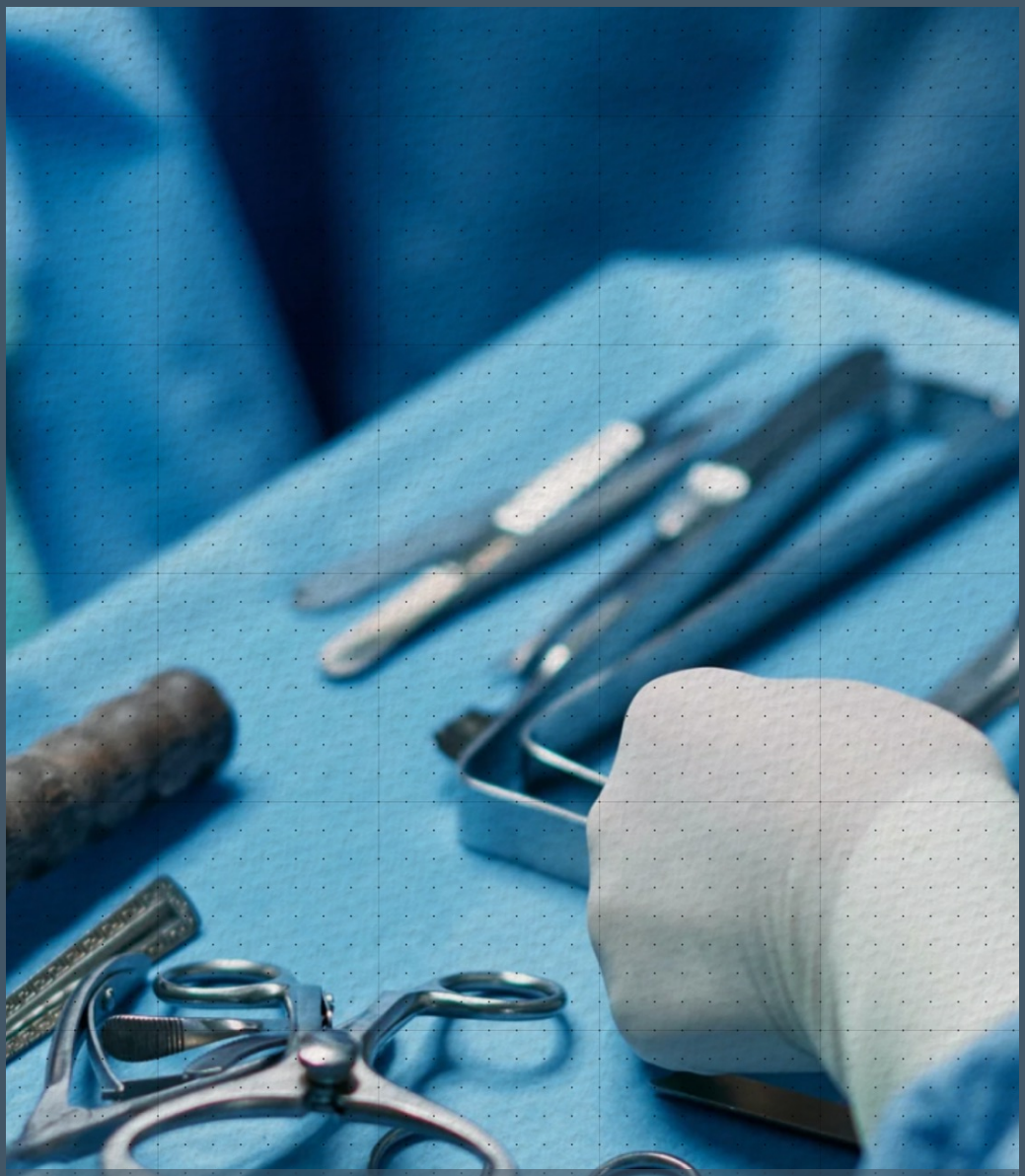


Integrating Product Carbon Footprint Strategies into Product Development of Medical Devices

How Product Carbon Footprint Calculation and System Generation Engineering Align to Deliver Sustainable Innovation in MedTech

CBR

Driven by a passion to expedite change in our pursuit of a sustainable future, we partner with businesses and industries to catalyse innovation, enable smarter decision-making and deliver positive impact.

