CardinalHealth
Essential to care™

Cardinal Health™ Negative Pressure Wound Therapy PRO/PRO TO GO

Patient User Manual

About Your Cardinal Health™ PRO/PRO to GO

Your doctor has chosen the Cardinal Health™ NPWT PRO/PRO to GO to remove fluid from your wound by using carefully controlled suction. It is important, however, for you to carefully watch the wound and the PRO/PRO to GO to make sure that it is working properly. Below is some important information and questions that you should ask your healthcare professional.

Things you need to know about your PRO/PRO to GO

- Do not allow the PRO/PRO to GO to get wet. Clamp the tubing and disconnect from the canister if you take a bath or shower.
- Keep the PRO/PRO to GO plugged in whenever possible to keep the battery fully charged. Always take the A.C. Power Adapter with you when you leave home.
- Keep the PRO/PRO to GO upright to avoid a false Canister Full Alert.
- Keep the PRO/PRO to GO turned on at all times unless there is bleeding from the wound or instructed by your healthcare professional.
- Do not change the Pressure Settings on the PRO/PRO to GO unless you are told to do so by your healthcare professional.

Things to ask your healthcare professional

- How to tell if there is a problem with your PRO/PRO to GO or dressing.
- What to do if you have a problem or a leak with your dressing.
- What to do if you notice bleeding from the wound.
- What to do if you must take your dressing off.
- What activities you can do while using the PRO/PRO to GO.
- Who to call if you need help.
- How to take care of your PRO/PRO to GO.

This Cardinal Health™ NPWT PRO/PRO to GO Patient User Manual is not a guarantee or warranty. It is intended only as an operational guide.

For additional information and questions, please contact Cardinal Health Customer Service at 1.866.484.6798.

In order for the PRO/PRO to GO to provide safe, reliable, and proper performance, the following conditions must be met. Failure to comply with these conditions will void all pertinent warranties.

- All assembly, operation, adjustment, modification, maintenance, and/or repair must be carried out only by qualified personnel authorized by Cardinal Health. Unauthorized modification of the PRO/PRO to GO may result in physical hazards, including delayed therapy, electrocution, and fire that may lead to injury or death.
- The electrical outlets in the room in which the PRO/PRO to GO is used complies with the appropriate national electrical standards.
- The PRO/PRO to GO must be used in accordance with this Patient User Manual and all associated labeling.

CAUTION: Federal law restricts this device to sale by, or on the order of, a physician. As with any prescription medical device, failure to follow product instructions or changing settings without the express direction and/or supervision of a trained clinical caregiver may lead to improper product performance and the potential for serious or fatal injury.

Safety and Warnings

Note to healthcare personnel providing training to lay users or lay caregivers (lay responsible organizations): Be sure to include all of the warnings below when providing training to lay operators, especially in a home care environment. Lay users and caregivers should contact Customer Support if there is a change in the performance of the PRO/PRO to GO. Additionally, lay users and caregivers should be instructed on proper cleaning procedures to avoid hazards such as electric shock. Lay users and caregivers should also be trained on inappropriate environments for use (e.g. bathtub). For guidance on training, please contact Customer Support.

WARNING: Strangulation hazard. Do not leave A.C. Power Adapter cord, tubing or other choking hazards where infants or young children can become caught. If these objects get wrapped around the neck, strangulation and death can occur.

WARNING: The PRO/PRO to GO contains small parts, which could become detached and pose a choking hazard. Some of these components could be inhaled or swallowed by a small child, toddler or infant, which could result in suffocation or death. Keep all parts of the PRO/PRO to GO out of reach of small children.

WARNING: Do not modify this equipment without authorization from the manufacturer. Modification of this system could result in physical hazards, including delayed therapy, electrocution and fire. These hazards could result in injury or death.

WARNING: Use only the Cardinal Health™ NPWT Dressing and accessories listed in this manual. Use of other dressings and accessories can create hazardous situations, including improper therapy or delayed therapy. This could result in improper healing, damage to the wound area, and infection.

CAUTION: Use the PRO/PRO to GO only as described in this user manual. Do not interconnect the PRO/PRO to GO with other devices not included in this user manual. Failure to comply could result in improper therapy and could result in damage to the PRO/PRO to GO.

CAUTION: This system is not intended to be used in MRI environments or in the presence of strong magnetic fields. Do not use this device in any areas with strong magnetic fields. The system contains metal components which could cause unintended movement. This unintended movement could cause clinician or patient harm due to falling objects or collisions.

CAUTION: If you are in an environment with pet hair, please use caution when adhering the wound dressing to the wound site. Pet hair could contaminate the wound site and prevent adhesion of the wound dressing. This could result in possible infection of the wound or reduced effectiveness of the system.

CAUTION: The PRO/PRO to GO system can be used outdoors for short periods of time (not more than 24 hours). Shelter from the rain.

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1. Introduction

1.1 Indications

The PRO/PRO to GO Negative Pressure Wound Therapy (NPWT) system is an integrated wound management system, indicated for the application of continual or intermittent negative pressure wound therapy to the wound as the PRO/PRO to GO may promote wound healing by the removal of fluids, including wound exudates, irrigation fluids, body fluids and infectious materials.

