Case Study: BAMBI – Baloon Against (post-partum) Maternal BleedIng

XLI ANNUAL SCHOOL

BIOMEDICAL ENGINEERING FOR SUSTAINABLE DEVELOPMENT

13 September 2022

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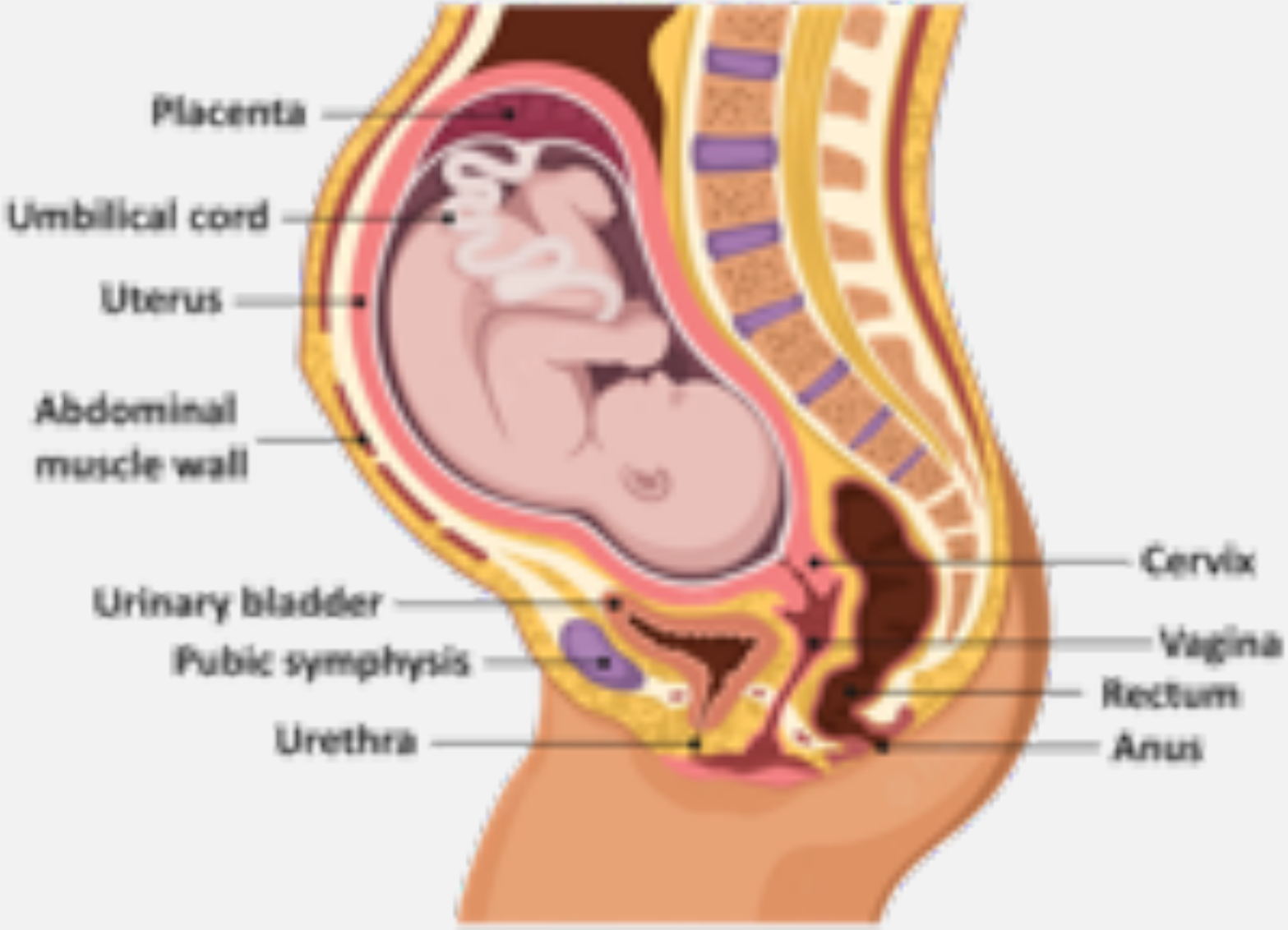
POLITECNICO MILANO 1863

