Overview Pre-Market Clinical Evaluation and Post Market Clinical Follow Up

of

Tegaderm™ Matrix PHI

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SUMMARY

This document provides an overall summary of the pre-market Clinical Evaluation data and Post Market Clinical Follow Up (PMCF) data relevant for Tegaderm™ Matrix PHI.

The summary of the pre-market studies supporting the clinical claim for Tegaderm™ Matrix PHI is provided as a basis of the state of knowledge at the time of market entry in Europe.

The PMCF studies aimed to evaluate the clinical safety and performance of the Tegaderm™ Matrix PHI in order to

- confirm the conclusion drawn from the pre-market clinical evaluation studies
- to assess if unforeseen hazards can be identified by field experience for which additional control measures are needed.

To evaluate the Post Market Clinical safety and performance of the Tegaderm™ Matrix PHI dressings input was pro-actively collected from health care professionals by case studies and during site visits, telephone interviews and observational studies in the periods 2003-2006 and 2007. In addition complaints from the field were carefully collected and reviewed.

During the PMCF evaluation periods the performance of wound dressings in a total of more than 200 wounds have been reported. The following types of wounds, mainly chronic, have been described: Leg ulcers, Decubitus, Diabetic ulcers, Post surgical.

Between 2003-2006 out of the 60 PMS reported wounds 78% did show complete healing and/or improvement. The poor healing tendency of the remaining 22% of the reported wounds was mostly related to the following generally known indications:

- complex pathology of Decubitus grade IV wounds
- acute termination of this anti-septical treatment might cause a re-activated inflammatory response
- extremely hard to heal wounds (Platzbauch)

Seven reports (4%) of the total amount of wounds have described a stinging burning pain sensation upon application. The content of citric acid might cause this painful reaction. Dr. Dissemond reported however in the observational clinical test with leg ulcers a pain reduction after the Dermax dressings treatment.

Overall the clinical performance of the Tegaderm™ Matrix PHI treatment has overall been recognized as very effective.

Based on the data obtained from PMS studies it can be concluded that Tegaderm™ Matrix PHI dressings are clinically safe and perform like intended. By these results the conclusion of the pre-clinical evaluation study is confirmed.

1. INTRODUCTION

This document provides an overall summary of premarket Clinical Evaluation data and Post Market Clinical Follow Up (PMCF) data relevant for Tegaderm™ Matrix PHI.

The summary of the pre-market studies supporting the clinical claim for Tegaderm™ Matrix PHI is provided in this report as a basis of the state of knowledge at the time of market entry in Europe.

In order to confirm the conclusion drawn from the pre-market clinical safety evaluation studies and to assess if unforeseen hazards can be identified by field experience for which additional control measures are needed a PMCF strategy was developed from which this report provides a summary of results.

During development the following product names were used:
- Tegaderm Matrix PHI
- Tegaderm
- DerMax
- DerMax PHI-5
- Dermax OBE

Tegaderm Matrix PHI has been CE-certified and successfully marketed since June 2002 in Europe under the name Dermax by Dermagenics BV. In the early stage Dermax wound dressings were impregnated with an ointment based in Oak Bark Extract (OBE). The nature derived Oak Bark Extract consisted for 95% of Potassium, Rubidium, Calcium and Zinc. To eliminate the variable factor of nature a synthetic variant was developed, referred as Dermax PHI-5 for which regulatory approval was obtained in Europe in October 2005. In 2009 Dermax is market under the name Tegaderm Matrix PHI.
No medical device related adverse event has happened for Dermax® since its first market introduction.

NOTE:
Taking the chemical composition of PHI-5 based Dermax® and that of Oak Bark extract based DerMax® into consideration it can be concluded that for product verification and validation purposes (e.g. biological safety, clinical evaluation), the Oak Bark extract based product can be considered as the worst case model: PHI-5 consists of Potassium, Rubidium, Calcium and Zinc in the same (or lower) proportions as in Oak Bark Extract, combined with citric acid and PEG 400/4000 in the same concentration and applied on Acetate Fabric with same amount. The only difference between Dermax® with Oak Bark Extract (natural) and Dermax® with PHI-5 (synthetic) is the origin of the metal ions, not the type nor the concentration.
It is therefore stated by Dermagenics Inc. that clinical data available for the Oak Bark extract based DerMax® is suitable for the evaluation of Tegaderm.

2. RELATION TO OVERALL RISK MANAGMENT

This biological evaluation is part of the overall risk evaluation of Tegaderm™ Matrix PHI[1].