The PRO/PRO to GO NPWT system is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. The PRO/PRO to GO NPWT system is intended for use in acute, extended and home care settings.

1.2 Contraindications

The NPWT PRO/PRO to GO is contraindicated for patients with malignancy in the wound, untreated osteomyelitis, non-enteric and unexplored fistulas, or necrotic tissue with eschar present. Do not place the Cardinal Health™ NPWT black foam dressing over exposed blood vessels or organs. The Cardinal Health™ NPWT Dressings are also contraindicated for hydrogen peroxide and solutions which are alcohol based or contain alcohol. It is not recommended to deliver fluids to the thoracic cavity.

1.3 Precautions

Precautions should be taken for patients with infected wounds, active bleeding, difficult wound hemostasis, or who are on anticoagulants.

- **Defibrillation:** The NPWT Dressing must be removed if defibrillation is required in the area of dressing placement. Failure to remove the dressing may inhibit electrical current transmission and/or patient resuscitation.
- **Magnetic Resonance Imaging (MRI):** The PRO/PRO to GO is not MRI-compatible and cannot be used in the presence of strong magnetic fields. Do not take the PRO/PRO to GO into the MRI area or any area of high magnetic fields. The PRO/PRO to GO contains metal components that could cause unintended movement resulting in harm due to falling objects or collisions.
- **Hyperbaric Oxygen Therapy (HBO):** Do not take the PRO/PRO to GO — whether on or off — into a hyperbaric chamber. The PRO/PRO to GO must be disconnected before HBO treatment.
- During negative pressure wound therapy, the PRO/PRO to GO and Cardinal Health™ NPWT Dressing are a closed system and are NOT vented to atmosphere.
- When the NPWT Canister is full, replace immediately (**2.3 Changing the Canister**). Fluids are not removed from the dressing once the canister is full.

1.4 Safety Tips

Keep Therapy On

The PRO/PRO to GO should be operated at least 22 hours out of every 24-hour period. Contact your healthcare professional if negative pressure wound therapy stops or if the PRO/PRO to GO is OFF for more than 2 hours in a 24-hour period. Your dressing must be changed by your healthcare professional.

Monitoring the Wound

Inspect the dressing frequently to ensure that the dressing is collapsed and that negative pressure wound therapy is being delivered in a consistent manner. Monitor wound exudates for signs of active bleeding. Monitor your wound and the canister and tubing for signs of active bleeding. Monitor around your wound for signs of infection or other complications. Signs of possible infection may include fever, tenderness, redness, swelling, itching and rash, increased warmth in the wound area, sudden increase in pain, purulent discharge or a strong odor. Nausea, vomiting, diarrhea, headache, dizziness, fainting, sore throat with swelling of the mucous membrane, disorientation, high fever, refractory hypotension, orthostatic hypotension or periwound induration (a sunburn-like rash) may be added signs of more serious complications of infection. Extra care and attention should be given if there are any signs of possible infection or related complications. Infection can be serious. With or without the PRO/PRO to GO, infection can lead to many adverse complications including pain, discomfort, fever, gangrene, toxic shock, septic shock and various other complications. With signs of more serious complications of infection, discontinue the use of the PRO/PRO to GO until the serious infection is diagnosed and properly treated by your healthcare professional.

NPWT Dressing Use

Your healthcare professional will apply and change your dressings for you.

NOTE: All dressing components of the NPWT Dressing Kit are packaged sterile. The decision to use clean versus sterile/aseptic technique is dependent upon your healthcare professional's preference. All components of the PRO/PRO to GO, the NPWT Dressing Kits, the canisters and other accessories are made without natural rubber latex.

Be sure to comply with **1.2 Contraindications** and **1.3 Precautions** for the PRO/PRO to GO.

2. Getting to Know the PRO/PRO to GO

2.1 Getting to Know the PRO/PRO to GO

You may not need to use many of the buttons on the PRO/PRO to GO, but it is important that you are familiar with what they are and their location (**Figure 1**).

NOTE: The PRO/PRO to GO is quiet during normal operation with a well-sealed dressing.

