REACTIVATES HEALING
and accelerates the formation of granulation tissue favoring closure

SWITCHES THE WOUND FROM THE INFLAMMATORY
to the proliferative phase, leading to patient’s own cells to reactivate the healing process

REMARKABLE EFFICACY
in exposed bones and tendons including stagnant hard to heal wounds

PROVEN LONG TERM EFFICACY AND SAFETY
Reduction in wound care expenditure and hospitalization burdens

UNIQUE MICROSPHERE TECHNOLOGY THAT REACTIVATES WOUND HEALING
PolyHeal® Micro, a suspension of polystyrene Negatively Charged Microspheres (NCM) in a concentration of \(4.5 \times 10^6\) microspheres/ml, in 22% glycerol and water for injection.

**INDICATIONS**

For the treatment of ulcers of different etiologies and stagnant hard to heal wounds, including those with exposed bones and tendons without infection.

- Diabetic foot ulcers, venous and arterial leg ulcers, pressure ulcers;
- Post-traumatic, post-surgical wounds;
- Other ulcers in co-morbid patients.

**TREATMENT WITH POLYHEAL® MICRO**

Medical Device Class IIB.

1. Before application of PolyHeal® Micro

In a chronic wound situation there is an overall decrease in all components of the Extracellular Matrix. Cells lose their ability to proliferate and, as a consequence, end up in apoptosis.

2. After application of PolyHeal® Micro

NCM provide a passive temporary surface for cell attachment and proliferation. This increases the number of cells in the wound bed, reestablishing the Extracellular Matrix.

**POLYHEAL® MICRO REACTIVATES THE HEALING PROCESS AND ACCELERATES THE FORMATION OF GRANULATION TISSUE FAVORING CLOSURE.**

2 outcomes can be expected after the application of PolyHeal® Micro:

- ** Closure by Epithelialization**
- **Formation of Healthy Red Granulation Tissue**
  (closure by secondary intention or skin graft)
MECHANISM OF ACTION

1. CYTOKINE MODULATION

- After the application of PolyHeal® Micro, the persistent activation of the inflammatory phase is not further maintained due to local cytokine balance reestablishment.4,5

2. ADDITIONAL SURFACE AREA FOR CELL ATTACHMENT

- NCM mimic the functions of native Extracellular Matrix providing an additional surface area for cell attachment, enabling cells to activate the processes aimed at wound healing, such as collagen synthesis and angiogenesis, among others.1,2

3. METALLOPROTEINASES SEQUESTRATION (MMPs)

- When metalloproteinases come into contact with NCM, they can be adsorbed onto their surface favoring tissue regeneration.6,7

AFTER THE APPLICATION OF POLYHEAL® MICRO A SYNCHRONIZED SERIES OF EVENTS ARE TRIGGERED SWITCHING THE WOUND FROM THE INFLAMMATORY TO THE PROLIFERATIVE PHASE, LEADING TO PATIENT’S OWN CELLS TO REACTIVATE THE WOUND HEALING PROCESS.1,6
CLINICAL EVIDENCE

RANDOMIZED CLINICAL TRIAL

47% of patients treated with NCM reached ≥ 75% coverage with LRG tissue compared with 15% in the control group (OR=5.95; P=0.01).

≥ 75% coverage with light-red granulation (LRG) tissue

1.8 times faster (27 vs 49 days) reaching the primary endpoint of ≥ 75% coverage with LRG tissue.¹

EXPOSED BONES AND TENDONS (EB&T)

NCM trigger the wound healing process in recalcitrant lesions, specially those with EB&T.

57% of the EB&T wounds treated with NCM compared with zero in the control group achieved ≥ 75% of coverage with LRG tissue after 4 weeks.¹

¹Double-blind randomized clinical trial. Patients with hard-to-heal wounds, defined as refractory to treatment for at least 4 weeks, or those with exposed bone, tendon or ligament, were eligible for inclusion and were randomized to either NCM or control, both applied for 4 weeks. Fifty-eight patients completed the study.

