THE USE OF BIOTITUS® DERMA PRODUCTS IN THE MANAGEMENT OF ACUTE AND CHRONIC CUTANEOUS ULCERATIONS – BENEFITS AND DRAWBACKS

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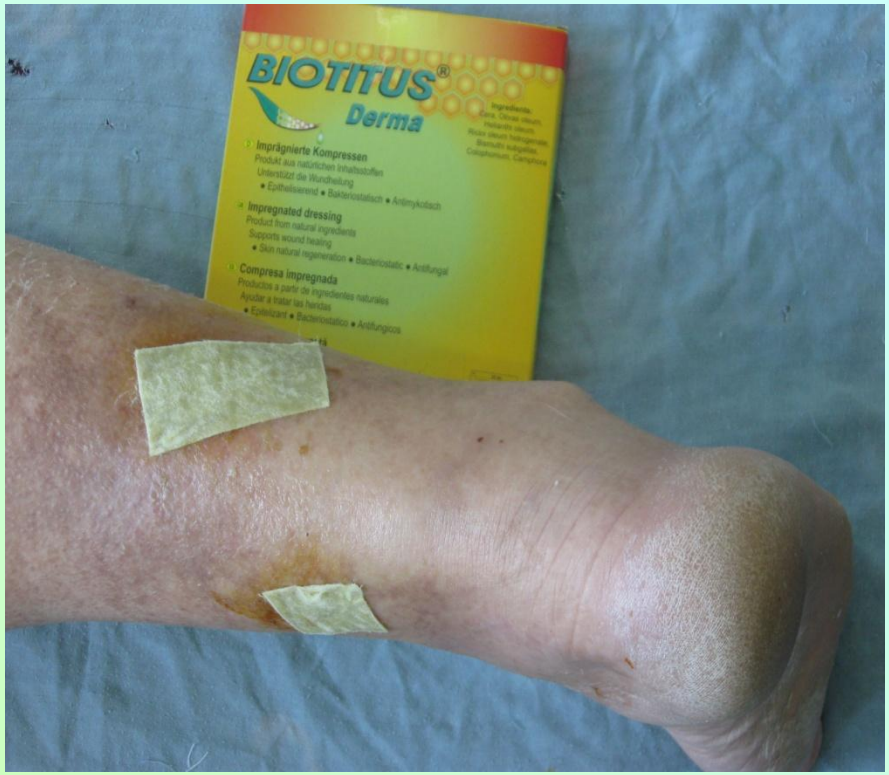
- *Clinical trial: "The use of **BIOTITUS® Derma** products in the treatment of burns, pressure sores, chronic vascular ulcers and diabetic foot";* SR EN ISO 14155:2011 (Plastic Surgery Unit, County Emergency Hospital Constanta)

- Medical devices II b, in accordance with 93/42/EEC, 2007/47/CE, with the CE 1868 conformity mark

- A full range of hydroactive products: impregnated compresses on a viscose and polypropylene nonwoven support, 10x10cm and ointment (20, 50, 100 ml)

- Composition - vegetal extracts and excipients: olivae oleum, helianthi oleum, cera, camphora, colopohonium, ricini oleum hydrogenate, bismuthi subgallas.