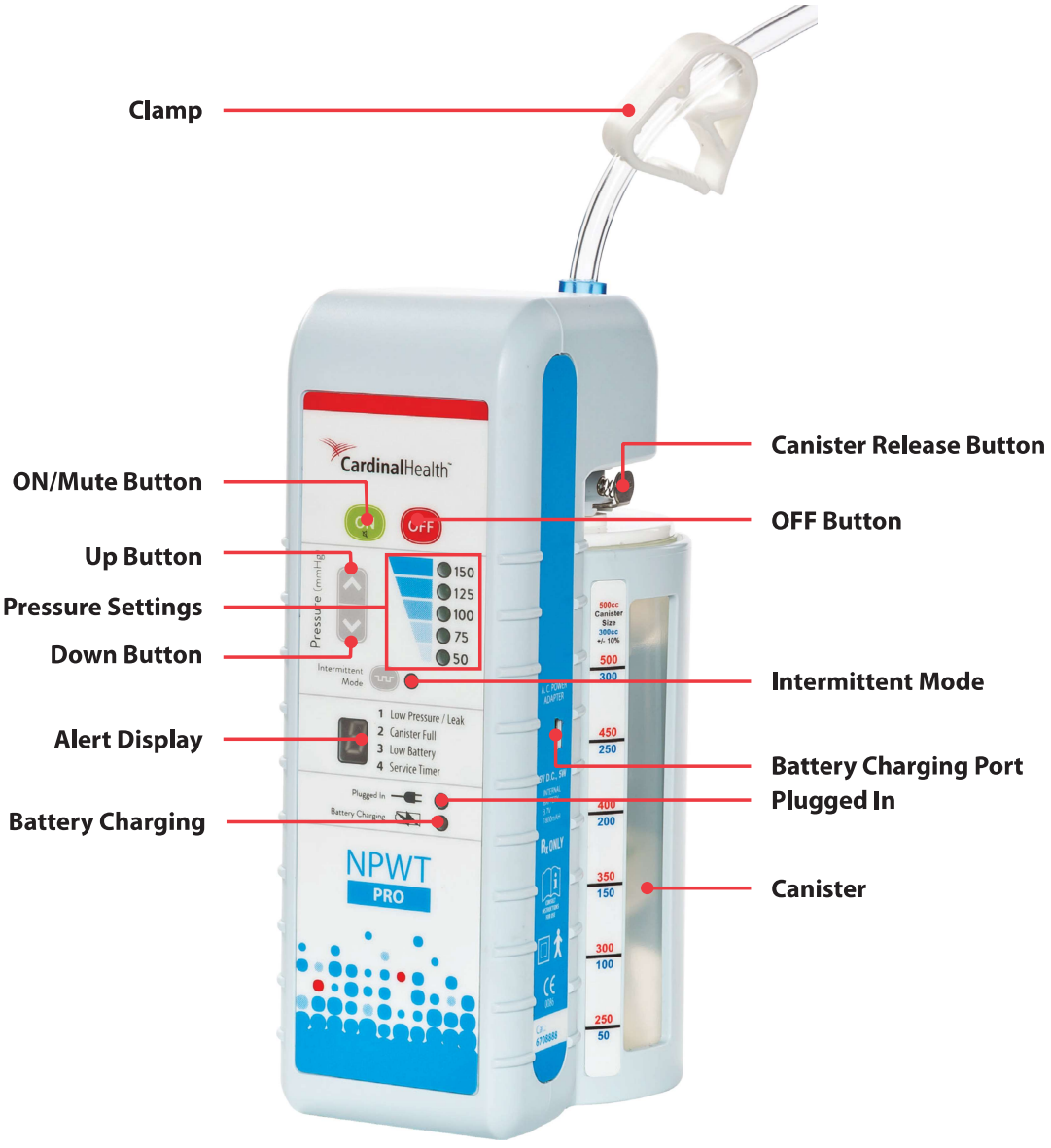


Figure 1

2.2 Charging the Battery

The PRO/PRO to GO has an internal battery that provides up to 24 hours of operation from a fully-charged battery. When the battery is running low, an alert sounds to let you know you must plug in the PRO/PRO to GO to charge the battery. See section **3.2 Troubleshooting**.

1. Plug the A.C. Power Adapter into a wall outlet.
2. Insert the A.C. Power Adapter into the Battery Charging Port on the side of the PRO/PRO to GO (**Figure 2**).
3. When the PRO/PRO to GO is connected to an outlet, the green light next to the Plugged In symbol comes on (**Figure 2**). If the battery is charging, the yellow light next to the Battery Charging symbol comes on. Once the battery is fully charged, the light goes off.

   NOTE: If the PRO/PRO to GO is plugged in and the green light does not turn on, check to make sure the outlet is working properly.
4. The PRO/PRO to GO continues to work when charging.

CAUTION: The PRO/PRO to GO must be used with the supplied A.C. Power Adapter. Use of another adapter/power cord could result in physical hazard, including delayed therapy, electrocution, and fire. These hazards could result in injury or death.

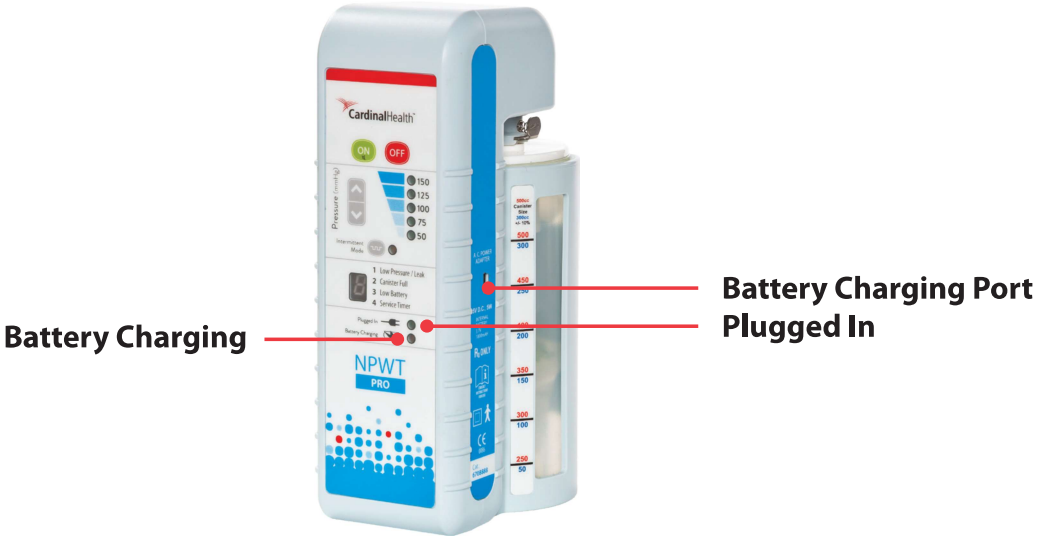


Figure 2

Average Battery Life

The battery life of the PRO/PRO to GO with a fully-charged battery is up to 24 hours. The actual life is dependent on the integrity of the dressing. A leak in the dressing can significantly reduce overall battery longevity.

