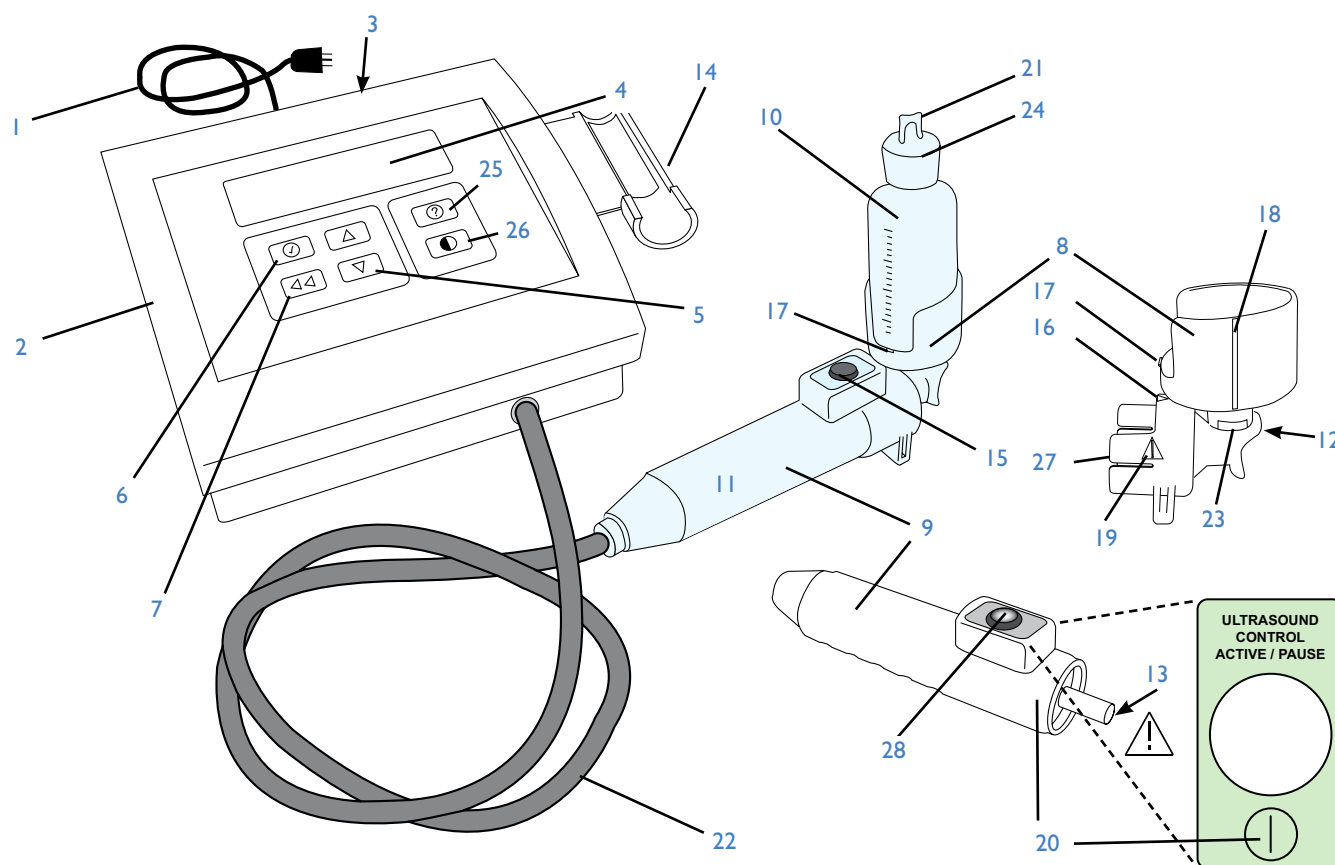


Instructions for Use



PLEASE READ INSTRUCTIONS BEFORE USE. This medical device is to be used only when prescribed by a physician or licensed practitioner and operated by trained personnel in accordance with the instructions for use.



