the NEWSSTAND

Making the move from disposable medical devices to reusable

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If you were to go into surgery today, chances are that your operation would be performed with instruments that have been reprocessed. This means that the repair of the torn cartilage in your knee or the removal of your tonsils would rely on single-use instruments that have been cleaned and sterilized by FDA-regulated, third-party processors.

Because of increased sustainability efforts and a dramatic adoption of reprocessing in recent years, Clemson University has established the Medical Device Recycling and Reprocessing Certificate Program, the first program geared toward engineers who seek to enter the medical device industry in product development or research.

The program, offered by the Department of Bioengineering, is housed at the Clemson University Biomedical Engineering Innovation Campus (CUBEInC) in the lab of Melinda Harman, assistant professor of bioengineering, where students work specifically with the recycling and reprocessing of surgical instruments.

“There was a time when surgical instruments were made to be disposable,” Harman said. “In the ’80s, there were concerns related to infectious disease transmission, such as HIV, and this was also the era when manufacturers were able to start making devices out of plastics and materials that were less expensive. They could just be thrown away.”

Harman said that now, however, there’s a new push for controlling the amount and type of waste hospitals generate, as it costs a lot of money to control biohazardous waste. Not only are hospitals interested in controlling this cost, but companies are also interested in a more sustainable model. As a result, some instruments are now being reprocessed so that they can be safely reused for different surgeries. Additionally, insurance companies are no longer funding certain medical devices for individual patients, so work toward making such devices reusable is also being done.

There are various medical devices that can be considered for reprocessing in nearly all hospital departments. A few examples of reprocessed devices include electrophysiology catheters for cardiac irregularities and numerous devices used during endoscopic surgery, as well as noninvasive products such as pulse oximetry sensors and various disposable compression therapy devices.

As an engineer, the process involved in designing a reusable medical device greatly differs from that of designing a disposable device, as various degrees of functionality, cost and usability have to be closely considered.

“Disposable means it only has to function one time and you’re done. It can be made cheaper and with less durable materials and such,” Harman said. “If you’re going to make it reusable, you have to think about additional safety concerns: Can it be reliably cleaned, and can it be disassembled easily and then reassembled? Further, how do you clean the center of a tube and prove that it’s clean? That’s a challenge.”

Engineers in the program consider reprocessing protocols that adhere to FDA regulations for reprocessing in hospitals and in reprocessing companies, which control cleaning, inspection, labeling, packaging and sterilization processes applied to medical devices. The lifetime of a device is also of great importance.

"That matters from the manufacturer's perspective because that determines cost, but it also matters from the user's perspective because it determines functionality," said Harman.

Harman went on to say that engineers also have to consider the degradation of a device throughout reprocessing.

"There is a certain amount of degradation that would occur from cleaning," she said. "For example, even if you were to use a nylon brush, by scrubbing the inside of an instrument tube, it would become altered and the chemicals would start to degrade that surface. So knowing that degradation and knowing how it affects infectious biological materials attaching to it is something the engineers have to think about, and we use it for designing new instruments and reprocessing protocols."

Harman's goal with the program is to train Clemson engineering students to integrate that thought process into the design process for medical instruments and to help them understand the reality of cleaning and sterilization in hospitals and reprocessing companies. Such training helps Clemson engineers become more competitive in the medical device industry and fill the growing demand for engineers knowledgeable in reprocessing.

Designed as a five-course, 15-credit sequence targeted toward master's degree students, the program is meant to appeal not only to bioengineers, but also to other engineering specialties.

"Solving these problems is a multi-discipline effort, and this program gains tremendous benefit from the input provided by other faculty in the College of Engineering and in the Department of Biological Science, as well as local biotech business leaders. These combined efforts help to bring real-world applications into the classroom," Harman said.

Additionally, Harman says that when students begin the sequence, they qualify to compete for internships in medical device recycling and reprocessing.

"One course is an industry internship, and involves the placement of interns in companies that deal with reprocessing," she said.

Harman said that the program is also working with Stryker Sustainability Solutions, a company that handles reprocessing, toward continuing to create sustainability in the field.

"Reprocessing is one of the top financial and environmental sustainability initiatives currently employed in U.S. hospitals," Brian White, president of Stryker Sustainability Solutions, said. "Clemson deserves to be recognized for developing a new program that meets an important industry need."

And with these efforts, the program is encouraging students to engage with recycling and reprocessing on a local, regional and global scale.

"I don't think that sustainability is going to go away," Harman said.

CUBEInC is located at the Greenville Hospital System University Medical Center Patewood campus.

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