Average Time for Recharging

To ensure the battery has been fully charged, the PRO/PRO to GO should be connected to an outlet via the A.C. Power Adapter for approximately 3 hours. After approximately 2 hours of charging, the PRO/PRO to GO reaches 80 percent of total battery capacity.

Low Battery Alert

While running on battery, a Low Battery alert "chirps" every 10 seconds and the OFF Button flashes when remaining capacity of the battery is less than 20 percent (**3.2 Troubleshooting**). Typically, the PRO/PRO to GO continues to operate for approximately 1 hour after the Low Battery Alert sounds.

If the battery charge gets too low, the PRO/PRO to GO shuts off and the negative pressure wound therapy is stopped. At this point, the PRO/PRO to GO must be plugged into an outlet using the A.C. Power Adapter for negative pressure wound therapy to resume. Once the A.C. Power Adapter is plugged in, press the ON Button to restart the PRO/PRO to GO.

2.3 Changing the Canister

When the PRO/PRO to GO detects that the canister needs to be changed, a Canister Full alert sounds. The PRO/PRO to GO continues to work until the canister completely fills. When the canister is completely full, the PRO/PRO to GO turns off. To change the canister:

1. Clamp the tubing closed (**Figure 1**).
2. Turn the PRO/PRO to GO off by pressing the OFF Button.
3. Disconnect SpeedConnect™ tubing connector from top of canister by twisting off the tapered connector.
4. To remove the canister, press the Canister Release Button located above the canister and gently pull the bottom of canister down to remove from the PRO/PRO to GO.
5. Cap the canister and ask your healthcare professional how to properly dispose of a used canister.
6. To install a new canister, hold the new unused canister at the bottom and slide upwards into the holder.
7. Line up the two ports on the canister with the two ports on the PRO/PRO to GO. Press the canister up and into the PRO/PRO to GO until it clicks and locks into place.
8. Connect the distal end of the SpeedConnect™ tubing with the blue tapered connector to the patient port of the canister. Gently twist and push the connector on just enough to secure and seal it.
9. Reopen the tubing clamp by pushing down on the top of the clamp until it releases.
10. Turn the PRO/PRO to GO on by pressing the ON Button to resume negative pressure wound therapy.

2.4 Disconnecting from the PRO/PRO to GO

You may disconnect the PRO/PRO to GO from your dressing for short amounts of time for activities such as bathing or showering. Ask your healthcare professional about care of your dressing during bathing or showering.

NOTE: The PRO/PRO to GO should be operated at least 22 hours out of every 24-hour period. Contact your healthcare professional immediately if negative pressure wound therapy has stopped or is off for more than 2 hours in a 24-hour period. Your dressing may need to be changed.

To disconnect from the PRO/PRO to GO:

1. Clamp the tubing closed.
2. Turn the PRO/PRO to GO off by pressing the OFF Button.
3. Disconnect SpeedConnect™ tubing connector from top of canister by twisting the tapered connector off the canister.
4. If canister is full, change the canister (**2.3 Changing the Canister**).

To reconnect to the PRO/PRO to GO:

1. Connect the distal end of the SpeedConnect™ tubing with the blue tapered connector to the patient port of the canister. Gently twist and push the connector on just enough to secure and seal it.
2. Reopen the tubing clamp by pushing down on the top of the clamp until it releases.
3. Turn the PRO/PRO to GO on by pressing the ON Button to resume negative pressure wound therapy.

3. Operating Instructions

Carefully read **1.3 Precautions** and **1.4 Safety Tips** in the **1. Introduction** section before attempting to operate and adjust the PRO/PRO to GO.

CAUTION: The PRO/PRO to GO must only be used with the supplied A.C. Power Adapter. Use of another adapter/power cord could create a shock hazard for you or your caregiver, cause fire, and/or severely damage the PRO/PRO to GO. If you need a replacement A.C. Power Adapter, call Cardinal Health Customer Service at 1.866.484.6798.

3.1 ON / OFF

The ON and OFF Buttons are located on the front of the PRO/PRO to GO.

1. Press the ON Button. All lights on the PRO/PRO to GO will sequentially light up during the power-on self-test.
2. Each time the PRO/PRO to GO is turned on, it goes through self-test and the Alert Display shows a series of numbers and/or letters.
3. The dressing should slowly collapse, indicating the presence of negative pressure. If there is a Low Pressure/Leak alert, there may be a problem (**3.2 Troubleshooting**).
4. The PRO/PRO to GO should be operated at least 22 hours out of every 24-hour period. Contact your healthcare professional if the PRO/PRO to GO is OFF for more than 2 hours in a 24-hour period. Your dressing must be changed by your healthcare professional.