Background: Uterus and pregnancy



Post Partum Haemorrhage (PPH)

- **500 ml** or more
- within **24 hours** after birth
- leading cause of maternal death worldwide

Social relevance and expected social impact

World cases

Health Organization (2018)

Related deaths

Herrick et al. (2017)

Deaths in low-income countries

Health Organization (2018)

Social relevance and expected social impact

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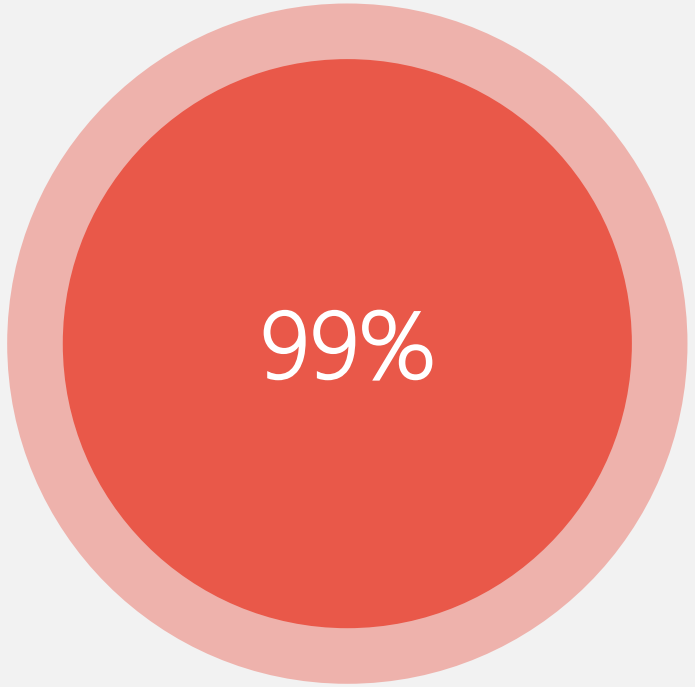
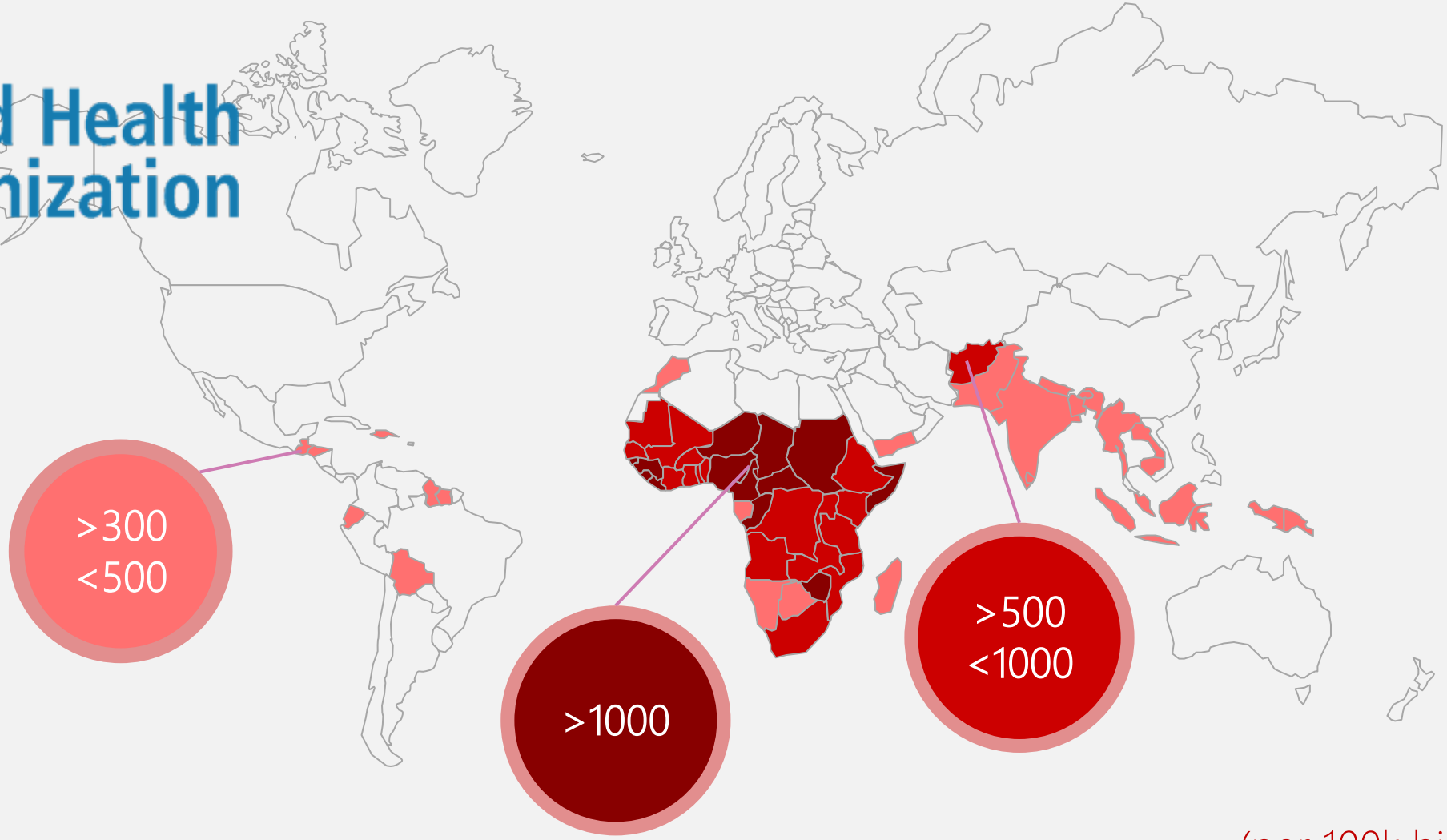