3. OBJECTIVE AND SCOPE

The objective of this PMS study is to evaluate the clinical safety and performance of the Tegaderm™ Matrix PHI in order to

- confirm the conclusion drawn from the pre-market Clinical Evaluation study
- to assess if unforeseen hazards can be identified by field experience for which additional control measures are needed.

4. APPLICABLE STANDARDS AND GUIDELINES

- EN ISO 14155-1:2003 Clinical investigation of medical devices for human subjects – General requirements

- EN ISO 14155-2:2003 Clinical investigation of medical devices for human subjects – Clinical investigations plans
- MEDDEV 2.12-2 Guidance document on post market clinical follow up for medical devices.

5. PRODUCT DESCRIPTION

5.1 Tegaderm™ Matrix PHI

Tegaderm™ Matrix PHI is a sterile wound dressing impregnated with Polyhydrated Ionogens (PHI) (DerMax®) ointment and is intended for use in healing chronic wounds. DerMax ointment contains a synthetic blend of trace elements (metal ions) that normally occur also in serum and wound exudates. The inert carrier, a dressing material of acetate mesh fabric, is impregnated with DerMax®. The ointment is released to the wound surface after the dressing is applied to the wound's surface.

Tegaderm™ Matrix PHI is supplied in 2 sizes:
5 x 6 cm.
8 x 10 cm.

Tegaderm™ Matrix PHI shall be stored at room temperature, dry, and not in sunlight. It may also be stored in a refrigerator, but not in a freezer (5 - 25ºC). Tegaderm™ Matrix PHI has a shelf life of 3 years.

5.2 Product properties

Tegaderm™ Matrix PHI is intended for use with chronic and acute wounds. Tegaderm™ Matrix PHI normalizes the wound micro-environment by reducing excessive inflammation, thereby facilitating re-epithelialization of the wound. Matrix metalloproteïnases (MMPs) play an important role in both tissue matrix degradation and regeneration. Re-epithelialization is related to a correct distribution of MMPs within the wound environment. Tegaderm™ Matrix PHI has specific properties intended to assist the wound environment by regulating the level of moisture and acidity at the wound surface during the healing process. Tegaderm™ Matrix PHI also helps to protect wounds against mechanical trauma. Tegaderm™ Matrix PHI allows for proper drainage of wound exudates.

Tegaderm™ Matrix PHI should be used on problematic chronic wounds or on wounds where a faster and easier healing process is desired, including the following types of wounds:

<u>Acute severe wounds</u>
• Burns
• Surgical wounds
• Traumatic wounds
• Other acute wounds where fast epithelialization is required

<u>Chronic severe wounds</u>
• Leg ulcers
• Diabetic ulcers
• Decubitus ulcers
• In conjunction with corticosteroid use.

Contra-indications
Tegaderm™ Matrix PHI should not be used on patients with a known extreme sensitivity to acetate or PHI.

Precautions
Occasionally, upon application, transitory wound discomfort such as a stinging sensation, has been reported.

5.3 Instructions for Use

After carefully inspection of the wound, cleaning of the wound using standard wound care practices and removal of the backing paper Tegaderm™ Matrix PHI is be applied to the wound ensuring maximum contact. Tegaderm™ Matrix PHI dressing can be secured with (perforated) adhesive tape. In cases of moist or wet wounds, a secondary dressing may be applied on top of the Tegaderm™ Matrix PHI to provide absorption.
Tegaderm™ Matrix PHI is for single use only. A new dressing can be applied. For dressing change the Tegaderm™ Matrix PHI can be pre-moistened if necessary to facilitate removal

5.4 Package system

For easy user handling purposes Tegaderm™ Matrix PHI dressings are covered with backing paper “Silthene LD70 M2DE”. This 70 µm thick backing paper is composed of low density polyethylene which is siliconised on one side. The backing paper is applied to both sides of the dressing, silicon side down.
As sterility barrier and for maintenance of the moisture environment the Tegaderm™ Matrix PHI dressing with backing paper is packed in PerfecFlex® foil.

6. SUMMARY PRE-MARKET CLINICAL EVALUATION AND POST MARKET CLINICAL FOLLOW UP

Below an overview is provided of pre-market Clinical Evaluation studies, Post Market Clinical Follow Up data and of studies supporting the clinical performance. Details can be found in the referred documents:

6.1 A novel formulation of metal ions and citric acid reduces reactive oxygen species *in vitro* (2003)[3,4].

Reactive oxygen species, including superoxide anions, are thought to play an important role in impairing wound healing. Additionally, superoxide anions react with nitric oxide produced by macrophages to form peroxynitrite, another strong oxidant with detrimental effects on surrounding tissue. This *in vitro* study investigated whether samples of metal ions and citric acid are able to reduce levels of reactive oxygen species.

