

From Linear to Circular – Sustainability in the Medical Device Industry

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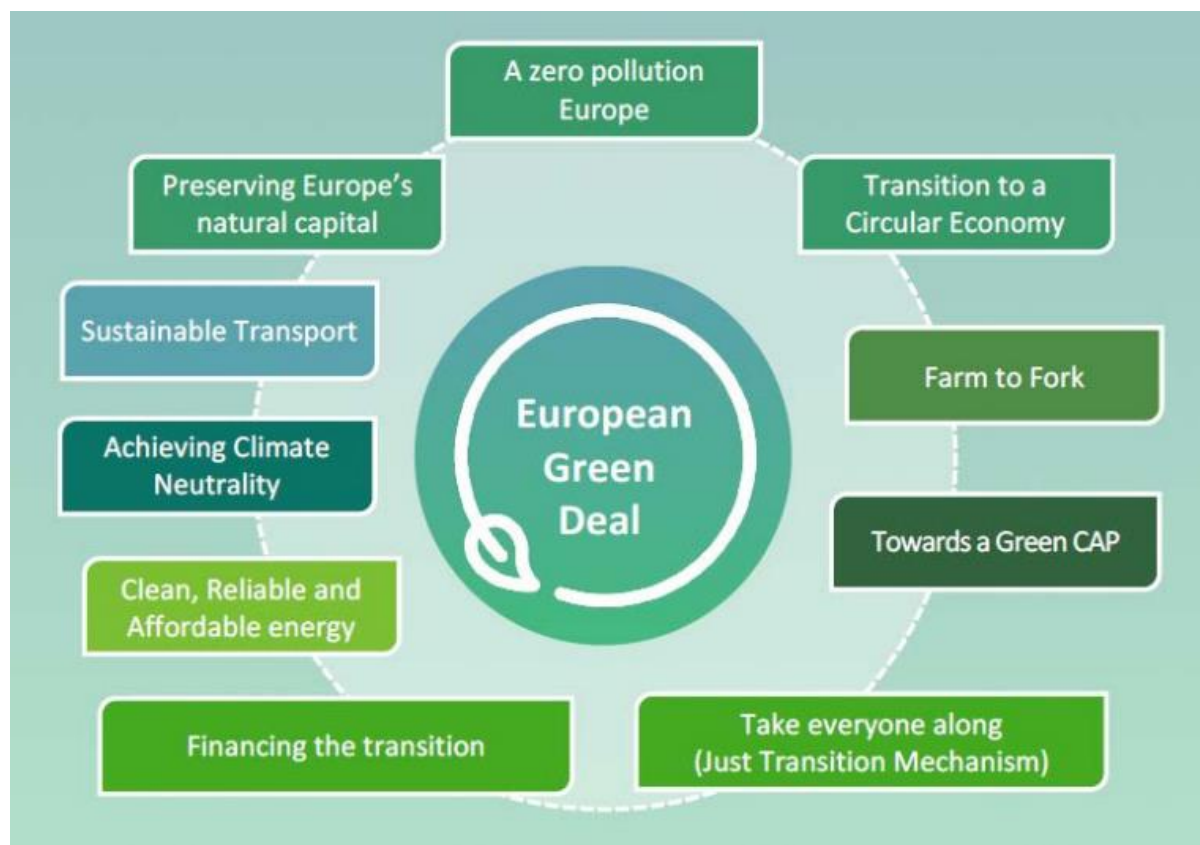
Background

The European Green Deal ⁽¹⁾ is the strategy aiming to transform the EU into a modern, resource-efficient and competitive economy, with no net emissions of greenhouse gases by mid-century. The main goal is to harness the significant potential in global markets for low-emission technologies, sustainable products and services in order to achieve climate neutrality by 2050. However, achieving a climate neutral and circular economy requires the full involvement of industry, and each Member State playing its role. The EU industry strategy will lead with twin green and digital transitions with an eye to yielding greater competitiveness globally. As corollary, it is expected that industry will be able to reduce its carbon footprint by providing affordable, clean technology solutions and by developing new business models.

