ETHICAL PARALLEL TRACK OF LIPOCOAT'S INNOVATION JOURNEY

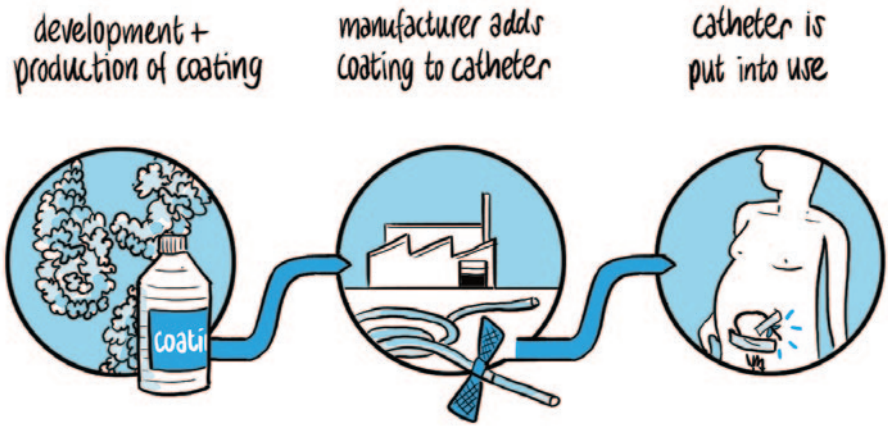
Biologically inspired coatings for catheters

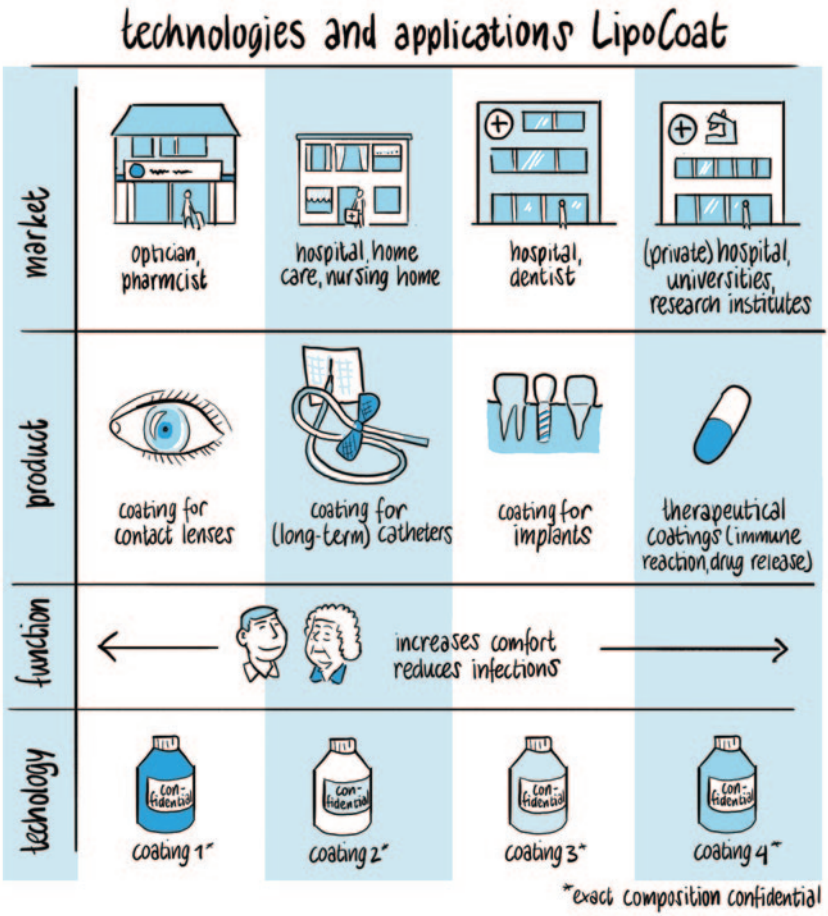
SAXION HOGESCHOOL

INTRODUCTION

The use of medical devices is often uncomfortable and increases the risk of infections. LipoCoat, a biotechnology company from Twente, aims to address this issue by applying a biologically inspired coating that is also biocompatible. To proactively identify ethical and societal challenges, it is essential to critically examine the societal and ethical impact of an innovation, in addition to its technical aspects. The Saxion Applied Nanotechnology research group has engaged with LipoCoat, offering their expertise to guide a portion of the innovation process with ethical and social science interventions. This project is carried out in collaboration with the Saxion Ethics & Technology research group.

