EXECUTIVE SUMMARY

During cardiopulmonary bypass surgery cold cardioplegia solution is delivered to the patient's heart to induce hypothermia and prevent cell death. In the U.S. and Europe they use sophisticated cardioplegia delivery systems. However, In China they use an unreliable ice bucket method which is at risk of multiple modes of failure and requires additional focus from the perfusionist, therefore putting the patient at additional risk. Our project is to design a cold cardioplegia delivery system that will be competitive in the Chinese market and will be effective at delivering cardioplegia at temperatures from 0-12°C [1]. In accomplishing this goal, we met several key customer requirements we obtained from our sponsor Medtronic, perfusionsists, and graduate students who have done preliminary research on this project. Table 1 below gives our engineering specifications with the target and actual resulting values of our final device. All specifications were successfully validated and fulfilled.

Table 1: Engineering specification target values and corresponding actual value for our final device.

Engineering Parameter	Target Value	Actual Value	Specification Met?
Biocompatibility	ISO 10993-1	ISO 10993-1	Yes
Solution Temperature at Outlet	0-12°C	4.7-6.8±0.5°C	Yes
Cost to Manufacture	≤$40	$23.57	Yes
Priming Volume	≤44 mL	42.5 ± 0.5 ml	Yes
Operating Solution Flow Rate	100-500 mL/min	100-1500±10 mL/min	Yes
Device Volume	≤ 0.018 m^3	0.0013 ± 0.00005 m^3	Yes
Maximum Water Pressure	2 bar	2 bar	Yes
Maximum Solution Pressure Device Can Withstand	1 bar	2.0 ± 0.1 bar	Yes

After a rigorous concept generation and selection methodology process we selected our final concept. Our final concept involves a stainless steel coil inside a polycarbonate annulus housing. The interior walls are profiled in a way that will increase turbulence and therefore heat transfer. Lids are placed on the top and bottom of the housing and include ports for the blood and water line connections. The water line connection is in the center of the lid to encourage an even flow of water around the annulus. We chose this concept because we felt that it would be very inexpensive to manufacture, while still maintaining the equivalent heat transfer and reliability of modern devices. CFD and Matlab modeling supported our belief that the right amount of heat transfer would occur. To fabricate our device, we plan to injection mold the housing and inner column out of clear polycarbonate. Both lids will be identical and the outer shell will be split into two pieces, both identical as well. The coil will be bought already coiled from a supplier and will be coated with biocompatible coating in house after it is received by Medtronic. The device will be glued together and UV cured for easy assembly. Using production volumes of 20,000 units per year over five years, we determined that the final cost to manufacture our device will be $23.57, well below the target value of $40.

We created a near identical prototype of our final device out of 3D printed material and used it for validation and testing. We tested our device in a hospital lab under conditions very similar to how it will be used during an operation, using a roller pump, water chiller, and thermometer. Our results showed that the solution output temperature of our device ranged from 4.7ºC-6.8± 0.05ºC across solution flow rates of 100-500ml/min and water flow rates of 4.5-12.8 L/min, giving us an efficiency ranging from 90-96± 0.00%. These values are competitive or outperform modern, expensive cardioplegia heat exchangers.

Given further opportunity to improve the device, we would optimize the device size and add a thermometer port so it is competitive with modern devices, while maintaining the same heat transfer ability. We would also verify the impact of the turbulators to try and reduce tooling costs if they are not needed. Overall, we have deemed our project a success, meeting all specifications (Table 1) and therefore providing China with a viable, better option to the ice-bucket method.