Consider the case of the German National Sustainable Development Strategy (GSDS). This strategy is the single most important enabling factor for implementing the EU Green Deal requirements. A vital element of this wider drive is the so-called Lieferkettengesetz 2021 policy directive⁽³⁾. By 2023, it will affect German companies employing more than 3.000 people, and by 2024 companies employing more than 1.000 people. It covers aspects of sustainability in the supply chain for manufacturers, from raw material to finished product and will be an instrumental vehicle to help Germany achieve its sustainability goals. It is our conviction that this type of policy – although agnostic in its approach vis-à-vis all manufacturers – it should be seriously considered by Medical Device manufacturers.

NB: As of the most recent United Nations Sustainability Development Goals report ⁽²⁾ Germany is ranked 6th out of the 34 participating countries ranking progress to achieving sustainability

Picture 1 – The EU Green Deal



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Another more direct example effecting the med-tech and health care industry is the focus in the UK on ethical and sustainable practices and supply chains serving the NHS. The UK is currently ranked 20 in the progress ranking to UN SDGs and this sector is important in improving this ranking. Currently NHS tenders require bidding companies to be able to demonstrate sound ESG strategies with strong weighting awarded towards such companies in tender processes. Procurement policy PPN 06/20⁽⁴⁾ sets out these standards that suppliers and contractors who wish to do business with the NHS must prove they adhere to, and that they are on track to achieve the goals as set out in NHS sustainability and ethical standards. Overall, industry practice is shifting towards more sustainable supply chains as evidenced by the fact that globally operating companies are requesting that their suppliers provide evidence of sustainable business practices. To do so, they are employing certifications such as Ecovadis.

Clearly countries are working hard to establish new directives and regulations at pace to support sustainability. Across the board, ESG agendas are becoming increasingly important to large medical device manufacturers as they work hard to establish green operations and supply chains.

Picture 2 – The NHS Campaign to NET Zero



Regulation

Medical Device Regulation (MDR) in the EU has evolved, and so too has the requirement to track a device throughout its complete lifecycle. This includes right up to the point of disposal. MDR 2017/745⁽⁵⁾ dictates that – *method and detail of a products disposal should be recorded and directed. It goes on to direct – devices should be designed and manufactured in such a way as to facilitate their safe disposal, and the safe disposal of related waste substances by the user, patient, or other person. To that end, manufacturers should identify and test procedures and measures, as a result of which, their devices can be safely disposed after use. Such procedures shall be described in the instructions for use.*

This clearly has an impact on a medical devices final destiny and planned variation in terms of possible recycling instead of usual disposal to medical waste that leads to either incineration or landfill. For example, as per the requirements of MDR rules, if a device follows a sustainable pathway to recycling, the instructions for use (IFU) for that device would need to reflect this pathway and the methods of preparation for recycling such as post use cleaning and decontamination prior to recycling. This is currently not the case with most IFU's. Currently most IFU's of single-use medical devices will have instructions on how to clean and recycle any batteries the product may have, but not the actual device itself. The IFU will usually only direct and instruct correct disposal to waste of the product. Manufacturers will possibly need to consider, and take the necessary steps in the future to allow safe and validated cleaning processes of the whole product. This could mean conducting the necessary testing on products to validate these extra cleaning and decontamination activities so that the product IFU reflects and directs this new pathway. Often Hospital and Decontamination services rely on the product IFU to guide how to process the product and a lack of clarity here could lead to refusal or confusion at this key stage in this new chain.



Single Use Disposable (SUD) Devices

SUDs have been a major area of commercial growth for medical device manufacturers in recent years as companies develop their business models to adapt to the needs of hospitals and clinics in terms of having the lowest barrier to use. Since SUD Devices are typically sterile packed and don't require processing and preparation in the hospital setting, they can help to reduce labour burden and ensure that ready-to-use-products are always available for operations, with extremely low risk of infection from instruments and equipment.

These SUD devices commonly will go to incineration after use, and there is limited legislation to support the pathway to recycle these devices. Legislation related to general waste recycling is extensive and becoming better understood across industries year on year, but the extension into medical devices still requires further development. There are difficulties regarding classification of SUD Devices in terms of waste type post-use. Variabilities, such as the nature of the procedure, the infection profile of the patient they are used on, the extent of post-use clean conducted by a health care professional, and materials the device are composed of can have a complicating effect on this classification.