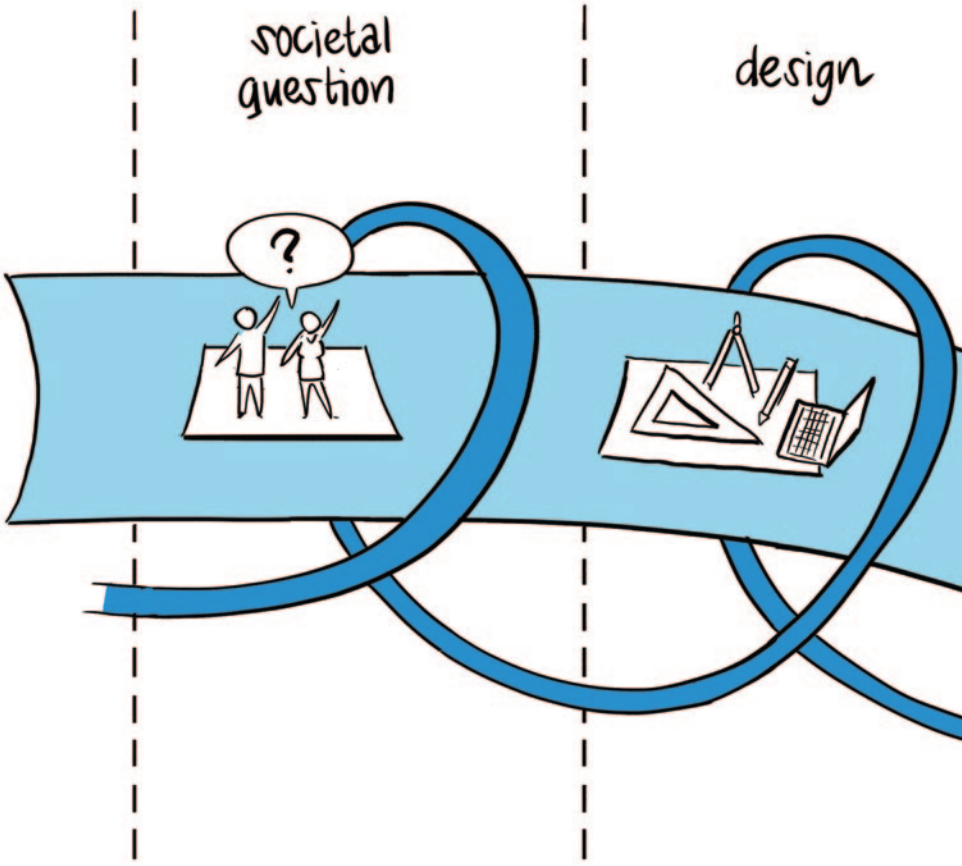
LipoCoat is developing a coating for contact lenses, catheters, implants, and therapeutic purposes. The coating for contact lenses has already been developed and will be introduced to the market soon. The coatings for catheters, implants, and therapeutic purposes are currently still in development.





