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Program Director for Medical Device Reprocessing

1. What is Medical Device Reprocessing?

Medical device reprocessing is an essential practice in healthcare delivery and plays a key role in the more than 100 million surgical procedures in the U.S. each year. In practice, “reprocessing” involves the cleaning, disinfection, and sterilization of medical devices. It integrates advanced technologies and specialized process control systems for handling contaminated medical devices and rendering the reprocessed devices safe for reuse. It also encompasses related procedures, including validation and testing to assure the performance and functional safety of devices is maintained after each use. Reprocessing is regulated globally, and it involves both reusable devices and approved single use devices.

Medical device reprocessing demands a multi-disciplinary approach for understanding medical device designs in their end-use environment. There is a need for engineers with knowledge of bioengineering, human factors engineering, microbiology, packaging science, and quality science to meet this demand.

2. Why is knowledge of medical device reprocessing important for engineers?

Medical device reprocessing involves engineers in all phases of design, development, manufacturing, and the design phases of healthcare technology. Reprocessing is an integral part of cost containment and infection control in healthcare, and it is growing in complexity and need as more complex devices and instruments are used for patient care. FDA recognizes medical device reprocessing among its top 10 regulatory science priorities and clearly identifies the important role of engineering, stating “From the earliest stages of device design and engineering, manufacturers should consider alternative designs to facilitate effective reprocessing”. That sentiment is echoed by a 2014 statement from the World Health Organization (WHO) that “trained and qualified biomedical engineering professionals are required to design, evaluate, regulate, maintain and manage medical devices, and train on their safe use in health systems around the world.”

3. What is the job market / growth potential for the medical device industry? Who are major employers for this type of degree?

The fast-growing global medical device industry is poised for steady growth (~5% annually) and is forecast to reach \$800 billion by 2030. Such growth in the U.S. is spurred by innovation, with roughly 4000 new products cleared through the FDA each year. Or to think of it another way, there are roughly 10,000 medical device “families” encompassing over 500,000 different products. Increasing numbers of technologies and applications for medical devices and healthcare equipment, and demand for informed healthcare technology assessments, require the services of biomedical engineers with advanced skills.

Recent surveys from the International Federation of Medical and Biological Engineering, in collaboration with the WHO, document one million biomedical engineers and technicians employed in 79 countries worldwide. According to the US Bureau of Labor Statistics, there were 21,200 jobs in the biomedical engineering field and employment of biomedical engineers is projected to grow 5% from 2019 to 2029, faster than the average for all occupations.

There are employment opportunities across many industries, from entrepreneurial start-up companies to established global industries to healthcare agencies. For example, the European Union has ~25,000 healthcare technology companies, of which >80% are small to medium sized enterprises. The advanced skills gained by graduates of the Medical Device Reprocessing MS program will increase their competitiveness in the labor market and provide the workforce needed to serve the biomedical device industry (original equipment manufacturers), the bioscience market, and the medical device reprocessing industry.

4. What unique value/skills do students gain from the Medical Device Reprocessing program?

The Master of Science degree program in Medical Device Reprocessing curriculum provides students skills to innovate solutions that address global challenges affecting medical device safety and healthcare sustainability. It integrates multi-disciplinary knowledge healthcare technology assessment from the fields of bioengineering, human factors engineering, microbiology, packaging science, and quality science.

Upon successful completion, students will:

- Demonstrate interdisciplinary strategies for medical device reprocessing
- Communicate skills in optimizing & validating biomedical technologies while maintaining regulatory compliance
- Address issues in global health, healthcare sustainability and risk assessment
- Target a career path in the medical sector of green technology
- Display increased competitiveness for entering the biomedical device industry, the bioscience market and the medical device reprocessing industry

5. Can you give a brief overview of the Medical Device Reprocessing MS degree?

The Master of Science in Medical Device Reprocessing degree is open to graduate students holding a bachelor’s degree in STEM disciplines. Designed by industry experts, the yearlong, 30 credit hour program emphasizes optimizing and validating biomedical technologies to support safe reuse of medical devices and healthcare products. Integrating fundamental principles of bioengineering, industrial engineering, medical device design and quality science, the curriculum is eleven graduate-level courses and an immersion/training experience in research or industry.