MedTech SGE & PCF

How PCF and System Generation Engineering Align to Deliver Sustainable Innovation

1. MedTech manufacturers need to act now, as customer awareness on emissions increases, and the long product life cycles bear high transitional risks.

MedTech manufacturers in Europe face growing pressure to support a decarbonized economy. As the European Union advances toward its 2050 goal of climate neutrality, the medical sector – often overlooked in past decades – is increasingly in the spotlight. Studies show that up to 5% of global carbon emissions stem from healthcare systems, with medical devices and pharmaceuticals representing the largest shares of supply chain emissions of approximately 60% in the healthcare sector **[1].**

At the same time, MedTech companies face a structural constraint: long product life cycles due to high regulatory requirements. From concept to market, including clinical validation and regulatory approval under frameworks like the European Union Medical Device Regulation (MDR) or the Food and Drug Administration (FDA), it often takes 3 to 7 years to bring a new product generation to market **[2].** For any product released in the late 2020s or 2030s, the pressure to align with climate goals will be even higher. Simultaneously, procurement behavior in hospitals is shifting. Public and private providers increasingly demand Product Carbon Footprint (PCF) data as part of green procurement strategies and awareness on their emission contribution. Healthcare systems in countries like the UK, Sweden, and France have already made carbon transparency a criterion in purchasing decisions **[1,3,4].** This shift creates a strong signal: Consequently, MedTech manufacturers must act now to ensure that products entering the market post-2030 comply with climate neutrality demands.

> *“ MedTech innovation must now meet both patient safety and climate performance.*

To address these challenges, the integration of System Generation Engineering (SGE) in combination with Product Carbon Footprint assessment offers a promising methodological approach – one that will be explored in detail in the following sections.