Samples of materials were tested in assays for the following: inhibition of reactive oxygen species production by human polymorphonuclear neutrophils (PMNs); antioxidant activity (scavenging of superoxide anions in a cell-free system); inhibition of human complement (limiting the generation of complement factors that attract and stimulate PMNs, thereby reducing levels of reactive oxygen species).

Metal ions were shown to inhibit both PMN production of reactive oxygen species and the activation of complement via the classical pathway, whereas citric acid was found to be a scavenger of superoxide anions.

It was concluded that the beneficial effects of using formulations containing metal ions and citric acid on chronic wounds may be explained in part by a reduction of reactive oxygen species in these wounds.

6.2 Analysis of morphological and immunohistochemical changes during treatment with DerMax (2003)[3,5].

There are important differences between healing and chronic wounds. One of the latest most important findings is the different expression of endo-peptidases called matrix metalloproteineases (MMPs). The MMPs are capable to degrade all the extracellular matrix (ECM) components. During a normal wound healing there is a balance between “construction” and “destruction” of ECM. In chronic wounds an imbalance is observed, with a high level of MMP-2. DerMax is a new device in the market that claims to decrease the production” of MMP-2.

Biopsies from chronic wounds were taken in day 0, 2 weeks and 6 weeks. An analysis was made of the morphological changes in comparison with fibrocytes MMP-2 expression during the healing process. Fibroblasts imbalance is observed, with a high level of MMP-2. Biopsies were performed in 4 chronic wounds during treatment with DerMax. The samples were evaluated morphologically and submitted to immunocytochemical techniques using monoclonal MMP-2antibodies (NeoMarkers).

During treatment with DerMax the most striking (immuno-) histological changes were the loss of the fibro-necrotic cap covering the wound bed, the reactivation of the fibroblasts in the granulation tissue and the sharp decline in the expression of fibroblast MMP-2.
In this study the application of DerMax induced an improvement of wound healing both clinically and histologically. Fibrocytes MMP-2 producers were substituted by fibroblasts ECM components producers, leading to the wound healing.

6.3 Poly Hydrated Ionogens regulate Matrix Metalloproteinases expression and reactive oxygen species production in recalcitrant wounds (2003)[3,6].

Impaired healing in recalcitrant wounds is related to MMP/TIMP imbalance and protracted inflammation. Protracted inflammation is associated with release of hydroxyl radicals, hypochloric acid and peroxynitrate (ROS). Poly Hydrated Ionogens (PHI) regulate protease imbalance, down-regulate ROS production and stimulate re-epithelialization.

Experimental burns treated with carbodiimide (cross-linking agent) showed strong MMP-2 expression in three pigs. A topical ointment with a low pH in an inert synthetic carrier containing PHI (DerMax) was applied daily. Contra-lateral" mirror image" wounds were treated with a placebo (ointment without metal ions). MMP-2 was estimated qualitatively by immunohistochemical staining tissue biopsies of recalcitrant wounds. The inf1uence of PHI on ROS production by granulocytes was estimated in vitro.

Non-healing burn wounds treated with PHI showed MMP-2 down-regulation in fibroblasts and re-epithelialization again. There was no healing in placebo treated wounds. Recalcitrant wounds had a high expression of MMP-2 in fibroblasts and endothelium. Within two weeks of treatment MMP-2 expression was down-regulated and re-epithelialization initiated. In vitro ROS production of granulocytes was down-regulated. PI-U caB influence MMP metabolism and induce reepithelialization in recalcitrant wounds. Topical application of PHI caB control MMP/TIMP imbalance, down-regulate ROS production and stimulate re-epithelialization.

6.4 Summary of a comparing study on the healing effects of DerMax OBE and DerMax PHI-5: A Pig study (2003)[3,7].

In previous animal experiments with daily application of OBE ointment (botanical equivalent of PHI-5) clearly induced re-epithelialization in non-healing wounds in contrast to contra-lateral placebo treated wounds.

Also in human patients induction of epithelialization could be observed in therapy-resistant recalcitrant wounds. In acute wounds in humans as well as pigs an acceleration of epithelialization could be demonstrated also.

The burn wound model in the Yorkshire pig can be used for the macroscopic evaluation of differences in wound healing in a mirror image way. Differences in epithelialization, contraction and scar tissue formation can be observed clearly.

