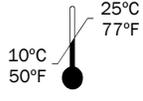


# TransCu O<sub>2</sub>® OXYGEN GENERATOR and OxySpur® ABSORBENT FOAM DRESSING, ADHESIVE and NON-ADHESIVE, for CONTINUOUS DIFFUSION of OXYGEN THERAPY

## INSTRUCTIONS FOR USE



Latex-Free



Store at Room Temperature



Keep Dry



## PRODUCT DESCRIPTION

The TransCu O<sub>2</sub> System consists of the TransCu O<sub>2</sub> Oxygen Generator, Oxygen Delivery Extension Sets, Battery Charger, Carrying Case and the OxySpur Oxygen Diffusion Dressings. Optional Humidicant Packs are available for use in low humidity environments.

The TransCu O<sub>2</sub> Oxygen Generator uses fuel-cell technology to continuously produce oxygen. It is rechargeable and should be recharged daily. The pure, humidified oxygen flows out of the O<sub>2</sub> port through the Oxygen Delivery Extension Set to the OxySpur Oxygen Diffusion Dressing.

The OxySpur Oxygen Diffusion Dressing is a hydrophilic dressing designed for use with the TransCu O<sub>2</sub> tissue oxygenation device in the management of wounds. The dressing is available in two forms: OxySpur for wounds with medium to high levels of exudate, and OxySpur LITE for wounds with low to minimal exudate.

The OxySpur dressing is a multi-layer construct with a highly absorbent hydrophilic foam layer directly adjacent to the wounds, a highly absorbent hydrophilic foam layer with channels for oxygen distribution, and a super absorbent polymeric laminate, all of which are covered by an occlusive film. The adhesive version also includes a hydrocolloid adhesive border. All versions contain an integrated oxygen delivery cannula that supplies oxygen into the oxygen distribution foam layer. The super absorbent layer converts wound fluids into a gel, absorbing and retaining fluid from the foam wound contact layer, thereby maintaining an optimally balanced moisture level in the wound contacting layer for an extended period.

OxySpur LITE differs in that it has a non-adherent mesh layer directly adjacent to the wound, two hydrophilic, yet less absorbent foam layers which are covered by an occlusive film, and an acrylate adhesive border. OxySpur LITE is to be used on wounds with minimal to low exudate, such as later in the healing cycle when wound exudate levels decrease.

One goal of oxygen therapy is to provide an uninterrupted and continuous supply of oxygen to a moist wound. The dressing is designed such that the oxygen is supplied in a manner that most closely approximates the normal diffusion of oxygen in moist tissues, yet at a rate sufficient to fuel the increased oxygen demands required in healing tissues. This therapy is known as Continuous Diffusion of Oxygen (CDO) therapy. The dressing helps to provide an environment for optimal wound healing by providing CDO therapy while managing wound exudate levels, protecting against wound dehydration and protecting against external contamination.

OxySpur is available with or without a hydrocolloid adhesive border. OxySpur LITE is only available with an acrylate adhesive border. Both versions are referred to simply as OxySpur herein.

## INDICATIONS

Under the supervision of a healthcare professional, the TransCu O<sub>2</sub> System

provides an oxygen-enriched, moist environment conducive to wound healing and is indicated to treat lightly to heavily exuding wounds such as:

- Skin ulcerations resulting from:
  - diabetes
  - venous stasis
  - post surgical infections
  - gangrenous lesions
- Pressure ulcers
- Infected residual limbs
- Skin grafts
- Burns
- Frostbite

Since the dressings are able to absorb and retain fluid under pressure they are suitable for use under compression. The dressings may be used to provide moisture management and protection throughout the healing process.

While OxySpur can be used on highly exuding wounds, the level of exudate will determine the effective wear time of the dressing, and the wound should be monitored accordingly.