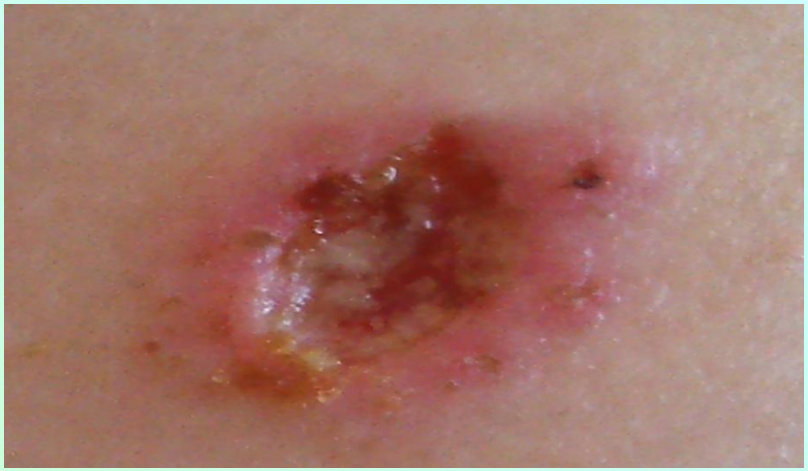


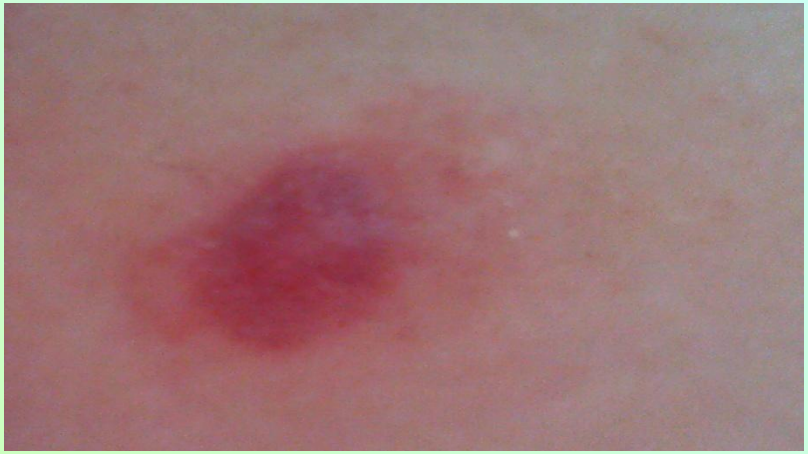
Therapeutic properties

- Stimulates the formation of granulation tissue by *new blood vessel formation*
- Promotes the healing process by *stimulation of epithelial cells, keratinocytes and endothelial cells*; stimulate the production of collagen and elastin; *restores the skin's lipid barrier*
- In the case of deep wounds it *activates the residual epithelial cells*
- Wound debridement by the absorption of exudate excess
- Antiseptic action – proven *bacteriostatic effect* against Enterococcus, Escherichia coli, Klebsiella pneumoniae, Klebsiella oxytoca, Enterobacter cloacae, Enterobacter aerogenes, Providentia stuartii, Proteus mirabilis, Pseudomonas aeruginosa;
- Limited *bactericide effect* against Staphylococcus aureus and Streptococcus pyogenes gr.A.
- Antifungal activity against Candida albicans and Aspergillus niger.

Indications

- Local treatment of acute wounds: superficial burns (I, IIa, IIb), excoriations, ulcerations, dermabrasions
- Local treatment of donor area after split skin graft harvesting
- Local treatment of chronic wounds: vascular ulcers, pressure sores, radiodermatites
- Local treatment of pathologic scars (hypertrophic, keloids)
- After chemical peeling or laser treatment.





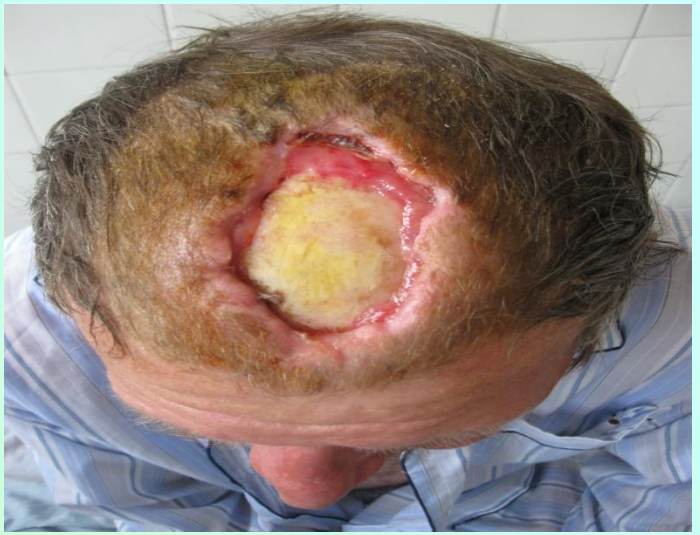
Full epithelization of a postoperative dehiscent wound of the arm – 10 days of ointment application