6.5 A prospective randomized study in recalcitrant pressure ulcers in poly Poly Hydrated Ionogens is feasible(2004)[9].

This prospective study was designed to determine the potential efficacy of PHI in treating a variety of pressure ulcers.

Patients (n=17) with stage II, III, and IV pressure ulcers were selected from three nursing homes. The ulcers (n=19) were treated daily with DerMax dressings (which contain PHI) after standard surgical or enzymatic debridement.
Treatments were continued until full closure occurred or if no change was observed over six weeks of treatment. Progress was reviewed once a week.

Treating patients with DerMax (with PHI-5) resulted in full closure for 100% of stage II (n=1) and stage III (n=10) pressure ulcers with an average healing time of less than six weeks. DerMax did not perform as well with stage IV ulcers (n=8). Healing was reached only in 12.5% or 20% if dropouts are excluded. No adverse events or side effects were observed.

Based upon DerMax's excellent (100%) healing rate with stage II and stage III pressure ulcers in this study, a randomized, double blinded clinical trial with stage ll and stage III pressure ulcers is both feasible and recommended in order to produce definitive, statistically significant findings. Visual observations of DerMax treated wounds over the course of the study revealed that the wounds seem to become covered with a thin layer of transparent wound fluid. These exudates diminish over the course of treatment as the wound full heals. DerMax dressings, if used in the pelvic region, should be fixed in place with perforated tape under an absorbing bandage.

6.6 A perspective study for determination of the efficacy of Dermax Poly Hydrated Ionogens (PHI-5) in the treatment of Diabetic Foot Ulcers (2004)[10].

A multicentre pilot study for determination of the efficacy of DerMax® Poly Hydrated Ionogens (PHI-5) in achieving stable wound closure in Diabetic Foot Ulcers.

The multi centre study was designed:

- To determine the potential efficacy of the treatment of Diabetic Foot Ulcers Wagner grade 1 to 2 with DerMax® PHI-5, resulting to full closure by normalization of the wound micro-environment.

- To determine the efficacy with regard to the normalization of the wound micro-environment by evaluation of the following parameters:
  - Reduction of excessive inflammation
  - Regulation of the level of moisture
  - Facilitation of re-epithelialisation

- To determine the feasibility of a multi-centre, prospective, randomized, blinded clinical trial in order to produce definitive, statistically significant findings.

Patients (n=20) with therapy resistant Diabetic Foot Ulcers were selected from three European tertiary referral hospitals.

Conclusions:
Overall healing rate:
Treating patients with DerMax® PHI-5 resulted in an overall full closure of 75%.

Normalization of the wound micro-environment:
We noted a reduction of exudate levels and wound slough and recruitment of controlled amount of granulation tissue with progressive epithelialisation from the wound edges leading to stable wound closure

Feasibility of a randomized, double blinded clinical trial:
Based upon DerMax's promising (75%) healing rate with Diabetic Foot Ulcers in this study, a randomized, blinded clinical trial is both feasible and recommended in order to produce definitive, statistically significant, evidence based findings.

6.7 A novel formulation of metal ions and citric acid reduces reactive oxygen species *in vitro* - Polyhydrated Inogens (PHI) alters patterns of gene expression in normal and diabetic fibroblast cultures (2005)[3,8].

Reactive oxygen species, including superoxide anions, are thought to play an important role in impairing wound healing. Additionally, superoxide anions react with nitric oxide produced by macrophages to form peroxynitrite, another strong oxidant with detrimental effects on surrounding tissue. This in vitro study investigated whether samples of metal ions and citric acid are able to reduce levels of reactive oxygen species.

Samples of materials were tested in assays for the following: inhibition of reactive oxygen species production by human polymorphonuclear neutrophils (PMNs); antioxidant activity (scavenging of superoxide anions in a cell-free system); inhibition of human complement (limiting the generation of complement factors that attract and stimulate PMNs, thereby reducing levels of reactive oxygen species).

Metal ions were shown to inhibit both PMN production of reactive oxygen species and the activation of complement via the classical pathway,where as citric acid was found to be a scavenger of superoxide anions.

The beneficial effects of using formulations containing metal ions and citric acid on chronic wounds may be explained in part by a reduction of reactive oxygen species in these wounds.