Currently many single use devices and implants are disposed of via incineration which generates dangerous release of greenhouse gases and has poor green credentials. Despite this, any other potentially “greener” options of disposal should be carefully considered, as their benefits are not always easily realised with complications such as collection, sorting and transportation potentially adding as much damaging emissions to the chain as incineration, especially if the scales and volume are not managed well.

Six Pathways to More Sustainable Medical Devices

Each medical device is unique, and there is no “one-size-fits-all” solution to improve sustainability, but there are some common elements that manufacturers may consider. Here are six potential pathways to improved device sustainability and questions for manufacturers to consider in the design phase.



Please click below [Building Sustainability into Medical Devices \(battelle.org\)](https://www.battelle.org)

- **Materials selection:** Can you swap out a petroleum-based plastic for a bio-based material? Or reduce the number of different materials used so that the device is easier to recycle at the end of the lifecycle? Or swap plastic for glass or stainless steel so it can be refurbished and reused?
- **Device design:** Can you reduce the overall dimensions or weight of the product to minimize materials use, packaging and distribution-related carbon emissions? Can you shrink electronic components to reduce their eventual disposal impact? Is there an opportunity to reduce the battery size or switch to a more sustainable battery technology (e.g., rechargeable batteries)?
- **Manufacturing process:** Are there manufacturing options that will reduce energy and water use? Could additive manufacturing be used to reduce material waste? Does your contract manufacturer follow environmental best practices for carbon capture and disposal of waste streams?
- **Packaging:** How can packaging waste be minimized? Can recyclable or compostable packaging materials be used? Can the use of plastic or petroleum-based foam packaging elements be eliminated?

- **Distribution**: Can manufacturing and warehousing locations be chosen to minimize long-distance transportation?
- **Disposal**: Is it possible to switch from a single-use device to a reusable device? Can the device or elements of the device be recycled? Could it be returned to the manufacturer to be refurbished?

Some of the bigger players in the market are starting to consider how they can turn this situation around. Initiatives that can make the medical device market more sustainable are not new but have always been influenced strongly with a lean towards commercial success. The huge growth in single-use disposable devices in the last 15 years is an example of this with companies aggressively driving sales based on ease of use, less labour required, availability and cleanliness of product, and supposed (but often unproven) green credentials related to reduced chemicals and water used in sterilisation of reusable instruments for example. This increase in single use disposable devices can only mean a dramatic increase in waste to incineration, and possibly landfill compared to 15 years ago when predominately these instruments were re-usable for many procedures, possibly for many years.



Re-processing of Devices

Approaches such as re-processing of used devices have been born out of the SUD device industry, offering hospitals an alternative to sending good materials to incineration. The used devices are collected by a re-processing company, cleaned, and decontaminated. They are then checked and fixed accordingly with any defective elements being replaced. They are then tested, re-validated and re-packaged sterile. The hospital benefits by being able to purchase validated re-processed devices back at competitive prices compared to newly manufactured devices.

Indeed, this is a burgeoning business area, with companies such as Vanguard⁽⁶⁾ leading the way. But this approach is not applicable to all geographies, with some countries like Italy and France having strict rules against the reprocessing of used medical devices. France due to the incidence of blood borne pathogens effecting public health, have taken extremely strong positions on this kind of activity.

The re-processing of medical devices is not simple, with a reasonably involved regulatory process for the re-processor that requires them to re-validate as a new product what is for the most part materially an unchanged device post re-processing. This of course takes both time and money but is required to ensure the safety of the patient.



Recycling of Devices

Picture 2 – Novo Nordisk Pen needle



An area of healthcare increasingly coming under review is medical waste in relation to used medical devices. It is an area where it is difficult to find new routes for used devices due to blind areas of regional regulation and incomplete EU guidance especially in the recycling of single use disposable devices.

A large source of this waste is products that are used outside of the Hospital Operating Room such as devices like pen needles. These combination devices (so called as they combine both a medical device and a drug in one) have a pen housing with a needle inside that punctures the skin to dispense a drug that is stored within the housing i.e. insulin for diabetics. These products are now the focus of much opportunity to improve circular sustainability of what is a huge area of medical waste.