- 1 Generator Power Cord
- 2 Generator
- 3 Power Switch (Back of Generator)
- 4 Generator Screen
- 5 Scroll Button
- 6 Select Button
- 7 Back Select Button
- 8 Applicator
- 9 Transducer
- 10 Celleration MIST Therapy Saline Bottle

- 11 Treatment Wand (Transducer and Applicator Assembly) *shaded in blue*
- 12 Leading Edge of Applicator
- 13 Transducer Tip
- 14 Transducer Cradle
- 15 Ultrasound Control Button
- 16 On/Off Indicator Arrow
- 17 "Off" Indicator Arrow
- 18 "On" Indicator Arrow
- 19 Symbol for "See Accompanying Documents"

- 20 Symbol for "Momentary Contact"
- 21 Saline Bottle Vent Tab
- 22 Transducer Cable
- 23 Saline Flow ON/OFF Indicator
- 24 Removable Saline Bottle Cap
- 25 HELP Button
- 26 CONTRAST Button
- 27 Applicator Single-Use Indicator Flag
- 28 Indicator Light in Ultrasound Control Button

DESCRIPTION & INDICATIONS FOR USE

Description: The MIST Therapy System uses ultrasound technology to atomize saline and deliver it as a continuous mist to the treatment site. The mist generated has a relatively uniform droplet size that acts as a conduit for transmitting ultrasonic energy to the treatment site.

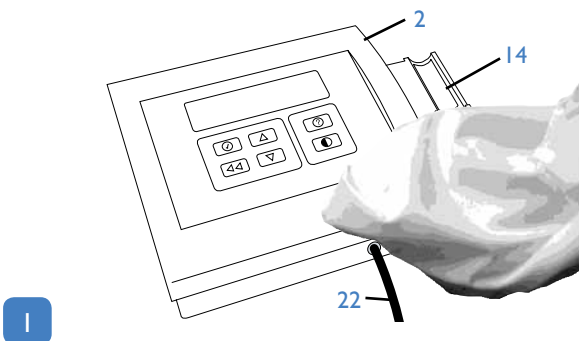
Indications for Use: The MIST Therapy System produces a low energy ultrasound-generated mist used to promote wound healing through wound cleansing and maintenance debridement by the removal of fibrin, yellow slough, tissue exudates and bacteria.

PREPARING THE PATIENT FOR TREATMENT WITH THE MIST THERAPY® SYSTEM

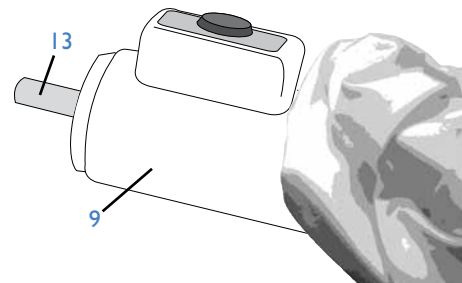
- Depending on the wound location, position the patient in a comfortable position for treatment.
- Remove soiled dressings and discard all contaminated materials (gloves, dressings, pads) prior to MIST Therapy treatment.
- Use appropriate Infection Control Procedures throughout the treatment session.
- Treatment with the MIST Therapy System will require a clean environment. Clean the transducer (9) with the provided germicidal wipes prior to and after use.
- Place an absorbent pad under the portion of the patient being treated to collect the saline runoff.
- MIST Therapy applicators are approved for single patient use only. Do not reuse applicators.

CLEANING THE MIST THERAPY SYSTEM

Clean the Mist Therapy System prior to and after each treatment session with the Power Button (3) in the “off” position.



1 Prior to treatment use the first germicidal wipe to clean the system. First, wipe the generator (2) and cradle (14). Then wipe the transducer cable (22), transducer handle (9), and then proceed to wipe the transducer tip (13). Do not sterilize the treatment head (11) with steam, ETO, or cold sterilants.



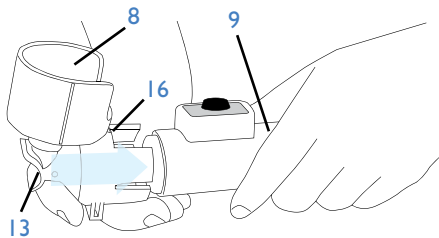
2 After completion of the MIST Therapy treatment, discard the single-use disposable applicator and use the second germicidal wipe provided to repeat the cleaning process as described in step one.

CAUTION: Celleration Mist Therapy Saline Bottle (10) and Applicator (8) are designed as single patient-use disposable units to avoid contamination. Do not re-sterilize or reuse applicators. Re-using the applicator may result in infection and degraded performance.

PREPARING THE MIST THERAPY SYSTEM

1

Plug the Generator Power Cord (1) into an electrical outlet.