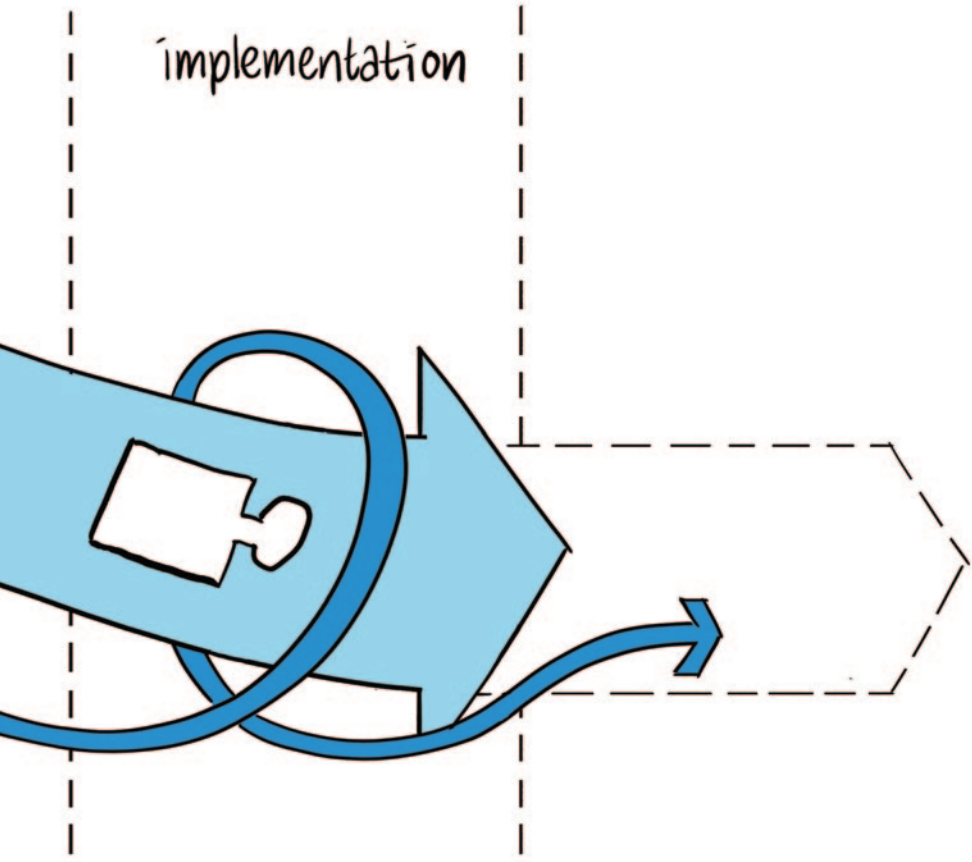
BIOLOGICALLY INSPIRED COATING

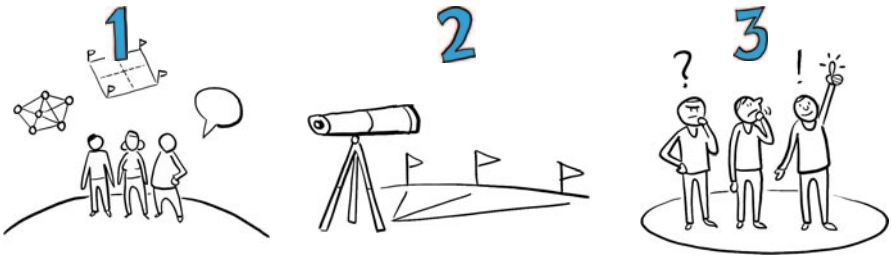
The biologically inspired coating developed by LipoCoat is approximately 5 nanometer thick and is composed of lipids that mimic the human cell membrane. This results in a reduced risk of infection, improved user-friendliness, and enhanced acceptance of the coating by the body. The surface properties of the coating are adaptable based on the application.



ETHICAL PARALLEL TRACK

The ethical parallel track comprises a series of practical tools to guide an innovation trajectory in order to map out the social and ethical aspects. In this project, various tools have been applied for the different applications of LipoCoat's innovation, including a stakeholder analysis, the creation of various scenarios, and an Ethical Readiness Check. This brochure focuses on the impact of the coating for catheters.