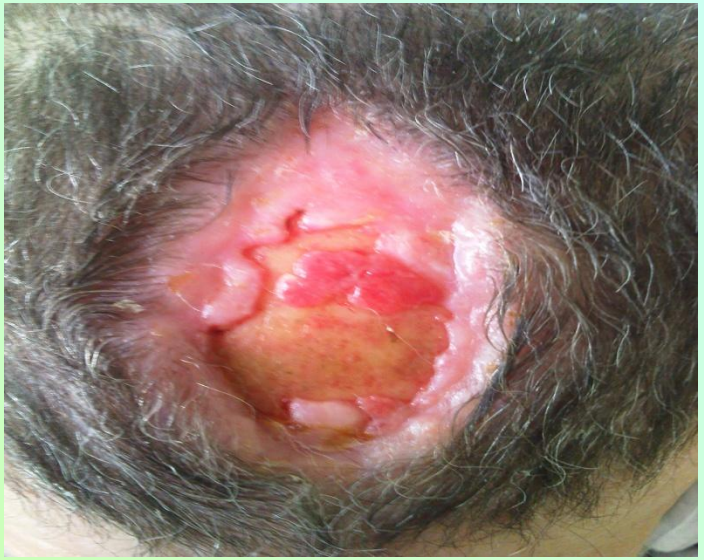
Use instructions

- The wound is cleaned with hypertonic solutions
- The adjusted **BIOTITUS® Derma** impregnated compress or 1-2 mm **BIOTITUS® Derma** ointment is applied directly on the wound followed by a sterile dressing
- The dressing is changed every 24 – 48 hours – depending on the quantity of exsudate

Possible body reactions:

- Immediately following application: local hyperthermia, burn sensation, pruritus – self-limited after 30-40 minutes
- Seldom – local allergy (if the patient is allergic at one of the components!).