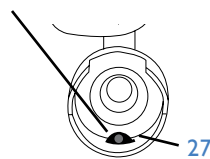
2

Remove the Applicator (8) from its package and press the Applicator (8) onto the Transducer (9) in one continuous motion, insuring the metal tip (13) is in the center of the Applicator (8). You should feel a click as the Applicator (8) is properly seated onto the Transducer (9).

Note: When placing the applicator onto the transducer, make sure the On/Off Indicator Arrow (16) and the "Off" Indicator Mark (17) are aligned, to ensure that saline does not flow when bottle is inserted in step 3.

Note: Do not remove the applicator until the treatment has been completed. The applicator has an integrated mechanical locking mechanism that prevents reuse or re-engagement to the transducer once removed.

Locking mechanism is in the "locked" position and can not be reused.

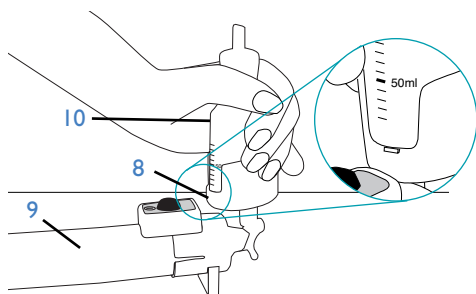


3

Place the Celleration Mist Therapy Saline Bottle (10) upright into the Applicator (8), using the Applicator walls as guidance. The "cup" opening and gradations on the bottle should be facing the Transducer (9).

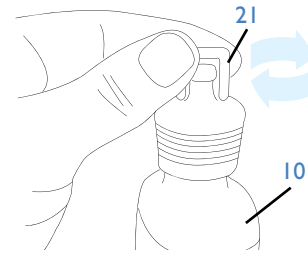
Engage the Celleration Mist Therapy Saline Bottle (10) using one forceful, downward thrust into the Applicator (8) to puncture the Celleration Mist Therapy Saline Bottle (10).

The Applicator (8) is designed as a disposable unit to avoid contamination risk. Do not remove the Celleration Mist Therapy Saline Bottle (10) once engaged.



4

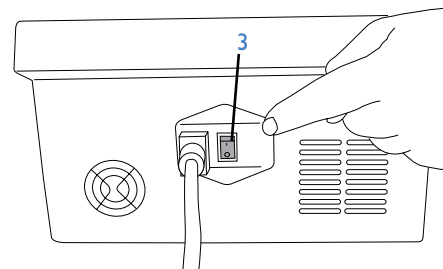
Hold the saline bottle and cup firmly in one hand and gently twist off the Vent Tab (21) from the Celleration Mist Therapy Saline Bottle (10) by grasping the Vent Tab (21) and turning. Discard the Vent Tab. This will create a vent in the Celleration Mist Therapy Saline Bottle (10). Be sure not to turn the bottle and portion of the Applicator (8) holding the bottle at this time.



5

Turn the Generator (2) "on" using the Power Switch (3) on the back of the Generator (2).

Warning: Do not touch the Transducer Tip (13) at any time while the power is on.

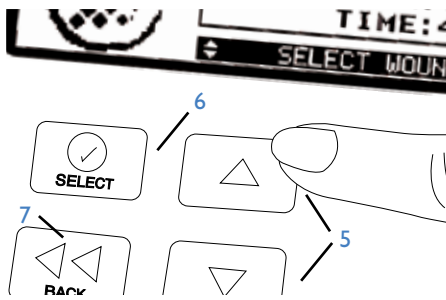


6

Once "on", you will hear 3 short tones as the Generator (2) performs a system check (approximately 5 seconds). If the screen (4) does not respond and remains dark, see Trouble-Shooting. When the Generator Screen (4) reads "Select Wound Size", you are ready to continue the setup process.



PREPARING THE MIST THERAPY SYSTEM CONTINUED



7

Choose the wound size (cm²) by moving the Arrow Buttons (5) on the Generator (2) unit up or down. The corresponding treatment time for a given wound size will appear as well.