1. Stakeholder analysis
2. Scenarios
3. Ethical Readiness Check

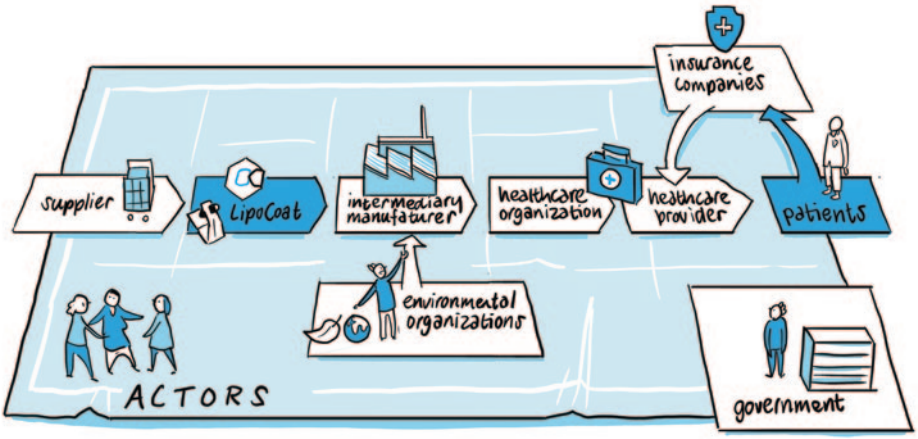
1 STAKEHOLDER ANALYSIS

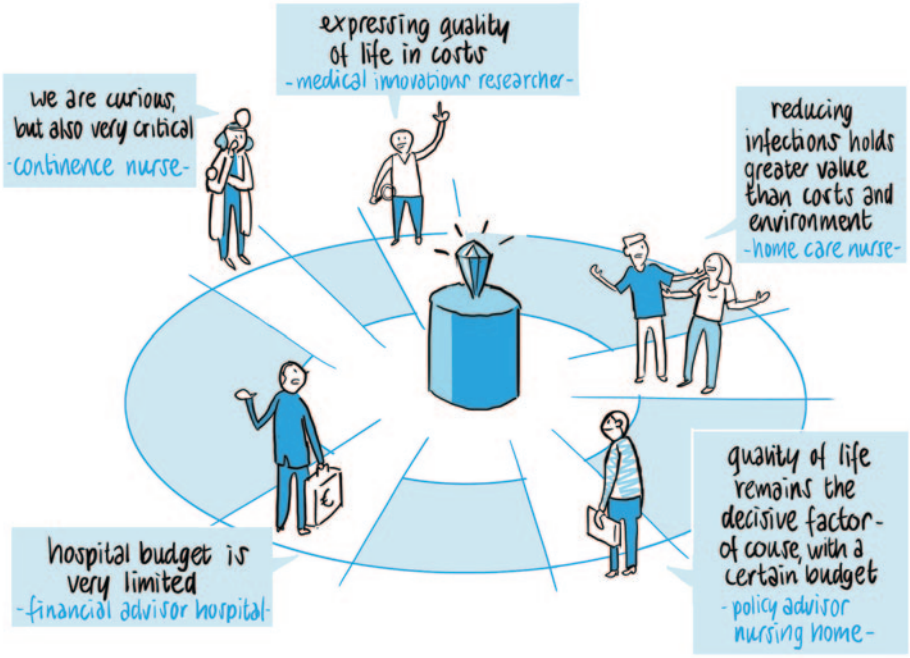
In a stakeholder analysis, the stakeholders (individuals, groups, or institutions) and their positions in relation to the technology are identified. This can be used, among other things, to stimulate a dialogue among stakeholders and to consider various interests during the development process.

The approach in this project included:

- Creating an overview of stakeholders
- Conducting interviews with stakeholders

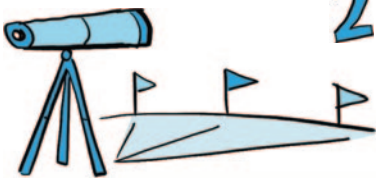
From the overview, it becomes clear that LipoCoat has no direct contact with the end user and relies on an intermediary manufacturer who selects the product, the catheter, or on healthcare organizations (hospitals, nursing homes) that implement the product. Other relevant stakeholders who are not directly involved in the development process but have an impact on the product's introduction are insurance companies and environmental organizations.





