



Circularity for Healthcare Plastics: The Challenges and Opportunities

INTRODUCTION

Modern healthcare would not be possible without the use of plastic. Plastic has proven to be one of the few materials versatile enough to adapt to the dynamic nature of the healthcare industry, delivering benefits that include sterility, quality, durability, and most significantly, patient and healthcare worker safety. With endless design applications, plastics are found in everything from syringes, tubing, and IV bags to prosthetics, prescription bottles, and sterile packaging. Plastics are incredibly cost-effective to produce and lightweight to transport when compared to their metal and glass predecessors.

Despite the many benefits, there are environmental consequences linked to plastics use in healthcare, most importantly, the waste created. Healthcare facilities in the United States generate approximately 14,000 tons of waste per day, most of which is being disposed of in landfills or by incineration. It is estimated that between 20 and 25 percent of that volume can be attributed to plastic products and packaging. In addition, 85 percent of the hospital waste generated is non-hazardous, meaning its free from patient contact and contamination.

Today, a paradigm shift is occurring in the plastics healthcare landscape as traditional linear models of resource consumption, i.e. “make-use-dispose”, are being eschewed in favor of more circular approaches. The healthcare industry is adopting a lifecycle approach to plastic waste management, one that aims to recover, reuse, and recycle plastic products and packaging within the framework of the circular economy.

In this paper, we bring healthcare plastics into the circular economy discussion. More specifically, we identify challenges and opportunities for using post-consumer recycled (PCR) and post-industrial recycled (PIR) content in medical devices and medical device packaging. We outline pressing regulatory, technical, infrastructure, and economic barriers to promoting circularity in healthcare plastics, as well as the opportunities on the horizon that could enable greater circular solutions for medical devices and medical device packaging applications.

TABLE OF CONTENTS

INTRODUCTION.....	2
TABLE OF CONTENTS	3
SECTION 1: DRIVERS FOR RECYCLED CONTENT IN MEDICAL PLASTICS.....	4
Customers	4
Customer Trends in the European Union (EU)	5
Legislation and Other Requirements	5
Manufacturers	6
SECTION 2: CURRENT CHALLENGES	7
Performance Characteristic Challenges	7
Traceability Challenges	8
Market Limitations and Regulatory Constraints	8
SECTION 3: POTENTIAL OPPORTUNITIES.....	9
Non-Sterile Healthcare Applications for Recycled Content.....	9
Improved Recycling Infrastructure	9
New Recycling Technologies	9
CONCLUSION	11
REFERENCES	11
ABOUT HEALTHCARE PLASTICS RECYCLING COUNCIL	12

SECTION 1: DRIVERS FOR RECYCLED CONTENT IN MEDICAL PLASTICS

Modern healthcare would not be possible without the use of plastic materials. Plastics have improved the safety and efficacy of medical products in countless ways, and they continue to do so. They also continue to generate a lot of waste -- waste that does not go unnoticed by hospital staff, patients, and the manufacturers of the products themselves. In this section, we explore the drivers for recycled content in medical devices and packaging, including customer trends, legislation, and perspectives from manufacturers.

Customers

The end users of medical products are increasingly signaling to manufacturers their interest in products and packaging that contain some level of recycled content. These customers recognize that the extraction and processing of raw materials into resins and components, and the subsequent disposal of used products and packaging, have a negative impact on the environment and human health. It should come as no surprise that customers would prefer that more recycled materials were used, reducing the need for new raw materials, and reducing overall volumes of wastes. By signaling the desire for products with recycled content, customers are creating demand within the value chain.

Examples of increased customer awareness and desire for healthcare plastics recycling are presented here.