## CONTRAINDICATIONS

The TransCu O<sub>2</sub> System is contraindicated for the following:

- Wounds with inadequate perfusion to support healing
- Ulcers due to acute thrombophlebitis
- Ulcers due to Raynaud's disease
- Necrotic wounds covered with eschar or slough
- Wounds with fistulae or deep sinus tracts with unknown depth

## PRECAUTIONS AND OBSERVATIONS

CAUTION: Sterility of the dressing and cannula is guaranteed unless the pouch is damaged or opened prior to use. DO NOT use if either has occurred.

- Increased drainage, which can be significant, often occurs after application of CDO therapy and may require more frequent dressing changes
- Do not use petroleum based products in the moist wound bed as they will prevent oxygen from diffusing into the wound tissue
- The sterile dressings and cannulas are intended for single use only
- Do not use after expiration date
- In case of intolerance to the dressing, remove and clean the area carefully
- During the body's natural healing process, edema may decrease and non-viable tissue may be removed from the wound (autolytic debridement), which could initially make the wound appear larger
  - If the wound continues to grow larger after the first few dressing changes, consult a healthcare professional
- Appropriate supportive measures should be taken where necessary (e.g. use of graduated compression in the management of venous leg ulcers or pressure relief measures in the management of pressure ulcers, systemic antibiotics and frequent monitoring in the treatment of wound infection, control of blood glucose for diabetic ulcers, etc.)
- The wound should be inspected during dressing changes
  - Consult a healthcare professional if there are: signs of infection (increased pain, increased redness, wound drainage); excessive bleeding; an unexpected change in wound color and/or odor; irritation (increased redness and/or inflammation); sensitivity (allergic reaction); no signs of healing.
- These instructions are not intended to supersede the instructions of your health care professional
- If you have additional questions about your TransCu O<sub>2</sub> System please call your local wound care supplier
- If you have immediate medically related questions or concerns, please call your physician or clinical caregiver
- Federal law restricts this device to sale or rental by or on the order of a physician

## DIRECTIONS FOR USE

System set up

- Be sure to have these items available to complete your system set up:
  - TransCu O<sub>2</sub> Oxygen Generator
  - TransCu O<sub>2</sub> Oxygen Delivery Extension Set (connecting tubing)

- OxySpur Dressing (size of dressing is determined by your clinical caregiver)
- Optional items:
  - TransCu O<sub>2</sub> Carrying Case
  - TransCu O<sub>2</sub> Humidicant Pack
  - Skin prep
  - Compression sock or wrap
  - Fixative film
  - Alginate or other hydrophilic fill materials

## APPLYING THE OxySpur DRESSING

- Prior to application of OxySpur Oxygen Diffusion Dressing, cleanse the wound area as necessary.
- NOTE: Do not use petroleum based products in the moist wound bed as they will prevent oxygen from diffusing into the wound tissue.
- Select a dressing that will allow the wound contact area to completely cover the wound and extend onto healthy tissue.
- Remove the sterile dressing from the package.
- CAUTION: If the immediate product packaging is damaged (torn or punctured) on products marked as sterile, such as dressings and extension set tubing, do not use the damaged products and select an undamaged product.
- NOTE: When placing the OxySpur dressing, keep in mind the direction of the cannula (tube) coming from the dressing. It can be helpful to place the dressing so that the cannula is facing up, toward the head of the body rather than pointed to the feet. This will provide the highest range of motion when connected to the device.
- For an adhesive dressing (has a hydrocolloid border):
  - Remove part of the white liner to expose the adhesive (hydrocolloid) portion of the dressing.
  - Position and smooth into place while removing the second half of the white plastic liner.
  - Carefully smooth around the edge of the dressing to ensure good contact between the adhesive film border and the periwound skin.
- For a non-adhesive dressing (no hydrocolloid border):
  - Place the dressing over the wound.
  - A secondary film dressing or conforming bandage should be applied over the OxySpur dressing to secure the dressing in place.
  - If required, the dressing can be cut, although note that this may increase the risk of product delamination.
- NOTE: slight pressure should be placed on the entire dressing to ensure that the dressing contacts the surface of the wound. This enables wicking of excess fluid from the wound bed into the dressing and can be achieved using a wrap or a sock.
- For highly exuding wounds, make sure to secure any fixative film over all the edges of the dressing.
- Ensure that the edges are firmly sealed. Gaps or tears could allow excessive exudate to damage the periwound and potentially lower the oxygen concentration at the wound site, which could affect the efficacy of the therapy.

