ResQPOD® ITD Key Study Summary

The ResQPOD, or an earlier version of the impedance threshold device (ITD), has been the subject of over 40 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.**(41) 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, 30,31,32,33,35,39,42
- ACD-CPR: 4,13,14,18,26,41

These studies have shown that the ResQPOD:

- Improves hemodynamics:
  - Increased $ETCO_2$ (4,39)
  - 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% (19,39)
  - 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% (25,30,42)
  - Survival to hospital discharge with favorable neurologic outcome improved 53 - 120% (30,31,35,41,42)
  - Survival to one year with favorable neurologic outcome improved 49% (41)
  - 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 (42)

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
- ACD-CPR: 1,3,6,7,9,10,11,12,20,21,24,28,37,38,40

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) and blood flow to the heart (2,5,7[doubles],10)
  - Increased cerebral perfusion pressure (20,22,23,24,25) and blood flow to the brain (1,2[≥50%],5,9,10,20,22,23, 24,25,27)
  - Raised aortic blood pressure (1,8,9,10,11,15,24)
  - Lowered intracranial pressure during the chest wall recoil phase of CPR (23,25)
  - 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)
- Improves hemodynamics and survival when used in combination with sodium nitroprusside (37,38,40)
- 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 (42) offering state-of-the art post-resuscitation care to optimize neurologic recovery (e.g. therapeutic hypothermia). Go to www.takeheartamerica.org for more information.

IMPEDANCE THRESHOLD DEVICE BIBLIOGRAPHY

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The generally cleared indication for the ResQPOD is for a temporary increase in blood circulation during emergency care, hospital, clinic and home use. Studies are on-going in the United States 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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