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Appropriateness of Clinical Data

Clinical Evaluations & MDR Art. 61(10)

DISCLAIMER

This presentation is intended for education purpose only and does not replace the legal text of the legislations, standards or guidance documents.

This presentation presents my personal opinion and interpretation as subject matter expert. It is emphasized that no liability is assumed for the accuracy, timeliness, and completeness.

AGENDA

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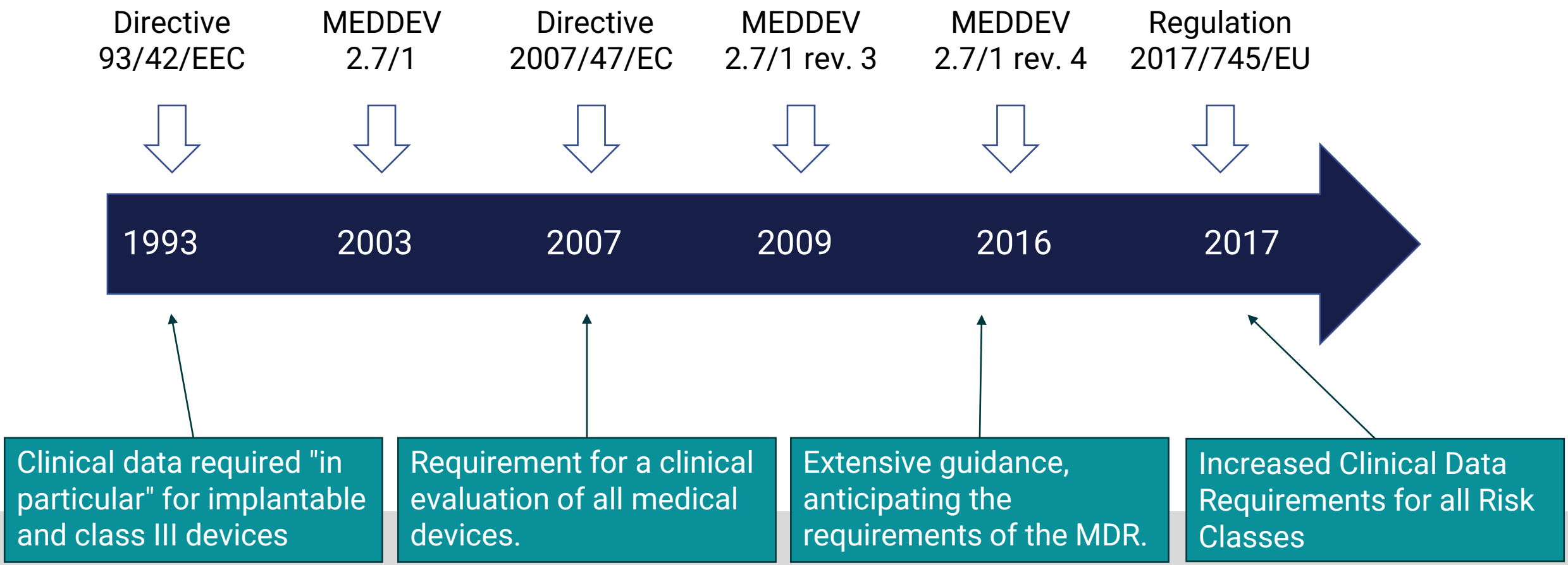
02 Current Interpretation of „Appropriateness of Clinical Data“

03 Research: Laparoscopic Insufflator

04 What can we do?

05 Introducing ECliPSE

01 Clinical Data Requirements



01 Clinical Data Requirements under MDR

Clinical Evaluation: Paths for demonstration of conformity with relevant General Safety and Performance Requirements (GSPR)

Product without medical purpose (acc. Annex XVI)

Art. 61 (9) MDR

Based on clinical data

Based on the results of non-clinical testing methods

Art. 61 (10) MDR

Sufficient level of clinical evidence
in view of the characteristics of the device and its intended purpose - Art. 61 (1) MDR

- Data concerning safety incl. PMS/PMCF
- IA Clinical investigation

"Equivalence pathway"

Art. 61 (5), Annex XIV, Part A (3) MDR

Clinical data to the subject device:

- relevant scientific literature
- Clinical investigation Art. 61 (4-6) MDR

"Performance pathway"

performance evaluation / bench testing / pre-clinical evaluation

01 Current Situation

"When we consider that European medical device rules have been developed without a thorough evaluation of scientific principles, is it any wonder that the EU regulatory framework for medical devices is not more 'fit for purpose'?"