Although other factors governing wound healing may also be important, such as MMPs, these results show that metal ions inhibited human complement activation via the classical pathway and inhibited production of reactive oxygen species by activated PMNs, and that citric acid scavenged superoxide anions. In addition, incubation of PMNs in up to 100µl/ml MI-CA5 did not have any cytotoxic effects.
Unpublished data suggesting the beneficial effects of formulations containing metal ions and citric acid (DerMax) on chronic ulcers may be in part explained by a reduction of reactive oxygen species in these wounds.

6.8 Clinical experience of a new wound dressing (Dermax PHI-5) in the local treatment of chronic leg ulcers (2005)[11].

These case studies (2) demonstrate the benefits of an interactive MMP modulating dressing on two leg ulcer patients who have very different aetiology for leg ulceration. Both were referred to the Leg Ulcer Clinic for specialist treatment because of failure of the ulcers to heal. With the use of Dermax both patients achieved complete closure of the wounds at 14 and 16 weeks after commencement of Dermax dressing as wound therapy.

The outcomes of these two case studies further support existing data on the benefits of MMP modulating dressing in the management of chronic wounds.

6.9 MMP-2 Assessment as an Indicator of Wound Healing: A Feasibility Study, R.B. Karim, Adv. Skin Wound Care (2006)[12].

The objective of this study was to evaluate the feasibility of assessment of fibroblast matrix metalloproteinase-2 (MMP-2) expression as an indicator of wound healing in wounds that change from chronically inert to actively healing.

A Phase II feasibility study was performed with 4 patients with non-healing wounds (duration, z 3 months; surface area, z 1 cm2). Wounds were treated with a dressing impregnated with oak bark extract (DerMax) and evaluated weekly; biopsies were performed every 2 weeks until wound healing.

Therapy-induced wound healing and immunohistochemical measurements of MMP-2 expression paralleled the clinical characteristics of wound healing.

It was concluded that MMP-2 expression offers a reliable indicator for clinical wound healing induced by DerMax treatment.

6.10 An observational study of the use of a polyhydrated ionogen impregnated dressing (DerMax) in the treatment of wounds (2006)[13]

This clinical study was based on a series of case studies and is not strictly based on research principles. The overall aim was to demonstrate how DerMax can be used in general, hard to heal wounds, in order to rebalance MMPs through normalization of the wound micro-environment. Healing in 'real life' wounds cannot be shown through randomized Controlled Trials, as the inclusion / exclusion criteria are so strict that it excludes the wound types that are currently causing difficulties with healing in the community.

In these case studies, there was an overall healing rate of 48% of those wounds treated with DerMax and a predicted potential for a 72% healing rate.

Pain was experienced by those with already painful leg ulcers (3 = 13%). No other patient reported any pain. The 3 patients who experienced pain were discontinued from the study – all other patients and Health Care Professionals expressed satisfaction with DerMax in application, removal and outcomes.

6.11 Successful treatment of therapy-refractory chronic wounds with Dermax, (2006)[14].

In a prospective clinical trial 5 patient with chronic wound that were refractory to therapy were investigated. The wounds existed in at an average of 18.4 months. The average wound size could be reduced of 13.5cm^2 to 3.1cm^2 in the observation period of 10 weeks. In all patients an induction of the stagnated wound healing could be achieved. In one patient the wound healed completely within 6 weeks. Furthermore pH-value measurements were done initially and once a week. By the application of Dermax a decline of the pH value from 0.504 log appeared between the first and second pH measurement. Also the pain intensity was reduced from 1.4 to 0.62 (scale0-5). No objective side effects could be observed.
The prospective clinical study demonstrates in all patients with a therapy refractory chronic wound an induction of the wound healing and a reduction of the pain after the application of Dermax.

6.12 Post market clinical follow up by interviews

To evaluate the Post Market Clinical Performance of the Tegaderm™ Matrix PHI dressings input was pro-actively collected from health care professionals during site visits, telephone interviews and observational studies in the periods 2003-2006 and 2007. In addition

complaints from the field were carefully collected and reviewed. Overall results were summarized and evaluated for improvement measures.

6.12.1 PMS evaluation Dermax dressings 2003-2006

Over a period of four years (2003-2006) the performance of Dermax dressings in a total of 181 wounds have been reported. Following the PMS standard procedure 55 wounds and through observational clinical studies 121 wounds have been reported.
The following types of wounds, mainly chronic, have been described:

- Leg ulcers
- Decubitus
- Diabetic ulcers
- Post surgical

Out of the 60 PMS reported wounds 78% did show complete healing and/or improvement.
The poor healing tendency of the remaining 22% of the reported wounds was mostly related to the following indications:

Decubitus
Decubitus grade IV stage results are in line with the outcomes of the observational pilot study of the "Van Leen study". The underlying pathology is mostly complex.

