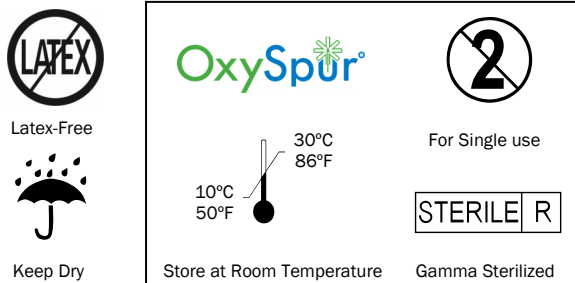


OxyGeni® OXYGEN GENERATOR and OxySpur® ABSORBENT FOAM DRESSING, ADHESIVE and NON-ADHESIVE, for CONTINUOUS DIFFUSION of OXYGEN THERAPY

INSTRUCTIONS FOR USE



PRODUCT DESCRIPTION

The OxyGeni System consists of the OxyGeni Oxygen Generator, Oxygen Delivery Extension Sets, USB Charger, OxyGeni Power Pack, Carrying Case and the OxySpur Oxygen Diffusion Dressings. Optional Humidicant Packs are available for use in low humidity environments.

The OxyGeni 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 O2 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 OxyGeni 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, one hydrophilic, yet less absorbent foam layer which is covered by an occlusive film, and an 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 an adhesive border. OxySpur LITE is only available with an adhesive border. Both versions are referred to simply as OxySpur herein.

INDICATIONS

CDO therapy is designed for patients who would benefit from wound oxygenation as it may promote wound healing via increased collagen production, angiogenesis, reactive oxygen species generation, and increased cell metabolism. The OxyGeni System is indicated to treat wound types including:

- Skin ulcerations resulting from:
 - diabetes
 - venous stasis
 - postsurgical 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 OxyGeni 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 is guaranteed unless the pouch is damaged or opened prior to use. DO NOT use if either has occurred.

- A significant increase in exudate may occur during the early phase of CDO therapy, resulting in the need for more frequent assessment and dressing changes. To reduce the frequency of dressing changes, you may add absorbent dressings under the OxySpur dressing
- The sterile dressings 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
- It is important that occlusive materials, such as film dressings or oil-based products (such as petrolatum, salves or ointments), are not applied over the wound bed below the OxySpur dressing as this will impair performance of CDO
- The OxySpur dressing has an occlusive film on one side (the side with bubbles) and care must be taken to apply the dressing such that the occlusive film is facing away from the wound not contacting the wound surface as this will impair CDO performance
- Appropriate supportive measures should be taken where necessary (e.g. use of compression in the management of venous leg ulcers or pressure redistribution measures in the management of pressure ulcers, systemic antibiotics and frequent monitoring in the treatment of wound infection, control of blood glucose and offloading for diabetic ulcers, etc.)
- The wound should be assessed during dressing changes
- When showering the OxyGeni should be disconnected from the dressing; ensure the dressing and the end of the tubing attached to the dressing are protected so that water does not enter the top of the tube or the dressing
- Do not take the OxyGeni apart
- Do not cut tubing or pull on the tubing
- Do not connect a Y splitter to the tubing since this may impair CDO performance
- The OxyGeni can be charged using any other USB charger than that supplied with the system
- Always ensure that the dressing is positioned centrally over the wound: the dressing tubing should be positioned uppermost (going toward the head) on intact skin and not extend over the wound so that the risk of fluid collecting around the tubing and potentially blocking the flow of oxygen is minimized
- CT scans and x-ray have the potential to interfere with some electronic medical devices: where possible, move the OxyGeni out of the x-ray or scanner range: if the OxyGeni has been taken into the CT scan or x-ray range, check that it is functioning correctly following the procedure
- This OxyGeni is single patient use only: use of any part of this system on more than one patient may result in cross-contamination that may lead to infection
- High temperatures and humidity may reduce wear times of dressings
- 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 have additional questions about your OxyGeni System please call your local wound care supplier
- If you have immediate medically related questions or concerns, please call your physician or clinical caregiver
- Please report any serious incident that has occurred in relation to the OxyGeni System to EO2 Concepts and the authority having jurisdiction in your locale.
- Federal law (USA) 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:
 - OxyGeni Oxygen Generator and Wound Monitoring Device

- OxyGeni Oxygen Delivery Extension Set (connecting tubing)
- OxySpur Dressing (size of dressing is determined by your clinical caregiver)
- Optional items:
 - OxyGeni Power Pack
 - OxyGeni Carrying Case
 - OxyGeni Humidicant Pack
 - Skin prep
 - Compression sock or wrap
 - Fixative film
 - Alginate or other hydrophilic fill materials

APPLYING THE OxySpur DRESSING

Prior to application:

- Cleanse the wound area.
- Debride wound of devitalized tissue (eschar, slough, etc. may interfere with oxygen delivery)
- Select a dressing that will allow the wound contact area to completely cover the wound and extend onto healthy tissue
- Use Skin protection before applying an adhesive dressing

NOTE: Do not use oil based products such as petrolatum, salves or ointments: they do not allow oxygen to penetrate and will impair the efficacy of CDO therapy. Gels and creams are typically water based and work well with CDO.

