Product Information Sheet

CDO (Continuous Diffusion of Oxygen) Therapy	
Classification	**Oxygen Therapy**
British Columbia Practice	• Use under direction of NSWOC, Wound Clinician, Physician or Nurse Practitioner.
Key Points	• Therapy consists of OxyGeni Oxygen Generator (unit) and OxySpur Oxygen Diffusion Dressing; both are required to provide continuous diffusion of oxygen (CDO) therapy. • The OxyGeni Oxygen Generator: ◦ Provides a continuous diffusion of humidified oxygen into an oxygen-compromised wound to accelerate wound healing while maintaining a moist wound healing environment. ◦ May promote wound healing via increased collagen production, angiogenesis, reactive oxygen species generation and increased cell metabolism. ◦ Is small, silent, and allows for client mobility. • The OxySpur Oxygen Diffusion Dressing: ◦ Is a multilayered dressing comprised of a highly absorbent hydrophilic foam layer, a super absorbent polymeric laminate layer and a thin film covering. ◦ Has a cannula that provides CDO therapy through channels built into the dressing. ◦ Does not have an adhesive border. ◦ Manages wound exudate while protecting against wound dehydration. ◦ Protects against external contamination. ◦ May be used as a primary or secondary dressing. • CDO Therapy is also known as EO2, OxyGenie, OxySpur Dressing.
Indications	• For wounds of all etiologies, including ischemic wounds with a potential for healing, of any depth, moderate to large/copious amounts of exudate and clean of slough/necrotic tissue. • Under the direction of the MRP, can be used directly on split thickness skin grafts, donor sites skin substitutes and in with extracelluar matrix products, (i.e., DermaGraft, ApliGraf). • May be used under compression, removable off-loading device or total contact casting (a window may be left for dressing changes if needed).
Precautions	• A significant increase in exudate may occur during the early phase of CDO Therapy. • Do not apply occlusive materials (transparent film, or oil-based ointments/contact layer) under the dressing. • Do not cut tubing and do not connect a Y-connector as this may impair CDO performance. • Where possible move the OxyGeni unit out of the x-ray or scanner range. If not possible check that it is functioning correctly following the procedure. • High temperatures and humidity may reduce dressing wear time; use of the humidicant pack will reduces the humidity, extending the dressing wear time. • Has not been evaluated on pregnant/lactating individuals or neonates/infants, consult with physician/NP prior to using on this/these population(s).
Contraindications	• Sensitivity or allergy to any components of the dressing. • Wounds with inadequate perfusion to support healing (e.g., ischemic arterial ulcers). • Wounds with slough and/or necrotic tissue. • Wounds with fistulae or deep sinus tracts with unknown depth. • Ulcers due to acute thrombophlebitis.
Formats & Sizes	• OxyGeni Oxygen Generator To place order for rental unit: orders@braemed.ca (allow 1-2 days for delivery) • OxySpur Oxygen Diffusion Dressing ◦ Non- Adhesive 12.7 x 17.8 cm ◦ Non-Adhesive 10 x 12.7 cm ◦ Non-Adhesive 5 x 5 cm • Extension Set Tubing (183 cm) • Dual Port Cannula (91 cm) • Humidicant Pack  