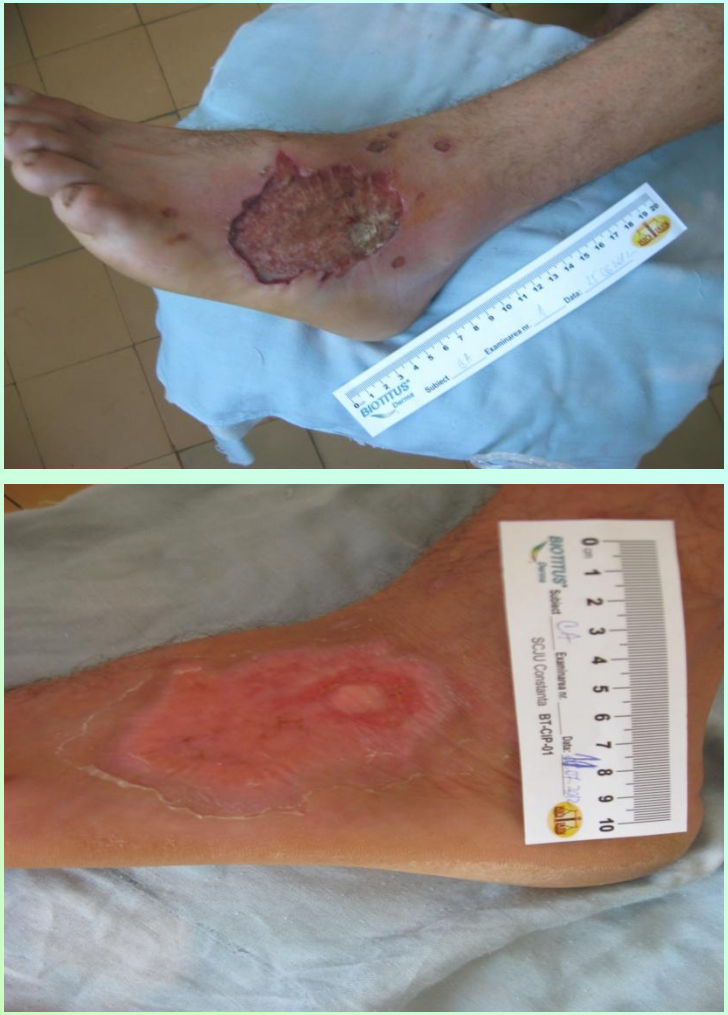


Complex scalp defect with exposure of the calvarium; reduction by half after 21 days of daily dressing with **BIOTITUS® Derma**

Material and methods

- Between July and December 2011, we added **BIOTITUS® Derma** in the local treatment of burns (superficial and intermediate), pressure sores, donor area of split skin graft, extensive dermabrasions, chronic wounds and hypertrophic scars.

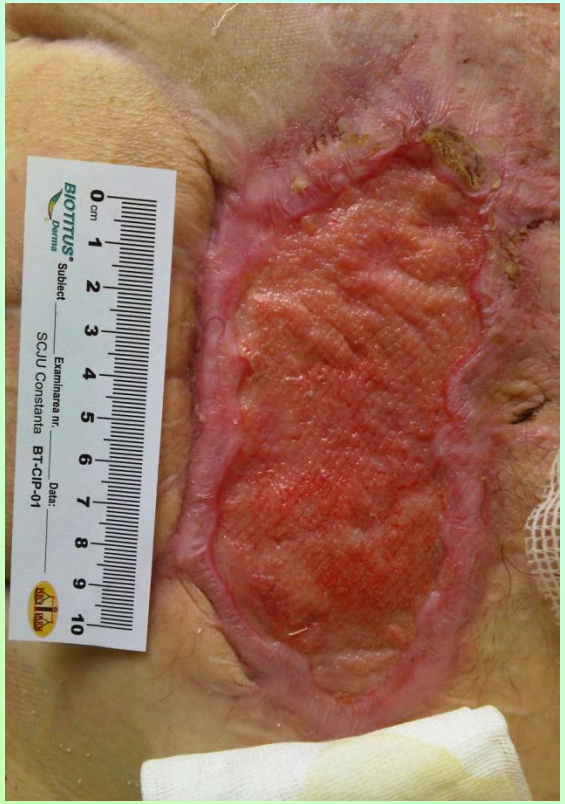
- A clinical trial started in January 2012 and is ongoing. The product's efficiency criteria are the dimensions of the wound (area and volume), the absence of infection as well as the proportion between necrosis / granulation tissue / fibrin / new epithelium.

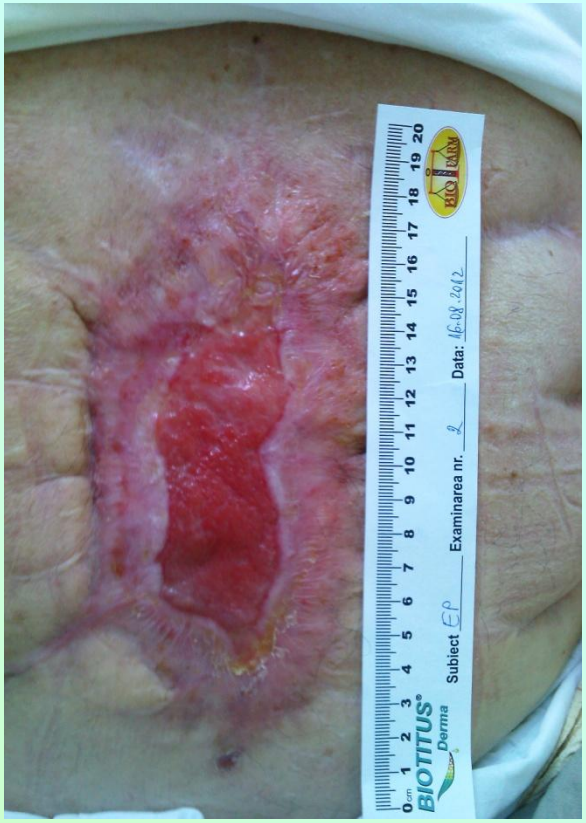


Complete healing of an intermediate burn of the foot after 16 days of daily Biotitus Derma application