NOTE: If an alert persists and cannot be resolved, please call Cardinal Health Customer Service at 1.866.484.6798.

CAUTION: In the event of an emergency, please contact your treating physician, caregiver or your local emergency responders.

3.2 Troubleshooting

Alert Volume

The Alert Display indicates the volume level, which ranges from 1 to 5. The volume of the alert can be adjusted.
To increase the alert volume, press and hold the ON Button while pressing the Up Button. To decrease the alert volume, press and hold the ON Button while pressing the Down Button. Pressing the ON (MUTE) Button after an alert silences the alert for 5 minutes. The alert continues to sound every 5 minutes until the problem is corrected. The alert showing number 4 in the Alert Display cannot be muted and you must call your healthcare professional.

To clear an alert, use the **Troubleshooting** table on the next page.

NOTE: If an alert persists and cannot be resolved, please call Cardinal Health Customer Service at 1.866.484.6798.

CAUTION: In the event of an emergency, please contact your treating physician, caregiver or your local emergency responders.

What you see or hear	Problem	What to do	More Information
FLASHING "1" **Low Pressure/Leak** **Single beep.** **Device is making more noise.**	There is an air leak in either the dressing or the tubing connections.	• Clamp the tubing. • If Low Pressure/Leak flashing "1" and audible alert resets, there is a leak below the clamp — often in the dressing. Reopen the clamp before addressing the leak. Gently press around drape to check for leaks. If leak is found, patch with extra drape material. • If Low Pressure/Leak flashing "1" and audible alert continues, there is a leak above the clamp. Check tubing connection at the canister. Check to ensure the canister is fully seated and locked. Check for cracks in the canister or lid separation. If found, replace the canister. • Open the clamp.	The alert will reset, the pressure light will stop flashing, and the pump will become quiet after you find and seal the leak. Leaks often occur over areas of moist skin, creases or folds in skin, and wrinkles in the drape. They can occur if the drape snags on clothes or bed sheets.
FLASHING "2" **Canister Full** **Two-tone beep.**	The canister is full.	• Clamp the tubing. • Turn device off by pressing the OFF button. • Press the canister release button above the canister and slide the full canister out. Cap and dispose of properly. Slide new canister in, align the short ports and click into place. • Open the clamp and press the ON button to resume therapy.	The canister full alert begins when the canister is 90 percent full, but the device will continue to work until the canister completely fills. If the PRO/PRO to GO are placed on their fronts, fluid entering the canisters will cause a false canister full alert and require the canisters to be changed.
FLASHING "3" **Low Battery** **Three-tone beep.**	The battery is low and will run out in about 30 minutes.	Plug in the device.	Use only the power cord that came with the PRO/PRO to GO. When the device is getting power, a green light will illuminate on the front of the device. A yellow light below the green light will show that the battery is charging. It will turn off once the battery is fully charged.
FLASHING "4" **Therapy Time** **Four beeps every 10 seconds.**	Device therapy time has expired.	Contact your healthcare professional.	This alert cannot be muted or manually reset by cycling power.
Pressure Setting will not change.	Pressure lock-out is engaged.	Contact your healthcare professional.	Pressure Setting can only be changed per a healthcare professional's orders.
Device is quiet and fluid is not moving in the tubing.	This is NOT a problem.	No action needed.	When the dressing has a good seal, fluid may be removed from the wound and stay in the tubing. The foam will be compressed normally and the PRO/PRO to GO is quiet. Your healthcare professional will change the PRO/PRO to GO if required.
An amber light is showing on the front of the device below the pressure numbers.	This is NOT a problem. The device is operating in Intermittent Mode.	No action needed.	Intermittent mode maintains target pressure for 5 minutes and decreases to -25mmHg for 2 minutes.

4. Care & Cleaning

Your healthcare professional will handle much of the care and cleaning needed for your PRO/PRO to GO. Periodically check to make sure the PRO/PRO to GO is working properly.

If the PRO/PRO to GO does not seem to work properly or is showing an alert, see **3.2 Troubleshooting**. Contact your healthcare professional for help. If the A.C. Power Adapter is damaged, it must be replaced immediately. Contact your healthcare professional for help.

WARNING: The PRO/PRO to GO must only be used with the supplied A.C. Power Adapter. Use of another adapter/power cord could result in physical hazards, including delayed therapy, electrocution and fire. These hazards could result in injury or death.

4.1 Disposal of Used Components

Your healthcare professional should remove your dressings, tubing and used canisters.

4.2 Cleaning the PRO/PRO to GO

The PRO/PRO to GO should need only light cleaning. Make sure to unplug the PRO/PRO to GO before cleaning. The battery provides power when the PRO/PRO to GO is unplugged so negative pressure wound therapy is not interrupted. Clean the PRO/PRO to GO with a damp soft cloth and a mild soap and water solution.

Do not saturate the PRO/PRO to GO with liquid or allow liquid to pool on the PRO/PRO to GO. This can present a potential hazard for you and/or your healthcare professional.

WARNING: Avoid spilling or spraying liquid on any part of the PRO/PRO to GO. Liquids can cause corrosion when left on electronic controls which can lead to failure. Component failure may cause the PRO/PRO to GO to operate erratically, possibly causing a potential hazard to you or your caregiver.