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Selection	
The following is required for system set up: • OxyGeni Oxygen Generator unit (see rental info above). • Oxygen Delivery Extension Set (connecting tubing) – may not be needed. • Appropriately sized OxySpur Oxygen Diffusion Dressing. • Humidicant Pack. • Power Pack. • Carrying Case (universal or arm/leg strap), choose the appropriate carrying case based on the client situation and location of the wound. Ensure the OxyGeni unit is fully charged before using. For a wound with high levels of exudate may need: • An alginate, gelling fibre, or other absorbent dressing to cover wound bed. • A hydrocolloid, alginate rope, gelling fibre rope or other absorbent dressing to frame/window-pane the wound to protect periwound skin. For a wound with depth: • Choose appropriate wound filler for amount of exudate expected and the anticipated frequency of dressing change. Note: there can be only a maximum of 2 layers of dressing under the Oxyspur dressing.	Select a dressing size that will completely cover wound and overlap onto periwound skin. If the wound is larger than the available dressing sizes, consider using 2 or more OxyGeni System devices for the same wound. Dressing can be cut but it may increase the risk of delamination. Universal carrying case can be worn over shoulder, around the hip, or on belt whereas arm/leg strap carrying case will be worn around leg or arm. Unit should be shipped fully charged but occasionally may need charging upon arrival. Do not use an oil-based dressing as oxygen will not penetrate. See Wound Packing Procedure or QR Code below. Do not use an oil-based product as oxygen will not penetrate.
Preparation	
Cleanse wound and periwound / surrounding skin with sterile normal saline or agency approved wound cleanser. Ensure that wound bed is free of debris and devitalized tissue (e.g. eschar, slough). Dry periwound / surrounding skin. Apply barrier film, silicone protectant, or zinc protectant to periwound skin.	See Wound Cleansing Procedure or QR Code below. Devitalized tissues may interfere with oxygen delivery. See Conservative Sharp Wound Debridement (CSWD) Guideline/Procedure or QR Code below if CSWD required. To protect periwound skin from moisture associated skin damage (MASD). A significant increase in exudate may occur during the early phase of CDO Therapy. Do not use oil-based skin protectant products (e.g. petrolatum) as these will not allow oxygen to penetrate and will interfere with CDO Therapy.
Dressing Application	
For wounds with large/copious amounts of exudate: • Apply alginate, gelling fibre, or other absorbent wound filler to wound bed. • 'Picture-frame' the wound with hydrocolloid, alginate rope, gelling fibre rope or other absorbent dressing. • Apply OxySpur dressing as described below. For wounds with minimal depth (less than 1 cm) OxySpur dressing may be placed directly over wound bed as described below. For wounds with depth (more than 1 cm) lightly fill dead space up to skin level with appropriate wound filler. Apply OxySpur dressing over wound filler as described below.	Picture-framing the wound with an absorbent dressing will increase the wear time of OxySpur dressing and protect periwound skin from MASD as a significant increase in exudate may occur during the early phase of CDO Therapy. Do not use oil-based products as these will not allow oxygen to penetrate and will interfere with CDO Therapy. A non-adherent contact layer may be used. Do not use an oil-based non-adherent contact layer.

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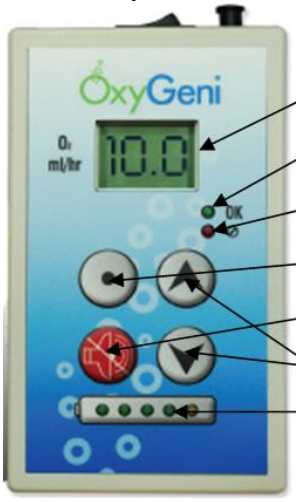
For undermining/tunneling lightly pack with one piece (where possible) of appropriately sized wound filler. Leave a tail of the packing so it can easily be seen. If required, lightly fill dead space up to skin level with appropriate wound filler. Apply OxySpur dressing over wound filler as described below.	See Wound Packing Procedure or QR Code below. Oxygen will penetrate through wound filler. Do not use an oil-based wound filler. Use one piece of packing whenever possible. Overpacking undermining/tunneling can lead to tissue necrosis. The tail will facilitate the removal of packing. See Wound Packing Procedure or QR Code below.
Application of OxySpur Dressing Place OxySpur dressing over wound ensuring foam side of the dressing is face down and bubble print is facing out. Position the dressing: • Centrally over the wound. • With the tubing on top/facing up as it exits the dressing when the client is resting or standing. • Ensuring the luer lock is accessible. Secure the dressing in place using transparent film, tape, self-adherent wrap, tubular bandage, or conforming gauze roll. For wounds with large/copious amounts of exudate secure all edges of dressing with tape. Apply slight pressure over the entire dressing using a self-adherent wrap, tubular bandage, or a sock. If appropriate for client use compression stockings or wraps.	Bubbles indicates outer side (cover film) of dressing. Positioning the tubing upward will help to prevent exudate from entering the tubing. To achieve the best possible air-tight seal around the wound. Gaps along the edge of the dressing allow exudate to leak out of the dressing causing skin damage to the periwound /surrounding skin and may decrease the oxygen level within the wound. Slight pressure ensures that dressing is in contact with the surface of the wound. This enables wicking of exudate from wound into dressing.
The OxyGeni Oxygen Generator	
Top of OxyGeni Generator  Battery Charging Port Luer Lock Power Switch Battery Charging Light	**Front of OxyGeni Generator**  LCD Display Screen Green OK Light Red Blockage Light Set Button Mute Button Up/Down Buttons Battery Charge Indicator
Setting up the CDO Therapy	
Connecting the Dressing to the OxyGeni • If required, connect the Extension Set to the luer lock located at the top of the OxyGeni Generator – turn clockwise until secure (about ¼ turn). • Connect the other end of the Extension Set to the luer lock	Extension Set is only required if dressing cannula tubing is