Vizient

As the nation's largest Group Purchasing Organization (GPO), Vizient, Inc. represents more than \$100 billion in annual purchasing volume. In October 2017, Vizient began requiring the reporting of product environmental attributes as a non-financial criterion in all contract awards and standardized 23 Environmentally Preferred (EP) medical and surgical product attributes, which have been adopted by others within the healthcare industry. Vizient has also asked all group purchasing organizations to adopt this standardized set to expedite change towards safe and sustainable healthcare products. EP attributes related to waste include:

- the recyclability of the product;
- the recyclability of the packaging;
- the product contains 10% or more post-consumer recycled content for the product;
- the product does not create a hazardous waste product;
- the primary packaging contains more than 10% post-consumer recycled content;
- the secondary packaging contains more than 30% post-consumer recycled content;
- using consumer friendly recycling labels that meet U.S. Federal Trade Commission Green Guides; and
- Forest Stewardship Council Certification from 100% well managed forests, from responsible sources, or made from recycled material.

Cleveland Clinic

Located in Cleveland, Ohio, Cleveland Clinic is a nonprofit, multi-specialty academic medical center that integrates clinical and hospital care with research and education. Today, with nearly 1,400 beds on the Cleveland Clinic main campus and 5,895 beds system-wide, Cleveland Clinic is one of the largest and most respected hospitals in the country. Cleveland Clinic is an HPRC advisory board member.

The Cleveland Clinic requires contracted vendors to provide sustainability metrics around their key enterprise goals. This includes providing detailed information in support of some of the Cleveland Clinic's numerous environmental initiatives such

as waste reduction and recycling. They are also partnering with their vendors to increase recycling rates by improving the recyclability and PCR content in product packaging and fostering end-of-life product take-back programs.

Kaiser Permanente

Founded in 1945, Kaiser Permanente is one of the nation's largest not-for-profit health plans, serving 12.2 million members, with headquarters in Oakland, California. Kaiser Permanente is an HPRC advisory board member.

In 2017, Kaiser Permanente launched their Environmentally Preferable Purchasing Principles and Standards, where specific considerations are given to products that contain high PCR content. Products are required to meet at least two of Kaiser Permanente's waste criteria, which include the following:

- the product contains 10% or more of PCR content;
- the primary packaging contains more than 10% PCR content; and/or
- the secondary packaging contains more than 30% PCR content.

Customer Trends in the European Union (EU)

There is a growing interest in increasing PCR content and/or the recycling of medical packaging in the following markets: Norway, Sweden, Denmark, and the United Kingdom (NHS England)¹. For example, Aarhus University Hospital in Denmark developed procurement criteria focused specifically on recyclability, elimination of specific materials (e.g. PVC), and avoiding multi-layered materials. In 2018, the hospital launched a pilot tender for irrigation bottles that would be fit for recycling,² integrating criteria identified in the Plastic Recyclers Europe Design Guideline. Tender submissions showed that none of the suppliers scored more than 50% of the of the points needed to meet the tender criteria. Aarhus University Hospital is reaching out to other healthcare organizations in the Nordics and across Europe with an intention of creating a platform to share best practice and drive consistency in purchasing practices. As EU customers continue to push for more packaging recyclability and the inclusion of PCR content in new products, their views will undoubtedly become formalized in EU recycling legislation. Aarhus University Hospital is an HPRC advisory board member.

Legislation and Other Requirements

In North America, there is no current legislation that mandates the use of recycled content in medical devices and packaging. However, broader pledges have been made by certain industry groups including the American Chemistry Council pledge to recycle or recover 100% of plastics packaging by 2040, and the Canadian Plastics Industry goal for all plastic packaging to be reused, recycled, or recovered by 2040. In addition, over 400 organizations have signed the New Plastics Economy Global Commitment³, helping drive the circular economy through a commitment to a shared vision and the goals of eliminating problematic or unnecessary plastics; ensuring plastics are reusable, recyclable, or compostable; and keeping plastic items in use and out of the environment.

¹ Feedback from HPRC medical device manufacturers.

² HCWH Webinar: "[Public Procurement in Health: Setting Sustainability Criteria in Tenders](#)" (March 28, 2019)

³ Applying the principles of the circular economy, the New Plastics Economy initiative brings together key stakeholders to rethink and redesign the future of plastics, starting with packaging. The initiative is led by the [Ellen MacArthur Foundation](#) in collaboration with a broad group of leading companies, cities, philanthropists, policymakers, academics, students, NGOs, and citizens. In October 2018 it launched, in collaboration with the UN Environment Programme, the [New Plastics Economy Global Commitment](#), uniting over 400 organisations behind one common vision and an ambitious set of 2025 targets to address the plastic waste and pollution crisis at its source.

