

LIFE SAVER

INCREASING BLOOD FLOW DURING CARDIAC ARREST

A medical research and development firm created an innovative CPR enhancement device that substantially increases patient survival rate, and found a design and manufacturing partner to bring the new technology to market in record time.

During cardiac arrest, blood flow stops and starves the brain and other vital organs of essential oxygen. This can last only eight minutes, on average, before the brain suffers irreversible damage. Even when an arrested heart and lungs receive help through a mechanical pump, mouth-to-mouth resuscitation, manual hand pressure, or standard CPR, only about 25% of the needed blood flow occurs. Under these conditions, the patient survival rate is only about 5%.

Advanced Circulatory Systems, Inc., a medical device research and development company, Minneapolis, Minnesota, discovered, however, that placing a controlled restriction in the respiratory circuit to prevent air from being drawn into the lungs during the decompression phase of CPR increases blood circulation substantially. Based on these findings, Advanced Circulatory Systems designed and developed a device called the ResQPOD[®] that uses "impedance threshold technology" to regulate a vacuum in the chest cavity. The ResQPOD is a mechanical apparatus with a unique valve mechanism built within a plastic housing that is placed in the respiratory circuit between the ventilation source and the patient. The ResQPOD enhances the vacuum created by the expansion of the chest cavity during the decompression phase of CPR, filling the heart with more blood. It "primes the pump" so more blood is delivered to the brain and other vital organs during subsequent chest compressions. It also uses LED indicators to assist EMS or hospital personnel with delivering ventilations at the recommended rate of 10 per minute, as opposed to the 30 to 40 per minute sometimes experienced in the field. The ResQPOD boosts the needed blood flow from the typical 25% of normal to as much as 75% of normal to keep the brain sufficiently saturated while the heart recovers its natural rhythm. As a result, the patient's survival rate can be more than doubled.

Development hurdles

Despite being a research company of relatively small size, Advanced Circulatory Systems pulled together its resources in product design and development and produced a highly successful working model of the ResQPOD. After it was able to manufacture a few working models to validate the design goals and present it to the FDA for clearance for circulatory enhancement, Advanced Circulatory Systems sought help to fine tune the design and develop hard tooling for larger production quantities. The contract manufacturer they

selected would have to produce a reliable

and cost-effective product through precision tooling, careful assembly, and meticulous testing to meet internal QA standards as well as FDA requirements. After producing initial quantities Advanced Circulatory Systems decided to evaluate a number of other contract manufacturers to help launch the ResQPOD. After an intensive selection process, it finally selected Scientific Molding Corporation, (SMC, Molding and Manufacturing Division) Somerset, WI.

Advanced Circulatory Systems found SMC to come highly recommended in the medical technology field, and recognized SMC's history in custom injection-molded components and finished, assembled, and packaged products

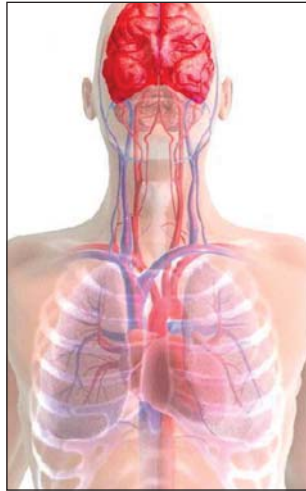
from its ISO9001, ISO13485, FDA-registered and UL-certified facilities. SMC manufactures numerous products for other leading medical device, instrument, and pharmaceutical companies. SMC was able to produce the ResQPOD with higher quality and reliability with lower scrap rates. SMC's manufacturing facility is equipped with the most advanced injection molding machines, assembly tools, controllers, and instruments available for manufacturing the most precision medical devices and equipment. Advanced Circulatory Systems was also impressed with SMC's technical team and their commitment to making the product a success through a few design enhancements and particularly more stable and improved manufacturability. SMC also brought some new and unique ideas to the manufacturing process, which greatly improved part quality and reliability.



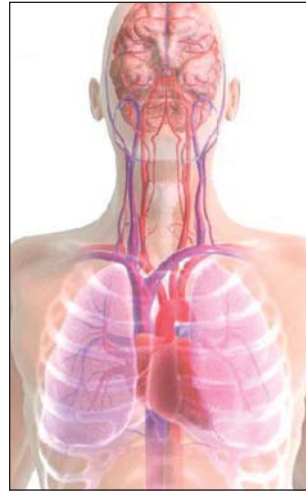
Blood Circulation during CPR



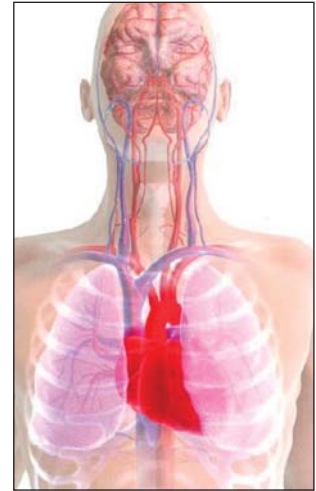
**Compression Phase
CPR alone**



**Compression Phase
With ResQPOD**



**Decompression Phase
CPR alone**



**Decompression Phase
With ResQPOD**

Experience Counts

SMC's success comes from its extensive experience working with Class I, II, and III medical devices, which must be FDA certified. FDA keeps continuous surveillance of the manufacturing process for the products' life cycle to ensure that every ResQPOD device that comes off the production line meets strict FDA requirements. As a result, SMC's personnel provide FDA product submission support and retain a detailed history of all devices manufactured. In addition, the managers maintain a look-ahead posture to prevent serious manufacturing and assembly problems from cropping up that could delay product deliveries.

SMC coordinated the generation of all files, drawings, and procedures for program management for both teams to ensure that all engineers were constantly aware of the product's design specifications and performance requirements. Advanced Circulatory Systems' engineers were informed of the products progress from initial design drawings through the tooling design for the molding process. All preliminary, pre-production, and initial production parts from hard tooling were reviewed, validated, and tested to specifications in a joint effort between SMC and Advanced Circulatory Systems to verify fit and function and ensure conformance.

SMC is familiar with the wide range of plastic materials needed and approved for medical devices. The ResQPOD's unique valving system required a variety of compatible plastic materials

and precision fitting components to ensure proper airflow and maintain pressure. SMC's experience in handling multiple resins and overmolding of different plastics ensured a successful final assembly. SMC also has extensive experience in meeting the FDA requirements for maintaining sufficient inventory of approved and certified materials to supply the product's needs for a planned life cycle. This takes the burden off of Advanced Circulatory Systems' personnel to constantly monitor component and material needs, keep pace with inventory, and manage the tooling cycle.

The ResQPOD is a single-use, disposable device so it had to be designed for a low-cost target point. SMC's experience in lean manufacturing principles, computer modeling, automation, multi-tool capacity, and moldflow analysis, enabled Advanced Circulatory Systems to stay within manufacturing budgets and achieve its cost goal.

Molding and cleanroom assembly, sonic welding, and molded membranes, all ensure that a complete ResQPOD is free of contamination that could render the device inoperable during an emergency. In addition, because the ResQPOD is used in the intimate respiration circuit, it had to be designed to work effectively with the production-line process.

Acknowledgements:

Roy Gruel, Program Manager, Scientific Molding Corporation, Inc., Somerset, Wis.

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