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of OxySpur dressing cannula – turn clockwise until secure (about ¼ turn). • Loop the dressing cannula tubing and secure to the dressing or to the skin adjacent to the dressing. • Route the Extension Set inside clothing and attach it to intact skin with tape.	not long enough to reach from wound to where OxyGeni will be placed. Provides extra security so dressing/tubing remain intact.
Turning the OxyGeni unit 'ON' • Turn the unit 'ON' by depressing the Power Switch located at the top of the OxyGeni from 'I' to 'O'. • The device will begin self-calibration, during which the LCD. • Display Screen will display 'CA'. • Following calibration, the oxygen flow rate (ml/hr) will be displayed on the LCD Display Screen. • The Green OK Light indicates that the device is functioning properly.	When turned on, the alarm will sound, and the lights will turn on briefly. Self-calibration takes approximately 3 minutes. The oxygen flow rate will occasionally change as the OxyGeni adjusts to accommodate environmental variances.
Setting Oxygen Flow Rate Flow rate is adjustable from 3 ml/hr to 15ml/hr. The OxyGeni is shipped with the oxygen flow rate set to 8 ml/hr. Based on client and wound assessment, the surface area dimensions of the wound and the amount of exudate the chart below can be used as a guide in setting flow rate. **Wound Surface Area (cm^2) / Flow Setting (ml/hr)** 13 / 3 26 / 6 39 / 9 52 / 12 65 / 15 If there are small gaps along on the edges of the dressing slightly increase the flow rate. If it is difficult to achieve a firm seal around the edges, the flow rate may be increased to the maximum of 15ml/hr to achieve higher oxygen concentrations. To change the oxygen flow rate: 1. Press and hold both the 'Set" and "Mute" buttons at the same time for 5 seconds. 2. Once the oxygen flow rate begins flashing: a. Press the 'Up' button to increase flow. b. Press the 'Down' button to decrease flow. 3. Once the desired oxygen flow rate is displayed, press the 'Set' button. If OxyGeni is turned off, it will run the last flow rate setting when turned back on. It is normal for the oxygen flow to vary once set, and on-screen values will change.	Variable flow rates are available to accommodate various wound sizes. This is a guide and provides a starting point for the oxygen flow rate. Oxygen flow rate can be increased and decreased as appropriate for client and wound (see below). The measurement (cm) of the length and width of the wound is used to calculate the wound surface area: L(cm) x W(cm) = Area (cm^2) If the 'Set' button is not pressed within 60 seconds the flow rate will revert back to the previous setting. The system responds to environmental conditions and adjusts so the rate may fluctuate on the unit.
Carrying Case *Universal Carrying Case* • Can be worn over shoulder, around the hip, or on belt: • Hook the straps onto the Carrying Case. • Unzip case, insert OxyGeni and Power Pack (if attached), inside the Carrying Case with the front side of the OxyGeni	

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unit facing the clear panel, and zip closed. • Turn the case over and lift Velcro top to see the unit. *Arm/Leg Strap Carrying Case* • Place OxyGeni inside the strap's pouch. • Secure Velcro strap over the top of the OxyGeni to close the carrying case. • Place arm or leg through the strap, tighten it to a comfortable fit and secure it with the Velcro strap. If using an off-loading boot, the OxyGeni can be strapped directly to the boot.	
Humidicant Pack Tear open the foil pouch using the tear slits on the edge of the pouch. Do not dry off. Remove the Humidicant Pack from the foil pouch. Place the Humidicant Pack next to the back side of the OxyGeni inside the carrying case and zip the carrying case shut. Replace the Humidicant Pack when it dries out and becomes hard.	Humidicant Pack provides the necessary humidity for the OxyGeni to function optimally. Will initially feel very wet as humidity has condensed on the outside of the package. May last up to 3 weeks depending on the humidity in the surrounding environment.
OxyGeni Troubleshooting	
Alarms Press the Mute Button to temporarily silence audible alarms. Determine cause of alarm. If unable to determine cause of alarm – turn unit off and on.	Turning the device off and on will sometimes resolve the alarm.
Exudate is difficult to manage Lower the oxygen flow rate by 25-40% until the exudate is under control, then slowly increase the flow rate weekly/ biweekly until back to original flow rate.	Decreasing the oxygen flow rate will decrease the amount of wound exudate.
Ischemic pain management If exudate level is under control, increasing the oxygen flow rate gradually by up to 15mls/hr may reduce ischemic pain.	If exudate level is not controlled after 2 weeks and client cannot tolerate the discomfort/pain, discontinue the treatment.
Blockage When a blockage occurs the Red Blockage Light will illuminate, and an alarm will sound. Mute the audible alarm by pressing the Mute Button. Determine the location of the blockage: • Inspect the tubing starting at the connection with the OxyGeni. Make sure there are no kinks or objects constricting the tubing. • If there is exudate or water in the tubing, turning the device off and then back on can clear the liquid. • If unable to identify a kink in the tubing, the blockage could be at the wound under the dressing. Gently pull on the tubing at the dressing to try to move the tubing within the dressing. If this does not resolve the blockage change the dressing.	The alarm will continue until the 'Mute' button is pressed or the blockage is cleared. During the calibration cycle, the flow rate goes to its maximum and this pressure can remove the fluid from the tubing.
Low Battery When the battery is at 25% remaining charge the fourth green Battery Charge Indicator light is illuminated, 'BAT' is displayed	

