

Stratamed[®]

medical use
scar therapy gel



First silicone-based scar therapy gel approved for the use on non epithelialized wounds and compromised skin.

Stratamed[®]

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The Product

Stratamed[®] can be applied open wounds and compromised skin surfaces including those from:

- fresh incisions and scar revisions
- laser treatments, chemical peels, dermal abrasion
- superficial radio therapy burns.
- late stage healing of wide spread burns

Stratamed[®] can also be used in conjunction with other invasive scar management options to improve overall results, including surgical excision and resuturing, intralesional steroid injections and pressure garments.

Stratamed®

medical use
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Stratamed® dries to form a silicone gel sheet, which is indicated for use on non epithelialised wounds:

- Preventing abnormal scar formation
- Creating an optimal environment for faster healing
- hydrating
- protects open wounds from chemical and microbial invasion
- Has an anti inflammatory effect

Stratamed® can be used in conjunction with secondary dressings and in support with usual wound care protocol

Stratamed®

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Directions for use

Ensure that the affected skin or wound is clean. Pat dry as much excess exudates or wound fluid from the wound 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. Stratamed® should be applied once daily, or twice daily to exposed areas or as advised by your physician. Once dry, Stratamed® can be covered by sun screen, cosmetics, pressure garments or casts.

On damaged skin or wounds requiring a secondary dressing:

Apply a very thin layer of Stratamed® then cover with the secondary dressing. Stratamed® should be reapplied when changing the dressing or checking wound progress, or as advised by your physician.

For best results Stratamed® should be maintained in continuous contact with the skin (24hrs day).

When applied correctly to exposed areas, Stratamed® should be dry within 5 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 CASE STUDY Bagdasar-Arseni Hospital. Bucharest, Romania 2011

It was study the effect of Stratamed on open wounds in The Plastic Surgery Unit from "Bagdasar-Arseni" Hospital.

Stratamed was used on donor areas for skin grafting, observing the local evolution of the wound, the re-epithelization time and the final aspect of the scar.

Stratamed was applied 1 time/day, in a thin layer all over the post-surgery wound, without covering the area.

Case no. 1

19 yrs old patient with a donor wound of 200 cm² on right arm



Before Stratamed



4 days after Stratamed – partial re-epithelization



6 days after Stratamed - complete re-epithelization of the wound, supple and painless scar.

STRATAMED CASE STUDY Bagdasar-Arseni Hospital. Bucharest, Romania 2011

Case no. 2

34 years old patient with a donor wound on the left leg



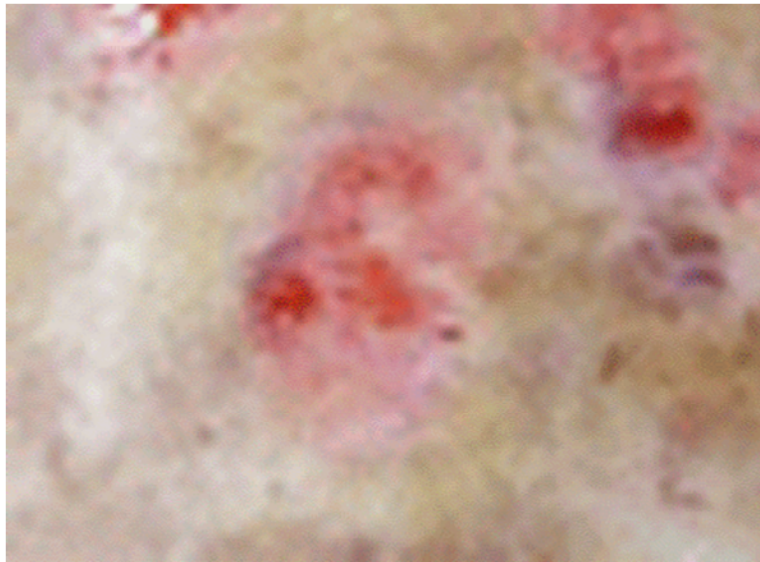
24 hours after Stratamed



After 7 days of treatment: complete re-epithelization of the wound, supple and painless scar

STRATAMED CASE STUDY Bagdasar-Arseni Hospital. Bucharest, Romania 2011

Case no. 3
84 years old patient with a basal-cell carcinoma in the
parieto-occipital area



Before Stratamed (re-epithelization 70%)