In the EU, the international voluntary standard ISO 11607⁴ addresses traceability requirements of materials included in primary packaging (e.g. sterile barrier packaging) of medical devices. ISO 11607 requires that the source, history, and traceability of all materials, especially recycled materials, are known and controlled to ensure that the finished product will consistently meet the requirements. ISO 11607 is widely used to demonstrate compliance with the EU Medical Devices Regulation (MDR), a CE-marking piece of legislation. As to MDR itself, concepts of safety, treatability, and post-market surveillance of medical device products, including packaging, are the key pillars of the regulation. The issue of PCR content is not explicitly addressed in the MDR.

The sustainable design of products and packaging is addressed in the Packaging and Packaging Waste Directive⁵ (PPWD), another important piece of EU legislation that addresses not only medical devices but all products that are placed on the EU market. Its objective is to drive environmental improvement of packaging and stimulate recycling rates in the EU Member States. It also supports the functioning of EU internal markets by ensuring free circulation of packaged goods in all EU member states.

Annex II of the PPWD lists essential requirements for packaging design; however, inclusion of PCR or PIR content is not explicitly mentioned. PCR content is mentioned in article 10 of the PPWD which promotes the development of European standards including “criteria for a minimum content of recycled material in packaging for appropriate types of packaging.” In article 20, the PPWD acknowledges the challenges in applying all the provisions to medical device products: “The Commission is empowered to adopt delegated acts (...) to deal with any difficulties encountered in applying the provisions of this Directive, in particular, (...) primary packaging for medical devices and pharmaceutical products,(...)”

Manufacturers

Medical device manufacturers promote recycling and use recycled content when possible. Many manufacturers have environmental sustainability goals for their products and operations. Recycling helps manufacturers reduce the environmental impacts of their products (e.g. carbon footprint) and build resilience into their material supply by, for example, using their own scrap material (such as re-grind). Manufacturers may also support recycling activities outside their operations to help develop the market and make recycling a more economically viable solution. Recycling helps medical device manufacturers meet the needs of their customers-- healthcare facilities, who want to reduce plastic waste and protect the environment.

⁴ [ISO 11607-1:2019](#)

⁵ [Packaging and Waste Directive 94/62/EC](#)

SECTION 2: CURRENT CHALLENGES

A variety of historical challenges have created hurdles to the use of PCR and PIR content in medical devices and medical packaging. Given the regulatory environment surrounding medical-grade plastics, the resins used need to be consistent in order to adhere to stringent quality and performance criteria. Introducing PCR and PIR content into the process can lead to variations in consistency, and in turn, potential negative human health impacts. In this section, we explore these challenges related to performance characteristics, traceability, market size, and regulatory constraints.

Performance Characteristic Challenges

When considering the use of recycled materials, a medical device manufacturer (MDM) needs to understand what impacts a variation in recycled content or in the source of the content has on the physical properties and function of the medical device and packaging. Medical packaging testing is often conducted in a “worst-case” manner to account for variations in product configurations (e.g. variety of sizes, etc.) and variation in manufacturing processes (e.g. sterile barrier sealing, sterilization, etc.).

With reclaimed material, the challenge is in identifying the worst-case blend of materials and then using this blend as a basis for testing to ensure consistency in meeting critical material performance requirements. Critical material performance requirements include things like:

- strength,
- flexibility,
- permeability,
- sterilization compatibility, and
- microbial barrier characteristics.

A product not meeting the specific requirements may result in decreased device performance, lack of biocompatibility, or loss of sterility.