Deaths in low-income countries

Health Organization (2018)

Maternal mortality ratio

World Health Organization



(per 100k births)

Existing Needs

Existing Needs

31-year gap in **life expectancy** between the developing and developed countries.

PPH is one of the **main causes**

COVID related effect

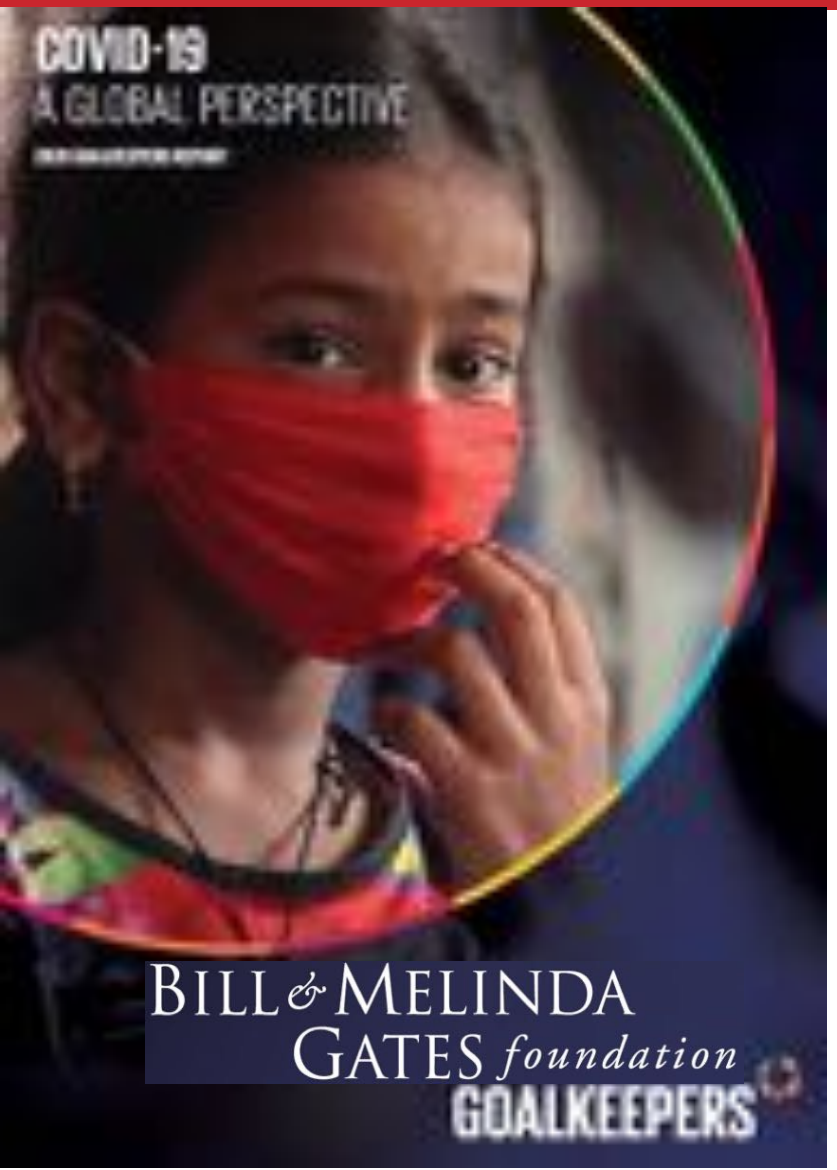
nature research

NEWS · 15 SEPTEMBER 2020

Stillbirth rate rises dramatically during pandemic

Researchers stress need for antenatal care, as emerging data link disrupted pregnancy services to increase in stillbirths.

COVID related effect



PPH related Maternal deaths per 100,000 live births 2030 target

Uterine Balloon Tamponade (UBT)

- Minimally Invasive Procedure
- Slows down or Stops the bleeding by exerting pressure on the uterus walls
- 1st choice in Low Resource Settings due to poor availability of pharmaco-therapeutic management (uterotonic agents es. Oxytocin)

