



NEW DEVICE: SAVING LIVES IN SECONDS

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by Ben Konuch, Student Public Relations Writer

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What started as a capstone project to develop a device that could save a life if the carotid artery is severed for a group of Cedarville University juniors and seniors in 2019 is now extremely close to receiving full FDA approval for manufacturing and distribution on a nationwide scale.

The Arterial Restrictive Clamp (ARC) project began in 2018 when Lauren Edmonson, who graduated in 2019 with a degree in allied health, came to Dr. Tim Norman, distinguished professor of mechanical and biomedical engineering at Cedarville, about a medical void in treating this injury, which she observed during her time as an EMT with the Cedarville Township Volunteer Fire Department. Under Norman's guidance, Edmonson recruited four mechanical engineering students who were pursuing the biomedical engineering minor —Austin Ballentine, Caleb Williams,

Devan Kienitz and Bennett Stouffer — to work on a device that could fill this need and be essential to saving lives.

Two of these engineering students, Ballentine and Williams, who graduated in 2019 took Edmonson’s vision to heart and went to work on solving a medical problem.

“This device that the students worked on is relatively new, but it addresses life-threatening injuries where there aren’t many solutions on the market today,” said Norman. “This device has the potential to meet a life-and-death situation where options are limited and the timeline is critical.”

Wounds to the carotid artery are often seen in the military during combat, but they can also occur in civilian life due to trauma and athletic competition. During a recent professional hockey game, former Pittsburgh Penguin and current member of the Nottingham Panthers died in a game in Sheffield, England, after his carotid artery was slashed by an opposing player’s skate.

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Video of the incident showed Adam Johnson skating with the puck toward Nottingham’s net when two opposing players collided, leading to one player’s skate elevating and the blade slicing Johnson’s carotid artery. Without medical assistance, Johnson skated toward his team’s bench before collapsing and dying on the ice.

With a carotid artery occlusion device, like what has been described here, Johnson’s life possibly could have been saved.

“The only treatment for this wound is to hold and apply pressure,” said Norman. “In the case of this kind of wound suffered in the military, where we see these injuries

occur, a medic is taken out of action by needing to stay with the injured and putting pressure on the wound. With our proposed device, the clamp can put pressure on the carotid artery and stop the bleeding. When this happens, the medic can care for other people who are injured or transport the patient.”

The ARC would be another option medical personnel could use to save the lives of severely injured individuals.

The Arterial Restrictive Clamp became the focus of this team consisting of Ballentine, Edmonson, Williams and Norman as well as a valuable new addition to the team, Dr. Jeff Williams, a surgeon. These individuals formed the company [Arc Trauma, LLC](#) to develop this device into a product that the medical industry could utilize fully.

After the capstone project was completed and with the aid of Dr. Williams’ boots-on-the-ground trauma experience, they continued development and testing until the final design emerged as the most viable option.

“The device was designed to be a kind of neck tourniquet,” said Norman. “The difference is that in all other tourniquets apply pressure circumferentially; however, we needed to ensure that the patient could still breath easily, medical providers could still access the airway, and the brain still received blood flow from the uninjured carotid artery. We came up with this device to fit around the neck and quickly apply pressure to the specific point of injury while allowing blood flow through the rest of the neck and keeping the air pathways open.”

After development, the device entered a period of sustained testing. As with most medical devices that occlude blood flow due to traumatic injuries, clinical testing on research volunteers is impossible. Instead, a cadaveric perfusion model was developed that simulates the conditions of blood flow to allow testing of the device in realistic conditions where no lives are put at risk.

After extended testing and modifications, which included adding multiple features to the device, such as a laryngoscope to ensure the device would maximize its value to EMTs and medics, the ARC device attained fantastic results. As members of the medical community expressed immense interest in the device, the ARC project moved forward to a stage of biological testing. Once this is completed, the device will be submitted for FDA approval which should be achieved in early 2024.

“We’ve been developing this as a company for almost three years now, so it hasn’t been a short timeline. There’s been a lot of work we’ve had to do, but the most important has been figuring out how to get that experimental data that proves that our product can do exactly what we’ve said it could do,” said Norman. “From a functional point of view, we have great data and know it functions well, so now we

just have to go through and check off all the other boxes and ensure that we're doing everything legally.”

Located in southwest Ohio, [Cedarville University](#) is a Baptist university with [undergraduate](#) programs in arts, sciences, and professional programs, and [graduate](#) programs. With an enrollment of 5,456 students in 175 areas of study, Cedarville is one of the largest private universities in Ohio and is recognized nationally for its authentic Christian community, rigorous academic programs, and high graduation and retention rates. For more information about the University, visit [cedarville.edu](#).

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