Material and methods

- In order to evaluate the tolerance to the product we estimated daily the easiness of dressing appliance and removal, the level of pain (using the Wong-Baker scale), and the wound's parameters – dimensions, smell, adjacent tissues.

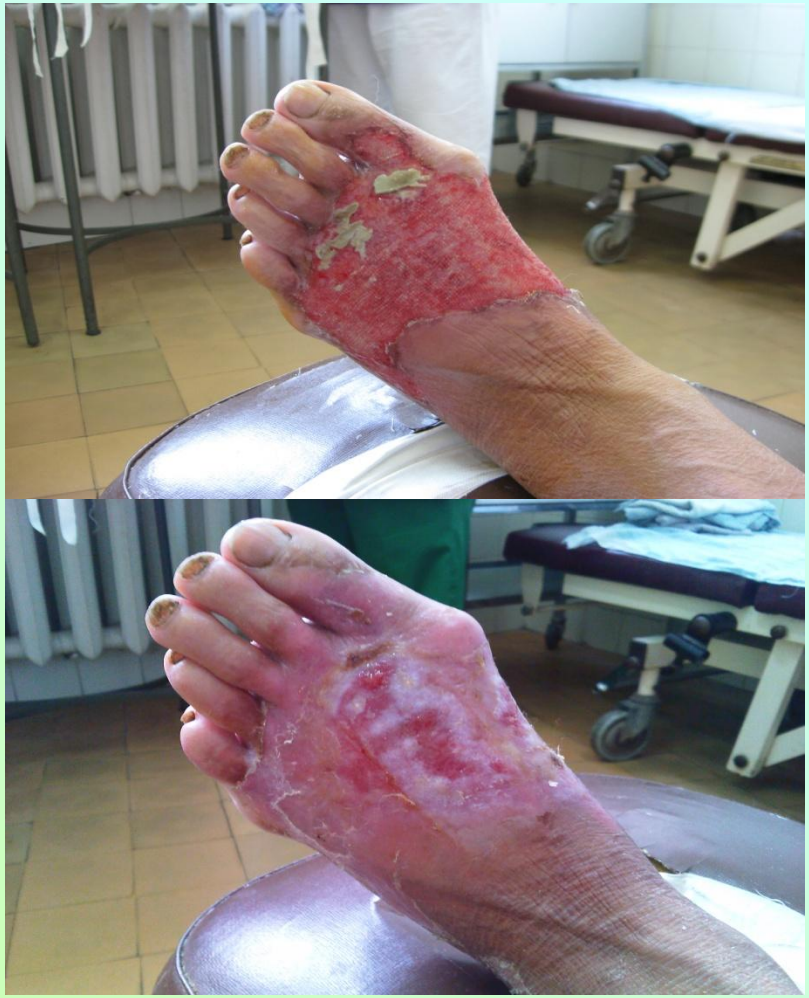




Dehiscent wound and eventration after neoplastic bowel excision – dimension reduction by half at 30 days