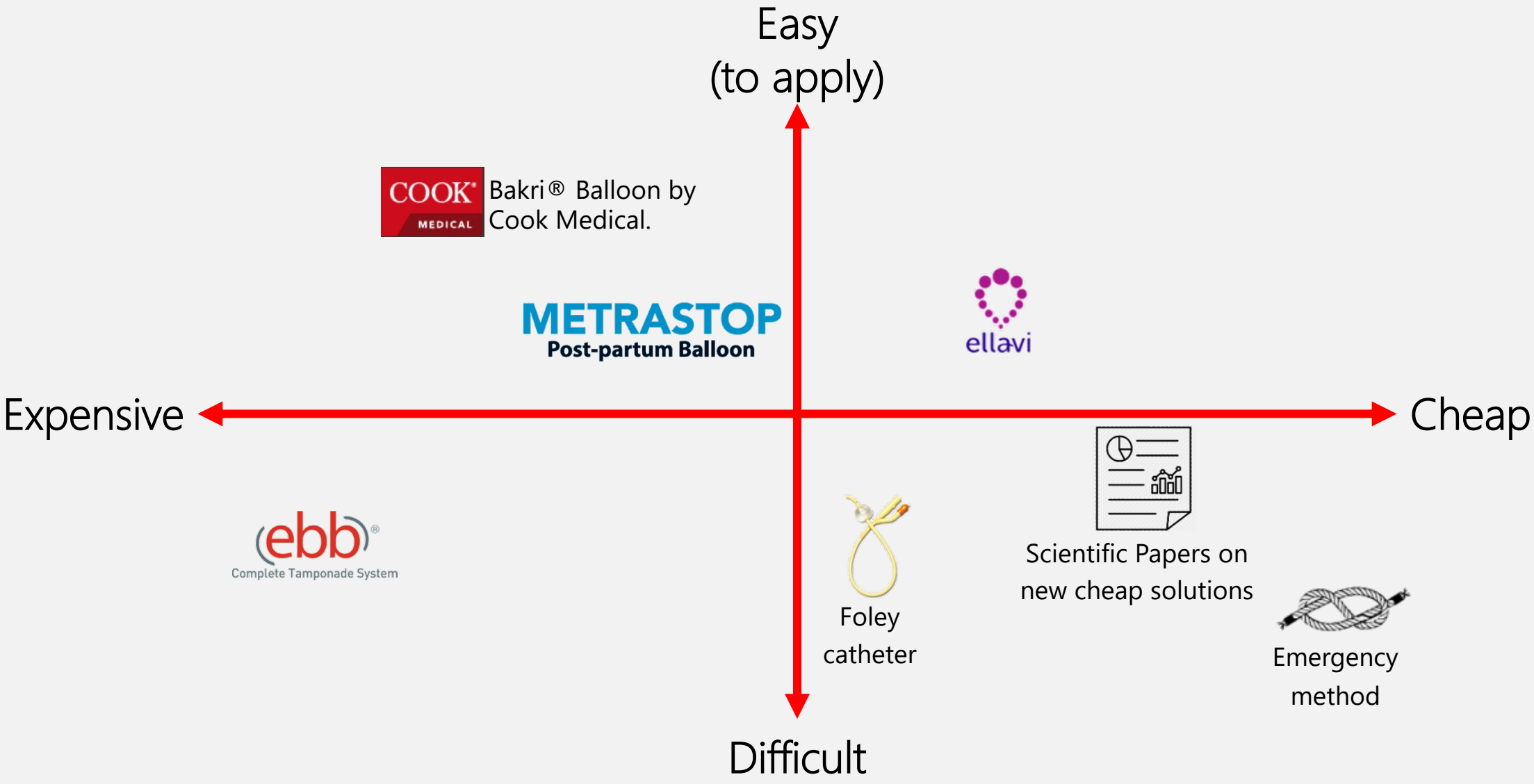
State of the Art - UBT Devices

Device	Price
COOK MEDICAL	$250 - $350
ebb Complete Tamponade System	$125 - $400
	$25 (more than one is needed)
ellavi	$10 (not on the market)