The primary endpoint was defined as coverage of > 75% of the wound area by light-red granulation tissue after 4 weeks of treatment.
2-YEAR FOLLOW UP

Long term efficacy and safety and reduction in wound care and hospitalization burdens.

NCM GROUP OUTCOMES VS CONTROL

- 50% more wounds remained closed.
- Lower incidence of adverse events (14.8% vs 30% respectively).
- 85% reduction of hospitalizations.
- Reduction of 80% in hospital length of stay (2 days vs 10 days respectively).

*After the RCT, patients were monitored bi-weekly for an additional 8 weeks, while treated with standard wound care, at the investigators’ discretion, and were re-evaluated 2 years after inclusion.

REAL WORLD EVIDENCE

Wound area reduction at 4 weeks in neuropathic and neuroischaemic DFU’s, including ulcers with EB&T.

100% of ulcers achieved complete healing at 12 weeks including those ulcers with EB&T.

EXPOSED BONES AND TENDONS

Wound Surface area reduction in ulcers with EB&T

Percentage of area reduction (PAR) 48%

*Prospective clinical case series of patients with a hard-to-heal DFU treated with NCM. DFUs were treated daily with NCM over four weeks, although the health professional could decide to continue NCM treatment in some patients. Cases were followed up for 12 weeks. NCM treatment was completed in 17 ulcers (16 patients).

Wollina score (granulation, colour and consistency tissue), wound area (cm²), percentage reduction and wound closure (%) were measured.
CASE STUDIES

NEUROISCHEMIC DIABETIC FOOT ULCER  |  55 YEARS / 12 WEEKS DURATION*
Outcome at 8 weeks: Complete epithelialization.

DIABETIC FOOT ULCER  |  56 YEARS / 3 WEEKS DURATION**
Outcome at 4 weeks: Percentage Area Reduction (PAR) > 50% and Healthy LRG tissue ≥75%.

VENOUS LEG ULCER  |  57 YEARS / 8 WEEKS DURATION***
Outcome at 9 weeks: Complete epithelialization.

ISCHEMIC ULCER WITH EXPOSED BONE AND TENDON  |  89 YEARS****
Outcome at 2 weeks: Healthy LRG tissue ≥ 75%.
INSTRUCTIONS FOR USE

WHEN SHOULD POLYHEAL® MICRO BE APPLIED

It is recommended that PolyHeal® Micro is applied on wounds which are debrided and without infection.

PolyHeal® Micro should be used on wounds with moderate to low level of exudate.

STEPS FOR APPLICATION

1 WOUND BED PREPARATION debrided and without infection.

2 APPLY POLYHEAL® MICRO DAILY in drops slowly to the wound surface.

3 COVER WOUND SURFACE with a non-woven gauze.

4 SATURATE THE GAUZE with PolyHeal® Micro.

5 BANDAGE THE WOUND using standard loose dressings.

For further information about the instructions for use, please visit: www.polyhealmicro.com
Unique Microsphere Technology that reactivates healing, including wounds with exposed bones and tendons.6

Easy and rapid topical application in difficult access areas like interdigital or cavitated.9

Can be applied by the own patient or a trained caregiver.9

Demonstrated efficacy leading to patient’s own cells to reactivate the healing process.1,6

Rapidly produces healthy red granulation tissue, regardless of wound etiology.1,6

Offers the choice of wound closure by secondary intention or grafting.1

Proven long-term efficacy and safety.

Reduction in wound care expenditure and hospitalization burdens.3

REFERENCES

*Illustrations provided by Mrs. Teresa Segovia Gómez, Direction Committee GNEAUPP. Spain.
**Illustrations provided by Dr. José Luis Lázaro-Martínez, Diabetic Foot Unit, Universidad Complutense de Madrid. Spain.
****Illustrations provided by Dr. Antonio de la Cuesta, Diabetic Foot Unit. San Lázaro Hospital, Seville. Spain.

This document is addressed to HCPs only.

For further information about Poly Heal Micro, please refer to the electronic Instructions for Use at the following website: www.polyhealmicro.com/docs/instructions_for_use.pdf