Carrying Case and IV Pole Adapter: Follow the same procedure as above.

4.3 A.C. Power Adapter Inspection

The A.C. Power Adapter should be inspected regularly for damage. If you notice any damage to the A.C. Power Adapter, call your healthcare professional for a replacement to avoid interruption of therapy.

WARNING: The PRO/PRO to GO must only be used with the supplied A.C. Power Adapter. Use of another adapter/power cord could result in physical hazards, including delayed therapy, electrocution and fire. These hazards could result in injury or death.

5. Symbols Glossary

Symbols Recognized by Standard/Law

Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
	ISO 13225-1, Clause 5.1.1	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Manufacturer	Indicates the medical device manufacturer.
	ISO 7000-3082	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.1.3	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Date of Manufacture	Indicates the date when the medical device was manufactured.
	ISO 7000-2497	Graphical symbols for use on equipment		
	EN 60417-6049	Graphical symbols for use on equipment	Country of Origin	To identify the country of manufacture of products. To identify country abbreviation, see https://www.iso.org/obp/ui/#-search.
	ISO 3166-1	Codes for the representation of names of countries and their subdivisions - Part 1: Country Codes		
	ISO 15223-1, Clause 5.1.2	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Authorized European Representative	Indicates the Authorized Representative in the European Union.
	ISO 15223-1, Clause 5.1.6	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Catalogue or Model Number	Indicates the manufacturer's catalogue number so the device can be identified.
	ISO 7000-2493	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.1.7	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Serial Number	Indicates the manufacturer's serial number so that a specific device can be identified.
	ISO 7000-2498	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.1.5	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Batch/Lot Code	Indicates the manufacturer's batch/lot code so that the batch or lot can be identified.
	ISO 7000-2492	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.1.4	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Use by Date	Indicates the date after which the medical device is not to be used.
	ISO 7000-2607	Graphical symbols for use on equipment		

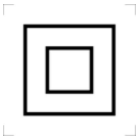
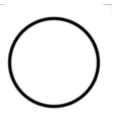
Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
	ISO 15223-1, Clause 5.5.1	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	*In Vitro* Diagnostic Medical Device	Indicates that a medical device is intended to be used as an *in vitro* diagnostic medical device.
	IEC 60601-1, Table D.1, Symbol 10	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	ISO 7000-0434	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.3.7	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 7000-0632	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.3.8	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Humidity Limitation	Indicates the range of humidity to which the medical device can be safely exposed.
	ISO 7000-2620	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.3.4	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Keep Dry	Indicates a medical device that needs to be protected from moisture.
	ISO 7000-0626	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.3.1	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Fragile, Handle with Care	Indicates a medical device that can be broken or damaged if not handled carefully.
	ISO 7000-0621	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.4.2	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Do Not Reuse	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.
	ISO 7000-1051	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.2.6	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Do Not Resterilize	Indicates that a medical device should not be resterilized.
	ISO 7000-2608	Graphical symbols for use on equipment		

Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
	ISO 15223-1, Clause 5.2.1	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Sterile	Indicates a medical device that has been subjected to a sterilization process.
	ISO 7000-2499	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.2.2	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Sterile Using Aseptic Techniques	Indicates medical device that has been sterilized by using accepted aseptic technique.
	ISO 7000-2500	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.2.3	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Sterilized by Ethylene Oxide	Sterilized by ethylene oxide
	ISO 7000-2501	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.2.4	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Sterilized Using Irradiation	Indicates a medical device has been sterilized using irradiation.
	ISO 7000-2502	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.2.5	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Sterilized Using Steam or Dry Heat	Indicates a medical device has been sterilized using steam or dry heat.
	ISO 7000-2503	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.2.9	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Sterile Fluid Path	To identify the presence of a sterile fluid path within the medical device when other parts of the medical device are not necessarily supplied sterile.
	ISO 7000-3084	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.3.2	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Keep Away From Sunlight	Indicates a medical device that needs protection from light sources.
	ISO 7000-0624	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.2.7	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	ISO 7000-2609	Graphical symbols for use on equipment		

Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
	ISO 15223-1, Clause 5.4.3	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Consult Instructions for Use	Indicates user needs to consult instructions for use.
	ISO 7000-1641	Graphical symbols for use on equipment		
	IEC 60601-1, Table D.2, Symbol 10	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Refer to Instruction Manual/Booklet	Indicates user needs to consult instructions for use.
	IEC 60601-1-2:2007, Clause 5.1.1	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	Non-ionizing Electro-magnetic Radiation	To indicate generally elevated, potentially hazardous, levels of nonionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.
	IEC 60417-5140	Graphical symbols for use on equipment		
	IEC 60878-5140	Graphical symbols for electrical equip-ment in medical practice		
	ISO 15223-1, Clause 5.3.9	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Atmospheric Pressure Limits	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	ISO 7000-2621	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.6.3	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Non-pyrogenic	Indicates that the medical device is non-pyrogenic.
	ISO 7000-2724	Graphical symbols for use on equipment		
	ISO 15223-1, Clause 5.2.8	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Do Not Use if Package is Damaged	Indicates that the medical device should not be used if the package holding device has been damaged or opened.
	ISO 7000-2606	Graphical symbols for use on equipment		
	ISO 7000-3079	Graphical symbols for use on equipment	Open Here	Indicates where the package can be opened and to indicate method of opening it.
	ASTM F2503	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment	Magnetic Resonance (MR) Unsafe	Keep device away from magnetic resonance imaging (MRI) equipment.

Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
	IS EN-15986:2011	Symbol for use in the labeling of medical devices. Requirements for labeling of medical devices containing phthalates.	Contains Presence of Phthalates	Indicates presence of Bis (2-ethylexyl) phthalate (DEHP).
	ISO 15223-1, Clause 5.4.5, Annex B.2	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Does Not Contain Natural Rubber Latex	The medical device or the packaging of the medical device does not contain natural rubber latex.
	ISO 15223-1, Clause 5.4.5, Annex B.2	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Does Not Contain Natural Rubber Latex	The medical device or the packaging of the medical device does not contain natural rubber latex.
	ISO 15223-1, Clause 5.4.5	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied	Contains or Presence of Natural Rubber Latex	Indicates the presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device.
	EN 50419	Marking of Electrical and Electronic Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE).	WEEE Wheeled Bin	This product contains electrical and electronic components that may contain materials which, if disposed with general waste, could be damaging to the environment. Residents of the European Union must follow specific disposal of or recycling instructions for this product. Residents outside the European Union must dispose or recycle this product in accordance with local laws or regulations that apply.
	IEC 60601-1, Table D.1, Symbol 20	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Type BF Applied Part	Identifies a type BF applied part complying with IEC 60601-1-11.
	ISO 7000-5333	Graphical symbols for use on equipment		

Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
	IEC 60601-1, Table D.1, Symbol 19	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Type B Applied Part	Identifies a type B applied part complying with IEC 60601-1.
	ISO 7000-5840	Graphical symbols for use on equipment		
IPN1N2	IEC 60601-1, Table D.3, Symbol 2	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Degrees of Ingress Protection Provided by Enclosure	Manufacturer-determined degree of particle and water ingress where N1= degree of protection from particles (scale of 0-6) and N2=degree of protection from water (scale of 0-8).
	IEC 60529	Degrees of protection provided by enclosures (IP Code)		NOTE: When a characteristic numeral is not required to be specified, it is replaced by the letter ÒXÓ.
IP28	IEC 60529	Degrees of protection provided by enclosures (IP Code)	Degrees of Ingress Protection Provided by Enclosure	Protected against solid foreign objects of 12.5mm and greater, and against the effects of continuous immersion in water.
IP48	IEC 60529	Degrees of protection provided by enclosures (IP Code)	Degrees of Ingress Protection Provided by Enclosure	Protected against solid foreign objects of 1.0mm and greater, and against the effects of continuous immersion in water.
IPX8	IEC 60529	Degrees of protection provided by enclosures (IP Code)	Degrees of Ingress Protection Provided by Enclosure	Protected against the effects of continuous immersion in water.
IPX7	IEC 60529	Degrees of protection provided by enclosures (IP Code)	Degrees of Ingress Protection Provided by Enclosure	Protected against the effects of temporary immersion in water.
IP22	IEC 60530	Degrees of protection provided by enclosures (IP Code)	Degrees of Ingress Protection Provided by Enclosure	Protection against the effects of insertion of fingers and will not be damaged or become unsafe when exposed to vertically or nearly vertical dripping water.

Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
℞ ONLY	21 CFR Part 801.1(c)(1)(i)F	Labeling - Medical devices; prominence of required label statements	Prescription Use Only	Requires prescription for sale in the United States and is used in place of the statement below: **CAUTION**: Federal law restricts this device to sale by or on the order of a physician, dentist or licensed practitioner.
	21 CFR Part 801.109	Labeling - Prescription devices		
CE	Directive 93/42/ EEC Articles 4, 11, 12, 17 Annex 12	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices	The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Directive.	Signifies European technical conformity.
	Directive 93/68/ EEC	CE Marking		
	IEC 60417-5172 Section 7.2.6	Class II equipment	Marking Requirements for Class II Equipment	Power adaptor meets the safety requirements specified for Class II equipment according to IEC 61140.
	ISO 7000-2616	External cord connected	External Cord Connected	Indicates that device is connected to an external power source.
	ISO 7000-5008	OFF (power)	OFF (Power)	To indicate disconnection from power.
	ISO 7000-5007	ON (power)	ON (Power)	To indicate connection to power.
	ISO 7000-5417	Programmable duration	Programmable Duration	To identify the control of a programmable timer to start an operation at a specific point in time and to stop the operation at a specific point in time or after a specific duration; or to identify a display of the programmed or to-be-programmed duration.

Symbol	Standard/Law Reference	Standard/Law Title	Symbol Title/ Text Reference	Explanatory Text
	ISO 7000-5546	Battery check	Battery Check	To identify the battery condition indicator.
	ISO 7000-0623	This way up	This Way Up	To indicate correct upright position of the transport package.