Fraser, A. G., Redberg, R. F., & Melvin, T. (2025). The origins of regulations for pharmaceutical products and medical devices – what can be learned for the governance of Medical Devices in Europe? European Review, 1–34. https://doi.org/10.1017/s1062798725000109

01 Current Situation

Clinical Affairs

- background in medicine, veterinary medicine or biology
- focus on **clinical data**
- **patient specific** outcome parameters
- qualitative and quantitative aspects of **clinical safety**

Technical Validation

- background in engineering
- focus on **technical standards**
- **product safety**
- **product performance**

02 Current Interpretation of „Appropriateness of Clinical Data“

MDR Art. 61(1): Confirmation of conformity with relevant general safety and performance requirements […] and the evaluation of the undesirable side-effects and of the acceptability of the benefit-risk-ratio […], shall be based on clinical data providing sufficient **clinical evidence**, […].

→ Non-clinical data only is the **exception**

02 MDR Art. 61(10)

clinical data not appropriate
≠
clinical data not available

Does not apply to class IIb implants and class III (except 61(6b)

Without prejudice to paragraph 4, where the demonstration of conformity with general safety and performance requirements based on clinical data is not deemed appropriate, adequate justification for any such exception shall be given based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performance intended and the claims of the manufacturer.

Clinical Evaluation based on non-clinical data

In such a case, the manufacturer shall duly substantiate in the technical documentation referred to in Annex II why it considers a demonstration of conformity with general safety and performance requirements that is based on the results of non-clinical testing methods alone, including performance evaluation, bench testing and pre-clinical evaluation, to be adequate.

pre/non-clinical data is always required

Considerations

Risks

Interaction between device and human body

Clinical performance and claims

03 Research

1. Is it still possible under MDR to perform a clinical evaluation of a newly developed class IIb non-implantable active medical device **without performing a clinical investigation**?
2. Which **role** does **data from the same generic device group** / the clinical state of the art play in this context?
3. Which **factors** determine the **type of (clinical) data** required to show safety, performance, and benefit-risk ratio of a medical device?

Expert Interviews

- Interview Partner: **Clinical experts** from various **Notified Bodies**
- Goal: find clinical strategy accepted by **all** interview partners

Questionnaire on use of non-clinical data

- **Notified Bodies**, **Manufacturers**, **Consultants**
- Distributed via **BVMed**, to **Interview Partners** and via **LinkedIn**

03 Subject Device

Laparoscopic Insufflator

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Classification

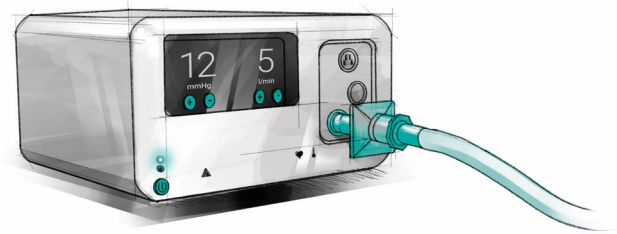
IIb

Performance and Benefit

Delivers CO_2 to create abdominal cavity, allows laparoscopic procedures

Device-Body-Interaction

Delivers CO_2 to human body, **well understood**. can be simulated in non-clinical setting



Manufacturers Claims

No clinical claims

Novelty and Risks

Standard of care for over 20 years, mechanism behind risks well understood

Appropriateness / Feasibility

Feasible to collect clinical data: yes

appropriateness?

