

# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

## Medical technologies guidance

### SCOPE

#### The MIST Therapy system for the promotion of wound healing in chronic and acute wounds.

## 1 Technology

### 1.1 *Description of the technology and claimed advantages*

The MIST Therapy system aims to promote wound healing in chronic, “hard to heal” and acute wounds by delivering low energy, low intensity ultrasound to the wound bed via a continuous saline mist. The mist generated has a relatively uniform droplet size and is intended to act as a conduit for transmitting ultrasonic energy to the treatment site, supporting energy transfer to a beneficial depth to reduce bioburden and stimulate cells.

Wound healing involves three phases: inflammation, proliferation and remodelling. In non-healing wounds, progression through the three phases is impeded and standard wound care becomes ineffective. The MIST Therapy system is claimed to address these barriers to wound healing by stimulating the healing environment, actively treating the wound bed and accelerating the healing process. The MIST Therapy device is also claimed to promote wound healing through wound cleansing and maintenance debridement by the removal of yellow slough, fibrin tissue, exudate and bacteria.

The evidence provided suggests that MIST Therapy:

- has an anti-inflammatory effect in wounds with chronic inflammation.
- stimulates the production of chemical mediators which activate fibroblasts resulting in early release of growth factors.
- increases deposition of blood vessels providing a stronger more natural collagen in granulation tissue.
- decreases bioburden through mechanical stress, including Methicillin-Resistant *Staphylococcus aureus* (MRSA), Vancomycin-Resistant *Enterococcus* (VRE) and *Pseudomonas* species .
- increases blood flow.
- bathes and cleanses the wound painlessly.

The non-contact MIST Therapy device comprises a generator with user-friendly controls, a transporter head to transport energy, a single use applicator and a sterile saline bottle. After the wound surface area is selected on the MIST Therapy device, the appropriate treatment time is automatically determined. Once the applicator and saline bottle are attached, treatment commences. A continuous mist is delivered across the wound bed via slow even strokes. The distance between the applicator and the wound bed is 0.5cm to 1.5cm. An audible and visual bubbling may occur until the treatment is complete and the generator switches off automatically.

The MIST Therapy device is claimed to reduce bioburden and increase the closure of wounds by 40-70% within 6-12 weeks through accelerating the wound healing process. This could reduce the use of silver dressings and topical antibiotics and as a result, decrease the high treatment burden and the risk of silver or antibiotic resistance for the patient. It is also claimed that the use of the MIST Therapy device to treat wounds is painless for the patient and does not increase the risk of exposure to hazardous bacteria aerosols for the clinician or patient. The recurrence rate of ulcers following treatment with the MIST Therapy system is claimed to be minimal.

The MIST Therapy system can be used for many indications including burns, pressure ulcers, leg ulcers, diabetic foot ulcers and surgical wounds in addition to potentially being used as a wound bed preparation tool to increase the likelihood of success using biologics rather than multiple applications of an artificial skin substitute. It is also claimed that the MIST Therapy device promotes wound healing and reduces treatment time when it is used in isolation and in conjunction with Negative Pressure Wound Therapy.

The advantages to the health system claimed by the manufacturer are reductions in treatment time and associated costs including hospital stay, nursing time, cost of wound dressings, surgical intervention and other wound care technologies.

The MIST Therapy device claims to be safe, portable, easy to use and suitable to be utilised in both in-patient and out-patient clinics. Most treatments with the MIST Therapy device take 5-7 minutes to complete and are performed when the wound dressings are changed three times a week, ensuring convenient treatment sessions within normal clinical appointment times.

Owing to the claimed healing rates achieved using the MIST Therapy device, the use of silver dressings and topic antibiotics may be reduced resulting in a decrease in the high treatment burden and a reduced risk of the development of silver or antibiotic resistance within the NHS. When yellow slough is present in wounds, MIST Therapy may also provide an alternative to expensive hydrosurgery systems to cleanse the wound and facilitate healing.

## **1.2      *Relevant diseases and conditions***

MIST Therapy system is indicated for chronic and “hard to heal” wounds including diabetic foot ulcers, arterial ulcers, pressure ulcers and venous ulcers. It is also indicated for acute wounds including traumatic wounds, post-surgical wounds and burns. New studies suggest the use of MIST therapy in deep tissue repair enables tissue damage from pressure to be addressed before the wound actually occurs.

Between 1.5 and 3.0/1000 people have active leg ulcers. Prevalence increases with age to about 20/1000 in people aged over 80 years. Most leg ulcers are secondary to venous disease; other causes include arterial insufficiency, diabetes and rheumatoid arthritis. The annual cost to the NHS has been estimated at £300 million. This does not include the loss of productivity due to illness. The prevalence of venous leg ulcers is estimated to be 150,000 in the UK with 28% of ulcers remaining open for more than 2 years.