The Association for the Advancement of Medical Instrumentation (AAMI) has developed a standard, ISO TIR 65:2015, that focuses on the sustainability of medical devices, acknowledging the challenges in maintaining quality and product integrity when incorporating recycled content. AAMI suggests that non-sterile medical packaging poses fewer challenges to incorporating recycled materials. The most viable option for PIR content inclusion in sterile barrier packaging may be from in-process re-grind (see side bar) given that it involves using material from the same lot, making it traceable.

A further challenge when including PCR content is impacts to manufacturing operations due to inconsistencies in factors such as viscosity and forming

IS SCRAP PLASTIC CONSIDERED RECYCLED CONTENT?

Where manufacturing practice allows, manufacturers will typically collect scrap plastic material (such as spills, scrap from the start up and/or end of a process, etc.) and with minimal processing, mix this re-grind with virgin material. Optimizing the process in this way not only reduces waste but also reduces the amount of virgin materials required. As this is normal practice, and therefore the scrap material would not typically enter the waste stream, the use of scrap in this manner is not considered recycling.

However, if - for example - manufacturing processes prevent scrap from being used in the production of the same product, but it can be used in the production of an alternative product, this may be considered recycling.

In order to make a recycled content claim for a product, a manufacturer must be able to demonstrate that post-industrial content would otherwise have entered the waste stream.

temperatures of the PCR content. Inclusion of PIR content can cause aesthetic issues due to the potential for discoloration of the final product. The final output can be hazy or inconsistent from component to component. This varies depending on the ratio of virgin to recycled content in the final product.

Traceability Challenges

Historically, the use of PCR content in medical devices and packaging has been deemed impractical based on the lack of traceability. Material traceability requirements for medical devices and packaging are found in standards and regulations such as ISO 13485:2016 and U.S. 21 CFR 820.65, which have specific requirements about maintaining a Device History Record (DHR) that traces material content from the final product back to the individual material sources. This information is used in the event of recalls, enabling medical device manufacturers to quickly and accurately identify the sources and extent of issues.

The international standard ISO 11607-1:2019, 5.1.5 states specifically, with regard to sterile barrier packaging materials that: “it is unlikely that anything other than virgin manufacturing waste will be used in recycled materials, due to insufficient controls to allow the safe use of other recycled material in sterile barrier systems.” As mentioned above, the most viable option for PIR content inclusion in sterile barrier packaging may be from in-process re-grind (see side bar) given that it involves using material from the same lot, making it traceable.

Material traceability also impacts material selection from a material biocompatibility perspective. Many engineers are already reluctant to incorporate new or modified materials into medical devices or sterile barrier packaging because such extensive testing of new or modified materials is required. If incorporation of PCR or PIR is considered, it is difficult to trace the source of polymer blends that vary in sources and content, which poses questions regarding applying biocompatibility data accurately. Relevant standards in this area are ISO 10993-1:2018, which is applicable to medical devices; and ASTM F2475:2011, which is applicable to medical packaging materials.

Market Limitations and Regulatory Constraints

The medical device industry accounts for a small percentage of the overall plastics industry. This results in less visibility and little traction to invest in the R&D required to safely incorporate PIR and/or PCR content into medical devices and packaging.

Due to the highly regulated nature of the medical device industry, and expense in validating and submitting changes to regulatory bodies, there is a tendency towards risk avoidance throughout the industry. Many MDMs are reluctant to shift from using virgin materials to new approaches with PCR and/or PIR content. Indeed, without a strong consensus between industry, standards development organizations, and regulators regarding appropriateness of PCR/PIR content, MDMs are unlikely to change practices.

SECTION 3: POTENTIAL OPPORTUNITIES

The recycling industry is undergoing a significant change in the wake of China's "National Sword" ban on plastic scrap imports (see sidebar). Investment and innovation in recycling solutions are growing at a pace that has not been seen in decades. Both upstream and downstream systems are being re-imagined with the goal of reducing waste and changing our current "throwaway" culture. In this section, we look at some of the most promising opportunities for recycling more healthcare plastics and incorporating recycled content into healthcare plastics.