2 days after Stratamed – complete re-epithelization

STRATAMED CASE STUDY Bagdasar-Arseni Hospital. Bucharest,
Romania 2011

Authors observations and conclusion

- The re-epithelization is faster (~6 days, depending the biological resources of the patient)
- The result of Stratamed treatment is an supple, not retractile, painless scar
- The treatment has been very well tolerated by all patients
- No adverse effect or infection of the wound

**STRATAMED CASE STUDY Bagdasar-Arseni Hospital. Bucharest,
Romania 2011**

STRATAMED CASE STUDY 105 Patients

Zentrum für Haut, Ästhetik, Laser und Venen in Linz, Austria. Dermatologische Gemeinschaftspraxis,
Bahnhofstraße 8, 94032 Passau, Germany
2009/ 2010

- **METHODS**

- This case series looks at the performance of a new product Stratamed in a series of standard procedures, including ablative and surgical procedures. Stratamed is a tube-dispensed silicone gel (Stratpharma AG, Switzerland), which forms a self-drying protective sheet. It consists of inert silicone polymers and can be applied directly to open wounds and to areas of the skin with weakened integrity.
- From 2009 to 2010, we monitored the performance of Stratamed on 105 patients in a case series at the author's clinic, following various invasive treatments.

Resurfacing Laser



Pre treatment



Stratamed immediately post laser



8 days post treatment

Dr Sandhofer, M. and Dr Schauer, P; Austria and Germany 2009/2010

STRATAMED CASE STUDY



Immediately post
Stratamed & resurfacing laser

7 days post surgery
Stratamed and resurfacing laser

Dr Sandhofer, M. and Dr Schauer, P; Austria and Germany 2009/2010



Immediately post treatment



4 weeks post-treatment

Combination Therapy

Dermal Abrasion + Stratamed in combination therapy enhances results

Dr Sandhofer, M. and Dr Schauer, P; Austria and Germany 2009/2010

Combination Therapy

Chryo-freezing + Stratamed in combination therapy enhances results



immediately post treatment

Dr Sandhofer, M. and Dr Schauer, P; Austria and Germany 2009/2010

Combination Therapy

Fitzpatrick solution (Steroids + 5FU injection) + Stratamed in combination therapy enhances results of hypertrophic scar treatment



Pre Treatment of hypertrophic scar
(please note this scar is not a keloid)



2 weeks post treatment with Fitzpatrick solution and Stratamed



7 weeks post treatment with Fitzpatrick solution and Stratamed

Dr Sandhofer, M. and Dr Schauer, P; Austria and Germany 2009/2010



Pre surgery



Immediately post procedure

Combination Therapy

Resurfacing laser +
Stratamed in combination
therapy enhances results

8 days post procedure



Dr Sandhofer, M. and Dr Schauer, P; Austria and Germany 2009/2010

- **DISCUSSION**

- The general observations from our case experience indicated that this new silicone gel wound dressing was well-suited for a wide range of dermatological surgery indications in our clinic, namely the treatment of open wounds, post resurfacing procedures and for the early use in abnormal scar prevention. The gel dressing was also well-suited to be used as a combination therapy with our standard postoperative wound care protocols. The Stratamed gel proved particularly helpful in the postoperative fraction system treatment, where we observed that erosive and ablative wounds were better protected than with the petroleum based moisturizing agents that we commonly use.

- The healing process was observed to also be supported more strongly. We propose that this is due to the Stratamed polymers having no measurable pH value, and therefore these polymers do not affect the protective acid mantle of the skin and do not react with the newly forming epithelial tissues. The result being, a favorable environment for the skin healing process, which we subjectively observed lead to a faster epithelial formation.

Authors observations and conclusion

From our trial experience we concluded there is no need to further adapt our existing wound treatment concepts when Stratamed is used, since it is an add-on therapy. The preparation was well-tolerated, without exception, and no contact sensitization or gel related infections were observed. In no instance was it necessary to remove the preparation. Given that the gel is inert and that to date no adverse topical silicone gel reactions have been published, predicted this result.

Patient compliance was very high; we propose that the factors that contributed to this result were in particular the simplicity of application, which could be done by all patients at home without difficulty, and the type of clientele treated at the clinic.

The patients seen at the authors clinic are highly “cosmetically conscious” particularly with regards to prevention of abnormal scarring and the authors believe this leads to a maximum level of postoperative compliance. Therefore, the 100% compliance observed with the surgical excisions was not surprising.

- The preliminary observations suggest that this self drying topical silicone gel wound dressing is an effective treatment contributing to faster epithelialization, reduced inflammatory response and reducing abnormal scar formation.