THE 1ST MICRO TECHNOLOGY THAT ACCELERATES WOUND HEALING

Accelerates healing
Accelerated granulation and epithelization, regardless of wound etiology

Remarkable efficacy
Including in wounds with exposed bones and tendons

Proven long term efficacy and safety
And potential reduction in wound care and hospitalization burdens

1st Active NCM Technology
With efficacy at cellular level, stimulates patient’s cells to restart healing

Praxis Pharmaceutical
**PolyHeal® Micro:**

PolyHeal® Micro is a suspension of polystyrene Negatively Charged Microspheres -NCM’s- in a concentration $4.5 \times 10^6$ microspheres/ml, in 22% Glycerol and water for injection.

**Indications:**

PolyHeal® Micro is indicated for the treatment of ulcers of different etiologies and hard-to-heal, partial and full-thickness wounds such as:

- Ulcers with exposed bones, tendons, ligaments and/or foreign material;
- Venous and arterial leg ulcers, diabetic foot ulcers, pressure ulcers;
- Drainage, post-traumatic and post-surgical wounds;
- Hard-to-heal wounds and other ulcers in co-morbid patients.
Application of NCM’s appears to trigger a synchronised series of events that shift the wound from the inflammatory to the proliferative phase, stimulating patient’s own cells to restart the wound healing process.\(^1\)\(^4\)

**MECHANISM OF ACTION**

NCM’s restart the healing process and accelerate the formation of Granulation tissue and Epithelization\(^4\)\(^7\)

- NCM’s interact with the main cell lines involved in the healing process: macrophages, fibroblasts, endothelial cells and keratinocytes.\(^4\)\(^5\)
- Cellular attachment to NCM’s results in its activation, proliferation and migration.\(^1\)\(^4\)\(^5\)
- NCM’s stimulate collagen synthesis and angiogenesis that results in granulation and epithelization.\(^1\)\(^4\)\(^5\)\(^7\)
- In addition, NCM’s have been shown to adsorb to its surface the excess of MMP’s.\(^1\)\(^6\)\(^8\)

Chronic wound situation without NCM’s: Stagnation of the healing process

Healing wound treated with NCM’s: Restart of the healing process
Treatment with PolyHeal® demonstrated rapid re-epithelialization rates.\textsuperscript{5,7}

**RANDOMIZED CLINICAL TRIAL**

**PATIENTS TREATED WITH NCM’S GOT A 2.5 TIMES HIGHER STATISTICALLY SIGNIFICANT WOUND AREA REDUCTION VS. CONTROL, AT 4 WEEKS**\textsuperscript{4}

![Graph showing relative change in wound surface area (%), by treatment group.](image)

Relative change in wound surface area (%), by treatment group\textsuperscript{4}

- NCM
- Control

-14.8%

-39%

\( p=0.02 \)

**CLINICAL EVIDENCE**

- **39%**
  - **21 OF 54 WOUNDS COMPLETELY CLOSED**
  - by both secondary intention or grafting\textsuperscript{1}

- **=50%**
  - **95-100% REDUCTION IN SIZE**
  - in about half of the wounds after an average of 4.5 weeks of active treatment\textsuperscript{1}
RAPIDLY PRODUCES HEALTHY RED GRANULATION TISSUE

In hard-to-heal wounds, the sudden development of healthy granulation tissue is an indicator measuring the initiation of the healing process.4

RANDOMIZED CLINICAL TRIAL

PATIENTS TREATED WITH NCM’S GOT A 6 TIMES HIGHER PROBABILITY OF MEETING THE PRIMARY ENDPOINT OF ≥ 75% OF LIGHT-RED GRANULATION - LRG - TISSUE AT 4 WEEKS OF TREATMENT (OR= 5.95; P<0.01)4

Almost 2 TIMES FASTER (27 VS. 49 DAYS) reaching the primary end point of ≥ 75% LRG Tissue coverage4

Among the post-trauma/postoperative sub-population, after 4 weeks of treatment, 59% (n=10/17) of patients treated with NCM´s achieved ≥ 75% LRG Tissue vs. 25% (n=3/12) of control patients4
REMARKABLE EFFICACY IN WOUNDS WITH EXPOSED BONES AND TENDONS

