

Medtech's Role in Extended Producer Responsibility (EPR) Programs



Design & Manufacturing

- FDA requirements govern the methods, facilities and controls used in the design, manufacturing, packaging, labeling, storage, installation, and servicing of all finished devices. This is to ensure that the products are safe and effective for patients and consumers.
- Medical devices must remain sterile, free from contamination and protected from any mechanical damage throughout the supply chain process. Packaging must be designed to meet these requirements, in order to protect the medical devices and help ensure their effective delivery.
- Manufacturers have very little control over the type of packaging available from their suppliers to meet these standards and therefore can't easily change it. Any additional requirements by individual states risk compliance with the FDA.



Devices in Action

- Once a medical device has been given the green light by the FDA, and is through the supply chain process, it's made available to patients, hospitals, and consumers through various distribution channels.
- Products and equipment typically remain in service with the end user until they reach the stage for disposal, at which time some hospitals operate recycling programs or participate in partnerships with manufacturers and other organizations to recycle or repurpose constituent materials.



Sustainability in Medtech

- Many medical device companies have specific sustainability goals and support recycling programs for their products and packaging. Some even operate stewardship and partnership programs to reclaim materials, including products and packaging, from consumers and hospitals to divert material from the waste stream and support the circular economy.
- The medtech industry is working to develop and redesign packaging to be more sustainable (recyclability/recycled content/sustainable sourcing) and use less materials while still meeting the rigorous standards of the FDA.
- Several companies are members of the Healthcare Plastics Recycling Council (HPRC), which is a consortium of the health care and recycling industry working to improve recycling of the plastic products that are vital to medical technology. HPRC partners with hospitals to create recycling programs and identify common challenges of recycling throughout the supply chain and potential solutions.

Bottom Line

Any legislation at the state level must prioritize access to medical equipment and allow for environmental stewardship to be carefully managed by federal regulators and the industry to ensure a consistent process and stable supply of lifesaving medical equipment.