6. Can students from other Clemson campus locations (e.g. Charleston, Greenville) enroll in these courses?

Yes, this program is open to graduate students holding a bachelor’s degree in STEM disciplines, regardless of location. With no residency requirements, students can pursue this degree from anywhere in the world.

7. Is this program open to biomedical professionals who are not enrolled as full-time Clemson students?

Yes! This program is tailored to accommodate the demanding schedules of graduate students and working professionals. All classes are delivered asynchronously via web-based technologies. The eleven graduate courses are scheduled over a 12 month period, with most students joining the program for courses beginning in the summer (May) or fall (August) each year.

8. How do I enroll in the Medical Device Reprocessing MS degree program?

Students are required to enroll as a “degree seeking student”. Formal application and entry requirements are established by the Clemson University Graduate School. Those students **who** accepted for admission are entered into the Clemson University ADMIT (Slate) approval system. The link to the Graduate School application is <https://www.clemson.edu/cecas/departments/bioe/academics/masters/application.html>

For AY2022-23, enrollment requires the following items.

- Completed application form
- Application fee
- Official transcripts from universities previously attended
- 2 letters of recommendation
- Official TOEFL scores reported by ETS (international students only)

9. Are any courses open to undergraduate students enrolled in a STEM degree program at Clemson University?

Yes, there are four courses offered as 4xxx/6xxx courses. Undergraduate students pursuing a STEM degree and formally enrolled in a BS/MS academic program are permitted to enroll in the 6xxx level courses. These 6xxx level courses can be used to meet the requirements of the Medical Device Reprocessing degree program.

MDR Courses (30 credits)	Credits	Semester
BIOE 6380/6381 Engineering Controls for Microbiological Systems (also offered as BIOE 4380/4381)	3	1 st summer
IE 6620 Six Sigma Quality	3	2 nd summer
BIOE 6390 Introduction to Medical Device Reprocessing	3	spring
IE 6300 HF Eng. in Healthcare (systems engineering)	3	spring

10. Other than a STEM degree, are there other entry requirements? For example, do I need to complete the Graduate Record Exam (GRE)?

The MS degree in Medical Device Reprocessing does not require completion of the GRE. Residency is not required, meaning you can enroll and complete courses from any global location.

11. Do I need to start this program in a specific semester?

No, this program uses revolving enrollment scheme. You can apply to the program in any semester and register for classes once your admission status is approved through the Clemson University Graduate School.

12. Do I need to be enrolled as a full-time student?

No, you do not need to enroll as a full-time student. This program is tailored to accommodate the demanding schedules of graduate students and working professionals. All classes are delivered asynchronously via web-based technologies. The eleven

graduate courses are scheduled over a 12 month period, with most students joining the program for courses beginning in the summer (May) or fall (August) each year. Costs are calculated per credit hour for the courses enrolled.

13. Do I need to maintain continuous enrollment?

No, you do not need to maintain continuous enrollment. This program is tailored to accommodate the demanding schedules of graduate students and working professionals.

14. What privileges are provided to student with online enrollment?

Enrollment in this online program provides access to Clemson University library resources and software licenses managed by Clemson Computing and Information Technology.

15. How long will it take for me to complete the Medical Device Reprocessing MS degree program?

Students must successfully complete a minimum of 30 credit hours. The usual minimum time period necessary to complete all requirements is 12 months. However, the length of enrollment is entirely dependent upon the number of credit hours enrolled by an individual student each semester.

16. Is the course load flexible so that I can best manage my current job and personal responsibilities? For example, can I use more than one year of enrollment to complete the courses in this degree program?

Yes, you can use more than one year to complete the courses in this MS degree in Medical Device Reprocessing. This program is tailored to accommodate the demanding schedules of graduate students and working professionals so that you are not required to complete all courses within one year. We encourage you to plan ahead because some course are offered in multiple semesters while other courses are only offered once per year.