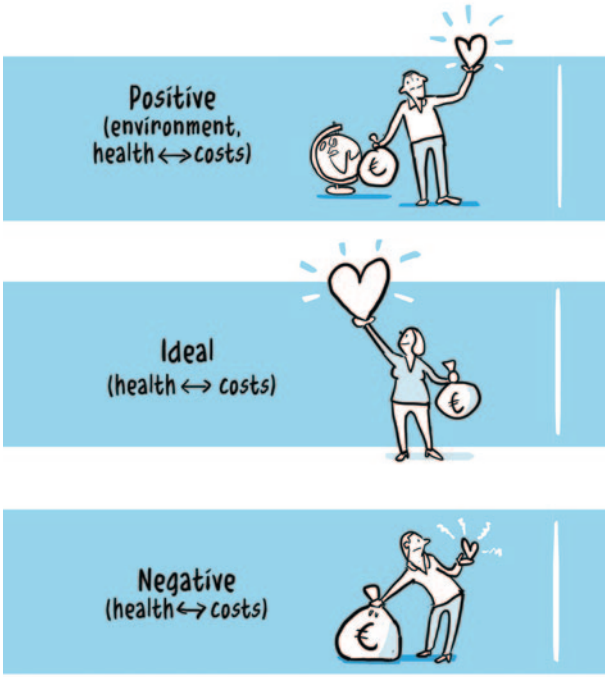
The stakeholder dialogue maps out the various interests of relevant stakeholders. For instance, it becomes evident that the value of health is paramount for stakeholders who will ultimately use the product directly (home care, nurses), whereas stakeholders responsible for implementing the product (hospital, innovation managers) may view higher costs as a potential barrier. In relation to the environment, reducing packaging material is mentioned as a significant aspect rather than an environmentally friendly coating.

Ideally, these differing perspectives would be integrated into the innovation trajectory by acknowledging conflicting values. This can be achieved by engaging in a dialogue with the involved stakeholders and involving them during the design, development, and implementation process.