Applying Adhesive OxySpur Dressings:

NOTE: Use of a skin protectant should be used before placing the adhesive dressing. If you are concerned that the patient's skin will not tolerate a strong adhesive, we advise using the non-adhesive dressing instead.

- Hydrocolloid adhesives work more efficiently when warm. Warm the adhesive portion with your hands prior to application. Remove part of the clear liner to expose the adhesive (hydrocolloid) portion of the dressing
- Orient the dressing such that the tubing exiting the dressing is on top/up when the patient is standing or resting. This will help to prevent exudate from entering the tubing when the patient removes the OxyGeni to shower or bathe
- Position and smooth into place (bubble-side up) while removing the second half of the clear plastic liner
- Carefully smooth around the edge of the dressing to ensure good contact between the adhesive film border and the periwound skin
- Briefly apply pressure to the adhesive until it becomes firmly attached to the skin (hydrocolloids activate with heat and pressure)

NOTE: The adhesive borders are designed to be strong enough to stay on the patient until the next dressing change. *Advise patients against lifting or removing the dressing between changes, unless instructed to do so by a clinical caregiver.* An adhesive remover may be needed when removing the dressing.

Applying Non-Adhesive OxySpur Dressings:

NOTE: Use of a skin protectant should be used before placing the dressing to protect the peri-wound from maceration.

- Orientate the dressing such that the tubing exiting the dressing is on top/up when the patient is standing or resting. This will help to prevent exudate from entering the tubing when the patient removes the OxyGeni to shower or bathe
- Place the dressing over the wound. *Ensure the foam side is face down against the wound (The side with the bubble print should be facing out)*
- A secondary film dressing, tape, wrap 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
- For highly exuding wounds, be sure to secure any fixative over all of the edges of the dressing

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. *All dressings are suitable for use with compression, from light compression stockings up to 4 layer compression wraps.*

NOTE: The seal around the dressing edges does not have to be perfect, yet gaps or tears could allow exudate to damage the periwound and potentially lower oxygen concentration at the wound site. Too tight of a seal may cause a blockage alarm over time (if more oxygen is being produced than consumed by the wound, the oxygen pressure will build in a tightly confined space).

- Patients are advised against lifting or removing the dressing between changes, unless instructed to by clinical caregiver. 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

OxySpur CANNULA ORIENTATION & PLACEMENT

For instructional videos, visit our [YouTube channel](#): search "EO2 Concepts" on YouTube.com.

Orient the OxySpur dressing such that the tubing is on top/facing up as it exits the dressing when the patient is standing or resting. This will help to prevent exudate from entering the tubing when the patient removes the OxyGeni to shower or bathe. The luer lock should be accessible to connect/disconnect.

NOTE: Cannula should be secured with tape in order to reduce any pressure that may result from the device.

CONNECTING OxySpur DRESSING TO THE OXYGENI

- Connect the dressing to the Extension Set by inserting the male luer fitting of the Extension Set into the female end of the OxySpur Dressing's cannula and turn clockwise until secure (about ¼ turn)
- To ensure the cannula does not get pulled out of the dressing, it is recommended to make a pigtail loop and secure it either on top of the dressing or adjacent to the dressing
- Route the Extension Set inside clothing and attach it to intact skin with surgical tape. Ensure to allow for the tubing to have freedom of movement
- Connect the female luer end of the Extension Set to the male port labeled "O2" on the top right side of the OxyGeni by inserting and turning clockwise (about ¼ turn)

NOTE: Ensure that all connections are secure so that oxygen does not leak out.

TURNING THE OxyGeni ON

- Turn the OxyGeni on by depressing the power switch down on the side with the symbol "⏻". The power switch is located at the top of the OxyGeni
- 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 OxyGeni should always be left in the "On" position until the course of therapy is completed and the OxyGeni is being returned.

- The OxyGeni 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 OxyGeni makes adjustments to accommodate environmental variances. This is normal. If the OxyGeni is flowing at a lower rate than it was set to 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 OxyGeni is functioning properly. Refer to the Features and Troubleshooting sections for more information on the features of the OxyGeni and how to troubleshoot the system, respectively

DRESSING CHANGES

- Frequency of dressing changes depends on multiple factors, including condition of the wound, level of exudate, etc. Dressing changes should be done once through (wound exudate reaching the top and edge of the dressing) is evident or at a minimum once per week.
- To apply a new dressing, follow the instructions and precautions in the "Applying the OxySpur Dressing" section.