Non-Sterile Healthcare Applications for Recycled Content

Many MDMs would like to use more recycled content in their products and packaging but are hampered by regulatory restrictions. One promising application for recycled content is in non-sterile packaging, such as secondary and tertiary packaging, and non-sterile products. Secondary and tertiary packaging materials often do not need to be sterile, and certain medical devices do not require sterile packaging because they are sterilized on location at the hospital. Similarly, certain products are not used in applications that require sterility. For example, sharps disposal bins must meet certain requirements for the storage and transportation of sharps but do not need to be sterile, posing fewer technical challenges to incorporating recycled resins.

Improved Recycling Infrastructure

China's ban on plastic scrap has served as a wake-up call to industry and government that our existing infrastructure for plastics recycling is outdated and ineffective. Investments are being made in domestic recycling infrastructure at a rapid pace. For example, in 2018, Closed Loop Partners, along with co-investors, invested over \$210 million dollars in companies that are driving recycling infrastructure⁶ and circular plastic solutions. On the government side, the RECOVER Act recently introduced in the U.S. House of Representatives would allocate \$500 million dollars in matching federal funds for states to improve their recycling infrastructure.⁷ These recycling infrastructure improvements aim to revitalize our domestic collection and processing abilities and overcome several primary barriers (i.e., the availability, quality, and price of recycled resins) to manufacturers incorporating recycled content into their products.

New Recycling Technologies

While mechanical recycling is the dominant method of plastics recycling in use today, it cannot effectively recycle all plastic waste. Plastic that is too degraded, too complex, or too contaminated cannot be mechanically recycled. Even for those plastics that can be recycled via mechanical means, polymer degradation is a problem which can lead to compromised material properties and

CHINA'S BAN ON PLASTIC SCRAP IMPORTS

After importing nearly half of the world's plastic recyclables for three decades, China banned the import of most residential and industrial scrap plastic in 2017. The ban is part of its efforts to clean its environment and improve quality of life.

Developed countries, like the United States, had until now been exporting much of their recyclable waste to China because they lacked the infrastructure and recycling systems to efficiently and cost-effectively process it domestically.

As a result of China's ban, governments, manufacturers, and recycling companies are scrambling to find solutions to the growing stockpiles of plastics, spurring much-needed investments in recycling facilities and technologies.

While these investments are a very promising step towards a more sustainable and circular plastics future, it will take time to develop and expand domestic systems and markets, and scale new technologies.

⁶ <https://www.closedlooppartners.com/wp-content/uploads/2019/03/Closed-Loop-Partners-Impact-Report-2018-1.pdf>

⁷ <https://cardenas.house.gov/media-center/press-releases/c-rdenas-bucshon-introduce-recover-act>

performance. New recycling technologies are being advanced that aim to recycle all types of plastic waste without degrading their quality. In some cases, the plastic polymers can be broken down and re-polymerized endlessly - generally through the application of heat and/or chemicals - giving them the qualities of brand-new, or virgin, resin.⁸ As such, these recycled resins can be used in the same applications as virgin resins, giving medical device manufacturers new opportunities for the incorporation of recycled plastics in their products.

Today, there are over 60 advanced recycling technology providers worldwide, most at least at the lab stage of maturity, with significant potential to grow in scale. More than 40 technology providers are currently operating pilot to full-scale plants in the U.S. and Canada or have plans to do so in the next two years⁹. Additionally, over 250 investors and strategic partners, including the world's largest brands, private investors, petrochemical companies, plastic manufacturers, and government and NGO partners, are already investing in and/or engaging with advanced recycling technologies.

Two examples of these advanced recycling efforts include the Advanced Circular Recycling and Carbon Renewal Technology initiatives announced by Tennessee-based Eastman Chemical Company, and Brightmark Energy's plans to build the nation's first commercial scale plastics-to-fuel facility.

Eastman Chemical Company

Eastman is a global specialty chemical company that produces a broad range of advanced materials, additives and functional products, specialty chemicals, and fibers that are found in products people use every day. As a world leader in the diverse markets it serves, Eastman is focused on delivering innovative and technology-based solutions while maintaining its commitment to safety and sustainability. Eastman is an HPRC member.