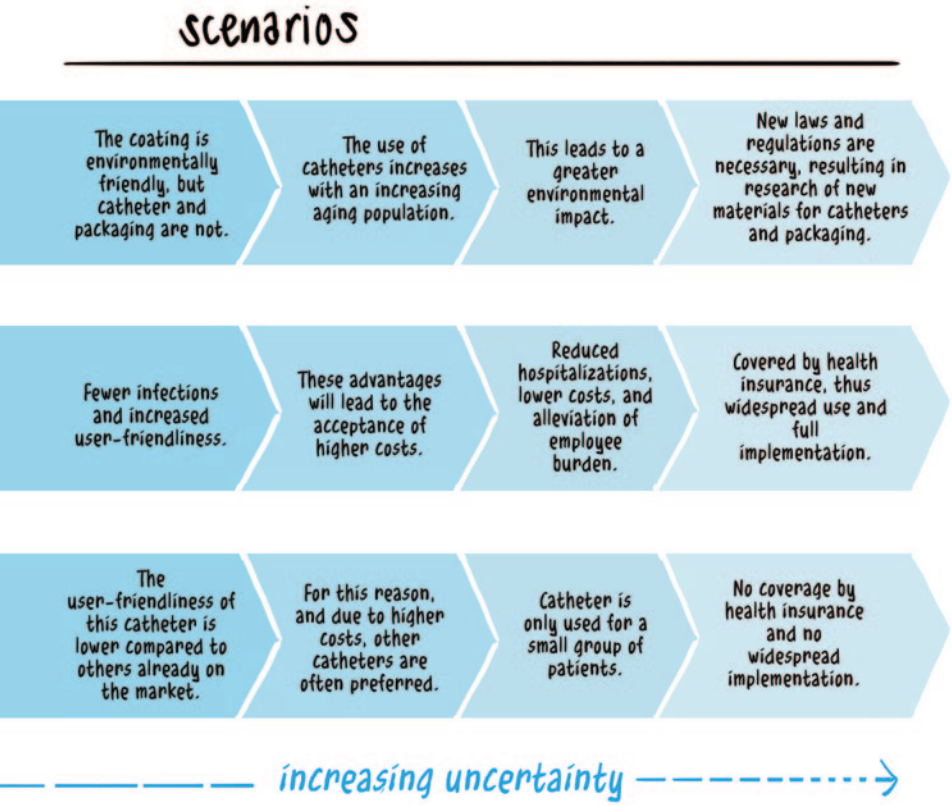
2 SCENARIOS

The success of an innovation depends on its ultimate impact – positive or negative. Therefore it is crucial to anticipate the impact of an innovation, taking into account tensions and future societal changes. The scenarios outline the future impact of the innovation in various situations and have been developed by considering expected societal



developments from the Public Health Future Exploration (VTV-2018, trend scenarios from RIVM), statements from LipoCoat, stakeholder interviews, and personal findings and assumptions. The figure below presents three different scenarios:

- Positive scenario: widespread use, leading to increased environmental impact
- Ideal scenario: Full implementation despite higher costs
- Negative scenario: High costs pose a barrier to implementation

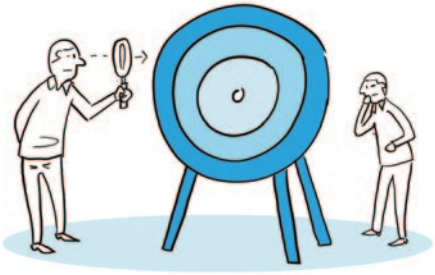


3 ETHICAL READINESS CHECK

To clarify that the technology should be a means to achieve a goal and not a goal in itself, this tool poses questions about purpose and means. The questions asked are relatively simple yet effective, thus contributing to the (ethical) reflection during the product development process.

Does the means serve a noble purpose?

- What is the purpose?
  Reduce infections and increase comfort (user-friendliness).
- Is the purpose clear and concrete?
  Yes, the innovation must perform at least as well as or better than the current product.
- Are there conflicting values?
  Yes, health, costs, and the environment.
- Are there hidden agendas?
  No.



Is it a good means for the purpose?

- Does the means work?
  Yes, but attention is needed for side effects.
- Is there potential for misuse?
  No
- Are there side effects?
  Yes, total costs and environmental impact.

CONCLUSION

The ethical parallel track provides insights into ethical and societal values and challenges that can play a significant role in the (future) innovation process. After the execution of the tools, it becomes apparent that the values of health (reduced infections), costs (higher costs compared to standard products), and the environment (environmentally friendly coating) will generate the most changes and tensions in the innovation trajectory. Concrete recommendations for LipoCoat include:

- Address potential implementation issues due to high costs. It's important to demonstrate that reduced infections could justify these higher costs. Engage stakeholders crucial for implementation (hospitals/nursing homes, care innovation coordinators, insurance companies).
- Besides reducing infections, prioritize user-friendliness (coating should reduce resistance during catheterization).
- Investigate the environmental friendliness of the product (catheter) itself, not just the coating (consider alternative materials for the product, reduce packaging material).
- Engage with users (patients, nurses, home care) to gain insights into crucial product requirements.

"Some tools from the ethical parallel track have already been executed by us to varying degrees. We continuously question whether a clinical study can be conducted and are constantly working on improving the product, the market, and the technology."
Jasper van Weerd, CEO & Founder of LipoCoat

Produced by:
Saxion University of Applied Sciences, Enschede
Research Group Applied Nanotechnology
Research Group Ethics & Technology
LipoCoat B.V.

Publication:
Saxion University of Applied Sciences, Enschede, 2023

For more information about the Ethical Parallel Track, visit:
www.cta-toolbox.nl

For more information about LipoCoat's coating, visit:
www.lipocoat.com

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Design: WAT designers