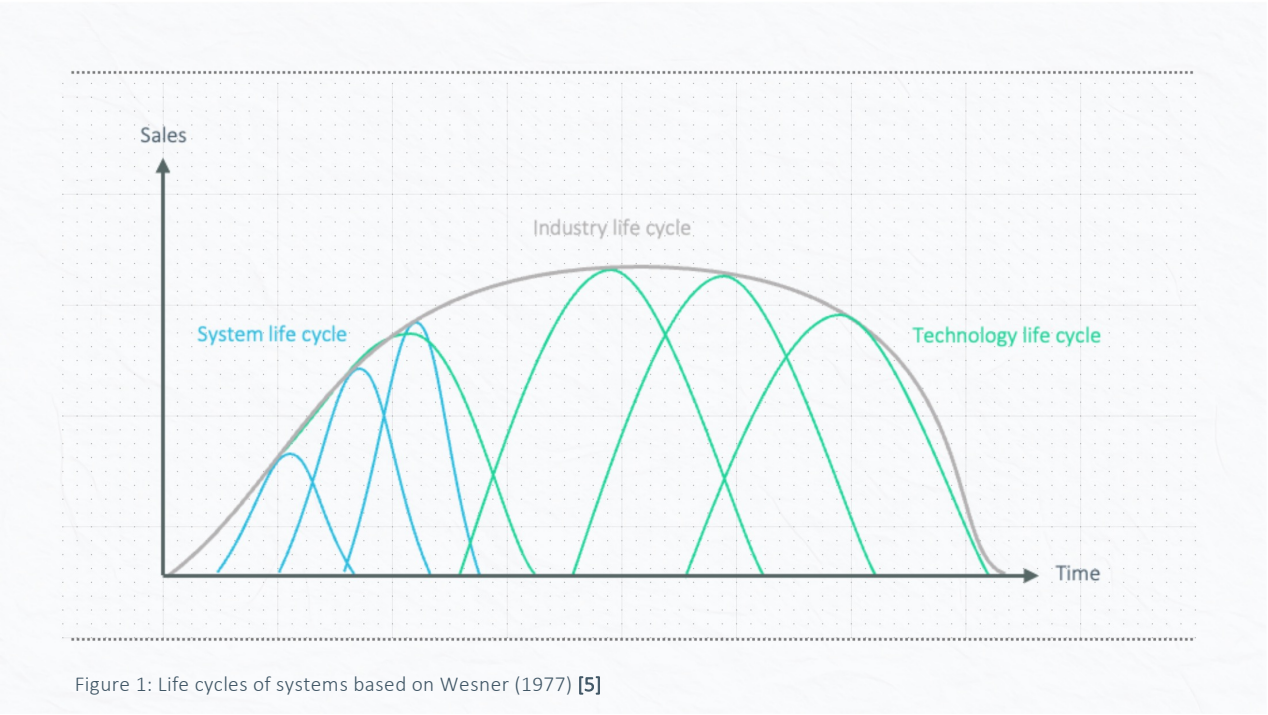


Figure 1: Life cycles of systems based on Wesner (1977) **[5]**

2. System Generation Engineering: A Model for Evolutionary Innovation

System Generation Engineering (SGE), introduced by Wesner and further developed by Albers, Bursac, and colleagues at IPEK (Institute of Product Engineering at the Karlsruhe Institute of Technology, KIT) has evolved into System Generation Engineering (SGE), which focuses on technical systems rather than products alone **[6]**.

The framework generalises the idea that every new technical system is developed from prior systems. It builds upon internal and external reference systems (e.g., an earlier model or competitor benchmark), using structured variation to introduce innovation while maintaining continuity. This generational logic allows developers to plan 'safe innovation,' balancing technical novelty with developmental risk and increasingly, with ecological sustainability.

Thus, each new developed system varies along three types of modification:

1. **Carryover Variation *CV*:** Reference system elements (RSE) are transferred with little or no change.
2. **Attribute Variation *AV*:** The underlying solution principle of the RSE is preserved, but parameters such as geometry, material, or size are altered.
3. **Principle Variation *PV*:** A new functional or technological principle is applied to fulfil the same objective.

This taxonomy allows developers to structure product innovation in terms of technical novelty, development risk, and investment.

It recognizes the value of prior art and encourages smart reuse while fostering sustainable evolution. It also facilitates risk control: CA are low-risk; AV bring moderate technical change; and principle variations represent high innovation potential with high complexity. Crucially, it offers a map for controlling innovation without re-inventing the wheel—an important factor in highly regulated fields like MedTech.

By applying this logic to environmental metrics, SGE allows companies to plan incremental or radical decarbonization steps across generations-rather than aiming for unrealistic, one-shot solutions.