The example from Novo Nordisk on the following page shows what is possible – ⁽⁷⁾

Case Study



The PenCycle initiative, launched by Novo Nordisk on 1 November 2021, enables patients that administer insulin using pre-filled FlexPen and FlexTouch devices, to return them for recycling through local participating community pharmacies or via pre-paid Royal Mailboxes. This initiative — is thought to be the first of its kind in the UK. In 2020/2021, nearly 2.5 million FlexPen and FlexTouch devices containing insulin were dispensed from community pharmacies in England. The recycling scheme, which is being run in partnership with Alliance Healthcare, Lloyds Pharmacy, the National Pharmacy Association (NPA) and Royal Mail, will be piloted in 13 clinical commissioning groups (CCGs) throughout Greater Manchester, Leicestershire and Rutland, as well as in the Greater Glasgow and Clyde areas; ahead of a planned national rollout in 2022 (including England and Devolved Nations). Any pharmacy in the pilot areas can sign up to join the scheme, and participating pharmacies will be sent practical guidance on the initiative, patient information and materials for patients to take home. Patients will be supplied with a return box which holds up to 12 used pen devices. The used devices (with needles removed) are then returned to the dispensing pharmacy. The pharmacy then stores filled return boxes in a recycling bin provided. The recycling is collected by Alliance Healthcare at scheduled timepoints. Pharmacies will only accept pen devices used for diabetes and weight management, with growth hormone pens collected via home delivery service run by Novo Nordisk – as growth hormone is a controlled drug. The pens will be sent to Novo Nordisk Head Quarters (Denmark), for the plastic to be recycled into a range of items, such as chairs and lightbulbs.

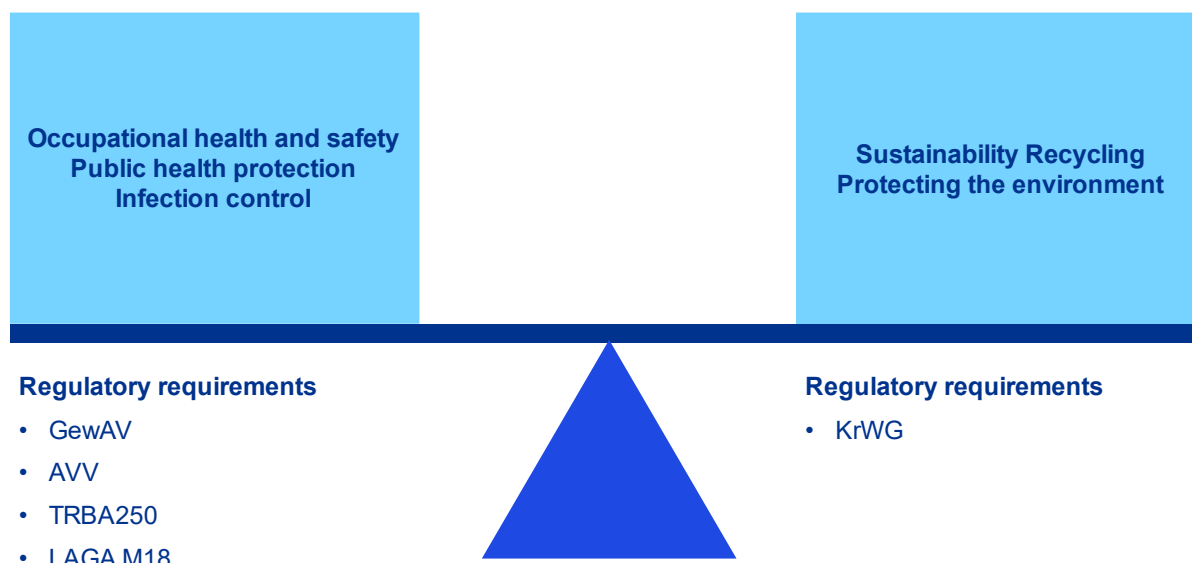
Discussion

Potentially some of these barriers discussed could be overcome by developing SUD Devices with the end in mind and could be solved by the correct regulation of devices for the complete life cycle, up to and including their disposal or recycling. With instructions for use (IFU) that reflect this with correctly tested and validated SUD Devices.

