

Accelerated Healing. Clinically Confirmed.

# Treatment of Recalcitrant Diabetic Foot Ulcers with MIST Therapy®

*Study Summary*



# Ultrasound Therapy for Recalcitrant Diabetic Foot Ulcers: Results of a Randomized, Double-Blind, Controlled, Multicenter Study

Ennis WJ, Formann P, Mozen N, Massey J, Conner-Kerr T, Meneses P, Mist Ultrasound Diabetic Foot Study Group.  
Ostomy/Wound Management 2005;51(8):24-39

## Study Overview:

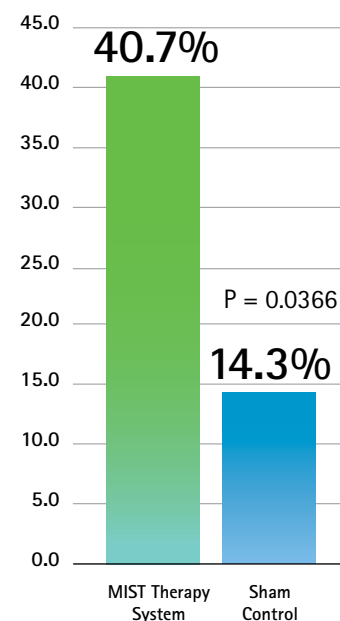
This prospective, randomized, double-blinded, controlled, multicenter study was designed to evaluate the safety and efficacy of the MIST Therapy® system compared to a "sham device" in the healing of recalcitrant diabetic foot ulcers. The study also evaluated the impact on total closure and quantitative bacterial cultures and the effect on healing of various levels of sharp/surgical debridement.

Fifty-five patients met criteria for efficacy analysis. They received standard of care, which included products that provide a moist environment, offloading diabetic shoes and socks, debridement, wound evaluation, and measurement. The therapy applied was either MIST Therapy or a sham device that delivered saline mist without the use of ultrasound.

## Key Findings:

Overall,  
**40.7%**  
of wounds in the Ultrasound  
Therapy Group plus standard of care (SOC)  
**were healed** after  
12 weeks of care compared  
to 14.3% of wounds healed in the Sham  
Group plus SOC. (P = <0.001)

## Significant Wound Closure with MIST Therapy®



## Accelerating the Rate of Healing

MIST Therapy uses low-frequency ultrasound to stimulate cells at and below the wound surface to activate healing. A painless procedure, it is the only noncontact, low-frequency ultrasound device for healing cleared by the FDA.

## Physician Observations

"People with diabetes account for 60% of all amputations performed in the US annually. The results of this double-blinded, randomized, sham-controlled trial demonstrate a positive effect on the healing of diabetic foot ulcers."

— Dr. William J. Ennis,  
Advocate Christ Medical Center,  
Oak Lawn, IL.

Before



After MIST Therapy



## Patients Like Yours?

This study examined diabetic foot ulcers among patients like Samuel, a 67-year-old male with Type I diabetes who does not smoke. He has a chronic diabetic foot ulcer (Wagner grade one) that he has endured for more than 30 days.

Samuel is ambulatory at least 75% of the time and is able to bear weight on his foot.

Samuel's wound was treated with MIST Therapy. It healed faster than the wounds of patients who were treated with the sham device.

Sound Science. Strong Results.

# Painless, Accelerated Healing with MIST Therapy<sup>®</sup>

MIST Therapy is an innovative, noncontact approach to wound healing. The system creates low-frequency ultrasound waves that produce and propel a gentle mist of sterile saline into the wound bed. The saline mist improves the transfer of ultrasound from the device without contact or pain to the patient.

MIST Therapy promotes painless wound healing through:

- Active cell stimulation
- Decreased bioburden
- Increased blood flow
- Cleansing and gentle/maintenance debridement

This study was funded through a grant to the Advocate Christ Medical Center by Celleration, Inc.

Results may vary based on individual patient characteristics.

For more information, contact your local  
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MIST Therapy System FDA Clearance. 510 (k) Clearance June 2005. "The MIST Therapy System produces a low-frequency ultrasound-generated mist used to promote wound healing through wound cleansing and maintenance debridement by the removal of yellow slough, fibrin, tissue, exudates and bacteria."

Please see full package insert for additional information on indications, contraindications, warnings, precautions, and side effects.