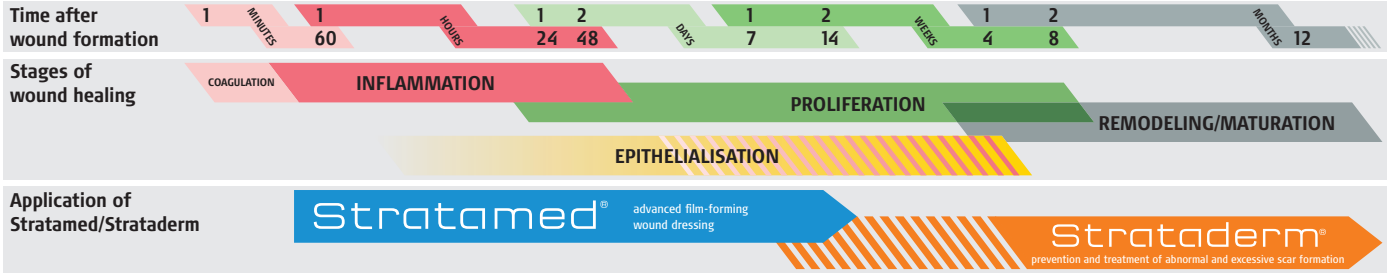
- Stratamed is recommended for **immediate treatment post-procedure** and should be continued until the skin has fully healed.
- For resurfacing and ablative procedures, continued use is recommended for a **minimum treatment of 30 days** or until no further improvement is seen.

Once the wound is healed or the sutures are removed:

Strataderm – for the prevention and treatment of abnormal scars, both old and new

Strataderm®
scar therapy gel

- Easy to apply once daily*
- Softens and flattens raised scars
- Relieves the itching and discomfort of scars
- Reduces redness and discolouration associated with scars



*Please refer to the Patient Information Leaflet (PIL).

Stratamed®

advanced film-forming
wound dressing

A breakthrough in wound healing and early abnormal scar prevention

Stratamed:

- Is indicated for use immediately following aesthetic and medical procedures, on chronic or acute wounds and compromised skin surfaces.
- Promotes a moist healing environment leading to faster re-epithelialisation and reduced downtime.
- Allows abnormal scar prevention to begin earlier than ever before (before suture removal).
- Is gas-permeable, allowing the skin to breathe and remain hydrated.
- Is bacteriostatic, reducing the risk of infection.
- Relieves itching, discomfort and reduces redness and discolouration associated with damaged skin.
- Is inert, contains no alcohol, parabens or fragrances.
- Is easy to apply on all wound surfaces without the need for removal before re-application.

If you have questions about Stratpharma products, orders, supply, etc. contact us at our Stratpharma Melbourne Office:
1800 567 007 or au.order@stratpharma.com



www.stratamed.com

Caution: Always read the label, use only as directed. For external use only. Stratamed should not be placed in contact with the eyes. Stratamed should not be applied over topical medications unless advised by your physician. Stratamed may stain clothing if not completely dry. If staining occurs, dry cleaning should be able to remove it without damaging the fabric. For correct storage please reclose the tube tightly with the cap. Should your wound show signs of infection or fails to heal after 30 days of initial product application consult your physician. If irritation occurs, discontinue use and consult your physician. Not suitable for highly exudative wounds, tunneling wounds or 3rd degree burns. Keep out of the reach of children. Do not use after the expiration (EXP) date printed on the tube. The expiration (EXP) date does not change once the tube has been opened. Do not use if the tube is damaged. Stratamed does not require special disposal methods. Please follow your local disposal regulations. For further instructions, please refer to the Patient Information Leaflet (PIL). Sterile until opened. **Ingredients:** Polysiloxanes, siloxane resin.

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