# Plan Overview

A Data Management Plan created using DMPonline

Title: Sustainable Packaging for Surgery kit used for Vitrectomy

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Template: TU Delft Data Management Plan template (2025)

Project abstract:

Healthcare in the Netherlands is responsible for 7.3% of the country’s carbon emissions. A large part of this comes from single-use products and their packaging. One of such single use products used in the medical sector in the Netherlands is the DORC EVA Nexus Kit, which is used for conducting Vitrectomies - a type of posterior eye surgery. This project looks at the environmental impact of the packaging used in the DORC EVA Nexus kit. The project connects to and aim to be in compatible with larger sustainability goals like the Green Deal 3.0 and the EU Circular Economy Action Plan.

The main question of the project is - how can the packaging of the EVA Nexus kit be redesigned to reduce its environmental impact, while still being safe for use in surgery and meeting all regulation requirenments? The focus is mostly only on the packaging, and not on the surgical tools and components included in the kit.

The goal will be to focus on optimizing this entire package through Circular Product Design, while meeting the sterilization and regulatory factors for medical products. The key opportunities include reducing the material used by making the entire product more compact and tailor it to the included components. Material Analysis can identify areas where reusable or biobased materials can be introduced..

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Copyright information:

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# Sustainable Packaging for Surgery kit used for Vitrectomy

## 0. Administrative questions

1. Provide the name of the data management support staff consulted during the preparation of this plan and the date of consultation. Please also mention if you consulted any other support staff.

Question not answered.

2. Is TU Delft the lead institution for this project?

- Yes, the only institution involved

Yes. This project is conducted as a Master's graduation thesis within TU Delft's Industrial Design Engineering faculty. Supervision is provided by professor and post-doc researcher from within TUdelft's Industrial Design Engineering Faculty.

## I. Data/code description and collection or re-use

3. Provide a general description of the types of data/code you will be working with, including any re-used data/code.

| Type of data/code | File format(s) | How will data/code be collected/generated?<br>For re-used data/code: what are the sources and terms of use? | Purpose of processing | Storage location | Who will have access to the data/code? |
|---|---|---|---|---|---|
| Written notes for Expert Interview | .cvs, .docs | Interview- Questions will be asked about participant's exprtise on topics from their field. - since the data does not contain personal information, it is free for reuse | 1. 3- 5 Expert participants including professionals with specialised knowledge in packaging design, material science, and medical device regulation will be contacted to understand project contexts, and understand packaging and circular design concepts better. These may be academics or industry professionals. Additionally, ophthalmic surgeons will be consulted as domain experts with clinical knowledge of the vitrectomy procedure and the EVA Nexus kit. Surgeons are included as experts and users of the kit than the users of the packaging. | TUDelft One Drive and personal laptop | Responsible Supervisor |
| Written notes for Observational Studies | .docs | written Notes documented during Observational studies - since the data does not contain personal information, it is free for reuse | To obtain information on Product Journey Analysis, Kit Components Use. | TUDelft one drive and personal laptop | Responsible Supervisor |
| Informed consent forms | pdf | Informed consent forms signed digitally. | To obtain and document informed consent of all the participants. | TUdelft One Drive Storage | Responsible Supervisor |
| Photo/Videos taken duting Observatioal studies and User Testing done with nurses | .mov, .png/.jpeg | Videos and photos will be taken for documentation and anlysis purposes during study conducted. During these, part of a participants body may be visible in the media file. However, neever will the participant's faces or identification mark be made visible. Any identifiable markings will be blockedout/sillouted out in reports. since the data does not contain personal information, it is free for reuse | Videos and photos will be taken for documentation and anlysis purposes during study conducted. This will be used to explain concepts and provide visual explanation in report, as well as document processes for analysis and study later on. | TUdelft One Drive Storage | Responsible Supervisor |

## II. Storage and backup during the research process

4. How much data/code storage will you require during the project lifetime?

- < 250 GB

5. Where will the data/code be stored and backed-up during the project lifetime? (Select all that apply.)

- TU Delft OneDrive

## III. Data/code documentation

6. What documentation will accompany data/code? (Select all that apply.)

- Data – Methodology of data collection
- Procedure – A description of data processing procedure(s) (such as laboratory setup, simulation workflows).