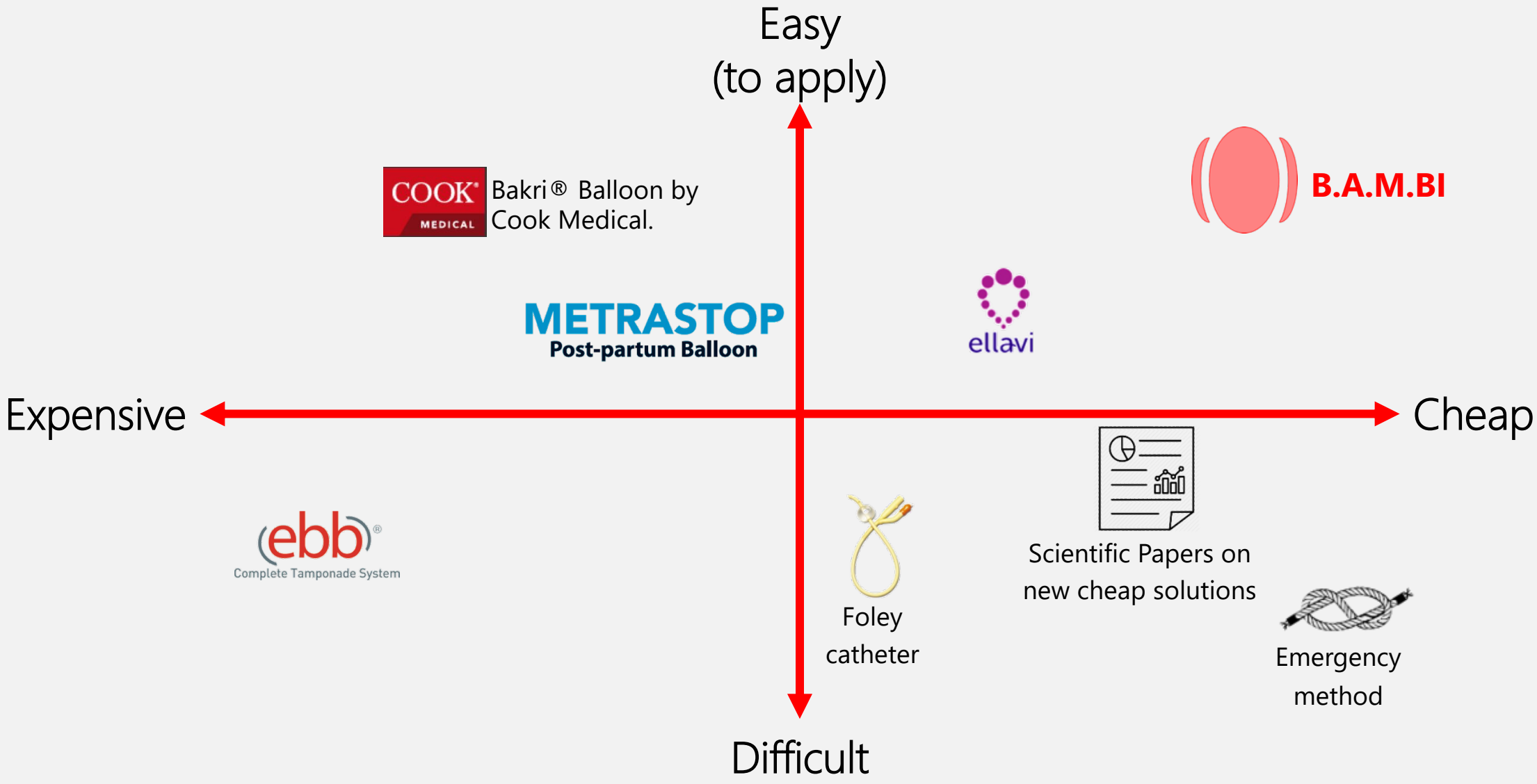
State of the Art - CBT Devices

Emergency Devices in resource-poor settings: **C**ondom **B**alloon **T**amponade (CBT) devices

BAMBI market positioning



BAMBI market positioning

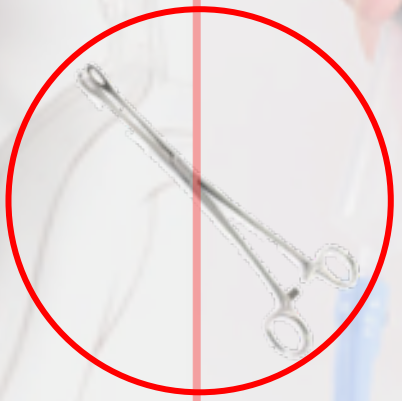


State of the Art

State of the Art – UBT vs. CBT Devices

UBT

Expensive
125 to 350 $



Require sterilized surgical instruments

CBT

Fluid leakage

Objective

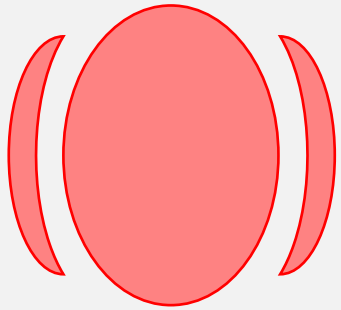
Issues:

Current CBT Devices:

- Present leakage
- Are time consuming to prepare
- Need specific training
- Are difficult to apply and often need surgical instruments

Our Proposal:

