ResQGARD®

The ResQGARD ITD is used to treat low blood circulation, which results from hypotension. Hypotension has a significantly detrimental impact on morbidity and mortality. Up to 20% of patients admitted to the hospital from the emergency department (ED) have a hypotensive episode, and **patients with hypotension are ten times more likely to have sudden and unexpected death.**[22] A large national trauma bank study found that for every 10 mmHg decrease in systolic blood pressure (BP), mortality increased 4.8%.[28]

The ResQGARD is an impedance threshold device (ITD) that harnesses the body's natural reflexes to enhance circulation. Over 40 published clinical trials, animal studies and review articles, many in collaboration with NASA and/or the US Department of Defense, have shown that the ResQGARD works to rapidly and noninvasively increase blood pressure from a variety of etiologies (e.g. hypovolemia, orthostatic intolerance, heat shock, renal dialysis and blood donation). In 2008, the ResQGARD received the US Army's SBIR Achievement Award for the technology's application in the non-invasive treatment of hemorrhagic shock.

Human Clinical Trials

The ResQGARD has been evaluated in 20 human clinical trials including models of normotension (6,7,18,24), orthostatic intolerance (6,7,18,24,25,36,38) and hypotension:

- In an ED and emergency medical services (EMS) setting (20,34,36,38,40,41)
- During simulated hemorrhagic shock (23,27,30)
- During orthostatic challenge (e.g. supine to standing ortilt-table/squat-stand test) (8,11,12,15,17,25,29)
- During renal dialysis (14) and pregnancy (41)
- Following blood donation (14)

These studies have shown that the ResQGARD:

- Improves hemodynamics
  - Increases systolic and diastolic BP 4 - 30% (4,6,7,14,18,20,23,36,38,40,41)
  - Increases mean arterial pressure (MAP) 5 - 27% (4,15,18,23,34,36,38)
  - Increases stoke volume and cardiac output 10 - 21% (7,15)
  - Reduces the drops in pressure, cardiac output and/or stroke volume during orthostatic stress (11,12,15,17,25,27,30)
  - Increases cerebral blood flow 9 - 11% (18,27,29)
- Increases BP in actual or simulated hemorrhagic shock, but not to levels typically associated with "popping the clot" (13,14,20,23,27,30,32,36,37,38,40)
- Reduces orthostatic symptoms (15,25,29)
  Lowers intrathoracic pressure during inspiration (6,7,18,23,24)
- Breathing through therapeutic resistance is well tolerated (6,7,14,23,24,36,38,40)
- Does not compromise oxygen saturation (23,38) or cause increase in heart rate (36)

Animal Studies

The ResQGARD has been evaluated in 12 animal studies (1,3,4,9,10,19,21,26,31,34,35,39) including animal models of hypovolemia and hemorrhagic shock (1,4,9,19,21,35,39), pediatric models of hypovolemia (4[w/PEEP],26), and models of heat shock (31).

These studies have shown that the ResQGARD:

- Lowers intrathoracic pressures during inspiration (3,4,9,10,19,21,31)
- Improves hemodynamics
  - Increases systolic and diastolic BP (1,4,9,10,31,34,35,39)
  - Increases MAP (4,19,31,34,35,39)
  - Lowers intracranial pressure during inspiration (3,21)
  - Increases cerebral perfusion pressure (3,21)
  - Increases coronary perfusion pressure (4,31)
  - Lowers right atrial pressure (3,21)
  - Increases cardiac output/index (9,10,34)
  - Increases stroke volume index (10)
  - Increases end tidal carbon dioxide (1,9,31)
  - Does not compromise arterial oxygenation (19,31)
- Compared to fluid therapy, does not dilute clotting factors (39)
- Increases blood pressure in hemorrhagic shock, but not to levels typically associated with "popping the clot" (9,10,19,21,26,35,39)
- Increases work of breathing but is well tolerated (26) "Buys time" and extends the "window of opportunity" during shock until fluids can be administered (1,9,10,19,31,39)
- Increases short-term (90-min) (19,26) and 24-hour survival (26)

Advanced Circulatory®
Perfusion on Demand

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The generally cleared indication for the ResQGARD is for a temporary increase in blood circulation during emergency care, hospital, clinic and home use. Research is on-going in the United States to evaluate the long-term benefit of the ResQGARD for indications related to hypotension from specific etiologies. The studies listed here are not intended to imply specific outcome-based claims not yet cleared by the US Food and Drug Administration.

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