Leg ulcers
Leg ulcers treated a long period with antiseptic agents disturbing the bacterial flora balance. An acute termination of this anti-septical treatment might cause a re-activated inflammatory response. This response is based on the prolonged application of anti-microbial agents. The wound environment can be out of balance based on toxic activity of these agents.
One report described an enlargement of two wounds with an increase of pain sensation.

Post surgical
Three large abdominal defects following total wound dehiscence, Platzbauch, did not show any improvement. These wounds have been classified as extremely hard to heal wounds.

No correlation could be found between the Dermax dressings treatment and the poor healing tendency of these indications.

Pain sensation
Seven reports, which is about 4% of the total amount of wounds, have described a stinging burning pain sensation upon application. The content of citric acid might cause this painful reaction.
It is not surprising that application is painful in leg ulcers and not pressure ulcers due to the fact that leg ulcers are often superficial and have the nerve endings exposed. In pressure ulcers the nerve endings are damaged or the tissue is dead and no longer contains nerve endings.
Dermax dressings are also less likely to cause pain in diabetic foot ulcers, as very many of these ulcers are caused by a lack of sensation due to neuropathy.

Dr. Dissemond reported however in the observational clinical test with leg ulcers a pain reduction after the Dermax dressings treatment[14].

The following recommendations have been communicated:

- Good analysis of the type of ulcer and underlying pathology is required during PMS studies. Arterial ulcers are described in the literature as painful caused by ischemia.
- Pain will be reduced once the treatment is combined with a more occlusive/moist treatment.

In that case a Hydrogel or a Hydrocolloid dressing is recommended as a secondary dressing to cover Dermax dressings.

Control measure:
- For future PMS studies the analysis of the type of ulcer and underlying pathology will be a point of additional attention
- It will be discussed with the CE holder if any additional note about “pain reduction by using Hydrogel or a Hydrocolloid dressing is recommended as a secondary dressing” shall be added to the Instructions for Use of Tegaderm.

Final conclusion:
The clinical performance of the DerMax treatment has overall been recognized as very effective.

6.12.2 PMS evaluation Dermax dressings 2007

PMS DerMax reports
Number of PMS reports: 3
Codes of reports: Netherlands 1500-07-01DM, Netherlands1500-07-02DM and Netherlands1500-07-03DM.

Results:
One patient has been advised to consult a vascular surgeon. No follow-up has been reported. (PMS form1500-07-01DM).
A second patient switched to another dressing after 3.5 weeks DerMax treatment due to a new medical indication (PMS form 1500-07-02DM).
The third patient passed away unforeseen after one week DerMax treatment (PMS form 1500-07-03DM). This SAE was not related to the treatment of Dermax.
No conclusions could be drawn from these three reported patient cases.

PMS DerMax study reports
Number of PMS Study reports: 2
Codes of reports: Slovenia 1500-07-04DM, Netherlands1500-07-05DM

Results:
A total of 23 leg ulcers have been included in the two studies.
Fifteen ulcers have been healed completely (65%).

Publications DerMax studies
Three DerMax studies have been published in 2007. Two studies have been announced in 2007 as accepted for presentation at the WUWHS congress in Toronto in 2008. All studies have been overviewed in Doc.1500-07-06DM.

Summary all reports
The sources from the reports vary from community care, nursing homes to general and university hospitals.
A total of 25 wounds treated with DerMax have been reported.
All indications, which have been reported, were chronic ulcers.
The following chronic indications have been described:
- Leg ulcers, venous
- Post traumatic ulcer

The following recommendations have been communicated:
The explanation of the technology to the nursing profession has been recognized as too complicated.

Control measure:

Presentations have been simplified. The Dermagenics binder including all references has been introduced.

Final conclusion:
The clinical performance of the DerMax treatment has overall been recognized as very effective.

7. OVERALL CONCLUSION

Based on the data obtained from pre-market Clinical Evaluation and Post Market Follow up studies it can be concluded that Tegaderm™ Matrix PHI dressings are clinically safe and perform like intended. By the results of the Post Market Follow the outcome of the pre-clinical evaluation studies is confirmed:

Taking the results of the pre-market Clinical Evaluation and Post Market Follow up studies and the intended use and application of Tegaderm™ Matrix PHI dressings into consideration Dermagenics Inc. states that Tegaderm™ Matrix PHI dressings are safe and perform as claimed by the Instructions for Use.

8. REFERENCES

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