## CONNECTING THE TransCu O<sub>2</sub> OXYGEN GENERATOR

- Connect the Oxygen Delivery Extension Set by inserting the male luer fitting of the extension set into the female end of the OxySpur dressing's cannula and firmly turning clockwise to ensure a solid air-tight connection.
- Secure the Oxygen Delivery Extension Set to intact skin with surgical tape as necessary. Allow slack at the connection to the dressing and in the tubing path for freedom of movement.
- Connect the female luer lock end of the Oxygen Delivery Extension Set to the male port labeled "O2" located on the top right hand side of the TransCu O<sub>2</sub> Oxygen Generator and firmly turning clockwise to ensure a solid air-tight connection.
- Turn the Oxygen Generator on by depressing the power switch down on the side labeled "On". The power switch is located at the top of the Oxygen Generator.
- Upon turning on, all of the lights and LCD segments will turn on briefly to confirm normal operation. The buzzer will also sound briefly.
- NOTE: The Oxygen Generator should always be left in the "On" position until the course of therapy is completed and the TransCu O<sub>2</sub> System is being returned.

- The Oxygen Generator will begin a self-calibration process, during which the LCD screen will display "CA".
- Upon completion of the self-calibration (approximately 3 minutes), the oxygen flow rate will be displayed on the LCD screen. The oxygen flow rate is set by, and can only be changed by, your clinical caregiver.
- NOTE: The oxygen flow rate will occasionally change as the Oxygen Generator makes adjustments to accommodate environmental variances. This is normal. If the device is flowing at a lower rate than it was set for for more than 30 minutes, please continue the therapy and contact your caregiver.
- The "System OK" green light is located just below the LCD display and indicates the system is functioning properly. Refer to the Features and Troubleshooting sections for more information on the features of the Oxygen Generator and how to troubleshoot the system, respectively.

#### DRESSING CHANGES

- Dressing change frequency depends on multiple factors, including the condition of the wound as well as on the level of wound exudate. Please consult your clinical caregiver.
- In general, dressings should be changed once strikethrough (wound exudate reaching the top of the dressing) is evident.
- DO NOT lift or remove the dressing between dressing changes, unless instructed to do so by your clinical caregiver. Doing so will compromise your wound-healing environment and can affect your healing process.
- To remove a bordered (adhesive) dressing, loosen the adhesive film border before lifting the dressing away from the wound.
- To remove a borderless (non-adhesive) dressing, gently lift the corners of the dressing away from the wound.
- If difficulty is experienced on removing the dressing, it should be irrigated with water or sterile saline solution.
- To apply the dressing, follow the instructions and precautions in the "Applying the OxySpur Dressing" section.

#### TransCu O<sub>2</sub> OXYGEN GENERATOR FEATURES

- O<sub>2</sub> Flow - the LCD display indicates the oxygen flow rate, which is displayed in milliliters per hour (ml/hr). The displayed flow rate may vary as the Oxygen Generator makes adjustments to accommodate changes in the environment.
- SYSTEM OK indicator - green light indicates that the device is functioning normally when lit.
- BLOCKAGE indicator - red light indicates there is a blockage when lit. Audible alarm will sound. Refer to the Blockage section of the instructions for further information.
- SET button - this button has no effect. It is used by the clinical caregiver to set the oxygen flow rate, yet does not respond during normal operation.
- +O<sub>2</sub>, -O<sub>2</sub> buttons - these buttons have no effect. They are used by the clinical caregiver to set the oxygen flow rate, yet do not respond during normal operation.
- MUTE - pressing this button will silence alarms temporarily.
- BATTERY charge indicators - these lights show approximate remaining charge as follows (from left to right on device):

● ● ● ● ●  
100-85% 85-65% 65-45% 45-25% 25-0%

- First Green Light (far left) at least 85% remaining
- Second Green Light at least 65% remaining
- Third Green Light (middle) at least 45% remaining
- Fourth Green Light at least 25% remaining
- Amber Light (far right) less than 25% remaining

#### BATTERY AND CHARGING

Insert the battery charger plug into any standard AC outlet. Connect the battery charger connector to the charging port labeled BAT on top of the TransCu O<sub>2</sub> Oxygen Generator. The BATTERY charge indicator should start flashing and the charger body light will turn red, indicating that the battery is being charged. Once the charger body light turns green, the battery has been fully charged and the charger may be removed.