BAMBI : **B**alloon **A**gainst **M**aternal **B**leed**I**ng

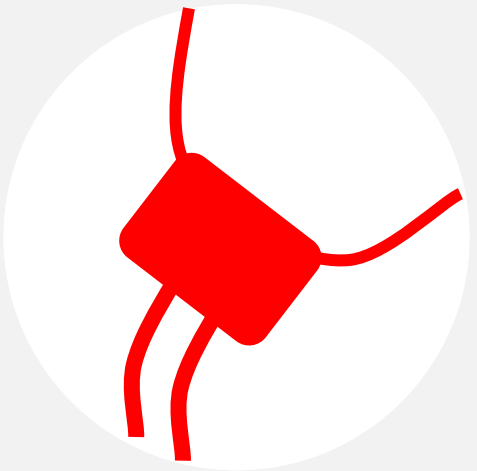


The BAMBI KIT

A **NEW DEVICE** able to STOP PPH

Economically affordable (<5$)

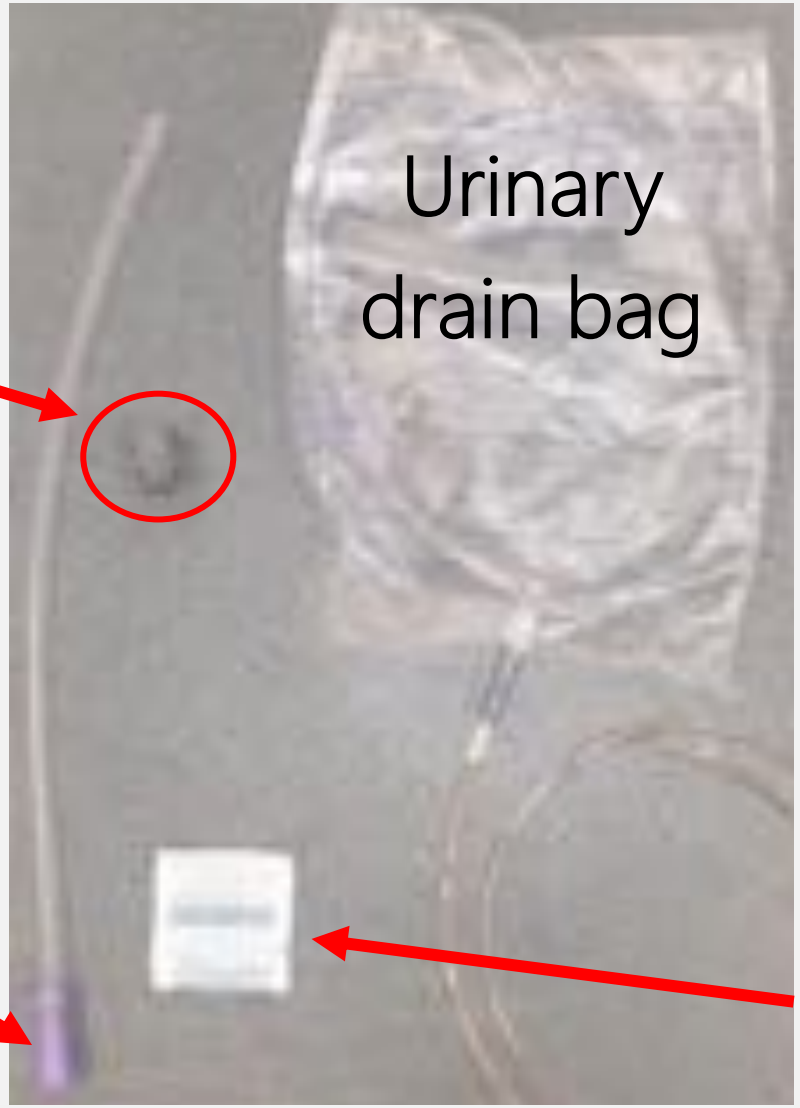
Easy to apply