Preliminary results

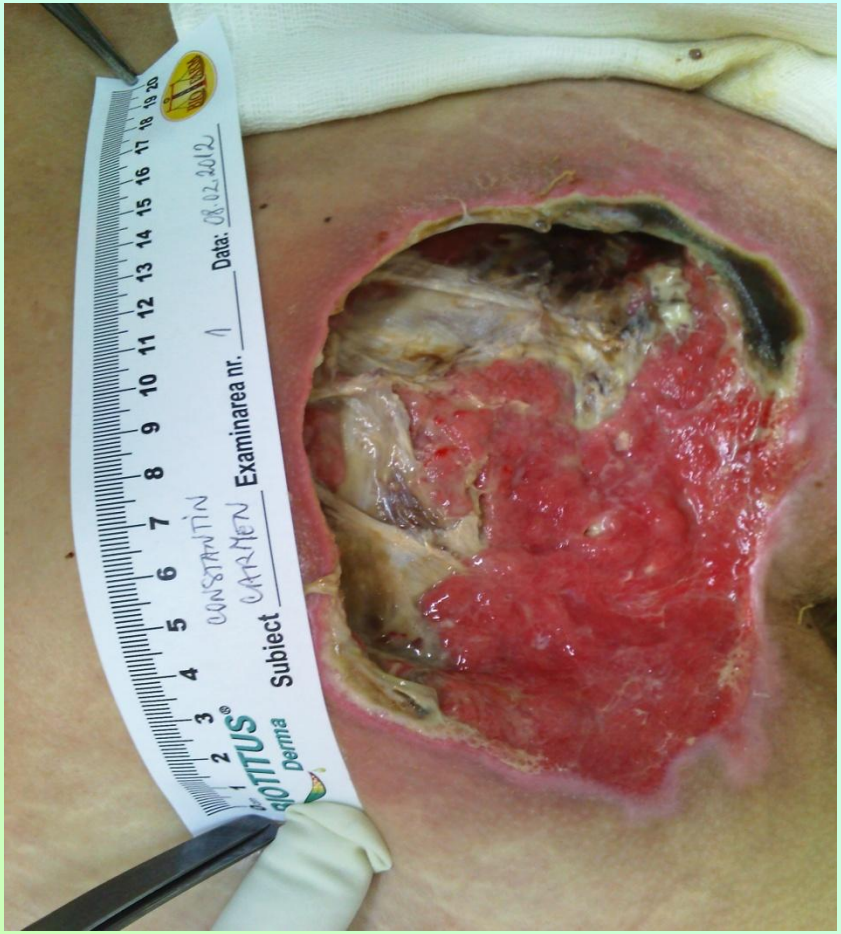
- As of August 2012, we included in the study 46 patients.
- The burns area was reduced by 50% after 7 days of treatment and the complete healing was achieved after 14 – 21 days, with a good quality and stabile epithelium.
- In the case of more profound lesions, after 21 days of daily appliance of **BIOTITUS® Derma** in addition to the marginal epithelization there was a good granulation tissue capable to support a skin graft.
- The medium pain intensity was 2.43



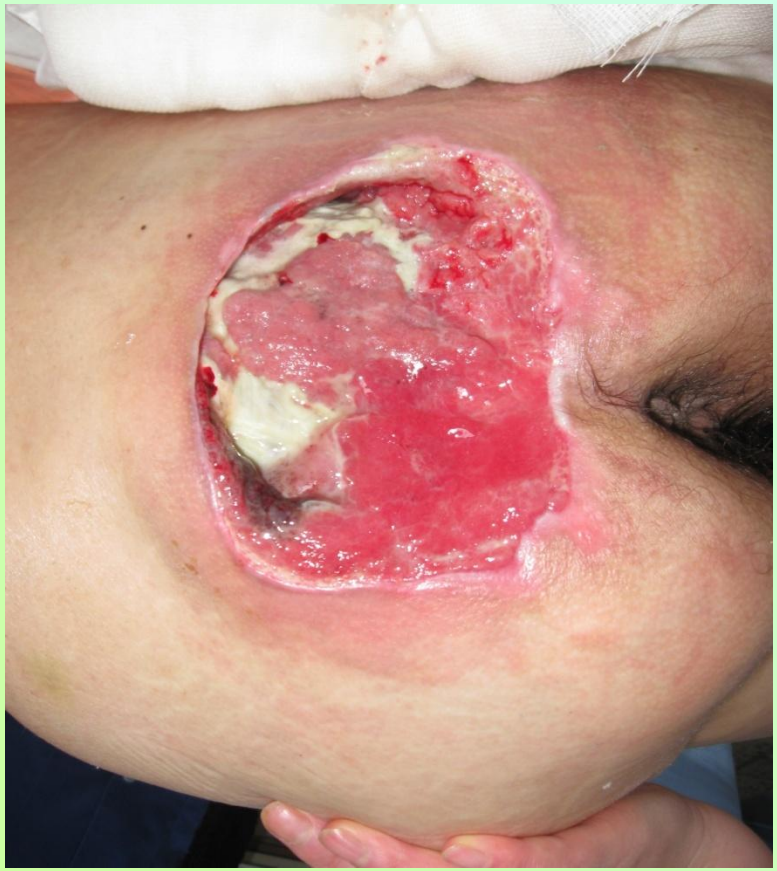
Intermediate burn in the 2nd and 20th day of treatment with Biotitus Derma