A balance requiring consideration in medical device recycling schemes is that to deliver green improvements they require scale and volume of materials recycled. This means collecting a high volume of materials from high numbers of devices and a carefully planned collection transportation operation. Only this will bring meaningful results in carbon reduction. If only a small number of devices are collected from multiple health care settings over a wide geography, then the vehicle emissions could possibly negatively affect any potential gains from the recycling of the materials from these Medical Devices.

In addition to this operational complexity there are wider changes and adaptations needed in the laws and legislations controlling waste and its movement related to medical devices. Indeed, some EU jurisdictions find their recycling and sustainability goals at odds with their public health and health and safety rules in these very pathways. With rules protecting the public and health care professionals from dangerous infections and public health risk also prohibiting potentially impactful and meaningful carbon saving initiatives such as the ones discussed in this article.

Picture 3 – Example of the balance of German regulations in relation to SDGs⁽⁸⁾



There are many cases now of local pilots leading to legislation and law changes to allow these pathways to operate in support of the circular sustainability recycling goals. EU law continues to evolve to allow easier establishment of green initiatives, but still requires extensive lobbying and the support of motivated companies, non-government organisations and government departments.

There are many challenges related to the movement of medical waste. An important factor related to this is the classification of waste. There are variations throughout Europe in the management and classification of medical waste and this variation, or absence (in some cases specific to SUDs) of local law or legislation leads to difficulty at key points in the chain. This chain can be affected at the

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point of use at the Hospital, where not completing the cleaning of a device with either a alcohol wipe after use or actually in the hospital decontamination department can greatly complicate the classification and transport of the device. A simple clean like this often conducted in the operating room prior to dropping the device into a collection bin or in the specific decontamination department within the hospital setting, can allow the device to be classified as general waste as opposed to medical waste, thus allowing a simpler route of transportation. As discussed before this cleaning and decontamination may be refused due to the product IFU not reflecting this step.

Another important consideration of this movement of waste is the complicated and bureaucratic administration at border crossings. The new EU Single window directive⁽⁹⁾ is one such initiative that may be able to help this difficulty and is proposed to come into force in 2024. Cross-border movement of waste could become a little easier with lower administrative burden as digital systems aim to coordinate and reduce red tape. There is some pessimism from operators in the EU that the policy will be delivered on time or deliver on its promise, but it is still a positive step towards aligned geographical directives and promotes geographical collaboration.

Picture 4 – [The EU Single Window Environment for Customs \(europa.eu\)](https://europa.eu)



Conclusion

Increasingly manufacturers are seeing the importance of exploring new approaches to lessen the environmental impact of the medical devices they bring to market. Clear responsibility is being laid at their feet for the complete life cycle of that product.

This has led manufacturers to bring company focus and resource to this challenge. Many of these companies are well placed to lead this new movement into medical device sustainability. We can see already in the market companies looking for improvement in the design of devices, such as making dismantling easier to allow recycling of separate materials, along with devices coming to market with less packaging that can be easily recycled with clear guidance on how stakeholders may do this. As this article has outlined the regulatory and legislative landscape currently make the goal complicated but not impossible and companies are starting to establish pilot schemes throughout Europe albeit in often siloed schemes with local work arounds when it comes to local laws and regulations.

Regulations need to evolve and to be established to guide and dictate these sustainable approaches throughout the medical device's life cycle from raw material to final disposal, and this may take some time. With continued work in this area by many of the larger medical device companies it should not be long until there is a more joined up and sensible processes, and EU wide systems are put in place.

Clearly, there is still a lot of work to be done to get close to the proposed sustainability goals set out by the EU, but slowly schemes and initiative are becoming established. We can be confident that these early schemes will start a snowball effect as more and more HCPs and hospital leaders and patients demand more sustainable products and processes. Let us be hopeful that with design that supports circularity such as recycling, and the regulatory development discussed here, a positive change can make a difference for a greener future.

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