In 2019, Eastman announced two new advanced recycling technologies. Advanced Circular Recycling is a chemical recycling technology that takes polyester wastes, which cannot be recycled by current mechanical methods, and uses methanolysis to break them down into their polymer building blocks. These building blocks can then be reintroduced into the production of new polyester-based polymers. Complementary to the methanolysis process is the Carbon Renewal Technology, a gasification process that is capable of recycling some of the most complex plastic waste, including non-polyester plastics and mixed plastics such as non-contaminated healthcare plastics and packaging. The Carbon Renewal Technology partially oxidizes the waste plastic, converting it back into the basic building blocks of Eastman's cellulose product lines that serve industries such as ophthalmics, durables, packaging, textiles, and nonwovens.

Brightmark Energy

Another great example of emerging technology for advanced plastics recycling is the recent announcement that Brightmark Energy plans to build the nation's first commercial scale plastics-to-fuel facility in Indiana. Brightmark is a San Francisco-based waste and energy development company that develops, owns, and operates waste and energy projects. Brightmark employs technology solutions including renewable natural gas, plastics renewal, and waste to energy solutions.

At its future plant, Brightmark Energy will use a state-of-the-art plastics-to-fuel process to recycle waste, including plastic film, flexible packaging, styrofoam, and children's toys. These waste products, and others, are converted into products such as fuels and wax. Brightmark is also exploring converting mixed waste into feedstock that can be used in plastics manufacturing, closing the loop for the circular economy of plastics. Currently, Cleveland Clinic, renowned academic medical

⁸ www.thisisplastics.com/environment/recycling-101-advanced-recycling

⁹ www.closedlooppartners.com/plastics/

center and HPRC advisory board member, is working toward a partnership with Brightmark Energy to begin using pre-surgical healthcare plastics as feedstock for this advanced recycling process.

As mentioned, there are many advanced recycling players that are working to curb plastic waste, keep materials in play, and grow markets for recycled content. The examples described above are just a couple of the innovative efforts currently underway that hold exciting potential for the healthcare industry.

CONCLUSION

As this paper explains, there are significant challenges to integrating PCR and PIR content into medical devices and medical packaging. While medical device manufacturers would like less plastic waste and more recycled content in their products and packaging, cost, quality, and regulatory requirements can hamper these aspirations. This is especially true when it comes to healthcare where positive patient outcomes take top priority. There is hope though, as strong, recent investments in domestic recycling infrastructure and new advanced recycling technologies are poised to deliver recycled plastic resins on par with their virgin counterparts. Until these technologies become widely available, medical device manufacturers will continue to look for viable options for PCR and PIR content within their product lines, as well as improve the management of plastic throughout its lifecycle, including reduce, reuse, and efficiency strategies. One thing is certain, while plastic in healthcare may be here to stay, its recycling landscape is changing rapidly.

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- ISO 10993-1:2018 Biological Evaluation of Medical Devices -- Part 1: Evaluation & Testing within a Risk Management Process
- ISO 11607-1:2019 Packaging for Terminally Sterilized Medical Devices -- Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems
- ISO 13485:2016 Medical Devices -- Quality Management Systems -- Requirements for Regulatory Purposes

ABOUT HEALTHCARE PLASTICS RECYCLING COUNCIL

HPRC is a private, technical consortium of industry peers across the healthcare, recycling, and waste management industries seeking to improve the recyclability of plastic products and packaging within healthcare. Founded in 2010, and made up of globally recognized members including Amcor, BD, Baxter, Boston Scientific, DuPont, Eastman Chemical Company, Gore Medical, Johnson & Johnson, Medtronic, Nelipak Healthcare Packaging, Ravago Recycling Group and ThermoFisher, HPRC engages in pioneering projects designed to help boost plastics recycling efforts in clinical settings of hospitals. Committed to continuous dialogue, the council explores ways to enhance the economics, efficiency, and ultimately the quality and quantity of healthcare plastics collected for recycling. For more information, visit www.hprc.org.