ResQPOD® ITD Key Study Summary

The ResQPOD, or an earlier version of the impedance threshold device (ITD), has been the subject of over 50 published animal and clinical studies. In 2011, *The Lancet* published the first clinical trial demonstrating improved long-term survival following cardiac arrest with device technology. In this study, when the ResQPOD was used in combination with active compression decompression cardiopulmonary resuscitation (ACD-CPR), **patients had a 53% improvement in survival to hospital discharge with favorable neurologic outcome, and this survival benefit persisted to one year.**(40) An ITD carries a Class II recommendation as a CPR adjunct in the 2010 American Heart Association (AHA) guidelines.(34)

Human Clinical Trials

The ResQPOD ITD has been evaluated in 18 clinical trials during both

- Conventional, standard manual CPR: 16,17,19,25,26,29, 30,31,32,33,35,38,41,51
- ACD-CPR: 4,13,14,18,26,40,46,47,48

These studies have shown that the ResQPOD:

- Improves hemodynamics:
  - Increased $ETCO_2$ (4,38,51)
  - Systolic BP during cardiac arrest improved 20 - 97% (4,17)
  - Mean coronary perfusion pressure improved 70% (4)
- Improves short- and/or long-term survival from prehospital cardiac arrest:
  - Survival to ED admission improved 50 - 71% (19,38)
  - Survival to 24 hrs in all patients improved 45 - 68% (13,14)
  - ROSC rates improved 31 - 80% (4,25)
  - Survival to hospital discharge improved 30 - 98% (25,30,41)
  - Survival to hospital discharge with favorable neurologic outcome improved 38 - 120% (30,31,35,40,41,47) even in the absence of therapeutic hypothermia (46)
  - Six-fold improvement in survival to 90 days with favorable neurologic outcome independent of therapeutic hypothermia (48)
  - Survival to one year with favorable neurologic outcome improved 49% (40)
  - Meta-analysis showed more than doubling of favorable neurologic outcome (26)
- Improves short- and/or long-term survival from inhospital cardiac arrest:
  - Survival to hospital discharge rates improved 60 - 65% with adoption of AHA guidelines (including an ITD) (32,33)
- Provides benefit in non-V-fib cardiac arrest rhythms:
  - In PEA patients, survival to 24 hrs more than doubled (16) and survival to hospital discharge improved >100% (32)
  - Survival in patients presenting in asystole tripled (19)
- Works effectively on a variety of airway adjuncts (3,18,36 [manikin])
- Is clinically and cost-effective (41)

Animal Studies

The ResQPOD ITD has been evaluated in 23 animal studies during both

- Conventional, standard manual CPR: 2,3,5,7,8,12,15,22, 23,24,25,27,50
- ACD-CPR: 1,3,6,7,9,10,11,12,20,21,24,28,37,39,42,43,44, 45,49,50,52,53

These studies have shown that the ResQPOD:

- Improves hemodynamics and vital organ blood flow:
  - Increased cardiac output (22), coronary perfusion pressure (1,5,9,10,15,20,21,22,24,25,50) and blood flow to the heart (2,5,7[doubles],10)
  - Increased cerebral perfusion pressure (20,22,23,24,25, 49,50) and blood flow to the brain (1,2[≥50%],5,9,10, 20,22,23,24,25,27,49)
  - Raised aortic blood pressure (1,8,9,10,11,15,24,50)
  - Lowered intracranial pressure during the chest wall recoil phase of CPR (23,25,49)
  - Increased $ETCO_2$ (8,22)
- Enhances negative intrathoracic pressure with an LMA (3,12)
- Improves survival (1,8,21,28) and neurologically-intact survival (8,20,49,53)
- Despite prolonged downtimes, improves hemodynamics and survival when used in combination with sodium nitroprusside (37,39,44,45) with good neurologic recovery (39,42,43,52)
- Improves cerebral metabolism (11) and hemodynamics (9,11) during hypothermic cardiac arrest, and induces cerebral hypothermia more rapidly after ROSC (21)
- Increases the likelihood of successful defibrillation (1) or the total energy required for successful defibrillation (21,23,28)
- Circulates drugs more effectively (9)
- Improves hemodynamics in a pediatric model of cardiac arrest (10,23,25)
- Optimizes and compliments current AHA CPR recommendations (22,27)

Finally, the best outcomes following cardiac arrest will be achieved combining a continuum of care and therapies, not a single drug or device. ACSI supports the approach taken by the Take Heart America™ Demonstration Project, which promotes a full spectrum of optimal therapies, including public recognition, widespread CPR training, performance of high -quality CPR with an ITD, and definitive, specialized care at Level One Cardiac Arrest Centers (41) offering state-of-the art post-resuscitation care to optimize neurologic recovery (e.g. therapeutic hypothermia). Go to www.takeheartamerica.org for more information.

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The generally cleared indication for the ResQPOD available for sale in the United States (US) is for a temporary increase in blood circulation during emergency care, hospital, clinic and home use. The version of the ResQPOD used in the ROC PRIMED Study and ResQ Trial is not yet approved for sale in the US. Research is ongoing in the US to evaluate the long-term benefit of the ResQPOD for indications related to patients suffering from cardiac arrest. The studies listed here are not intended to imply specific outcome-based claims not yet cleared by the US FDA.

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