Depending on flow rate and environmental conditions, a fully charged battery

should operate for between 14 - 18 hours before reaching Fourth Green status, which initially indicates 45% remaining charge (another 7-9 hours). When the Fourth Green light is illuminated, the letters BAT will be displayed on the LCD screen and an audible alarm will sound once.

When the Amber (last) light is illuminated on the Oxygen Generator, the letters BAT will be displayed on the LCD screen and an audible alarm will sound once. The "OK" LED will start flashing. You should charge your device as soon as possible.

On the charger body, a red light indicates that a charge is being supplied to the battery and a green light indicates that no charge is being supplied.

You may mute the alarm by pressing the MUTE button.

Always leave the TransCu O<sub>2</sub> Oxygen Generator switched on, even when charging.

NOTE: If you are experiencing charging issues, completely remove the charger from the AC outlet and the Oxygen Generator, wait at least 30 seconds, then plug the charger back into the AC outlet and the Oxygen Generator. The charger body light should turn red and the Oxygen Generator battery level light should start blinking, indicating that the Oxygen Generator is charging.

NOTE: If the battery is drained completely, the Oxygen Generator will shut off and stop producing oxygen. This will interrupt the CDO therapy and reduce the effectiveness of your therapy, yet does not present an urgent issue. Charge your device as soon as you can. In the meantime, you will continue to receive moist wound therapy.

#### Battery Charger Specifications:

Model 452240-LA  
Input: 100 - 240 VAC, 50-60Hz Max 0.2A  
Output: 1.3A - 4.2Vdc

CAUTION: Use of a charger other than the one provided may damage the Oxygen Generator.

#### BLOCKAGE ALARM

When a blockage occurs:

- The red "Blockage" light will illuminate
- An audible alarm will be heard
- The alarm will sound until the "Mute" button is pressed or until the blockage is cleared

#### Troubleshooting Blockage

- While you are trying to locate the blockage you may mute the audible alarm by pressing the MUTE button.
- Inspect the oxygen delivery cannula starting at the connection with the Oxygen Generator. Make sure there are no kinks or objects constricting the tubing that could possibly block the oxygen flow to the wound.
- If there are no visual indications that could cause a blockage and the RED Blockage light remains illuminated, the blockage may be at the wound site under the dressing.
- Gently tugging on the cannula, try to reseat the tubing within the wound.
- If the device continues to alarm and or alarms again after muting, change the OxySpur Dressing.
- If the Blockage continues, call your local wound care supplier for further troubleshooting.

#### CARE AND HANDLING

Avoid exposing the TransCu O<sub>2</sub> Oxygen Generator and OxySpur Dressings directly to water. The Oxygen Generator contains sensitive components. Do not drop, disassemble, microwave, burn, paint or insert foreign objects.

The Oxygen Generator is designed to operate normally between -25 °C and +55 °C (13 °F and 131 °F) and 15% to 95% relative humidity, non-condensing. Avoid dramatic changes in temperature or humidity as condensation may form on or within the device. Humidity levels above 35% relative humidity are required for optimal performance of the Oxygen Generator. For relative humidity levels below 35%, please use the Humidicant Pack in combination with the carrying case to raise the humidity level around the Oxygen Generator and ensure optimal performance.

Store at room temperature: 10 - 25°C (50 - 77°F). Keep dry.

If further information or guidance is required, please visit our website

([www.eo2.com](http://www.eo2.com)) or contact EO<sub>2</sub> for assistance at: (800) 825-2979  
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