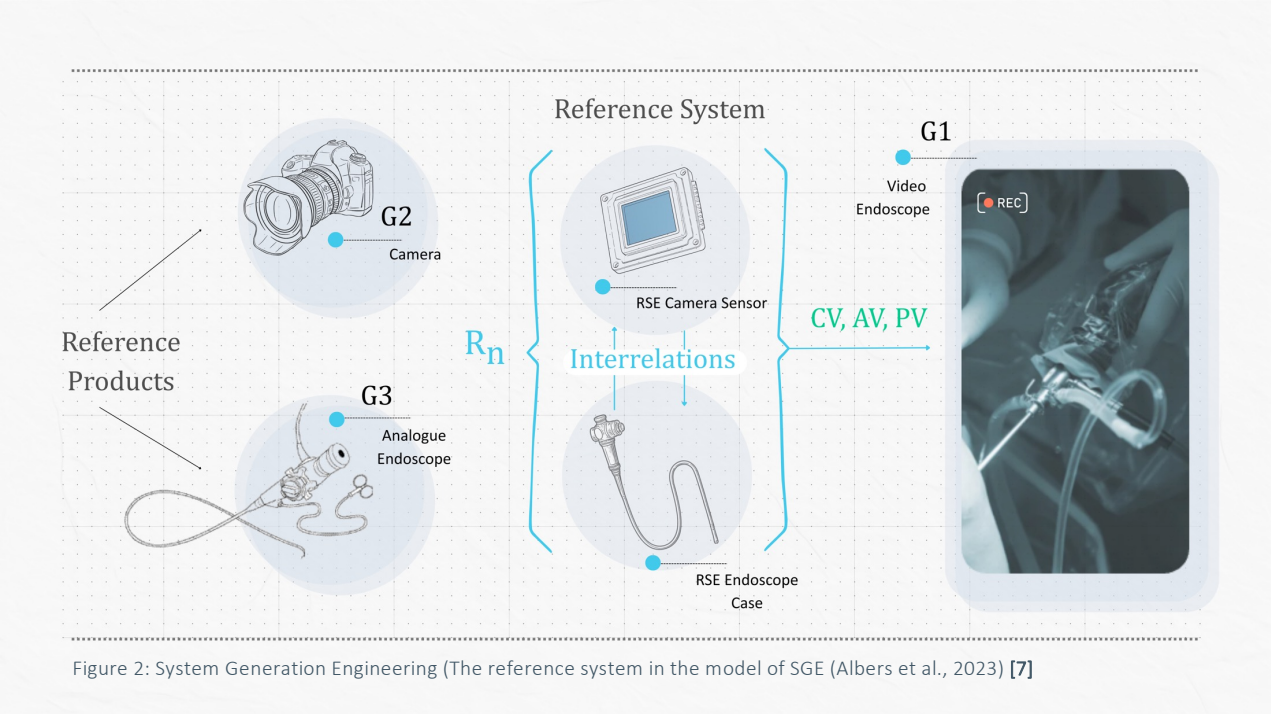


Figure 2: System Generation Engineering (The reference system in the model of SGE (Albers et al., 2023) **[7]**

3. Product Carbon Footprint:
A way to determine the product related emissions

A PCF quantifies the total greenhouse gas emissions (in CO_2-equivalents) associated with a product throughout its lifecycle, from raw material extraction to end-of-life. PCFs follow international standards such as ISO 14067 and are often derived from a Life Cycle Assessment (LCA).

In medical devices, key PCF hotspots include for e.g.:

- Material extraction and manufacturing (especially metals, polymers)
- Sterilization processes (e.g., steam, ETO, gamma)
- Packaging and transport (especially for single-use devices)
- Use-phase energy (for active devices)
- End-of-life incineration (due to infection control)

PCFs are product-specific and depend heavily on design decisions, making them a valuable metric during development. In the context of climate-neutral healthcare procurement, PCF data are becoming relevant.

4. Aligning SGE and PCF:
Plan and manage future-proof products

The integration of PCF data into SGE enables systematic decarbonization across generations. Here, the methodological distinction between AV and PV is critical:

In AV (Adaptation within the same principle), PCF data can be used to improve the environmental performance of known systems. Examples include:

- Switching to lower-carbon materials (e.g., bio-based polymers)
- Redesigning packaging to reduce material mass
- Improving manufacturing yield or energy efficiency

