Whitepaper

Envalior
Imagine the Future

SUSTAINABILITY IN THE MEDICAL DEVICE MARKET

Pragmatic and sustainable solutions for medical device challenges.

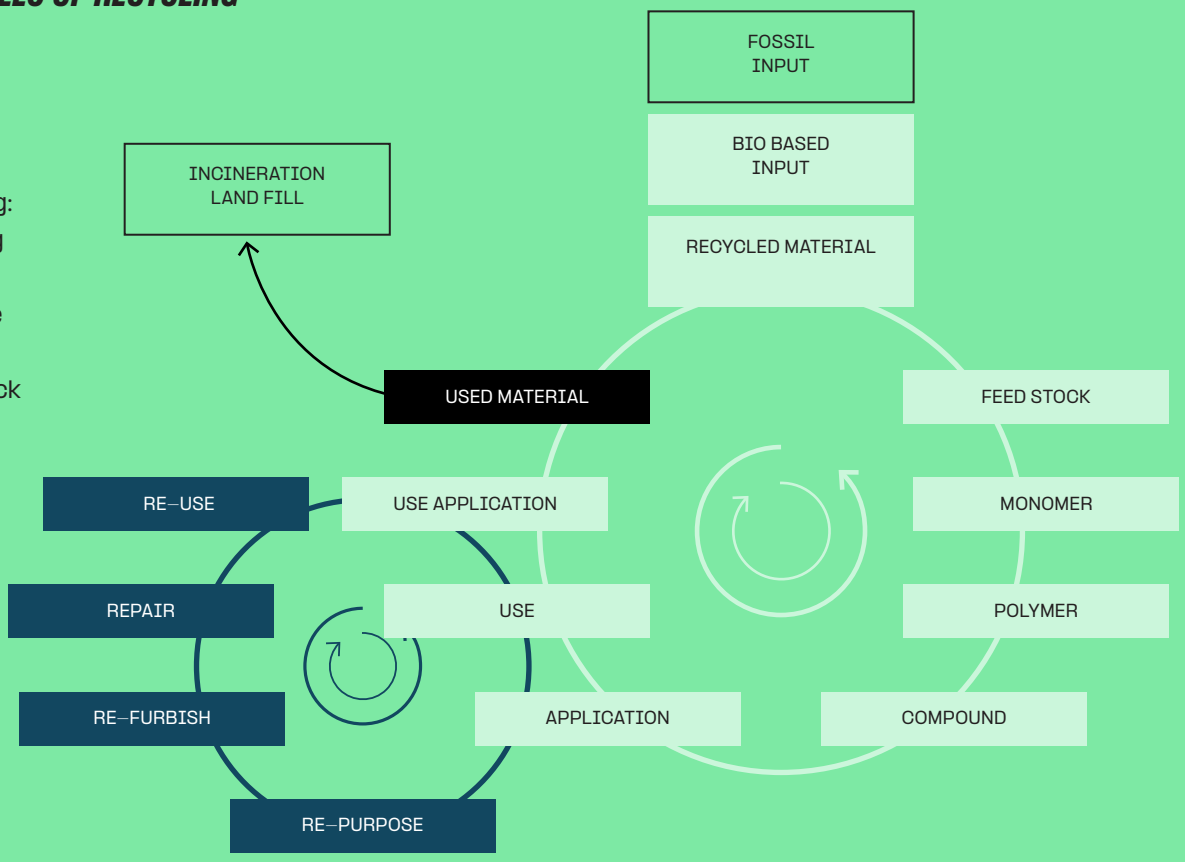
Climate change, plastic waste and depleting resources are three important environmental themes for the future use of materials. Governmental and corporate targets reflect the urgency for materials and goods producers to act now and in the near future.

There will be a shift to a circular economy. In a closed circle, suppliers become users and consumers suppliers. For companies, the challenge will be to drive this change to a circular economy in an economically attractive way. Clearly, we are at the brink of a major change in materials manufacturing, waste handling, and in doing business.

In a circular economy often two cycles can be defined. One where re–use and re–furbishment are used to enhance use time and reduce pressure on resources. The other, where new, virgin product manufacturing is needed. Both circles will ultimately be needed in the future. For medical applications there are some general

FIGURE 1: TWO CYCLES OF RECYCLING

Circular economy is about the cycling of material driven by an economic "engine." The two cycles of recycling: using materials as long as possible, as in the blue cycle; and recycle plastics and replenish with biobased feedstock in the green cycle.



Progress needs to be made in the face of stricter regulations, end–of–life mandates, and rapid education of consumers.

technical features which are different from many other applications. There is a large amount of packaging needed for hygiene and keeping devices sterile. Devices need to be designed with materials that are rigorously evaluated to minimize risk to the patient. In the context of collecting waste in order to implement a circular economy, there is also often patient contact and the associated potential biohazard post use. This gives additional opportunities and challenges to overcome for packaging and use of both disposable and multiple use medical devices. It can be expected that the "virgin products" circle in Figure 1 above, is a more pronounced solution in a medical circular economy than for other materials markets.

Envalior, the new name for the joint venture formed by the merger of DSM Engineering Materials and Lanxess High Performance Materials, has a long track record in leading the change to sustainable materials and supporting customers with data and certifications.

At Envalior, sustainability is a core value and has been for more than 30 years. Our team of experts has been driving our science based sustainability vision through our organization and into the engineering materials we manufacture. A full suite of tools and technologies is being implemented with an ever–expanding portfolio of commercial products that continuously improves the sustainability footprint of our operations and materials, including our medical grades.

