

# Clemson adds program for medical device industry



Melinda Harman, right, runs the reprocessing program. (Photo/Craig Mahaffey of Clemson)

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Clemson University is training engineers to design medical devices that can be reprocessed.

The program, which accepted its first class this summer, is preparing an engineering workforce for the medical device industry to do reprocessing, research and product development.

The Clemson University Biomedical

## The savings in reprocessing

- U.S. health care facilities have saved approximately \$290 million in supply costs this year as a result of reprocessing cardiovascular, laparoscopic, orthopedic/arthroscopic and gastrointestinal devices.
- Approximately 25% of hospitals reprocess at least one category of these devices.
- Larger hospitals are more likely to reprocess since reprocessing in bulk is more cost-effective. Approximately 45% of hospitals larger than 250 beds reprocess at least one category of medical devices, while only 15% of hospitals smaller than 50 beds do so.
- Smaller facilities are subject to more bargaining pressure from OEMs and are more fearful of litigation should a reprocessed device fail.

SOURCE: Millennium Research Group

Engineering Innovation Campus, or CU-BEInC, located at the Greenville Hospital System University Medical Center Patewood campus, developed the Medical Device Recycling and Reprocessing Certificate Program. It trains bioengineering students to recycle, reprocess and design medical devices.

Reprocessing is the cleaning and sterilization of single-use medical devices by third-party reprocessors regulated by the Federal Drug Administration.

"A lot of devices get thrown away or go out as medical waste. We're thinking about why they can't currently be reprocessed and how they could be reprocessed," said Melinda Harman, assistant professor in the Clemson bioengineering department. "We want to design the devices with a better design to avoid these problems in the future."

Many programs train technicians to reprocess devices. Harman said the Clemson program is unique because it trains engineers to design new devices to either replace those that can't currently be reprocessed, or to make it easier and more effective to sterilize devices that can already be reprocessed.

Students aren't designing products to bring to the market. They're learning how to design them. Harman, who heads up the new certificate program, wants students to gain firsthand experience with the devices in preparation for the growing opportunities in the reprocessing and product development arena.

The U.S. market for reprocessed medical devices will continue to show strong

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growth, averaging almost 9% per year through 2017, according to the Millennium Research Group, a global provider of medical technology market intelligence.

"This growth will be driven by budget-conscious hospitals seeking cost savings. Already large, this market will become increasingly significant in the coming years," according to the group.

Hospitals can often buy reprocessed devices for half the cost of the originals. In 2012, U.S. health care facilities saved approximately \$290 million in supply costs as a result of reprocessing cardiovascular, laparoscopic, orthopedic/arthroscopic and gastrointestinal devices, according to the Millennium Research Group.

The demand for engineers trained in reprocessing or product development is on the rise, Harman said, and it's driven by health care costs and patient safety.

Hospitals aim to reduce biomedical waste and the costs associated with paying to dispose of the devices, as well as to repurchase them. Patient safety and employees' time also plays a large role in device development, as health care providers desire devices that are easier and faster to clean.

"Infection is always a concern. How do we mitigate that? Let's bring the engineers into the paradigm so we're not just coming up with new chemicals or sterilization techniques, but we're designing devices that can be sterilized easier," Harman said.

Reprocessing devices can also reduce biomedical waste in landfills.

Numerous devices can be reprocessed, such as those used for endoscopic surgery, electrophysiology catheters for cardiac irregularities and those used for ear, nose and throat procedures.

While the Clemson students research and brainstorm new device designs for reprocessing and sterilization techniques, they also must develop methods to assure patient safety in compliance with FDA regulations.

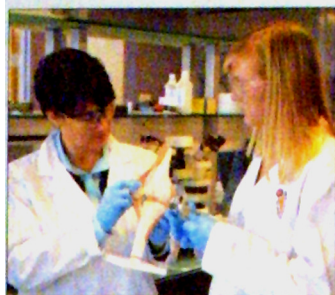
Plans for the program began about two years ago when Clemson researchers saw a need for highly qualified engineers to optimize medical device designs for reprocessing.

An advisory board was formed last year that included industry representatives from Steris Isomedix Services, a Spartanburg provider of sterile medical instruments, and Stryker Sustainability Solutions, a Tempe, Ariz.-based third-party reprocessor that performs work for the Greenville Hospital System.

Stryker Sustainability Solutions was formerly Stryker before it acquired a nationwide reprocessor, Ascent Healthcare Solutions. Stryker Sustainability Solutions provided unspecified contributions to the Clemson program.

Clemson looks to partner with local reprocessors and health care facilities. As it prepares to launch reprocessing internships next summer, the program also seeks industry partners for opportunities. ■

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Melinda Harman, left in the photo at left and center in the photo at right, works with Clemson University bioengineering students partaking in the new medical device reprocessing certificate program. The program trains students to design medical devices that can be reprocessed and reused, with a goal of reducing waste and the cost of medical device disposal. (Photos/Craig Mahaffey of Clemson University)