Topical application of NCM’s is an effective stimulator of the wound healing process in recalcitrant lesions, especially those with exposed bones and tendons.¹

RANDOMIZED CLINICAL TRIAL

57% of the patients treated with NCM’s compared with ZERO in the control group achieved ≥ 75% of wound coverage by Light-Red Granulation Tissue.⁴

CLINICAL EVIDENCE

ALMOST HALF OF THE WOUNDS (10 OUT OF 22) WITH EXPOSED BONES AND TENDONS ACHIEVED COMPLETE CLOSURE AFTER AN AVERAGE OF 5 WEEKS OF ACTIVE TREATMENT.¹

68% OF PATIENTS – 15 out of 22 actively treated by NCM’s, in average for 5.0 weeks, achieved ≥ 75% of wound coverage by Light-Red Granulation Tissue.¹

COST-EFFECTIVENESS

DECREASE IN HEALTH-CARE COSTS WITH NCM’S VS. SURGERY IN WOUNDS WITH EXPOSED BONES AND TENDONS.⁸

Initial management with NCM’s instead of surgery to treat all new patients is expected to save important surgical theatre time.⁸

<table>
<thead>
<tr>
<th>NCM’s treated patients</th>
<th>Surgically treated patients</th>
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<tbody>
<tr>
<td>need 0.2 surgical procedures per wound</td>
<td>need 1.2 surgical procedures per wound</td>
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</table>
RANDOMIZED CLINICAL TRIAL

- 50% more wounds that remained closed in the NCM’s group
- Less than half - 14.8% vs. 30% respectively - of the incidence of adverse events on the NCM’s Group vs. control

STATISTICALLY SIGNIFICANT REDUCTION OF 85% IN UNPLANNED HOSPITALIZATIONS IN THE NCM’S GROUP VS. AN INCREASE OF 55% IN THE CONTROL GROUP

Statistically significant mean reduction of 25 hospitalization days per patient vs. an increase of 0.91 days in the control group.
1st Active NCM Technology that accelerates healing, including in wounds with exposed bones and tendons[^4]

Easy and rapid topical application in hard-to-dress areas

Efficacy at cellular level, stimulating patient’s own cells to restart wound healing[^1,4]

Rapidly produces healthy red granulation tissue and epithelization rates, regardless of wound etiology[^1,4]

Offers the choice of wound closure by secondary intention or grafting[^4]

Long-term efficacy, safety and a potential reduction in wound care and hospitalization burdens[^9]

**CONTRAINDICATIONS**

- PolyHeal® Micro should not be used:
  - In patients with known sensitivity to the device’s compounds.
  - In severely infected or heavily exuding wounds.
  - In wounds suspected of malignancy.

**PRECAUTIONS**

- PolyHeal® Micro is not for use in heavily infected, profusely exuding and/or necrotic wounds.
- There is limited experience in the use of PolyHeal® Micro in deep-tunneled wounds and wounds connected to body cavities (abdomen, mediastinum and cranial cavities).
- PolyHeal® Micro is for single use only. Reuse could lead to contamination of the wound and infection.
- Do not re-sterilize. PolyHeal® Micro is sterile if the bottle is unopened and undamaged. Discard all opened bottles of PolyHeal® Micro.
- Do not use after the expiry date
- Keep out of reach and sight of children.
- Do not use PolyHeal® Micro in conjunction with ointments, creams, and oily products.
- In case the first few days of treatment with PolyHeal® Micro are accompanied by pain, itching, or skin burning sensation around the wound area, a systemic medication for pain relief can be used (do not apply local or topical medication) without interrupting the treatment with PolyHeal® Micro.
- In case of persistent or aggravated side effects, such as local infection, allergic reaction, excessive redness, pain, itching, skin burning sensation or swelling, the use of PolyHeal® Micro should be interrupted until the patient consults his/her physician.
- Treatment should be stopped if granulation tissue protrudes over the wound’s edges (over-granulation) and the wound may be topically treated to control the over-granulation.

**REFERENCES**


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**Product code**

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