As a global society, we produce more than 450 million T/yr of plastics, of which 35% is one–time use and only 9% is recycled. Approximately 12 million T/yr end up

in the oceans. The annual loss in the value of plastic waste in the United States alone during sorting and processing is estimated at US $80–120 billion. In the medical environment, packaging waste and single use devices are the most visible and criticized environmental concern of medical personnel and patients.

SUSTAINABILITY JOURNEY

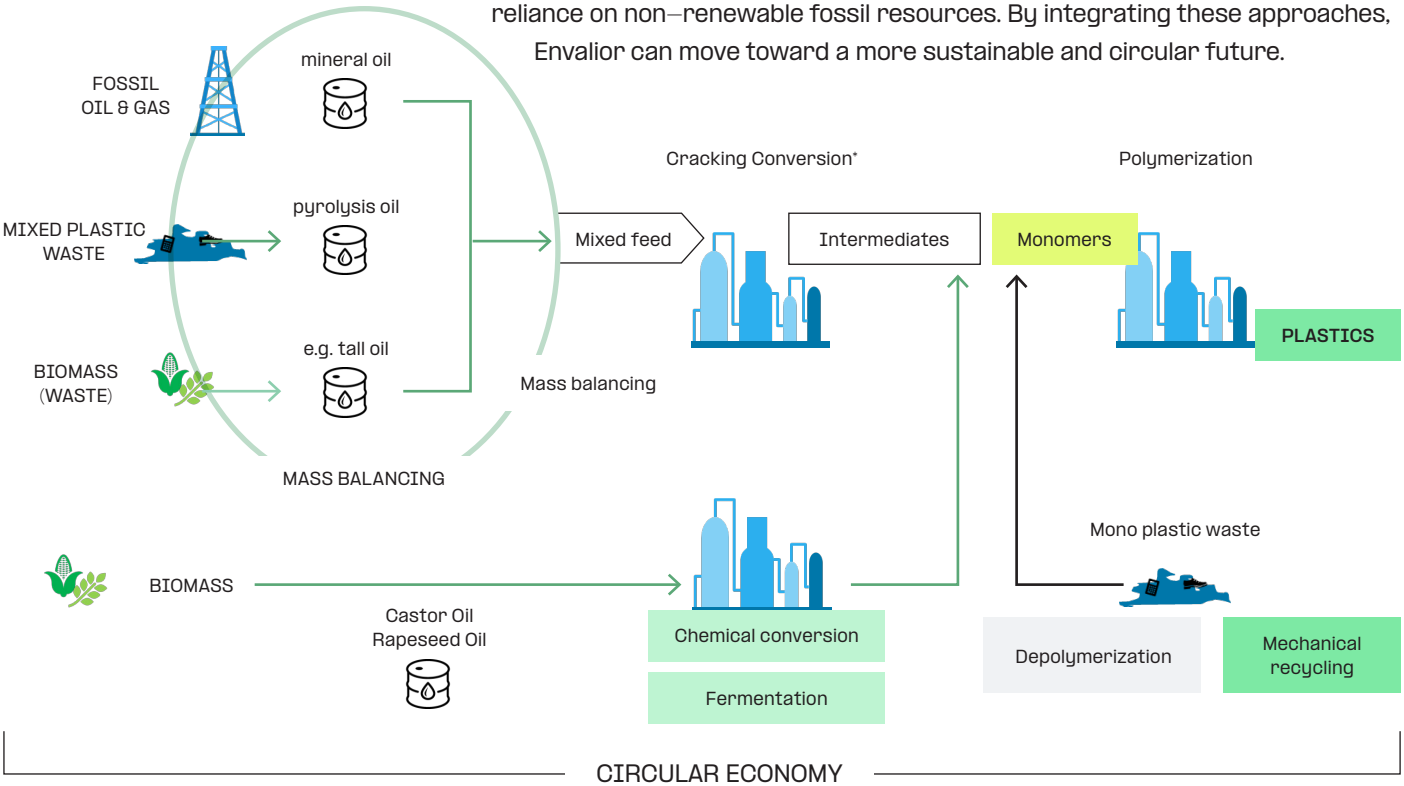
Sustainability is increasingly becoming a design criterion that must be considered for new devices and packaging, especially since not all progress improves impacts to the environment by the industry. For example, distributed healthcare, connectivity and batteries are increasing environmental challenges, making it more difficult to hit sustainability targets. There is progress being made in packaging and lightweighting, but more needs to be accomplished. Progress needs to be made in the face of stricter regulations, end–of–life mandates, and rapid education of consumers, and it needs to be done at a price society can afford. The healthcare industry emits between 4.5% and 5% of global carbon emissions. The pharmaceutical industry alone emits 13% more carbon than the automotive industry, even though it is 28% lower in economic output. If the healthcare industry were a country, it would be the 5th largest emitter of carbon on the planet.2 Although the consumer expects the plastics industry to fix the problem, it's fair to state we—industries, consumers, NGO's, governments, etc.—are all part of the problem and need to solve it together.

Pharmaceutical and medical device companies can leverage Envalior's sustainability and materials expertise to assist with their individual sustainability journeys. For the medical industry, there is bewildering information to collect and understand before intelligent strategies and decisions can be operationalized. The technology roadmap illustrated in Figure 2 is a useful tool to quickly visualize all the options available to medical organizations.