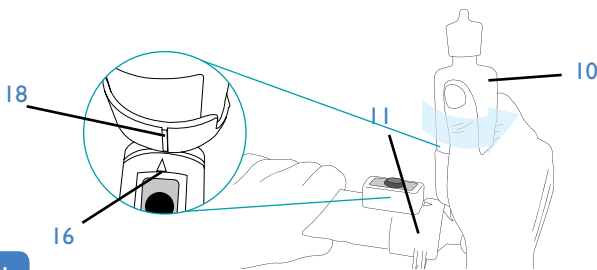
Press Select Button (6) to lock in the correct treatment time. If the incorrect time is entered, use the Back Select Button (7) to alter the treatment time by using the Arrow Buttons (5) and then, pressing the Select Button (6).

Treatment times greater than saline bottle can provide

When treating wounds with areas of greater than 30 cm² on the same patient, it will be necessary to refill the saline bottle approximately every five minutes or as required to fulfill a treatment.

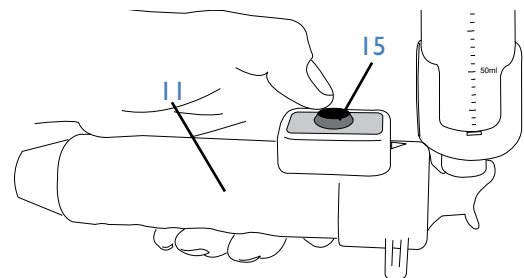
To refill, remove the cap (24) (the cap is scored for easy removal at the neck of the bottle) from the initial saline bottle that is already seated in the applicator assembly. If you know that you will be refilling for longer treatment times it is recommended that the cap be removed before starting the initial treatment. Refill the saline bottle using sterile 0.9% sodium chloride solution (Normal Saline). Multiple wounds on the same patient can be treated by refilling the saline bottle (10). Follow your local infection control procedures. Do not reuse applicator between patients or retain for future patient use. When treatment of a patient is complete, remove the applicator and discard.

TREATING THE PATIENT WITH MIST THERAPY SYSTEM



1

To initiate saline flow, turn Celleration Mist Therapy[®] Saline Bottle (10) and Applicator (8) in a counter clockwise motion until the "On" Indicator (18) on the applicator is aligned with the On/Off Arrow on the applicator (16). Allow the saline to flow through the applicator for 3-5 seconds. Do not let saline flow any longer than that or the saline will build up within the Applicator (8) and create an inconsistent therapeutic mist.



2

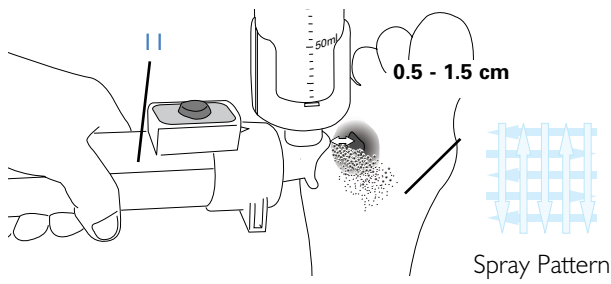
The Treatment Wand (11) should be held so that it is perpendicular to the wound with the Leading Edge of Applicator (12) approximately 0.5 to 1.5 cm (0.2 - 0.6 inches) from the wound. You are now ready to begin treatment.

Depress and release the Control Button (15) at the top of the Treatment Wand (11). Indicator Light (28) will be flashing green.

Note: You may pause treatment by pushing the Control Button (15) and rotating the saline bottle to the off position. Now Indicator Light is solid green.

Warning: Never activate the transducer (11) without applicator (8) in place.

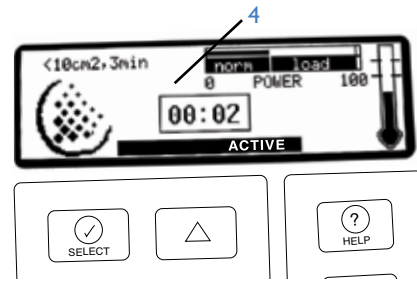
TREATING THE PATIENT WITH MIST THERAPY SYSTEM CONTINUED



3

The Mist Therapy System will begin to deliver a continuous mist. Move the Treatment Wand (11) vertically across the wound using multiple passes. Follow this by moving the Treatment Wand (11) horizontally across the wound using multiple passes. The Treatment Wand (11) should be moved in front of the wound using slow, even strokes and should not be waved in a swinging fashion. The distance between the Treatment Wand and wound can be varied as well between the 0.5 to 1.5 cm (0.2 - 0.6 inches) during treatment. Audible and visual bubbling may occur. This is normal when moving back and forth through the recommended treatment range. For best results, the Treatment Wand should be perpendicular to the wound and parallel to the floor during treatment.