03 What Data is required for initial CE-marking?

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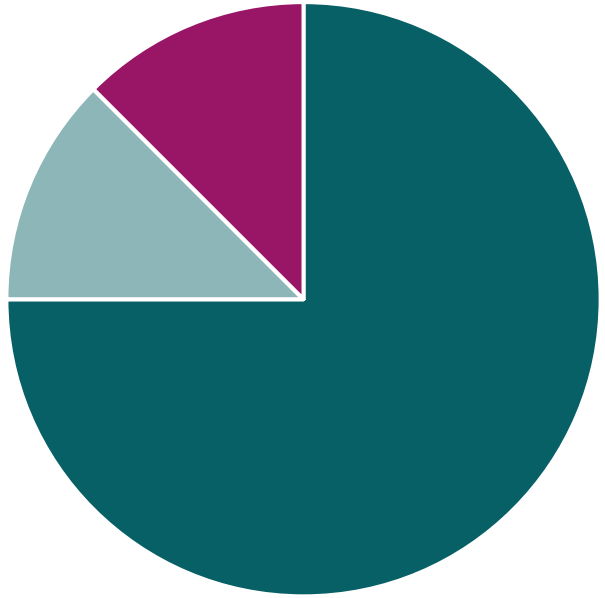
Clinical data requirements as defined by interview partners

- Non clinical data only
- Clinical data preferrable, but non clinical data only may be acceptable
- Clinical data necessary, but data from generic device group sufficient
- Clinical data from equivalent device required
- Clinical investigation preferrable, but data from equivalent device may be sufficient
- Clinical investigation required

Clinical data requirements ignoring MDR as defined by interview partners



Data from Interviews with 8 Notified Body Employees

03 Role of Data from the Generic Device Group

- Interviews: (5/6 interview partner) data from the generic device group **cannot be used as evidence for subject device**
- MDCG 2024-10 lists data from the generic device group as **non-clinical data**
- Can we use this data for **more than the SOTA**?

If no-one had ever performed a laparoscopy –

would anyone suggest that a clinical evaluation for a laparoscopic insufflator can be performed based on **non-clinical data only**?

03 Type of Non-Clinical Data

Survey comments:

- Notified Body reviewer stated that they **did not "dive too deep into non-clinical data"**

Interview responses:

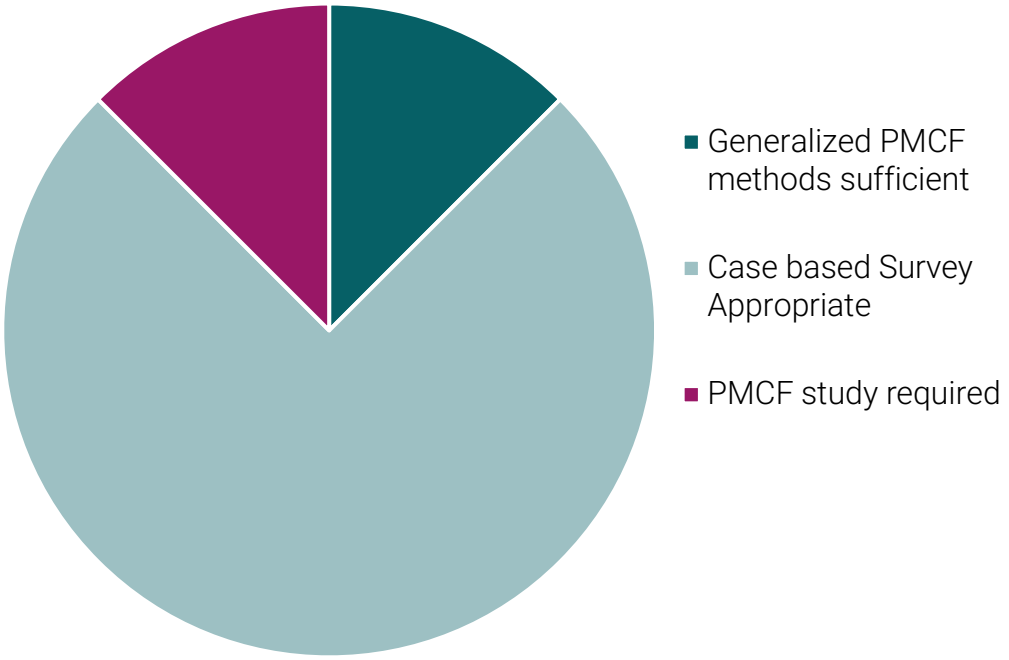
- Five of the respondents inquired as to the existence of any **common specifications or standards**
- Two asserted that deriving test criteria from scientific literature would be **advantageous**