Carbon footprint reduction is about lowering carbon emissions by energy efficiency and changing energy sources. Currently, energy is mainly produced from fossil resources like natural gas or coal, for direct heating or for generating electric power. Generally, for a medical

FIGURE 2: CIRCULAR AMBITIONS

Circular economy solutions for plastics involve a combination of advanced recycling technologies, sustainable sourcing from biomass, and cracking conversion of mixed feeds. Mass balancing plays a crucial role in accelerating these efforts by enabling the seamless integration of recycled and renewable materials into current production systems. These strategies aim to close the loop on plastic use, reducing waste and minimizing the reliance on non–renewable fossil resources. By integrating these approaches, Envalior can move toward a more sustainable and circular future.



* Chemical recycling denotes mainly the conversion of mixed plastic waste via Pyrolysis – this pyrolysis oil is then fed into the cracker system.

OEM product ca. 10–20% of the total energy need and CO2 emission is from a medical OEM's own production. The rest is from supplied materials. While it is important to reduce one's own energy emissions by changing the source of energy, it is critical to buy from suppliers with a low carbon footprint since most of the carbon footprint is bought into an organization from the upstream value chain. The latter is enhanced by cooperation with material suppliers like Envalior.

CHALLENGES OF MECHANICAL RECYCLING

Mechanical recycling is always the simplest and the most energy efficient circular solution. Mechanical recycling is the re–use of materials utilizing only physical steps like washing and melt processing. Because it appears simple, it is favored by many stakeholders in the sustainability discussion.

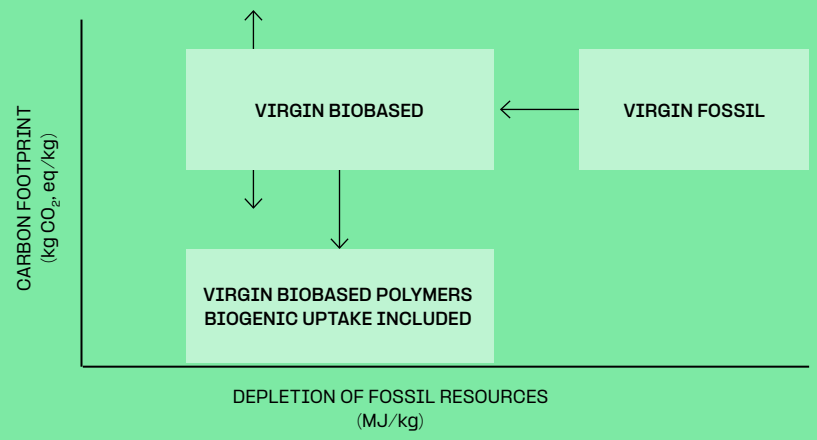
For medical, it can and is being done in extremely limited closed loop manufacturing environments. Efforts for mechanical recycling are gaining traction with secondary packaging that is "consumed" before use / patient contact. Clearly because of the potential biohazard from patient interactions, the logistics of mechanical recycling post use are difficult. In most cases, because of the strict demands with respect to collection and sorting, and the issues associated with cross contamination, hygiene, multiple heat histories and the potential degradation effects changing materials, the risks are assessed as not acceptable within the medical industry. This is unlikely to change.

DEPOLYMERIZATION MAY LEAD TO REQUALIFICATION

Depolymerization is a special type of chemical recycling process to derive virgin grade monomers that can be fed back into a polymerization unit. Monomers do not need to be re–produced, leading to a lower carbon footprint and better resource efficiency. However, only a limited number of polymers can be recycled in this manner. This technology will only be commercially interesting if well sorted waste streams with a high depolymerizable polymer content are available. A known example is PET, for which depolymerization capacity will increase in the near future. Depolymerization is currently less developed and promises to be more versatile than mechanical recycling.

FIGURE 3: CARBON FOOTPRINT VS DEPLETION OF FOSSIL RESOURCES

Fossil polymers have higher depletion because they also contain fossil energy stored in the polymer (when you incinerate them, fossil energy is released). Biobased virgin polymers have only a need for manufacturing energy and have lower fossil resource deletion potential, but may have higher or lower carbon footprint for manufacturing depending on the manufacturing process and source of energy used. Plants have a net storage of CO2. This process, known as biogenic uptake, reduces the carbon footprint of biobased materials.



The polymers produced are circular economy materials. If the monomer utilized has high enough purity to be able to manufacture chemically identical engineering plastics and mass balancing principles are applied, then requalification may not be necessary. In other cases, depolymerization can lead to a different end product, and requalification in the medical device may be necessary.

ADVANTAGES OF BIOMASS—TALL OIL

While mechanical and various forms of chemical recycling will reduce waste and reduce carbon footprint, it will not be sufficient as a solution to finite resource depletion. Biobased materials will also be needed to accommodate growth and replenish unavoidable losses. Biomass based plastics almost always have a lower carbon footprint relative to fossil oil–based materials. See Figure 3.

Biomass materials will come in three ways. The strategy for introducing biobased materials will be one of increasing complexity. Already we see monomers produced in existing assets made from biobased origin mixed with fossil input for existing products. A next step for some monomers will be that they are made from biobased but in new technology. Finally, the most complex use of biobased feed stock is if new polymers need to be made with new technology.