Note: It is important to maintain a 0.5 to 1.5 cm (0.2 - 0.6 inches) distance from the leading edge of the applicator (12) to the wound at all times to maximize therapeutic effect.

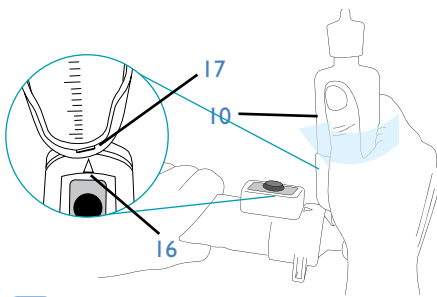


4

Continue treatment (ACTIVE) until you hear 3 audible tones and the Generator Screen (4) returns to the Select Treatment Time mode.

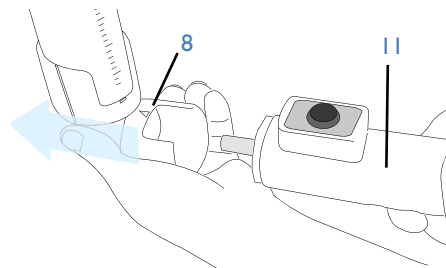
Once the treatment is completed, the transducer (11) will automatically deactivate, insuring accurate treatment time for the wound size selected.

TREATMENT CONCLUSION



1

Rotate the Celleration Mist Therapy Saline Bottle (10) in a clockwise direction to stop the flow of saline. There may be saline remaining in the bottle. This is normal depending upon the size of the wound selected.



2

With the system power off, remove the Applicator (8) from the Treatment Wand (11). Place the Transducer (9) into the Transducer Cradle (14) and discard the Applicator (8) appropriately.

TROUBLESHOOTING

PROBLEM	CAUSES	SOLUTIONS
SYSTEM WILL NOT TURN ON OR PROGRESS THROUGH THE SELF TEST TO "SELECT WOUND SIZE" MODE	System not plugged in and/or Power Cord not properly seated in the Generator outlet on back on instrument	Ensure Power Cord is plugged in and properly seated with one end attached to the Generator and the other end to the power outlet
	Power is not being delivered to outlet	After power is delivered to outlet, turn system on
	Ensure system is turned on	Toggle Power Switch located on back of system
	Fuse is out on system	Call Celleration Technical Service at 1-866-307-6478
BACK BUTTON IS NOT ALLOWING USER TO RETURN TO PREVIOUS SCREEN	System software error	Shut down system by turning off power and then restart
SALINE IS NOT COMING OUT OF APPLICATOR	Treatment time was not selected	Ensure treatment time was selected by pressing Select Button
	Saline bottle is not fully seated in applicator	Firmly push saline bottle into applicator cup holder without subsequent lifting
	Saline bottle is not vented	Completely remove vent tab off saline bottle to vent saline to ensure consistent saline flow
	Saline is not turned "on"	Rotate saline bottle and holder 90° in a counter-clockwise fashion
	Transducer tip is not properly aligned in center of Applicator	Ensure the Applicator is positioned correctly with pins seated all the way forward in Applicator slide openings and Transducer tip located in center of Applicator opening
	Control Button not pressed for treatment to begin	Ensure system power is on and Control button has been engaged by pressing and releasing Control Button
SALINE LEAKING AROUND APPLICATOR	Transducer tip is not properly aligned in center of Applicator	Ensure the Applicator is positioned correctly with pins seated all the way forward in Applicator slide openings and Transducer tip located in center of Applicator opening
	Saline bottle is not properly vented	Completely remove vent tab off saline bottle to vent saline to ensure consistent saline flow
	Saline bottle is not fully seated in applicator	Firmly push saline bottle into applicator cup holder without subsequent lifting
	Saline bottle was lifted or shifted to enlarge hole size and cause excess drainage	Replace Applicator and insert new Saline bottle with forceful downward thrust without subsequent lifting of the saline bottle
	The Treatment Wand was not perpendicular to the wound and parallel to the floor during treatment causing saline to leak out of Applicator	Align the Treatment Wand so it is positioned properly or reposition the patient
	Lengthy wait time between set up and beginning of treatment and/or saline was turned in "on" position for more than 5 seconds prior to beginning treatment causing saline to accumulate in the applicator	Ultrasound will still be delivered to the wound area if treatment is continued. Alternatively, replace Applicator and insert new Saline bottle.
	Saline was not turned "off" while treatment was paused, causing saline to accumulate in the applicator	Ultrasound will still be delivered to the wound area if treatment is resumed. Alternatively, replace Applicator and insert new Saline bottle.