03 Role of PMCF / the possibility to generate clinical data

Interview responses:

- One participant explicitly stated that if they accepted a clinical evaluation based on non-clinical data, **this could not be used to argue against the collection of PMCF data**.
- One participant said *"if you say that there is no need to collect clinical data before certification, automatically it means that we **cannot expect a clinical data in the post-market phase**"*

PMCF requirements as defined by interview partners



Data from Interviews with 8 Notified Body Employees

03 Non-Clinical vs. Clinical Data

Laparoscopic Insufflator

Non-Clinical Data

- Data from generic device group shows **conditions for safe and efficient use** for **all patient groups**
- Data from generic device group shows **circumstances under which adverse effects are more likely**
- Non-clinical testing using test models and test cases **based on scientific data** allows thorough testing representing **all patient groups** and **clinical scenarios**

Clinical Data

- Published clinical studies usually **only mention** the use of a specific device
- Clinical study evaluating safety regarding CO_2 embolisms (0.001% to 0.59%) requires data from more **than 160 000 patients**[1]

What do we gain from "**some clinical data**" before initial CE marking?

03 Conclusion (Research)

- All **scandals** leading to the introduction of the MDR related to **implants or new procedures**
- The goal of the MDR was to improve patient safety

Currently, there is **no consensus** on **appropriateness of clinical data** / applicability of MDR 61(10)

For medium risk, standard of care devices:

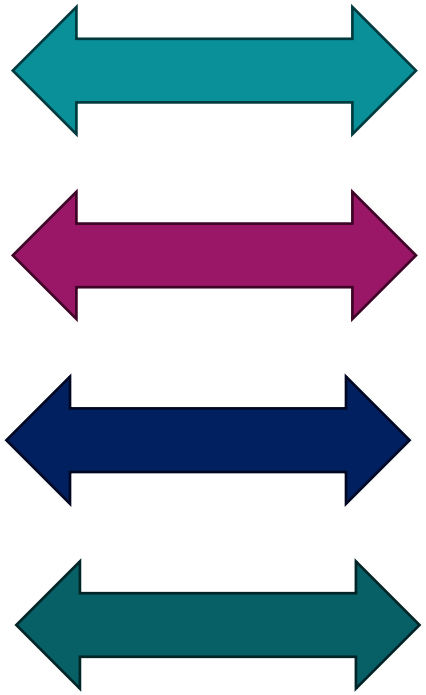
- Is data from the **generic device group** together with **advanced testing** enough for **initial CE-marking**?
- Is **more advanced bench** testing better suited to support patient safety than **pre-market clinical data**?
- Can this be improved by **PMCF**?

Further Research Is Needed

04 What's Next?

Clinical Affairs

- background in medicine, veterinary medicine or biology
- focus on **clinical data**
- **patient specific** outcome parameters
- qualitative and quantitative aspects of **clinical safety**



Technical Validation

- background in engineering
- focus on **technical standards**
- **product safety**
- **product performance**

04 Options for Manufacturers

Build a robust validation strategy including clinical and non-clinical data

Talk to your Notified Body
→ **structured dialogue**

Push back on unreasonable clinical data requirements

05

Introducing **ECliPSE**

Evidence Based Clinical and Pre-Clinical Strategies
for the Evaluation of Medical Devices

Which medical devices *really* need **clinical data for initial CE-marking**?

For which devices may data from **the generic device group** together with **advanced testing** be **enough for initial CE-marking**?

Is **advanced non-clinical testing** better suited to support **patient safety** than **pre-market clinical data** for some devices?

What do **advanced non-clinical testing strategies** look like?

What is the role of **PMCF** in this context?

http://eclipse-md.com

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Introducing ECliPSE

Evidence Based Clinical and Pre-Clinical Strategies for the Evaluation of Medical Devices

Evidence Mapping:
We categorize and assess both clinical and non-clinical data needs for different device types and risk classes.