New materials can be made from (relatively) new monomers: These biobased products are based on agricultural materials leveraging chemistry to convert agricultural oilseed crops into plastics. To date, fossil fuel derived materials have better economics than materials produced in biorefineries. Due to cost, the commercialization of these products is usually successful only for unique niche polymers that in most cases do not have fossil fuel derived alternatives. Because of the carbon sink associated with the agricultural crops, the carbon footprints are lower relative to fossil fuel–based plastics.

These materials are suitable for use in medical applications, and due to their often, lower environmental impacts are getting increased attention from medical device manufacturers. Like any other polymer, they need to be qualified for use in a medical device. They are not replacements for existing mainstream polymers and should be thought of as complementary specialty materials alternatives that in certain applications are the best solution to accomplish the medical device manufacturer's goals.

2 TECHNIQUES TO MAKE EXISTING PRODUCTS

Existing products can be made from monomers via alternative, new chemical routes: There are manufacturers developing new chemical processes and business models to produce mainstream base chemical building blocks from agriculture waste. For example, biobased BDO is being made commercially directly from sugar via a fermentation, and new plants with this technology are under construction and in development. These have the future potential, when built at scale, to effectively compete with fossil fuel derived base chemicals for use in medical devices. However, these biobased materials may require requalification.

Existing products can be made from mass balanced (waste) bio feed stock in existing assets: Low carbon footprint waste biomass feedstocks, like tall oils or post–consumer cooking oils, can be fed into crackers mixed with crude oil. Crackers simply take longer hydrocarbon chains and break them down in a structurally controlled manner into the different carbon length products that have commercial value. The cracker outputs are the base chemicals that are the building blocks of the plastics industry. Biomass based cracker products are chemically identical to their fossil–oil based counterparts. The carbon, irrespective of its source, is mixed at the molecular level in the cracker output and the carbon does not know if the source is biobased or fossil based. Streams are mixed at the input and obtained as blends in the outputs which gives a lot of versatility at low cost leveraging existing infrastructure. Because of this, you get a "genetically identical twin" to the current fossil–oil derived material, identical in composition and properties. Because the materials can be proven to be chemically identical, these mass balanced or biomass balanced materials are acceptable solutions for medical applications. No requalification is necessary. Since the use of these biobased inputs are mixed at the cracker with fossil–based feeds, the carbon footprint reduction is measured and secured based on biomass balancing principles.

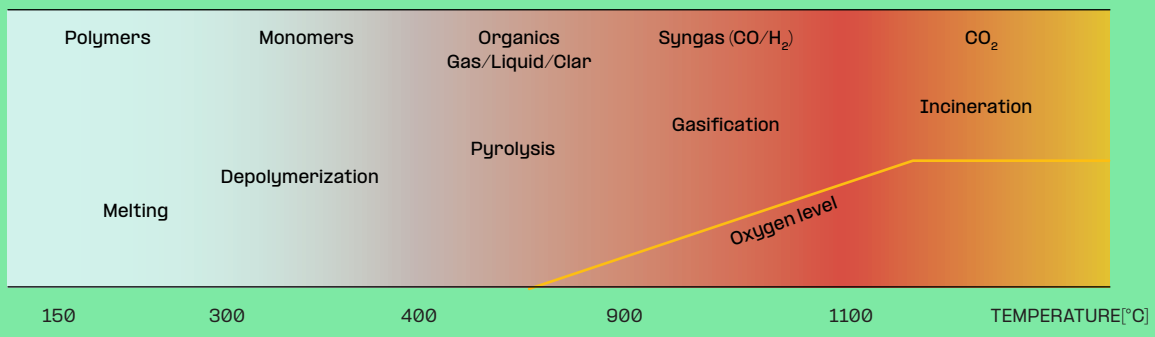
According to the Ellen MacArthur foundation, mass balancing is a chain of custody model to track the total amount of content in scope (bio– or recycled based feedstocks) through the production system and ensure an appropriate allocation of this content to the finished goods based on auditable bookkeeping. This principle is used to allocate the biomass to a given product and is traceable through the value chain to the OEM and their products. The value chain for biomass balanced materials is audited and certified by third party organizations like the International Sustainable Carbon Certification (ISCC) organization. It is a global living multi–stakeholder initiative organized in an association with 126 members. Envalior is an ISCC member, and our business units are already certified or in the process of being certified.

converts a mixed waste material back into virgin quality monomers but at higher energy cost than mechanical recycling. Today, we see a lot of activity intending to use existing hardware to co–produce chemically recycled products. By certified mass balancing it is possible to guarantee that sufficient material has been used to claim a 100% recycled–by–mass–balancing product. Large scale application is foreseen before 2030. The new polymers produced by pyrolysis are circular economy materials, chemically identical to the fossil–based virgin polymer. These will not need requalification.

While the carbon footprint of pyrolysis processes may lead to higher carbon footprint than current fossil–oil based materials, it is still a preferred solution when considering the end of life of a plastic part and the cradle to grave footprint. In view of depleting resources and plastic waste

FIGURE 4: CHEMICAL RECYCLING

Pyrolysis is a technology in a spectrum of options to break down materials into useful products. It is in between depolymerization and gasification. It requires more energy than depolymerization to produce monomers but less than gasification. This higher energy demand offers the option to be able to feed with a wider spectrum of polymers than in depolymerization. Incineration produces energy but cannot deliver the monomers generally needed.



