



PROVEN HEALING™

Common Predictors of Wound Healing

PARAMETER	DEFINITION ¹	WOUND HEALING POTENTIAL		
		HIGH	MODERATE	MINIMAL
ABI ² (Ankle brachial index)	A noninvasive test that determines the difference (ratio) in blood pressure measurements between the brachial and ankle pressures.	>0.7	0.4 – 0.7	0.1 – 0.3
TcPO ₂ ^{1,3} (mm Hg) (Transcutaneous partial pressure of oxygen)	A noninvasive measurement of oxygen levels at skin level.	>30	20 – 30	<20
Albumin ^{1,4} (mg/dL)	A protein produced by the liver that acts as a building block for cells and tissues.	>2.8	2.1 – 2.7	<2.1
Prealbumin ¹ (mg/dL)	A protein produced by the liver. It has a half-life of 2-3 days; a better indicator than albumin of acute nutritional changes.	10 – 30	5 – 9	<5

Other factors that may impair healing:

Obesity	Radiation therapy
Impaired mobility	Chemotherapy
Diabetes	End-stage renal disease
Edema, particularly in the lower extremity	Renal dialysis
Steroid therapy	Immunosuppression
Malignancy in the wound bed	Biliary or fecal fistulas leading to wound
Terminal cancer	

¹ Hess CT, *Wound Care, Clinical Guide, 5th ed.*, Lippencott Williams & Wilkins; 2005.

² Steed DL, *Diabetic Wounds: Assessment, Classification and Management*. In: Krasner DL, Rodeheaver GT, Sibbold RG, *Chronic Wound Care: A Clinical Source Book for Healthcare Professionals, 3rd ed*, HMP Communications; 2001.

³ Siegel A, *Noninvasive Vascular Testing*. In: Sussman C, Bates-Jensen BM, *Wound Care: A Collaborative Practice Manual for Physical Therapists and Nurses*, Gaithersburg, MD: Aspen Publisher; 1998.

⁴ Zagoran AJ, *Nutritional Assessment and Intervention in the Person with a Chronic Wound*. In: Krasner DL, Rodeheaver GT, Sibbold RG, *Chronic Wound Care: A Clinical Source Book for Healthcare Professionals, 3rd ed*, HMP Communications; 2001.



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MIST Therapy® System Treatment Guidelines

Bioactive Therapy | Cellular Stimulation | Reduction of Bacteria | Painless Ultrasound

Rationale

- MIST Therapy is a healing device for wounds.
- A bioactive therapy that promotes healing through cell stimulation while reducing bacteria.
- A painless non-contact ultrasound device for modern wound care.

Indications for Use

The MIST Therapy System produces a low energy 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.

Contraindications

Do not use near electronic implants/prosthesis (e.g., near or over the heart or over the thoracic area if the patient is using a cardiac pacemaker); on the lower back during pregnancy or over the pregnant uterus; over area of malignancies.

Precautions

Treatment requires an order by a physician or licensed practitioner. Only personnel trained on its use should perform MIST Therapy System treatment and it should be used only as directed.

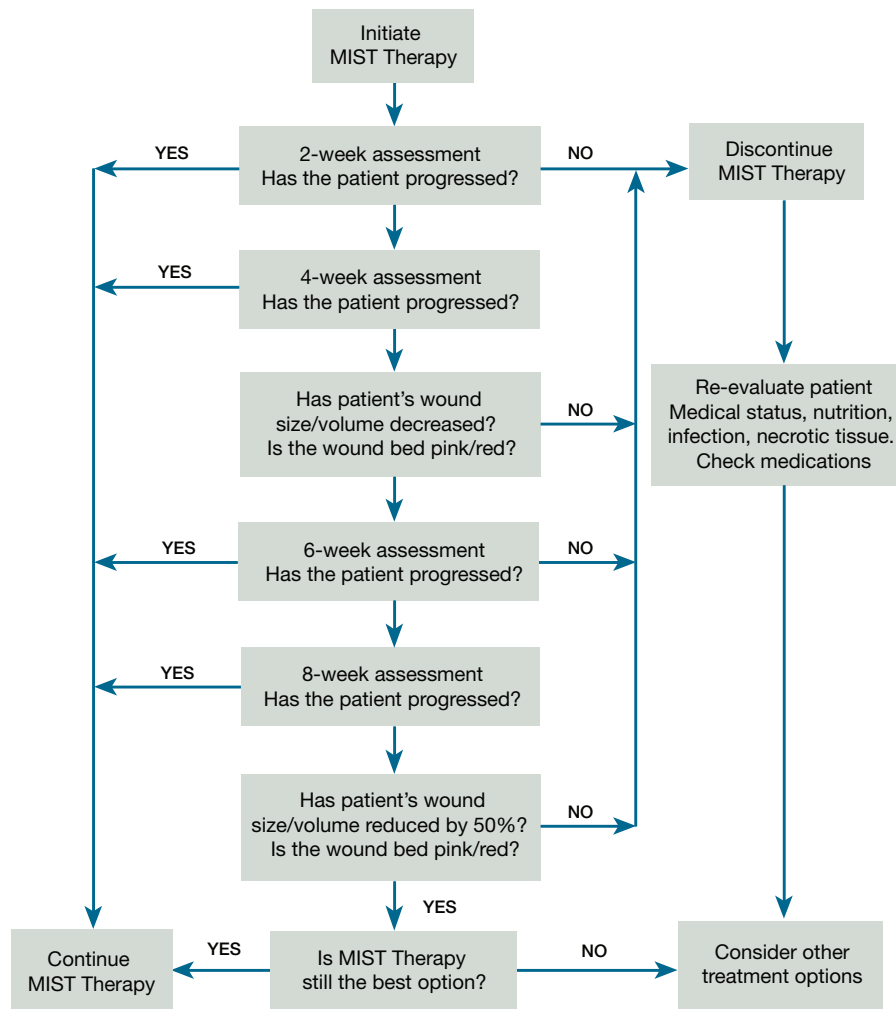
Treatment effectiveness will be diminished if:

- The Applicator is not fully engaged, aligned and securely attached to the Transducer and Saline has not been turned on with mist being produced within five (5) seconds of Ultrasound Control Button activation.
- The distance between the Leading Edge of the Applicator and the wound is greater than 1.5cm (0.6 inches).
- The Treatment Head is not held perpendicular to the wound.
- The Celleration MIST Therapy Saline has been contaminated.

If fluid is leaking around the applicator, turn power off and refer to the Trouble-Shooting section of the IFU.

Do not touch the inside surfaces of the applicator, and specifically the barb, as injury may occur.

Treatment Guidelines Flow Chart



The MIST Therapy System FDA clearance is not wound specific and may be used on the following major wound types:

- | | | |
|----------------------|-----------------------------|--------------------|
| Acute Wounds | Arterial Ulcers | Sickle Cell Ulcers |
| Chronic Wounds | Venous Insufficiency Ulcers | Colonized Wounds |
| Dehisced Wounds | Pressure Ulcers | Burns |
| Diabetic Foot Ulcers | | |



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