ResQPOD® ITD 10 INSTRUCTIONS FOR USE

Advanced Circulatory 1905 County Road C West Roseville, MN 55113 USA

Î∕ 60° C

The ResQPOD Impedance Threshold Device (ITD) 10 uses breakthrough technology to enhance blood flow and increase circulation.

The ResQPOD ITD 10 provides a safe, simple and convenient way to treat states of low blood flow. Use of this device reduces poor circulation. resulting in enhanced circulation and blood flow.

Indications for Use: The ResQPOD ITD 10 is indicated for the temporary increase in blood circulation.

Patient Population: The ResOPOD ITD 10 may benefit people who suffer from states of poor circulation and low blood flow that may be reflected in low blood pressure.



NOTE: The ResQPOD ITD 10 is for single patient use only.

Contraindications: The ResQPOD ITD 10 is contraindicated for use in persons with:

- 1. Dilated cardiomyopathy and/or congestive heart failure
- Pulmonary hypertension and/or aortic stenosis
- Chest pain
- Shortness of breath

Warning: The safety and effectiveness in persons suffering from arterial stenosis or asthma has not been established. Prescribing physicians or licensed practitioners should be aware of these conditions before prescribing

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or licensed practitioner.

Duration of Use: The ResOPOD ITD 10 should be used as prescribed. Duration and discontinuation of use should be as indicated by a physician or licensed practitioner. Some people using the ResQPOD ITD 10 may experience fatigue, shortness of breath or tired sensations. In the event that you experience any of these conditions, discontinue use of the ResQPOD ITD 10 and inform your physician or licensed practitioner.

Adverse Reactions: Possible adverse reactions associated with use of the ResQPOD ITD 10 may include respiratory distress, claustrophobia, shortness of breath and redness of the skin in direct contact with the facemask.

Do not use the ResOPOD ITD 10 if it or its packaging appears tampered with, damaged, broken, previously used or does not appear to function properly.

As with any medical device, consult a physician before beginning use.

The ResOPOD ITD 10 provides a small, but important, amount of resistance when breathing through the device. This resistance increases blood flow back to the heart, so that on the next heart beat, more blood is circulated throughout the body.



The ResQPOD ITD 10 is latex free and non-sterile.

Storage Conditions: Possible product damage may occur through mechani-cal/physical abuse such as drops exceeding one (1) meter, impact from falling objects, excessive dust, debris or vibration, or exposure to temperatures above 60° C and below -40° C. Do not expose the device to chemical solvents or harsh cleaning fluids.

Disposal: Dispose of properly when use is completed.

Customer Care:

For any questions or concerns regarding the use of the ResQPOD ITD 10 or its components please write or call:

> Telephone: 978-421-9440 www.zoll.com

Patent: www.zoll.com/patents

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The ResQPOD ITD 10 may be used with either a facemask or with an airway adjunct device (e.g. endotracheal tube) during assisted ventilation to improve circulation.

USE WITH A FACEMASK



- Optional: an adjustable head strap provides optional hands-free use. If desired, place an adjustable head strap's facemask connector over the facemask port. (NOTE: the adjustable head strap should only be used under supervision by a medical professional or trained party until the user and prescribing physician or licensed practitioner are assured that the user is able to use the device safely and with ease.
- Attach the bottom of the ResQPOD ITD 10 directly to the facemask.
- Be sure all pieces fit as tightly together as possible.
- If the facemask has an air-filled cushion and it is necessary, use a luer lock syringe to inflate the facemask's air cushion so that a tight facemask seal can be obtained.

Instructions for Use:

- Once assembled, gently but firmly, hold the ResQPOD ITD 10 with the facemask over the nose and mouth, ensuring a tight seal with the face.
- As an option, slip an adjustable head strap over the head and tighten, using the adjustable fasteners so that the facemask is tightly sealed and secure.
- Attach the ventilation assist device, if needed, such as a bagvalve resuscitator or mouthpiece, to the top ventilation port of the ResQPOD ITD 10.
- Breathe through the ResQPOD ITD 10 as prescribed by a physician or licensed practitioner, relaxing between each breath to prevent overexertion.

USE WITH AN AIRWAY ADJUNCT DEVICE

To assemble:



- Select appropriate airway adjunct (e.g. endotracheal tube).
- Place the airway adjunct, ensuring it is secure.
- Attach the bottom of the ResQPOD ITD 10 directly to the airway adjunct.
- Be sure all pieces fit together as tightly as possible and that the airway adjunct has not become dislodged.

Instructions for Use:

- Attach the ventilation assist device (e.g. bag-valve resuscitator) to the top ventilation port of the ResQPOD ITD 10.
- Slide the timing assist light switch to ON as a guide to administering ventilations.
- Administer ten (10) breaths per minute with each breath lasting 1.0 seconds.

Cleaning: The ResQPOD ITD 10 is a single person device. The device can be cleaned of secretions (e.g mucous, spit) by shaking the device.

DO NOT submerge the device in water or place in a dishwater for cleaning.

WARNING:

If, while using the ResQPOD ITD 10, respiratory or other distress develops, the device should be removed immediately and a physician consulted.