PROMISING FUTURE OF PYROLYSIS OIL

"Chemical recycling" is generally also used for a heating step ("pyrolysis") breaking down the polymer to oil, char, and gas, which is not directly a monomer. It is especially interesting if the feed stock is not a well–defined single polymer or a medical waste. The oil is intended to be fed into existing fossil oil–based operation to produce base chemicals which can serve as (a raw material for) monomers. This pyrolysis technology depicted in Figure 4 is currently less developed and promises to be more versatile than mechanical recycling. It

reduction, recycling is preferred over landfill, incineration and even many biobased solutions. If the choices are landfill or recover for energy (incineration), then pyrolysis and gasification have their place in the circular economy, even with their energy use disadvantages relative to other recycling processes. Pyrolysis technology is in its infancy, and there has already been rapid progress overcoming technical obstacles and making improvements. In the future, as capacities get built out and debottlenecked and processes to manage waste are developed and accepted by the industry, mixed plastic waste can be

repeatedly upcycled for reuse in new medical products with the same quality as current fossil–based devices.

LIFE CYCLE ASSESSMENTS TO MAKE SOURCING DECISIONS

An LCA is a critical tool that discriminates between environmental impacts, including carbon footprint, of products, manufacturing processes, and production locations. It is a comprehensive analysis of all the inputs and outputs (what is consumed, and the wastes emitted) associated with the manufacture of a product. The inputs and outputs are then evaluated for their adverse impacts on long–term sustainability of renewable and nonrenewable resources, human health, and biodiversity, amongst others. Full LCAs can be useful to help discriminate between materials. Once these are understood, better sourcing decisions can be made.

For now, biomass balanced solutions based on the bioeconomy feedstocks are the best way to go. They are available and can be used in existing cracker assets. However, in the long run it is important that a mix of biobased and all types of recycled based solutions will be required. In the future, recycling of plastics should be favored over biomass, e.g., for efficiency/yield reasons due to the chemical composition. In the US and EU, governments are looking at laws and regulations supporting this transition with growing focus on recycling as a major factor.

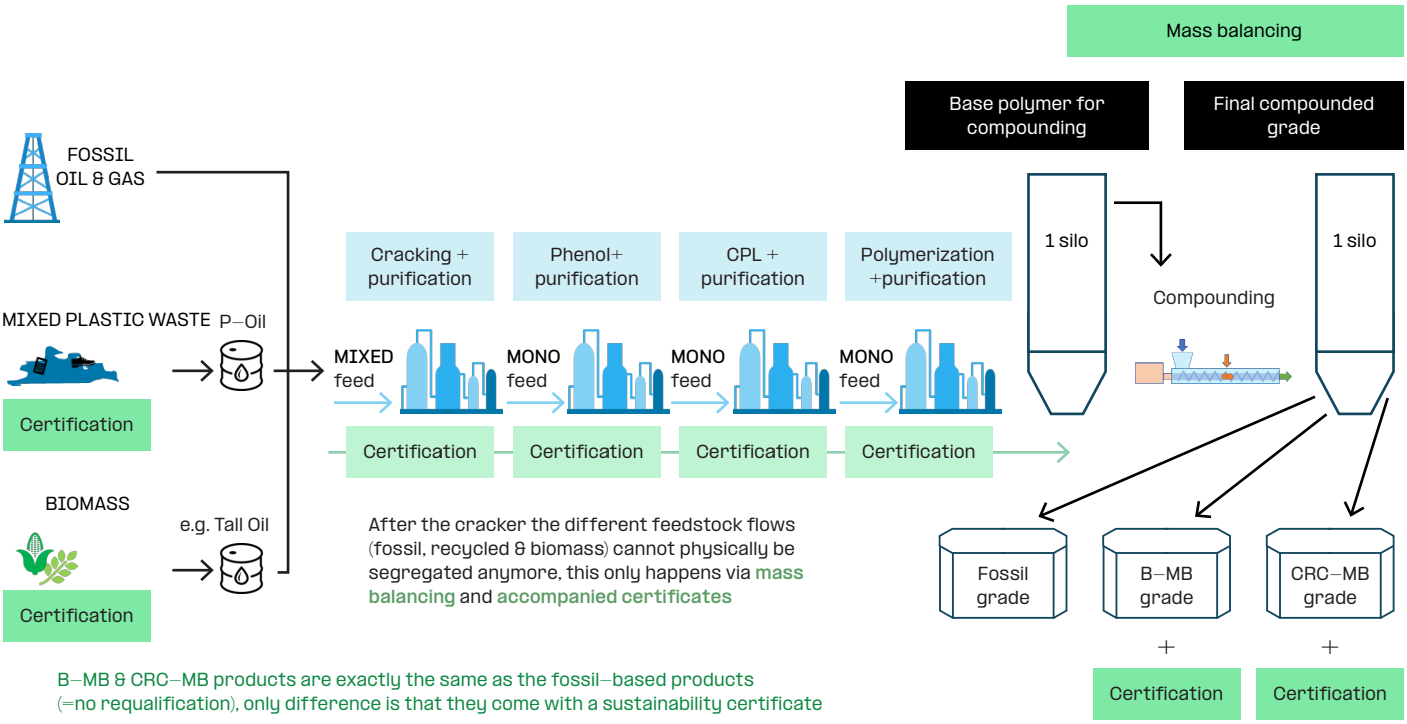
OTHER FACTORS WHEN CHOOSING A MATERIAL

In the drive towards more sustainable solutions, one may be tempted to only look at LCA or carbon footprint. The first focus should be on the required properties for a certain application keeping some flexibility in material specification for optimization. Once this has been chosen, one can find an optimized solution with price and sustainability aspects as the focus.