17. What is required to fulfill the 3-credit BIOE 8900 internship course?

The internship/research requirement is a variable credit course (1-6 credits) requiring 45 hours/credit of contact time in an applied setting. This can be accomplished at any type of biomedical company or healthcare setting and it does not need to specifically include tasks related to reprocessing. Those hours can be fulfilled in any timeframe (e.g. over more than one semester). If you are currently working in the biomedical field, those hours can be fulfilled with your current employer. For some students on campus, mentored research through BIOE 8150 also is an option. Students are responsible for seeking and securing internship opportunities. Students are required to submit an internship proposal (1 page form with short description) that is reviewed by the Program Director before the start of the internship and complete a short reflection paper documenting the experience.

18. While enrolled as a student at Clemson University, can I take other courses besides those required for the Medical Device Reprocessing MS degree program?

Absolutely, as long as other requirements for enrollment and admission through the Graduate School are met.

19. Can the internship course be fulfilled at my current place of employment?

Yes, if you are currently working in any type of biomedical company or healthcare setting, the hours of contact time required for the variable credit (1-6 credits) internship course (BIOE 8900) can be fulfilled with your current employer. It does not need to specifically include tasks related to reprocessing. Those hours can be fulfilled in any timeframe (e.g. over more than one semester).

20. In the Clemson University IROAR registration system, the classes are listed as “asynchronous online”, but a meeting place and time is listed. What does that mean?

This listing style was required by the registrar’s office and will be phased out for this program. In-person classes and interactions are not required for this course. All classes are delivered asynchronously via web-based technologies. Interaction with course instructors is managed using online video-conference software.

21. What are the main advantages of enrolling in a graduate degree offering “asynchronous online” courses?

The main advantage of online asynchronous learning is that it accommodates your schedule, enabling you to work full-time, or complete a long internship, or participate in other activities without having to be on-campus to take classes. It supports students as global citizens and engagement by STEM students around the world because coursework can be completed in any time zone.

22. What is the cost per course?

Students should use the Clemson University tuition and fees calculator that is available at this link <https://www.clemson.edu/finance/student-financials/tuition-fees/index.html>. Be sure to select the “online” tab and scroll to

“MS Medical Device Reprocessing” in the Program Name field. Tuition and fees for online programs are posted per credit hour. For AY 2021-22, the tuition per credit hour was \$955 plus an addition \$46 in fees (calculator accessed 28 Feb 2022).

Online Tuition and Fee Calculator

Fall 2021, Spring 2022, or Summer 2022

**This section is for programs entirely online, not individual online courses. See list in dropdown menu below*

Estimated Academic Tuition & Fees:

Please fill out all options below:

Program Name MS Medical Device Reprocessing	MS Medical Device Reprocessing <i>Hover over amounts for fee descriptions</i>
Credit Hours per semester 1	Academic Fee - Online Tier 2 \$955
	Information Technology Fee \$10
	Library Fee \$10
	Matriculation \$5
	Software License Fee \$21
	Est. Tuition & Fees per semester \$1,001

23. How are course materials, assignments and grading communicated with students?

All courses are managed through the enterprise learning management system (CANVAS) that is in use at Clemson University. Communication of course materials, assignments and grading is managed by the instructors of the individual courses and all communication methods used must support asynchronous online delivery of course content. For example, some instructors may post all course materials and assignments at the start of the semester with deadlines for assignments dispersed throughout the semester or only at the end of the semester. Other instructors may post course materials in modules centered on sub-topics and specific learning objectives, with assignment deadlines dispersed throughout the semester.

24. Can you describe the student-instructor and student-student interactions typically for the courses in this program and whether synchronous interactions with the instructors are possible?

Learning objectives and requirements vary between courses and diverse types of interactions are used. For example, some of the graduate courses in this program include group project assignment that require student-student interactions. Those interactions can be managed using video-conferencing between group members in different locations or in-person meetings if all group members are in the same location. Additionally, all course instructors are required to host office hours to support instructor-student interactions. Those interactions can be managed through written communications (email) or by scheduling synchronous video-conference communications or by scheduling in-person meetings if the instructor and student are in the same location.