Case report

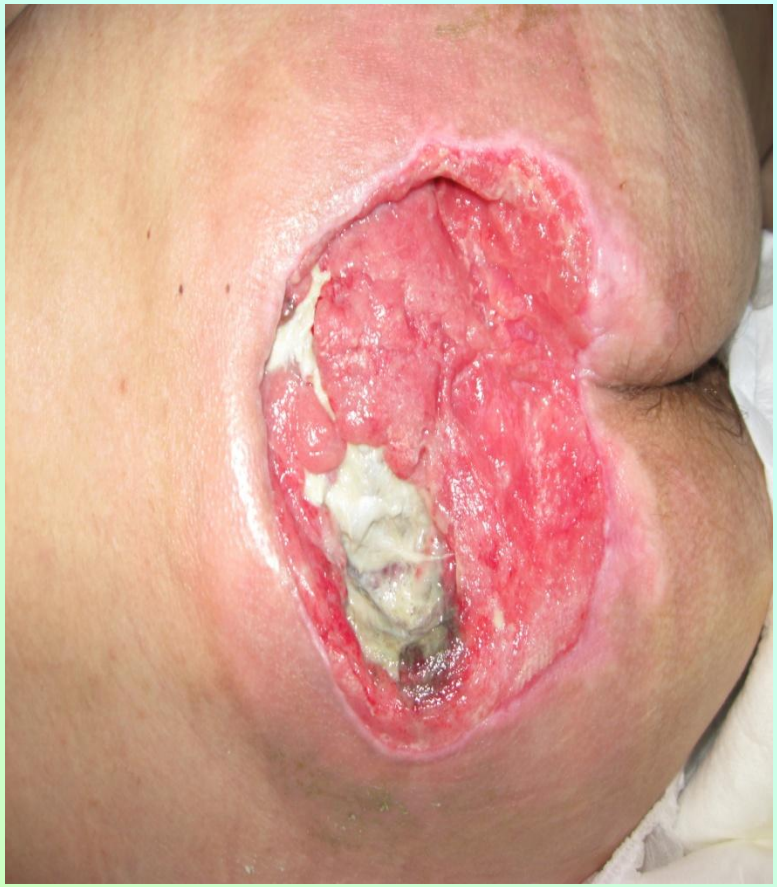
- A 44 years old woman, with multiple sclerosis (2004), spastic paraplegia, bicerebellar syndrome and urinary tract infection
- presents a 60 days old sacral pressure sore, IVth degree, 25/35/3 cm, with fetid necrosis and sacrum exposure
- daily dressing with BIOTITUS® Derma ointment and compresses for 4 months (February – June 2012)
- complete epithelization