One should also keep in mind that sustainability parameters for some polymers and applications may not always be the same. Examples may be

FIGURE 5: MASS BALANCING IN PRACTICE: COMPOUNDED PA6 GRADE

A practical opportunity is to feed a liquid biobased feed stock, for example used cooking oil or tall oil, into an existing cracker. The process cannot be stopped and restarted to change the feed stock. A 100% biobased material will lead to damage of the cracker. Pyrolysis oil can be used in unlimited quantities. Therefore, an acceptable limited flow of biobased material or unlimited quantities of pyrolysis oils can be mixed with fossil input to yield the same, virgin quality output and exactly the same virgin quality downstream products. The downstream product comes with a certificate stating that sufficient biobased material is used upstream to produce that downstream product: masses are balanced. This is known as mass balancing, and a popular certification is giving by the ISCC+ standard.



found where a biobased material is not automatically performing better on GHG emissions. Therefore, one should be critical and make informed choices. Envalior can help in that choice and by our offering.

Finally, the composting ability of some polymers is sometimes claimed as sustainable, suggesting some materials, both biobased and fossil based, may degrade once discarded in the environment. Especially, consumers may think that a biobased material is compostable, but in reality this is often not the case. Many of those polymers are not degradable under normal environmental conditions—an industrial process is needed. Next, degrading polymers makes them unavailable for recycling and we believe that we should do our utmost to facilitate that and avoid pressure on other virgin resources as much as possible.

MASS BALANCED MATERIAL IS AUDITED AND CERTIFIED

Now we must pragmatically implement the solutions. The chemical industry knows the three alternatives (virgin material, biomass–oil based material and pyrolysis oil–based materials) are chemically identical solutions. The mass balanced solution is secured with third party certification, like ISCC or REDCert.

In practice, the materials are, in every aspect, the same material. The polymers are made from comingled carbon. The only difference is the mass balanced material comes with an independent third party audited certification. Because these materials are the same, if the medical device manufacturer is already using a material from Envalior, then the biomass balanced material or the pyrolysis oil–based materials can be used with no requalification necessary. An example for a compounded nylon is illustrated in Figure 5, page 8.

There are many levels of processing between introduction of tall oils or pyrolysis oils and medical devices. Their introduction is so far upstream that these circular economy solutions are not going to have any impact on the material quality or impurities.

UNDERSTANDING REGULATORY GUIDANCE

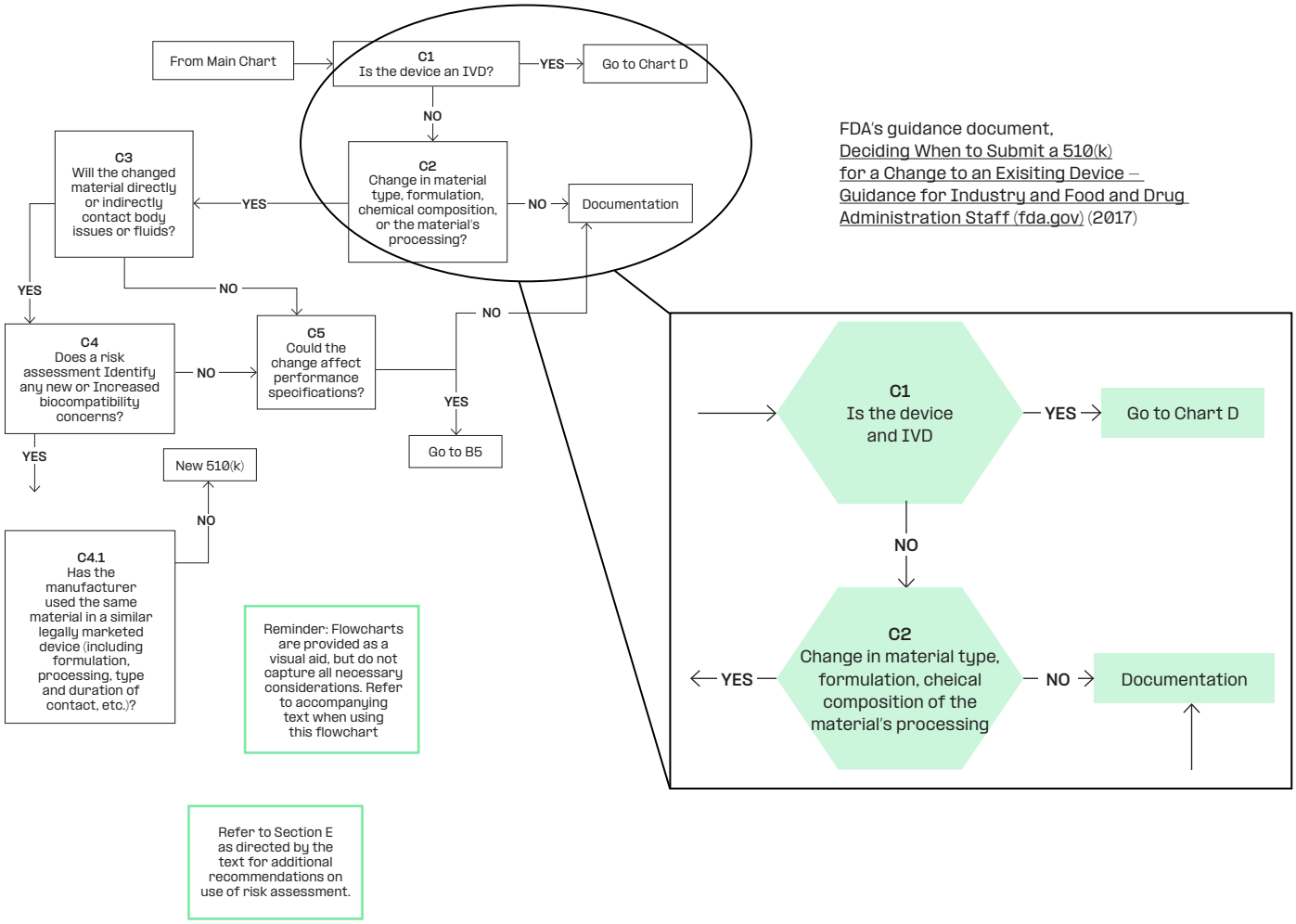
No materials discussion related to medical applications is complete unless there is an understanding of the regulatory pathway. We will take the FDA in the United States as a proxy. Like any other regulatory agency, the FDA's ultimate concern is patient safety and the performance of the medical device. We know the composition and specifications of the monomers and additives produced with the tall oil and pyrolysis oil type feedstock are identical to those produced from fossil feedstocks, including impurities.