Expert Interviews:
We conduct in-depth interviews with stakeholders including clinicians, engineers, regulatory professionals, and device manufacturers.

Delphi Study:
A three-round Delphi process engages experts across disciplines to build consensus on evidence requirements.

05 Introducing ECliPSE

Evidence Based Clinical and Pre-Clinical Strategies for the Evaluation of Medical Devices

Collaborative Research Project

- Prof. Tom Melvin
- Prof. Dr. med Michael D'Agosto
- Elisabeth Oltmanns

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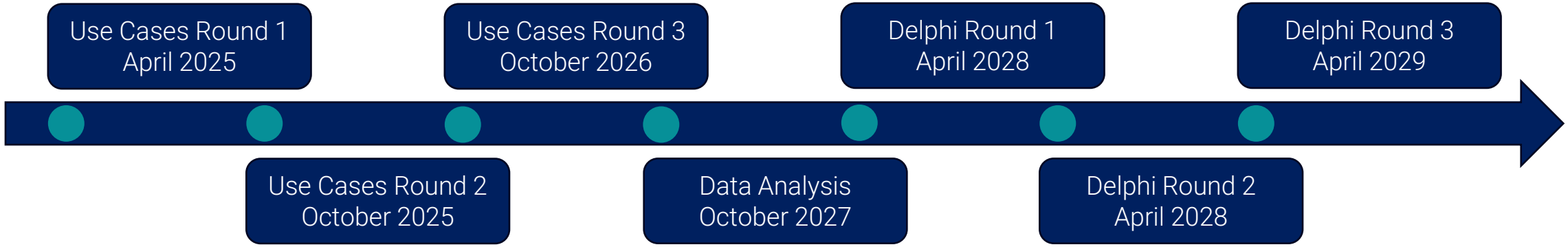
Introducing ECliPSE

Evidence Based Clinical and Pre-Clinical Strategies for the Evaluation of Medical Devices



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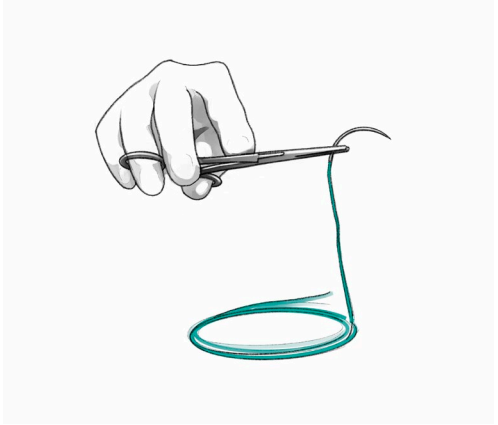
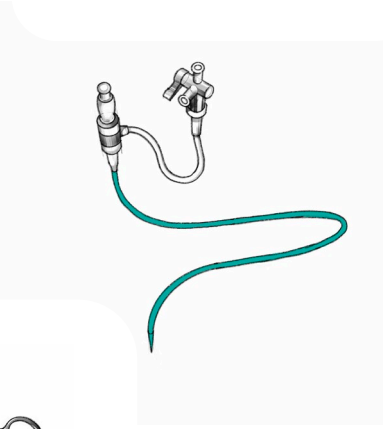
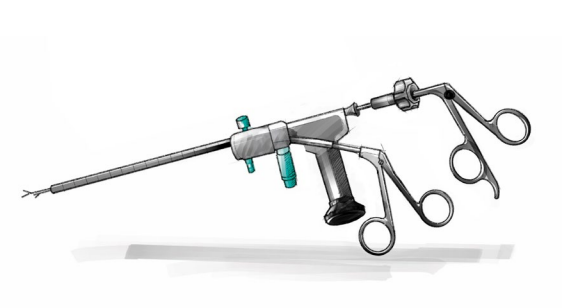
Use Cases Round 1

Well-established technology

- Suture
- Bone Screw
- Surgical Instruments (Neurosurgery)
- Introducer for Catheter / Stents







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Use Cases Round 2

Active Devices

- ICU Ventilator
- Electrosurgical Generator
- Insulin Pump
- ...

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