PROBLEM	CAUSES	SOLUTIONS
SYSTEM OVERHEAT ALARM	Multiple wounds on a patient caused treatment times to be longer than 20 minutes.	20 minutes is the expected minimum treatment time after periods of system inactivity. If the system has been running constantly: <ul style="list-style-type: none"> • Waiting 10 minutes in between treatments will allow the MIST system to run 15-20 minutes before experiencing the Overheat Alarm. • Waiting 5 minutes in between treatments will allow the MIST system to run 10-15 minutes before experiencing the Overheat Alarm. The System alarm for overheating indicates that the ultrasound is being turned off as a preventative measure and does not indicate a malfunction of the system.
	Multiple MIST treatments have been completed one after another	
	The MIST system was sitting in a hot room or car (outside operating temperature range) prior to beginning treatment	
SYSTEM AUDIBLE TONES ARE UNUSUAL	Fan blades may be obstructed	Clear obstruction or move system to another area
	System software error	Shut down system and restart
SYSTEM SHOWS ALARM WARNING	System software error and system shows "Paused by Alarm"	<ul style="list-style-type: none"> • Alarm condition: "FREQLIP"; Turn Power Button off and restart system. Call Customer Service if alarm condition continues. • Alarm condition: "OVERHEAT"; Turn Power Button off for at least five minutes and restart Generator. Call Customer Service if alarm condition exists after 10 minutes of non-use. • Alarm condition: "HI OUT"; Turn off Power Button and restart after five minutes. Call Customer Service if alarm condition continues. • Alarm condition: "COMMFALL"; Turn off Power Button and restart Generator. Call Customer Service if alarm condition continues. • Alarm condition: "LOW OUT"; Turn Power Button off and restart Generator. Call Customer Service if alarm condition continues. • Alarm condition: "HV CNTL"; Turn Power Button off and restart Generator. Call Customer Service if alarm condition continues.
UNABLE TO FULLY ENGAGE APPLICATOR ONTO TRANSDUCER	Applicator has already been used	Replace with new Applicator
	Applicator was adjusted or removed during set-up, causing single use flag to activate	

CAUTIONS/ATTENTION

Caution: Federal Law restricts this device to the sale by, or on order of, a physician or other practitioner licensed in the state in which said person practices.

Attention : *La législation fédérale (É.-U.) limite la vente de ce dispositif à un médecin ou à la prescription d'un médecin ou d'un autre praticien diplômé dans l'état où il exerce.*

Caution: Risk of electric shock - Do not remove cover or loosen cable connections. Refer servicing to qualified service personnel.

Attention : *Risque d'électrocution – Ne pas retirer le capot ni desserrer les branchements de câbles. Confier l'entretien à un personnel technique qualifié.*

Caution: Do not use if transducer or cables show evidence of deterioration or damage. Discard disposable applicator components appropriately.

Attention : *Ne pas utiliser si le capteur ou les câbles présentent des signes de détérioration ou d'endommagement. Mettre au rebut les composants jetables de l'applicateur de manière appropriée.*



Caution: Risk of burns - Do not touch the metal tip of the transducer during operation.
- Never depress button without applicator in place.

Attention : *Risque de brûlures – Ne pas toucher l'extrémité métallique du capteur en cours d'utilisation.
– Ne jamais appuyer sur le bouton sans que l'applicateur soit en place.*

Caution: Always have the applicator properly seated and saline turned on when activating the Ultrasound Control Button (15).

Attention : *S'assurer toujours que l'applicateur est correctement enfoncé et ouvrir l'arrivée de sérum physiologique au moment d'activer le bouton de commande des ultrasons (15).*

Caution: Use only the Celleration MIST Therapy saline with the MIST Therapy System.