25. What courses are included in the Medical Device Reprocessing curriculum and where can I find course descriptions?

The 30 credit-hour core curriculum consist of eleven graduate-level courses offered on a 1-year basis. Course descriptions are available in the Clemson University course catalog. The link to the general catalog is here <https://catalog.clemson.edu/> and the link specific to Medical Device Reprocessing is here https://catalog.clemson.edu/preview_program.php?catoid=34&poid=8855&returnto=1063.

26. Are there pre-requisites for the courses?

Pre-requisites for courses are waived for students enrolled in the MS degree in Medical Device Reprocessing. The order of course enrollment is important in some cases. For example, students must enroll in BIOE 8660 either before or concurrent with BIOE 8670 and BIOE 8680, so those latter courses note that requirement.

27. Are all courses offered each semester?

No, not all courses are offered each semester, they are delivered in a sequence over three semesters (fall/spring/summer). For example, the courses and semester offered for AY2021-22 are pasted in the table below and courses that are available in more than one semester are noted. All final determinations for AY2022-23 will be communicated online through the link to the Medical Device Reprocessing course catalog for that year. https://catalog.clemson.edu/preview_program.php?catoid=34&poid=8855&returnto=1063

MDR Courses (30 credits)	Credits	Semester
BIOE 6380/6381 Engineering Controls for Microbiological Systems (also offered as BIOE 4380/4381)	3	1 st summer
IE 6620 Six Sigma Quality	3	2 nd summer
BIOE 8660 Global Regulatory & Legal Requirements of Quality for the MedTech Industry	3	summer/fall /spring
BIOE 8510 Mentoring Undergraduates Research Teams (1-6 cr) OR BIOE 8900 Industry Practicum (1-6 cr)	1	summer/fall /spring
BIOE 8670 Product Development & Validation for the MedTech Industry	3	fall/spring
BIOE 8680 Medical Technology Risk & Failure Analysis	2	fall/spring
BIOE 8620 Pre-Clinical Assessment and Regulatory Affairs for Medical Devices OR BIOE 8630 Regulatory and Clinical Affairs for Medical Devices	3	fall/spring
IE 8000 Human Factors	3	fall
BIOE 8140 Medical Device Commercialization	3	spring
BIOE 6390 Introduction to Medical Device Reprocessing (formerly BIOE 8150 Design, Manufacturing & Validation Methods for Reusable Medical Devices)	3	spring
IE 6300 HF Eng. in Healthcare (systems engineering)	3	spring

28. Do any courses require special procedures to register?

In AY2022-23, some courses require registration overrides to enroll (e.g., IE 6620). Those requests are managed by the Graduate Student Services coordinators in Bioengineering (Trish Nigro) and Industrial Engineering (Meg Robbins).

29. I am preparing to graduate from this program. Do I need to complete a GS7 form and submit it to the Graduate School?

No, students graduating with the Medical Device Reprocessing MS degree do not need to complete the GS7 form or any program evaluation forms from the Graduate School.

30. How does this program differ from the traditional thesis-based MS degree or MEng degree offered in Bioengineering?

The MS degree in Medical Device Reprocessing is a formal collaboration between the Departments of Bioengineering and Industrial Engineering. It integrates multi-disciplinary knowledge from the fields of bioengineering, human factors engineering, microbiology, packaging science, and quality science.

	MS in Medical Device Reprocessing	MS (thesis-based) in BIOE	MEng in BIOE
Course credit hours	30 core credits	30 credits - 6 core - 18 elective - 6 research	30 credits - 15 core - 15 elective
Typically completed in 1 year	yes	no	yes
Asynchronous, online delivery	yes, all courses	no	select courses only
Supports enrollment from any global location	yes	no	no
Supports enrollment of working professionals	yes	no	no
Core curriculum includes:			
- Bioengineering	yes	yes	yes
- Human Factors Engineering	yes	no	no
- Six Sigma	yes	no	no
- Quality Science	yes	no	yes
Requires internship	yes	optional	optional
Requires research	no	yes	no
Requires a final project	no	yes, thesis	yes, capstone design
Requires thesis advisor / committee	no	yes	no
Requires in-person participation	no	yes	yes
Residency requirement	no	yes	yes