A review of the FDA's guidance document, Deciding When to Submit a 510(k) for a Change to an Existing Device – Guidance for Industry and Food and Drug Administration Staff (fda.gov) (2017) is appropriate. This document provides a framework for assessing changes to an existing medical device and determining whether a new 510(k) submission is required, or whether the basis for the change(s) should simply be documented in the device manufacturer's records or require an additional 510K to be filed. Section C considers the type and duration of contact and Section D discusses risk assessments with respect to materials changes and presents a series of questions to consider for medical products. Part C is illustrated in the flowchart in Figure 6, page 10, and is intended as a guideline. Note that per the FDA, the guidance document is nonbinding.

Box C2 is the most relevant. It asks the question if the change in consideration leads to a difference in the "change in material type, formulation, chemical composition or the materials processing." We know we are considering the differences between "genetically identical triplets." Since the answer is no, then the medical device manufacturer just needs to document the change, and no 510K resubmission is required. Following the guideline in Section D for In vitro devices should also lead to a decision to simply document. The documentation should be prepared in a way that an FDA investigator or other third party can understand what the change is and the rationale underlying the manufacturer's conclusion that submission of a new 510(k) is not required. This white paper stipulates the rationale. Third party legal opinions concur.

FIGURE 6: REGULATORY PATH

Customer Regulatory Team
needs to make their own conclusions



FDA's guidance document, Deciding When to Submit a 510(k) for a Change to an Exisiting Device – Guidance for Industry and Food and Drug Administration Staff (fda.gov) (2017)

Since the customer clearly has superior knowledge about his own device and the regulatory expectations for it, the customer is the ultimate decision maker if this approach is acceptable. This white paper only contends that a straightforward simple documentation exercise is all that should be required from a regulatory perspective. It is critical to note that no requalification should be necessary either. While this is a straightforward conclusion, the customer should not rely on it, and the customer is solely responsible for making their own regulatory determinations.

At Envalior, we have products based on all the circular economy recycling solutions available and commercial today in our portfolio across multiple product lines. Sustainable materials have a strongly reduced integral carbon footprint. They will be reused for waste and fossil–oil input reduction. Biobased feed stock will come into play to replenish losses.

Biomass balanced materials are currently our first choice to position for medical applications. We can organize and commercialize a biomass balanced product and introduce it to our portfolio of medical and FDA grades in about 90 days. Our team can complete and share LCAs including carbon footprint data, so our customers can make informed decisions. We are recognized by multiple third–party sources as best–in–class for transparency and leveraging science in our decision making. Because of our approach, the risk of using our products and resources to make informed environmental decisions relative to others in our industry has been characterized as low.

Customers can specify the materials today, but with only a small percentage of the worldwide plastics production leveraging biomass, a biomass balanced product is a specialty material and only the early adopters are currently purchasing these products. The economics will eventually converge with traditional fossil fuel–based

materials when capacities are built out a sufficient scale that costs become competitive. Plants still need to triple and quadruple in size before cost rivalry will become real. For now, chemical intermediates and monomers produced from biomass are sold at significant upcharges.

Today, most health care organizations are choosing traditionally produced fossil fuel materials because of the economics, especially for one–time use high volume disposable commodity applications that are price sensitive. However, that is starting to change. As a customer, you can start with traditional fossil–based materials and choose when to implement more sustainable solutions. You can blend traditional fossil fuel derived products with their lower carbon footprint counterparts to meet specific quantifiable carbon footprint reduction goals and mitigate some of the associated upcharges by optimizing a blend strategy, or you can take the leap and go directly to the most sustainable material.

The incremental costs can be offset by taking advantage of tax incentives and other methods. Note there is a carbon tax structure being put in place related to the carbon footprint of materials being imported into Europe. It is not applicable to polymers yet, but we can expect that it will eventually follow. Device produces for the EU markets should take this into account in their current equipment design. No matter the sourcing strategy, we have a solution that will fit your med device needs.