Attention : *Utiliser uniquement le sérum physiologique Celleration Mist Therapy avec le système Mist Therapy.*

Caution: Celleration MIST Therapy Saline Bottle (10) and Applicator (8) are designed as single-use disposable units to avoid contamination and should not be re-used.

Attention : *La bouteille de sérum physiologique (10) et l'applicateur (8) du système Celleration MIST Therapy sont conçus comme des composants jetables à usage unique pour éviter toute contamination. Ne pas les réutiliser.*

PRECAUTIONS/PRÉCAUTIONS

Treatment effectiveness will be diminished if any of the following occur:

L'efficacité du traitement sera compromise dans l'une des situations suivantes :

The Applicator (8) is not fully engaged, aligned and securely attached to the Transducer (9) and Saline (10) has not been turned on with mist being produced within 5 seconds of Ultrasound Control Button (15) activation.

L'applicateur (8) n'est pas enclenché à fond, aligné ni solidement attaché au capteur (9) et l'arrivée de sérum physiologique (10) n'a pas été ouverte avec production d'un brouillard dans les 5 secondes de l'activation du bouton de commande des ultrasons (15).

The distance between the Leading Edge of the Applicator (8) and the wound is greater than 1.5 cm (0.6 inches)

La distance entre le bord avant de l'applicateur (8) et la plaie est supérieure à 1,5 cm.

The Treatment Wand (11) is not held perpendicular to the wound.
La tête de traitement (11) n'est pas perpendiculaire à la plaie.

The Celleration Mist Therapy Saline (10) has been contaminated.
Le sérum physiologique Celleration Mist Therapy (10) a été contaminé.

Turn power off and see Trouble-Shooting section if fluid is leaking around applicator.

Mettre hors tension et consulter la section « Dépannage » en cas de fuite de liquide au niveau de l'applicateur.

Do not touch the inside surfaces of the applicator (8), and specifically the barb, as injury may occur.

Ne pas toucher les surfaces intérieures de l'applicateur (8), surtout sa partie crantée sous peine de blessures.

The Mist Therapy System requires an order by a physician or licensed practitioner. Only personnel trained on its use should perform treatment with the Mist Therapy System and should be used only as directed.

Le système Mist Therapy exige la prescription par un médecin ou un praticien diplômé. Seul un personnel formé à son utilisation doit effectuer un traitement avec le système Mist Therapy en l'utilisant conformément à son mode d'emploi.

POTENTIAL COMPLICATIONS

Tingling, redness

CONTRAINDICATIONS

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 areas of malignancies.

EVENTUELLES COMPLICATIONS

Fourmillement, rougeur

CONTRE-INDICATIONS

Contre-indications: Ne pas utiliser à proximité d'un implant ou d'une prothèse électronique ou à proximité ou au-dessus du cœur ou de la zone thoracique si le patient est porteur d'un stimulateur cardiaque; sur le bas du dos durant une grossesse ou au-dessus de l'utérus de la femme enceinte; au-dessus de zones de malignités.

TECHNICAL SERVICE

For technical questions about the operation of the MIST Therapy System call 1-866-307-MIST (6478).

MIST THERAPY® SYSTEM TECHNICAL DESCRIPTION

- System Classification: Class I, Type B Applied Part
- Resistance to ingress of fluid: IPX1, Drip-proof
- For US or Canadian Operation: (115V, 60Hz, 50W)
 - Use only Celleration part number CP-80003 detachable power cord rated for 'HOSPITAL USE', 125V, 10A
 - Replacement fuse: TO.630A 250V (5x20 mm)
- Transducer Output: Max. intensity at 10 mm: 1.7 W/cm²; Leading edge of applicator (12) is 10 mm from the transducer tip (13). Unintentional Output: < 100 mW/cm² to user.
- Storage: Store in a dry, ambient temperature environment.
- Operating Temperature: 50 to 90 degrees Fahrenheit at a relative humidity of 30 to 75% (non-condensing)
- Covered by or for use under one or more of the following U.S. patents: 6,569,099; 6,964,647; and 6,960,173; and other U.S. and foreign patents pending.



See Accompanying Documents



Class I, Type B Applied Part

IPX1

Rated as DRIP-PROOF Equipment



EC REP

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Single-Use Device (Applicator Kit)

STERILE R

Gamma Sterilized (Applicator)



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email: info@celleration.com

www.celleration.com

MIST Therapy System FDA Clearance. 510 (k) Clearance June 2005. "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."