## IV. Legal and ethical requirements, code of conducts

7. Does your research involve human subjects or third-party datasets collected from human participants?

If you are working with a human subject(s), you will need to obtain the HREC approval for your research project.

- Yes – please provide details in the additional information box below

The participants in the research will be Experts, Users and students.
1. 3- 5 Expert participants including professionals with specialised knowledge in packaging design, material science, and medical device regulation will be contacted to understand proect contexts, and understand packaging and circular design concepts better. These may be academics or industry professionals. Additionally, ophthalmic surgeons will be consulted as domain experts with clinical knowledge of the vitrectomy procedure and the EVA Nexus kit. Surgeons are included as experts and users of the kit than the users of the packaging.
2. Users - 2-5 Nursing staff from the OR will be the primary user group for prototype testing. Scrub nurses and circulating nurses working at UMCU are the principal handlers of surgical kit packaging during the pre-operative preparation phase. They are the ones directly working with opening and discarding the packaging. Recruitment will take place through existing contacts at UMC Utrecht from supervisors.
3. 3-5 Industrial design students from TUDelft may be recruited as a preliminary participant group prior to testing with clinical nursing staff. Their purpose is to conduct informal mock testing of the prototypes to identify obvious handling issues or prototype weaknesses before the sessions with professional end users. This allows time to refine the testing protocol and identify any prototype adjustments needed before engaging clinical participants.
All participants will be recruited through the TU Delft Faculty of Industrial Design Engineering, via referrals from supervisors or peer networks, and contacted via TU Delft email.
All participation is voluntary. No compensation above the TU Delft standard will be offered.

8. Will you work with personal data? (This is information about an identified or identifiable natural person, either for research or project administration purposes.)

- No

No personal Data will be documented or stored.

9. Will you work with any other types of confidential or classified data or code as listed below? (Select all that apply and provide additional details below.)

If you are not sure which option to select, ask your Faculty Data Steward for advice.

- No, I will not work with any other types of confidential or classified data/code

10. How will ownership of the data and intellectual property rights to the data be managed?

For projects involving commercially-sensitive research or research involving third parties, seek advice of your Faculty Contract Manager when answering this question.

The intellectual property rights are framed by a graduation agreement between Delft University of Technology and Arundhati Malkhede.

11. Which personal data or data from human participants do you work with? (Select all that apply.)

- Photographs
- Job title and/or employer
- Video materials
- Proof of consent (such as signed consent materials which contain name and signature)

Interview data may contain roles, institutional affiliations of participants. Photographic data from the OR may include images that showcase part of medical staff, such as their hands as they are handling the packages. Identifiable photographs will not be recorded. .

12. Please list the categories of data subjects and their geographical location.

The participants of the interviews are professional in the domain of Opthalmology and Sustainability.
They are all healthy adults, from a mix of academia, industry professionals and healthcare professionals. Some pre testing may be conducted with TUDelft masters students.

All participants are located in the European Union (NL, DE).

## V. Data sharing and long term preservation

26. What data/code will be publicly shared?

Please provide a list of data/code you are going to share under 'Additional Information'.

- All data/code produced in the project

28. How will you share your research data/code?

Select all that apply and provide additional details below.

- I am a Bachelor's/Master's student at TU Delft and I will share the data/code in the body and/or appendices of my thesis/report in the TU Delft Repository

30. How much of your data/code will be shared in a research data repository?

- < 100 GB

31. When will the data/code be shared?

- At the end of the research project

32. Under what licence(s) will the data/code be released?

- Other – please explain below

Copyrighted thesis

## VI. Data management responsibilities and resources

33. If you leave TU Delft (or are unavailable), who is going to be responsible for the data/code resulting from this project?

Jan-Carel Diehl, Responsible Supervisor, J.C.Diehl@tudelft.nl

34. What resources (for example financial and time) will be dedicated to data management and ensuring that data will be FAIR (Findable, Accessible, Interoperable, Re-usable)?

Masters students for graduation thesis would get 1TB of data/code per researcher per year free of charge for all TU Delft researchers. We do not expect to exceed this and therefore there are no additional costs of long term preservation.

35. Which faculty do you belong to?

- Faculty of Industrial Design Engineering (IDE)