Removing Adhesive OxySpur Dressing:

- OxySpur adhesive dressings are recommended to stay in place for at least 3 and no more than 7 days
- Disconnect the OxySpur dressing cannula from the extension set or OxyGeni with a counter clockwise turn
- To remove the adhesive border we recommend the use of a medical grade adhesive remover. Use the remover pad to gently pull up a corner of the adhesive border on the OxySpur dressing
- Once the corner is gently pulled up, use the pad under the dressing to assist in removing the adhesive, slowly releasing it from the skin
- Using a lateral stretch and the medical adhesive remover, alternate stretching the OxySpur dressing and removal of adhesive until the dressing has been fully released from the skin

Removing Non-Adhesive OxySpur Dressing:

- Disconnect the OxySpur dressing cannula from the extension set or OxyGeni with a counter clockwise turn. Gently lift corners of dressings away from wound and remove and dispose the dressing as you would any dressing

NOTE: If difficulty is experienced on removing the dressing, it should be irrigated with sterile saline solution or a similar solution.

OxyGeni FEATURES

- O2 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 OxyGeni makes adjustments to accommodate changes in the environment
- SYSTEM OK indicator - green light indicates that the OxyGeni is functioning normally when lit
- BLOCKAGE indicator - red light indicates there is a blockage when lit. Audible alarm will sound. Refer to the Blockage Alarm 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
- +O2, -O2 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 OxyGeni):

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

- First Green Light (far left) at least 85% remaining (18-24 hours)
- Second Green Light at least 65% remaining (15-18 hours)
- Third Green Light (middle) at least 45% remaining (10-15 hours)
- Fourth Green Light at least 25% remaining (6-10 hours)
- Amber Light (far right) less than 25% remaining (less than 6 hours)

BATTERY AND CHARGING

Attach one end of the Magnetic Charging Cable to the charging port on top of the OxyGeni Power Pack and attach the other end of the Magnetic Charging Cable to the battery charging port labeled "⚡" on top of the OxyGeni. The charging LED should turn red indicating that the battery is being charged. Once the charging light turns green, the battery has been fully charged and the Magnetic Charging Cable may be removed from the OxyGeni battery charging port.

NOTE: If the internal OxyGeni battery is completely dead when the OxyGeni Power Pack is applied, the charging LED will flash red until a sufficient charge is reached. Then the charging LED will turn solid red.

The battery level lights on the front of the OxyGeni will begin flashing in sequence during the charge cycle.

Upon removal of the OxyGeni Power Pack and Magnetic Charging Cable at charge completion, the battery level lights will continue cycling for a few seconds then stop at the battery level obtained.

When charging is complete, attach the OxyGeni Power Pack to the provided USB Charger so that a full charge is maintained.

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 25% remaining charge (another 6 - 10 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 OxyGeni, 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 OxyGeni as soon as possible.

Always leave the OxyGeni switched on, even when charging.

NOTE: If you are experiencing charging issues, completely remove the OxyGeni Power Pack and Magnetic Charging Cable from the OxyGeni, wait at least 30 seconds, then re-attach the OxyGeni Power Pack back via the Magnetic Charging Cable to the OxyGeni. The charger light should turn red indicating that the OxyGeni is charging.

NOTE: If the internal battery is drained completely, the OxyGeni 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 OxyGeni as soon as you can. In the meantime, you will continue to receive moist wound therapy.

OxyGeni Power Pack Specification:

Power Pack: 5000mAh 5Vdc

USB Charger Specifications:

Model 200151
Input: 100 – 240 VAC, 50-60Hz Max 0.2A
Output: 1.0A – 5Vdc

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 OxyGeni. 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 reset the tubing within the wound.
 - If the OxyGeni 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 OxyGeni and OxySpur Dressings directly to water. The OxyGeni contains sensitive components. Do not drop, disassemble, microwave, burn, paint or insert foreign objects.

The OxyGeni 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 OxyGeni. Humidity levels above 35%

relative humidity are required for optimal performance of the OxyGeni. For relative humidity levels below 35%, please use the Humidant Pack in combination with the carrying case to raise the humidity level around the OxyGeni to ensure optimal performance.

OxySpur: Store at room temperature: 10 – 30°C (50 – 86°F). Keep dry.

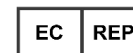
The OxyGeni and USB charger are intended to be re-used. After therapy is completed and before use on a different patient, the OxyGeni and USB charger should be thoroughly cleaned and undergo intermediate or low level disinfection, depending on the nature and extent of contamination, by a healthcare professional. The dressings and accessories, including extension tubing, Humidant Packs, carrying cases, etc., are for single use only and cannot be re-used after patient use is completed due to the difficulty to clean and decontaminate these items.

If further information or guidance is required, please visit our website (www.eo2.com) or contact EO2 for assistance at: (800) 825-2979
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