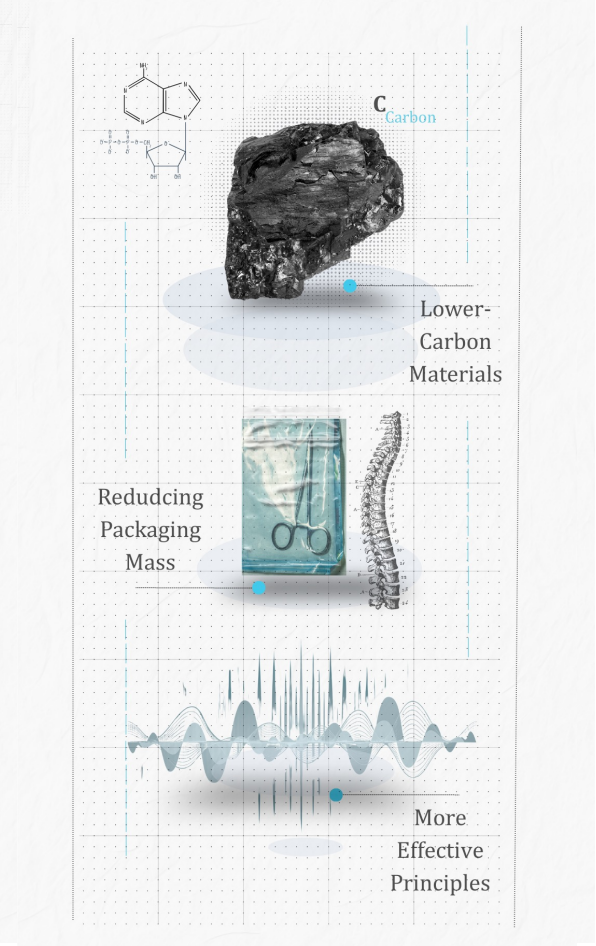
These changes keep the technical principle intact but reduce lifecycle emissions. PCF modeling supports these changes by quantifying the impact of design alternatives.

In PV (Principle change), PCF comparisons between alternative principles guide strategic decisions. For example:

- Switching from single-use to reusable designs (or vice versa)
- Replacing mechanical to electronical systems
- Moving from steam sterilization to low-energy methods

Here, early PCF estimations help identify the low-emission pathway among fundamentally different options. PVs often involve greater uncertainty and risk—thus PCF adds another lens for decision-making beyond patient safety, technical feasibility and cost.

Methodologically, this means integrating simplified PCF modeling tools into early development stages. In CV & AV, PCF becomes a continuous optimization criterion; in PV, it becomes a strategic differentiator.



5. How to Begin: Quantify and Benchmark the PCF of the Current Product Generation

To prepare the next product generation for lower emissions, the first step is to establish a baseline PCF of the current product (the reference system in SGE). This can be done using:

- Existing LCA databases (e.g. healthcarelca.com, ecoinvent, GaBi)
- Internal process data (e.g., material weights, energy consumption)
- Manufacturer-specific footprint data (e.g., from suppliers)

Once the PCF is known, development teams can:

- Identify carbon hotspots in the current design (materials, manufacturing, packaging, usage)
- Set quantitative carbon reduction targets (e.g., 25% lower PCF vs. previous generation)
- Translate these targets into design guidelines for CV, AV or PV (e.g., require recycled material, modular reprocessing, alternative principles)

A crucial success factor is cross-functional integration: sustainability specialists, development engineers, and regulatory affairs must collaborate. Moreover, PCF goals should be treated as equally relevant as cost, time-to-market, and performance.

6. Conclusion

In a sector defined by high regulatory burden and slow product cycles, medical device manufacturers must begin now to integrate carbon footprint strategies into their product generation planning. The SGE model provides a methodical foundation to structure development around known and novel elements (AV and PV). The PCF, in turn, delivers the environmental metric to evaluate and improve each path.

Together, SGE and PCF support climate-aligned innovation—so that future generations of medical products are not only more advanced and safer but also more sustainable.

Are you ready to future-proof your medical devices?

CBR Sustainability Partners supports MedTech manufacturers in systematically embedding Product Carbon Footprint (PCF) strategies into their product development workflows. Our consulting offering includes:

- PCF benchmarking for existing products
- Sustainability-driven design guidance
- Integration of PCF tools into early-stage development
- Cross-functional training on sustainable product generation
- Supplier data readiness and CO_2 transparency enablement

Whether you're launching a new device or re-engineering a platform: We can help align innovation with sustainability and regulation.

