Application in a **Two-Step Procedure**

The Two-Step procedure should be used for less well-vascularized wound beds or if a 2 mm thick MatriDerm® Dermal Matrix is necessary. In such cases it cannot be safely assumed that the wound bed is capable of ensuring immediate and adequate nutrition of a split-thickness skin graft (STSG) applied at the same time.

In the two-step procedure, MatriDerm® is initially attached to the wound. As soon as good vascularization of the collagen-elastin matrix is achieved, final grafting with the split-thickness skin graft can take place in a second operation following the initial application. Follow the guidelines from the One-Step Procedure as described below:

- Apply and repeat, if necessary, steps 1 (Wound Bed Preparation), 2 (MatriDerm® Dermal Matrix Application) and 4 (Wound Coverage of STSG) until growth of healthy granulation tissue is observed through the matrix. Often 5–12 days are sufficient. However, NPWT may be placed for additional 5–6 days, if required.
- Ensure that MatriDerm® Dermal Matrix does not dry out prior to application of the STSG, by maintaining a closed moist wound environment (e.g. with NPWT).

Place STSG as soon as healthy tissue has grown through the matrix:

- If applicable remove potential debris and/or hypergranulation from the wound surface before grafting.
- Place STSG as described in step 3 (Application of STSG) and apply and repeat step 4 (Wound Coverage of STSG) and step 5 (Dressing Changes and Aftercare) as described before.

NOTE: Integration of the 3 mm product is slower in comparison to 1 mm. Experience has shown that the usage of negative pressure wound therapy (NPWT) in conjunction with 3 mm thickness products supports the healing. Do not use 3 mm products in a One-Step Procedure. 3 mm products shrink a bit more than 1 or 2 mm when hydrated. This should be considered when trimming the product to the wound size.

Split-Skin Application

The best results have been achieved with unmeshed skin grafts. Fenestration can help avoid seroma. Good results can be achieved if the graft slightly overlaps the wound margins. If a meshed skin graft is indicated, care must be taken to minimize the shear forces between the graft and MatriDerm. Unlike in the wound bed, adherence of the graft to MatriDerm® is not promoted by the formation of fibrin.

Appearance of STSG at 1st **Dressing Change**

Wound appearance may not be as pink as with STSG only (Ghosting Effect). The suspicion could be that the graft has not taken. However, at day 5, vascularization starts but MatriDerm® Dermal Matrix has not been fully converted to dermal tissue yet. Therefore, a pale appearance of the wound at the first dressing change might occur but healing proceeds normally. Re-assess the wound at the next dressing change.

Example: day 5 post-operative (Ghosting Effect)

1. Panayi A. et al. Evidence based review of negative pressure wound therapy, World J Dermatol. Feb 2, 2017; 6(1): 1-16 These recommendations are designed to serve only as a general guideline, and are not intended to supersede institutional protocols or professional clinical judgment concerning patient care. All product and company names are trademarks ™ or registered ® trademarks of their respective holders. Use of them does not imply any affiliation with or endorsement by them. Please check complete indications and recommended application in your local Instructions for Use (IFU) before using MatriDerm® Dermal Matrix.

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Application Guide

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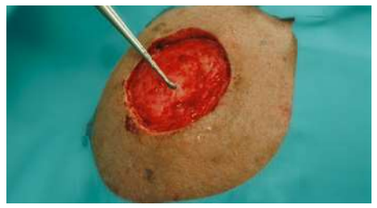
MatriDerm® Dermal Matrix Application in a One-Step Procedure

In a One-Step Procedure MatriDerm® Dermal Matrix is immediately covered with a split-thickness skin graft (STSG). The One-Step Procedure can be used if the wound bed is capable of supplying nutrients to the overlying graft even through the 1mm thick matrix by diffusion. The patient benefits in particular from the avoidance of a second operation and early mobilization.