Symbols Not Recognized by Standard/Law

Symbol	Guidance	Guidance	Symbol Title	Explanatory Text
	INDA and EDANA Flushability Guidelines	INDA and EDANA Flushability Guidelines	Do Not Flush	Do not flush in toilet.
				This container can and should be recycled.
			Powder Free	Gloves are powder free.
			Synthetic	Indicates medical device contains synthetic latex.
				This glove has been tested for resistance to permeation of various chemotherapy drugs per ASTM D6978, "Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs."

Symbol	Guidance	Guidance	Symbol Title	Explanatory Text
				This glove has been tested for permeation of various chemicals per ASTM F739, "Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact."
 1 Pair of Gloves			1 Pair of Gloves	Contains a pair of gloves.
			Russian Registration Mark	Signifies technical conformity in Russia.
			Open Arrow	Open at arrow.
			Peel Here	Peel here to open package.
 Pouch Opening			Pouch Opening	Directions on how to open pouch.
 1 Single Glove			1 Single Glove	Contains a single glove.
			UL Listed	UL has tested representative samples of a product and determined that it meets UL's requirements. These requirements are based on UL's published and nationally recognized Standards for Safety.
			UL Listed	Product is certified under UL's Listing and Classification services and for UL certifications for Canada and the USA.

Symbol	Guidance	Guidance	Symbol Title	Explanatory Text
			Device Plugged into an Outlet	Indicates that device is connected to an external power source.
			Battery Charging	Device is plugged into an outlet and the internal battery is charging.

6. Specifications

Cardinal Health™ PRO/PRO to GO

Dimensions ..... 19.3 x 11.1 x 7.1cm (7.6 x 4.4 x 2.8 in.)
Weight ..... 0.4kg (0.9 lb.)
Pressure Settings ..... -50, -75, -100, -125, -150mmHg

IEC Classification

- With respect to electric shock, fire, and mechanical hazards, conforms to IEC60601-1.
- Medical Equipment
- Equipment not suitable for use in presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
- Continuous Operation
- Type B Applied Part
- Class II Internally Powered Equipment
- IPX0

Battery

Duration (Fully Charged) ..... up to 24 hours

Electrical

External Power Supply Input ..... 100-240VAC, 50/60Hz, 0.5Amp Max
External Power Supply Output 5VDC, 1Amp

Environmental and Storage Conditions

Temperature Range ..... 10°F (-12°C) to 110°F (43°C)
Relative Humidity Range ..... 60 +/-25% (35% to 85%)
Atmospheric Pressure Range ..... 50kPa to 110kPa

Operating Conditions

Temperature Range ..... 40°F (4°C) to 90°F (32°C)
Relative Humidity Range ..... 60 +/-25% (35% to 85%)
Atmospheric Pressure Range ..... 80kPa to 110kPa
PRO Therapy Time ..... 1,000 hours
PRO to GO Therapy Time ..... 10 days

CAUTION: Federal law restricts this device to sale by, or on the order of, a physician.

6.1 Electromagnetic Compatibility

Guidance and Manufacturer's Declaration: Electromagnetic Emissions (IEC 60601-1-2)		
Emissions Test	**Compliance**	**Electromagnetic Environment**
Harmonic emissions IEC 61000-3-2	Class A	The PRO is suitable for use in all establishments, including medical facilities, domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	
RF emissions CISPR 14-1	Complies	The PRO is not suitable for interconnection with other equipment.

Recommended separation distance between portable and mobile RF communications equipment and the PRO.

The PRO is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PRO can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PRO as recommended below, according to the maximum output power of the communications equipment.

Output Power of Transmitter in watt(s)	Separation distance according to frequency of transmitter in meter(s)		
	150kHz to 80MHz	80MHz to 800MHz	800MHz to 2.5GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and Manufacturer's Declaration: Electromagnetic Immunity (IEC 60601-1-2)			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment-Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 percent.
Electrical fast transient/burst	±2kV for power supply lines ±1kV for input/output	±2kV for power supply lines ±1kV for input/output	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	±1kV line to line ±2kV line to earth	±1kV line to line ±2kV line to earth	Mains power quality should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle	<5% U_T (>95% dip in U_T) for 0.5 cycle	Mains power quality should be that of a typical commercial and/or hospital environment.
	40% U_T (60% dip in U_T) for 5 cycles	40% U_T (60% dip in U_T) for 5 cycles	
	70% U_T (30% dip in U_T) for 25 cycles	70% U_T (30% dip in U_T) for 25 cycles	
	<5% U_T (95% dip in U_T) for 5 sec.	<5% U_T (95% dip in U_T) for 5 sec.	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the A.C. mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3V rms 150kHz ~ 80MHz 3V/m 800MHz ~ 2.5GHz	3V rms 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the PRO including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. **Recommend separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80MHz and 800MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PRO is used exceeds the applicable RF compliance level above, the PRO should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PRO. [b] Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.			

7. Questions & Information

For questions or additional information on the Cardinal Health™ PRO/PRO to GO, please contact your local Cardinal Health representative, or:

Call Customer Service at 1.866.484.6798

Cardinal Health
Waukegan, IL 60085
www.cardinalhealth.com

Always consult a physician and product instructions for use prior to application.

CAUTION: Federal law restricts these devices to sale by, or on the order of, a physician.

Cardinal Health
Waukegan, IL 60085 USA
Rev. C 2019-07
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REF. 6708888, 47-0010

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