At Envalior, we are further along in our journey than most of our competitors and we are leading the market. Our medical team has many projects across multiple product lines in multiple application spaces where sustainability is a key driver. We have over a decade of implementing practical sustainable solutions for engineering plastics across our entire product portfolio. The progress is documented in Figure 7 below. We are also getting credit from the market and are recognized as a leader. To quote one of our customers, "There are many companies who have one or two grades in a set chemistry whereas you have a very nice portfolio of chemistries available which are expanding rapidly as part of your initiative. We want to help you in this manner when the opportunity arises."[5]

FIGURE 7: A VERSATILE PORTFOLIO OF CIRCULAR ECONOMY MATERIALS

Offering sustainable alternatives today, committed to offering
A bio–based or recycled alternative to every product we sell by 2030

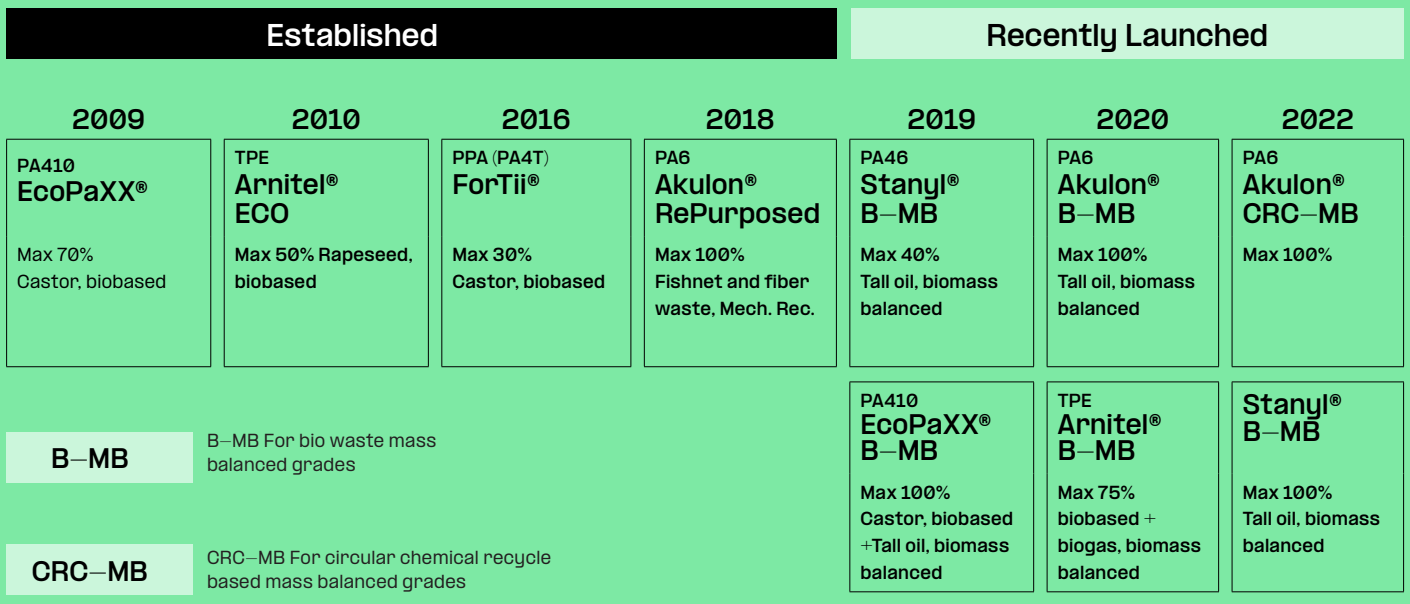


FIGURE 8: MATERIALS THAT HELP REDUCE THE CARBON FOOTPRINT OF YOUR DEVICES

Offering sustainable alternatives today, committed to offering
A bio–based or recycled alternative to every product we sell by 2030

Current Materials	PBT	PA6	PA66	POM	TPE	PPA
Industry Average CFP (kg Co2 eq.)	4–5	6–7	6–7	4–5	4–6	5
DSM Sustainable B–MB Offset	**Arnite®** Care T1U B–MB	**Akulon®** B–MB Polymer	**EcoPaXX®** B–MB Polymer	**Arnite®** CARE T1U B–MB	**Arnitel®** Eco B–MB (L400)	**ForTii®** Eco B–MB
Carbon Footprint Reduction	↓ 50%	↓ 79%	↓ 90%	↓ 50%	↓ 50%	↓ 50%

DRIVING DOWN OUR EMISSIONS

At Envalior, we continuously reduce emissions from our own operation—called scope 1 and scope 2 emissions. Scope 1 is about our direct emission from natural gas combustion, and we reduce that by energy efficiency programs and implementing alternative heating systems, such as heat pumps. Scope 2 is about indirect emissions from purchased fossil–based electricity. We are changing from fossil to globally renewable–based electricity, either purchased from sources, such as wind farms, or by our own electricity production at some of our sites.

The most challenging is scope 3 reduction—the emissions for the production at the producer of our purchased materials, which amounts to >80% of the carbon footprint in most of our products. The dynamic complexity for scope 3 is that we need to balance availability, price and carbon emission. As carbon footprint is geographically different, the same product produced at different locations in the world has different price–footprint combinations. In 2016 we started the successful "CO2Reduce" program, focusing on driving down the scope 3 emission for our products.

HOW CAN YOUR COMPANY LEVERAGE ENVALIOR'S SUSTAINABLE AND MEDICAL MATERIALS PORTFOLIO?

Connect with Envalior and provide material requirements for a broad range of potential products, along with estimated volumes and timing requirements. Envalior can partner with you on developing a strategic sustainability program including a scope of work, timeline, and associated costs.

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AUTHORS

Andre Oosterlaken, Sr. Global market development manager / Gerard Kwant Sustainability technology officer

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