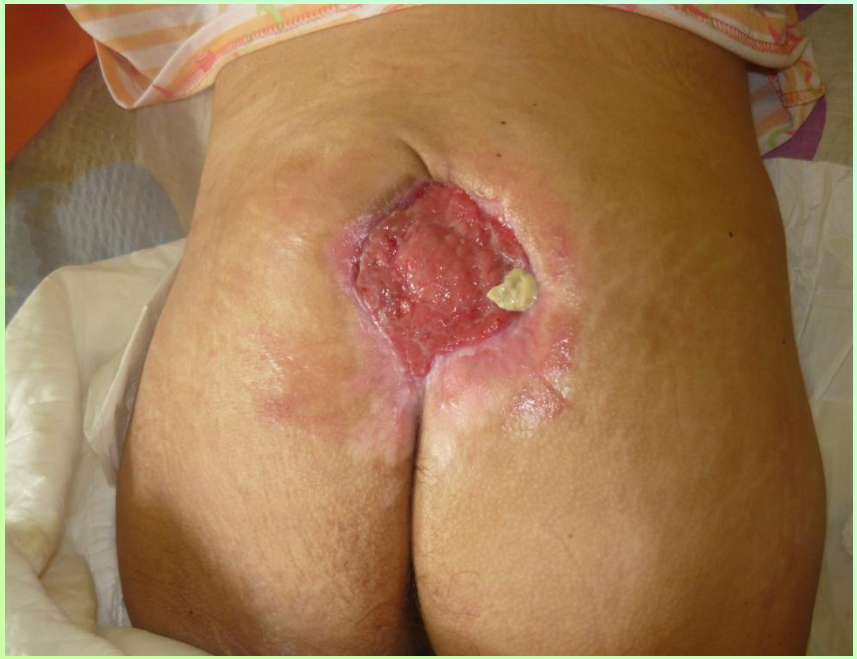
Initial aspect (after surgical debridement)



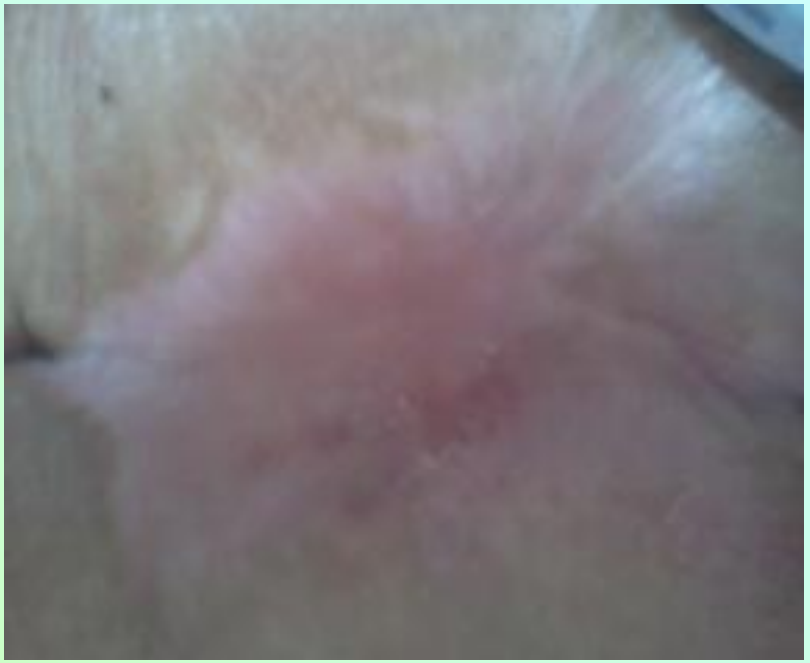
7th day of treatment



16th day of treatment



66th day of treatment



131st day of treatment – complete healing

Facts

- **BIOTITUS® Derma** is easy to apply, non-adherent to wound, with an non traumatically removal
- it triggers the formation of a good quality epithelial tissue
- no significant side effects
- reduces pain thus promoting early motion with good compliance to therapy
- Usually no antibiotics are needed if **BIOTITUS® Derma** – ointment is used
- reduces overall hospitalization costs by reduction of the healing time and material costs.