Endnotes

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Andreas is a Project Manager at CBR Sustainability Partners, specialising in Life Sciences, MedTech and sustainability. He focuses on advancing circular economy approaches in healthcare, supporting innovative products, manufacturing processes and business models that create long-term environmental and economic value.

With more than eight years of experience in multinational MedTech projects, he has worked across production, process validation, equipment qualification and the implementation of the European Medical Device Regulation, combining technical expertise with regulatory and sustainability strategy.

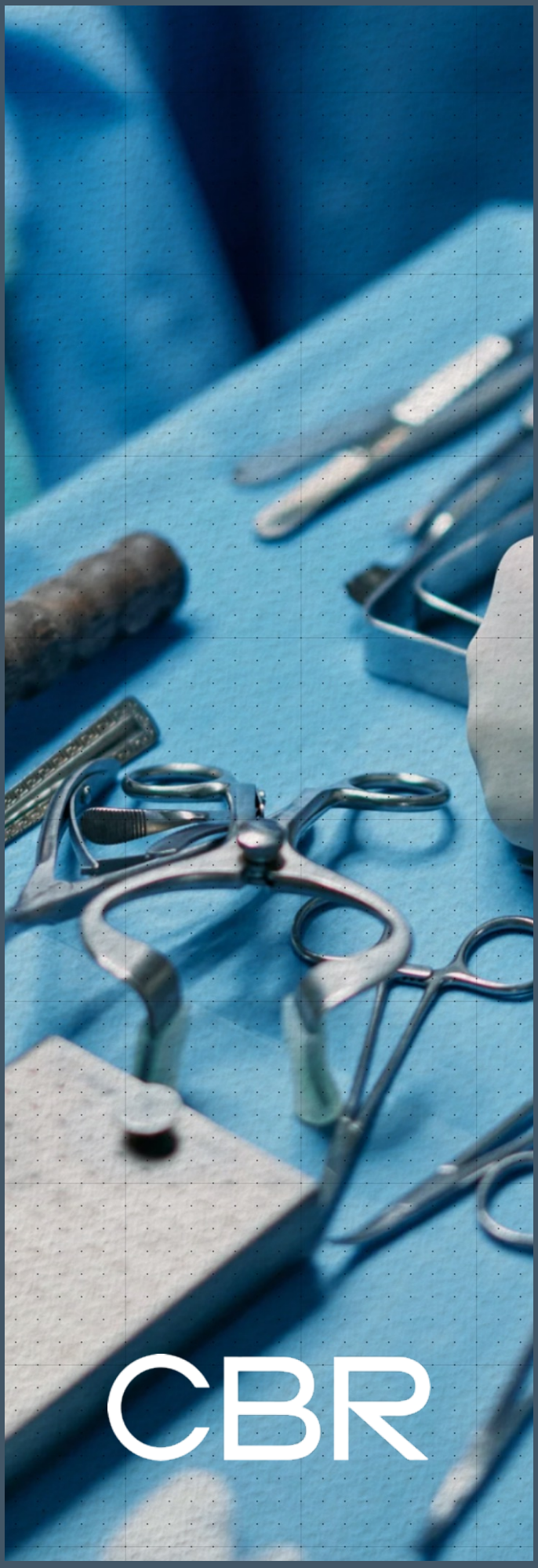
About CBR Sustainability Partners

CBR Sustainability Partners is an independent consultancy focused on sustainable transformation. Based in Hamburg and Mannheim, we support industry, technology providers and public institutions in implementing sustainable energy and transformation solutions.

Our team combines technological expertise with regulatory and market insight — particularly in the fields of alternative fuels, CO_2 infrastructure and hydrogen technologies.

Continue the Conversation

If you are looking to move from analysis to implementation, we are happy to discuss practical next steps.



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