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on the screen and an audible alarm sounds once. When the battery is low the amber (last) Battery Charge Indicator light is illuminated, 'BAT' is displayed on the screen and an audible alarm sounds once. Green OK Light will start flashing. Charge as soon as possible. If the battery is completely drained the OxyGeni will shut off and stop producing oxygen. Charge as soon as possible. DO NOT remove the dressing. Charge battery as described below.	OxySpur dressing provides moist wound healing when oxygen is not being delivered.
Daily Care	
Showering Before showering disconnect the OxyGeni from the dressing and protect the dressing and the end of the tubing attached to the dressing so that no water enters the tubing or the dressing.	
Charging Battery OxyGeni Generator battery should be recharged daily. To charge the generator use the provided USB charging cable to connect the Power Pack (external battery) to the magnetic charging port on top of the OxyGeni Device. DO NOT turn the generator off. Remove the power pack when the Battery Charging Light turns green. When charging is complete, attach the OxyGeni Power Pack (external battery) to the USB Charger and plug in to a wall outlet to recharge the Power Pack so that a full charge is maintained. The lights of the OxyGeni Generator Battery Charge Indicator lmoves from **left to right** and shows the **approximate** remaining charge. • First green light – at least 85% remaining (18-24 hours) • Second green light – at least 65% remaining (15-18 hours) • Third green light – at least 45% remaining (10-15 hours) • Fourth green light – at least 25% remaining (6-10 hours) • Amber light – less than 25% remaining (less than 6 hours) **Charging the Power Pack** The Power Pack should be connected to the charger after each use to maintain a full charge level. Insert the charger into a standard wall outlet. Using the provided USB connector, insert one end into the charger and the other end into the Power Pack top port. A light in the Power Pack will start flashing either red, yellow, or green depending on the charge level of the power pack. When the light turns green, and the flashing has stopped (from 1-3 hours) the Power Pack is fully charged.	A good practice is to only use the Power Pack to recharge the Generator at night and leave the Pack on the charger during the day. That way the client can be mobile during the night to use the washroom, etc. Can be charged using any USB charger, not only the one supplied with the system. The Battery Charging Light will turn red, and the Battery Charge Indicator lights will flash in sequence when the battery is being charged. The Battery Charging Light turns green when the battery is fully charged. The battery can last up to 24 hours.  The Power Pack can be left connected to the charge until needed.
Cleansing of OxyGeni, Charger and Power Pack	
Wipe down all hard surface components as per HA/agency procedures. Clean all organic material (visible soil or body secretions) prior	

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to disinfection. Use hospital-grade cleaners and disinfectants containing quaternary ammonium compounds or other similar disinfectant products. Use damp wipes or clothes and wipe all exposed surfaces, taking care to clean crevices and corners.	Avoid products containing bleach. Do not immerse or saturate the therapy unit or charger with fluids to avoid damage to the electronics.
Removing OxySpur Dressing	
Consider using adhesive remover to remove adhesives (e.g. tape). Disconnect the OxySpur dressing cannula from the extension set or OxyGeni with a counterclockwise turn. Gently lift corners of dressing away from wound and remove.	To decrease risk of medical adhesive related skin injury (MARSI). If difficulty is experienced on removing the dressing, irrigate with normal saline or similar solution.
Frequency of Dressing and Tubing Change	
Initially, dressing changes may be required 3-4 times per week until exudate subsides (about 2 weeks). Then at least weekly or if wound exudate strikes through reaching the top and/or edge of the dressing Change extension set weekly or if wound exudate has entered the tubing.	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. OxyGeni generator will alarm if tubing is plugged with wound exudate.
Returning Rental OxyGeni Unit	
When CDO Therapy has been discontinued: • Notify vendor by email or phone of discontinuation to stop the rental billing process orders@braemed.ca or 1-888-830-7744 (toll-free). • Vendor will provide the site/unit with a 'Return Waybill' envelope to ship the OxyGeni unit back to the vendor.	
Expected Outcomes	
Wound healing as noted by a decrease in wound size by 30% in 3 weeks. Exudate is managed with no periwound maceration. Product performs as expected.	If product does not perform as expected, notify NSWOC/Wound Clinician and then consider submitting a Supply Chain Product Concern Form.
QR Codes	
Wound Cleansing Procedure	**Wound Packing Procedure**
Conservative Sharp Wound Debridement	
For further information please contact NSWOC/Wound Clinician	