The prevalence of diabetic foot ulcers is estimated to be 84,000 in the UK annually and 5,000 diabetic patients undergo amputation annually.

The prevalence of pressure ulcers is estimated to be 412,000 in the UK annually, 24% of which are grade 3 or 4 ulcers.

## **1.3      *Regulatory status***

The British Standards Institution has certified that the Celleration MIST Therapy system indicated for the promotion of wound healing meets the relevant quality assurance system for CE marking (CE 512325).

## **2            *Reasons for developing guidance on the MIST Therapy System***

The Committee recognised that wound care represents a major burden to the NHS and that chronic, “hard to heal” and acute wounds can significantly impact the quality of life of patients. The MIST Therapy system could offer a cost-saving and effective treatment for patients with chronic, “hard to heal” and acute wounds.

The Committee asked if the MIST Therapy system could be practically used in the home and how easy the device is to clean. They also requested more information on the risk of exposing the clinician and patient to aerosols of harmful bacteria, and the risk of spreading bacteria to the surrounding area by using the MIST Therapy device.

Currently, a variety of advanced wound dressings are used to create the optimum wound healing environment for different types of wounds. The main comparators for the MIST Therapy system are advanced wound dressings: alginate, capillary action, charcoal, film, foam, honey, hydrocolloid, hydrocolloid fibrous, hydrogel sheets, iodine, low/non-adherent wound contact layer, silicone and silver and compression bandaging.

The clinical outcomes associated with the MIST Therapy system should include rate of healing, wound size, wound volume, wound area, treatment time, wound closure, time to heal, pain score and bioburden.

The MIST Therapy system is an adjunct to advanced wound dressings and therefore, current care pathways are unlikely to be impacted.

### 3 Statement of the decision problem

	<b>Final scope issued by NICE</b>
Population	Patients with chronic, “hard to heal” and acute wounds.
Intervention	MIST Therapy system
Comparator(s)	Advanced wound dressings: alginate, capillary action, charcoal, film, foam, honey, hydrocolloid, hydrocolloid fibrous, hydrogel sheets, iodine, low/non-adherent wound contact layer, silicone and silver. Any other wound care interventions including Negative Pressure Wound Therapy and combinations of treatments with MIST Therapy.
Outcomes	Outcome measures include rate of healing, wound size, wound volume, wound area, treatment time, wound closure, time to heal, pain score, quality of life, recurrence and bioburden. Adverse events and safety related complications.
Cost analysis	Comparative cost analysis of the MIST Therapy system and the most relevant UK comparator: Venous and arterial ulcers – compression bandaging Other chronic and “hard to heal” wounds – foam dressings Acute wounds – surgical debridement  The cost analysis should consider the price of the technology including capital costs, debridement costs, consumables, staff, running and maintenance costs, length of treatment and time to heal. The costs associated with complications, adverse events and recurrence relating to the use of the device and the comparator should be considered.  Sensitivity analysis should be used to address all parameter and model uncertainties including time to heal and recurrence. This should also include assessment of impact of the price differential between advanced wound dressings and the MIST Therapy system.
Subgroups to be considered	None
Special considerations, including issues related to equity or equality	N/A

## **4 Additional Technical Considerations**

The purpose of requesting additional technical information is to assess if the MIST Therapy system can be practically used in the home and how easy the device is to clean. It is also to determine if there is a risk of exposing the clinician and patient to aerosols of harmful bacteria, and of spreading bacteria to the surrounding area by using the MIST Therapy device.

The technical report should explain any risks of contamination for patients and clinicians when using MIST Therapy and discuss and provide evidence of the preventative measures that should be implemented to reduce this risk. Evaluate all published and unpublished evidence relating to the risk of exposure to hazardous bacteria aerosols for the clinician or patient and the surrounding environment when using MIST Therapy and explain the cleaning protocol for the MIST Therapy device.

## **5 External organisations**

### **5.1 *Professional organisations***

#### **5.1.1 Specialist societies contacted for expert advice**

Royal College of General Practitioners

Foot in Diabetes UK

Royal College of Nursing

#### **5.1.2 Societies or organisations for consultation**

### **5.2 *Patient organisations***

NICE's Patient and Public Involvement Programme contacted the following organisations for patient commentary:

British Skin Foundation

Changing Faces

Counsel and Care

CritPaL – Patient Liaison Committee of the Intensive Care Society

Diabetes UK

ICU Steps

Let's Face It

MRSA Action UK

National Concern for Healthcare Infection (NCHI)

Royal College of Surgeons Patient Liaison Group

Skin Care Campaign

The Patients Association