1 Wound Bed Preparation

+ Optional

- Negative Pressure Therapy (NPWT) may be used to optimize the wound bed by stimulating granulation tissue formation, blood vessel sprouting (vascularization) and cell proliferation (e.g. to reduce the area of exposed structures like tendons or bones).[1]
- In case of wound infection, use NPWT until infection has been resolved. See manufacturer's instructions for use

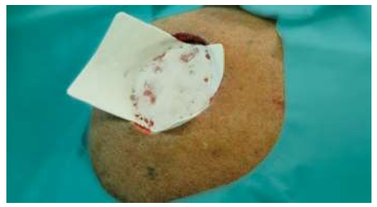


Example: Wound bed after excision of nodular malignant melanoma at the scalp and 7 days of NPWT

- Appropriate debridement to obtain a clean and well-vascularized wound bed which must be free of infections and necrosis is highly recommended
- If applicable: excise scar tissue completely
- If applicable: shave granulation tissue and refresh wound edges (chamfer wound edges if necessary)
- Achieve hemostasis according to surgeon's preferred method: e.g. saline + adrenaline, mild cauterization
- Thoroughly clean and irrigate wound according to local protocol using normal saline or other solution as indicated by treating physician

! Note: Do not use antiseptics containing iodine or enzymatic debridement agents in direct conjunction with MatriDerm® Dermal Matrix, as the collagen elastin matrix can be damaged as a result. Rinse wound thoroughly to wash off the antiseptic or enzymatic debridement agents prior to MatriDerm® Dermal Matrix application.

2 MatriDerm® Dermal Matrix Application



Example: Dry application of MatriDerm® Dermal Matrix prior to trimming

- Dry application of MatriDerm® Dermal Matrix is recommended. If more than one sheet of MatriDerm® Dermal Matrix is used, the sheets should overlap by approximately 2–3mm
- Trim roughly to fit the skin defect

Example: Rehydration of MatriDerm® Dermal Matrix

- Rehydrate in wound bed using saline or Ringer's solution. Please ensure the solution is not warmer than room temperature
- Make sure MatriDerm® Dermal Matrix evenly adheres to the wound bed
- Gently remove air bubbles

3 Application of STSG

Example: Trimming of STSG

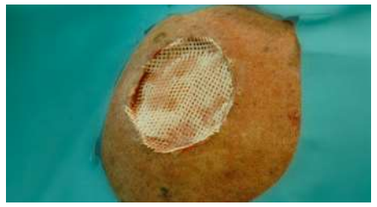
- Use STSG with optimal thickness of 0.006 inch or 0.2mm
- Unmeshed graft shows best aesthetic results (fenestrate STSG slightly)
- Mesh the STSG if necessary (e.g. limited donor site availability). Less extension leads to better aesthetic results, with good results demonstrated for 1:1.5
- Ensure direct contact between the matrix and the skin graft
- Ensure there is no gap between the wound edge and STSG

Example: Fixation of STSG with histoacryl tissue adhesive

- Fix MatriDerm® Dermal Matrix and split-thickness skin graft (STSG) using surgeon's preferred method (e.g. sutures, staples or fibrin glue)
- If more than one piece of MatriDerm® Dermal Matrix is required, it is advisable to have the seams of the STSG at right angles to the MatriDerm® Dermal Matrix seams

4 Wound Coverage of STSG

Primary Dressing:



Example: Placement of non-adherent dressing on top of STSG

- Place a non-adherent wound contact layer (e.g. fatty gauze, Cutimed® Sorbion® Plus, ADAPTICTM, Mepitel®) on top of STSG with 1cm skin overlap
- If required you may additionally use an antimicrobial dressing (e.g. silver impregnated dressing) to prevent infection

Secondary Dressing:

Select a secondary dressing based on surgeon's preference, localization of the wound and amount of exudate:

A: NPWT

Example: NPWT therapy initiated

- Apply dressing immediately after graft placement
- Set therapy at 75mm Hg continuous suction if used in areas that are not subject to shear forces; set therapy at 125mm Hg if used in areas where shear forces are present or in highly contoured areas. The higher pressure may help to hold the graft more firmly in place
- For skin protection guidelines follow NPWT manufacturer's instructions

B: Conventional Dressing

Example: Fixation with tight bandaging

- Apply 3–4 layers of bulky dressing; add bolsters if necessary
- Moisten with saline to prevent MatriDerm® Dermal Matrix and STSG from drying out
- Fixation with tight bandaging is mandatory for optimal cell ingrowth and to avoid shear forces and hematoma/seroma formation

- Ensure appropriate immobilization/splinting according to localization of the wound
- Leave dressing and therapy on for 5–7 days for optimal splinting effect

5 Dressing Changes and Aftercare

Example: Wound appearance after 12 days

- Do not let the graft dry out
- Perform first dressing change after 5–7 days (if possible not earlier to avoid disruption of the implant)
- The non-adherent wound contact layer may stay in place
- Perform further dressing changes every 5–7 days