Reliable and safe

BAMBI KIT

Connector

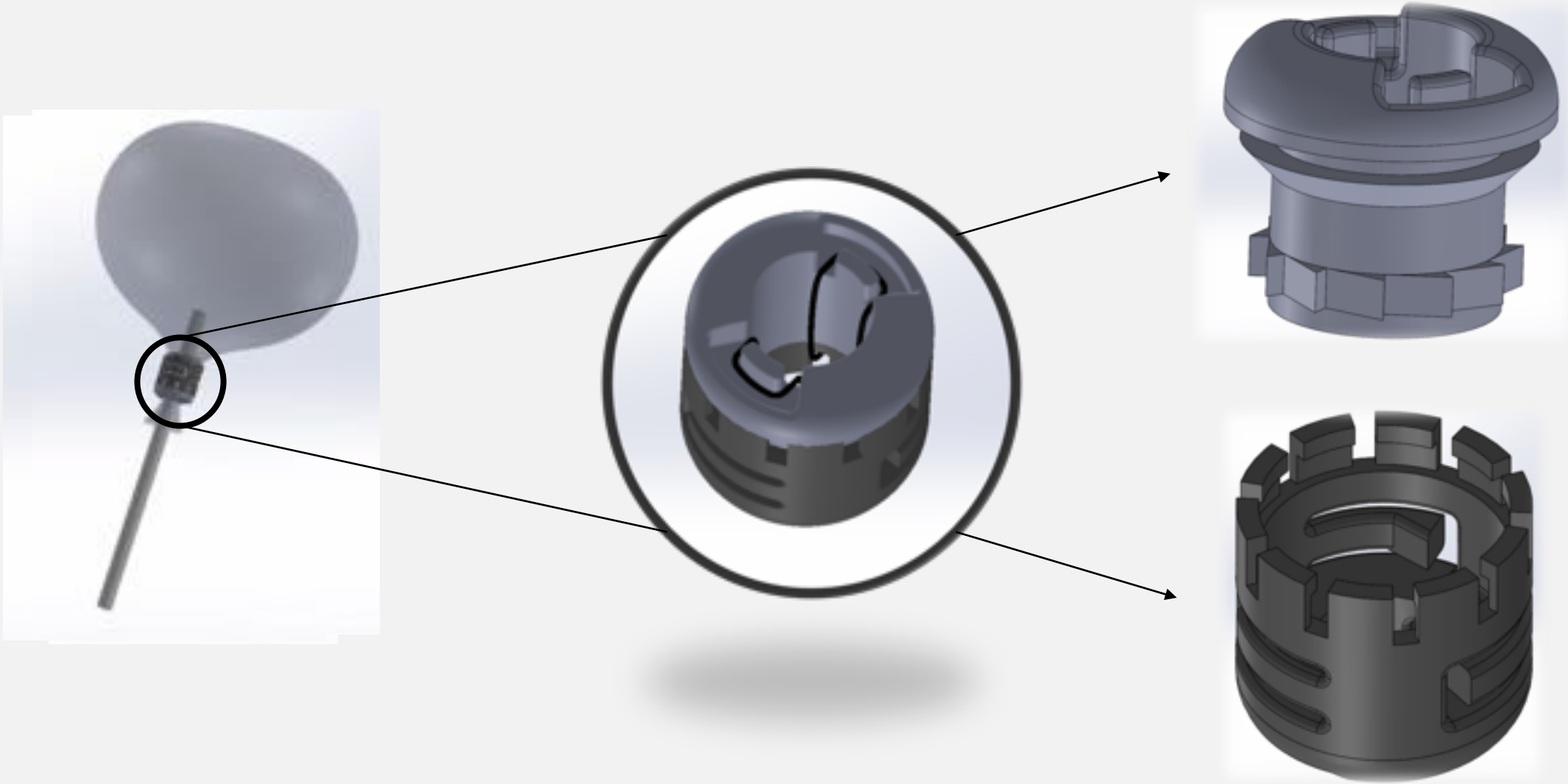


Rectal
Probe

Probe Cover

Social Patent n.
102020000009016

BAMBI – Connector Mechanism



BAMBI - How it works

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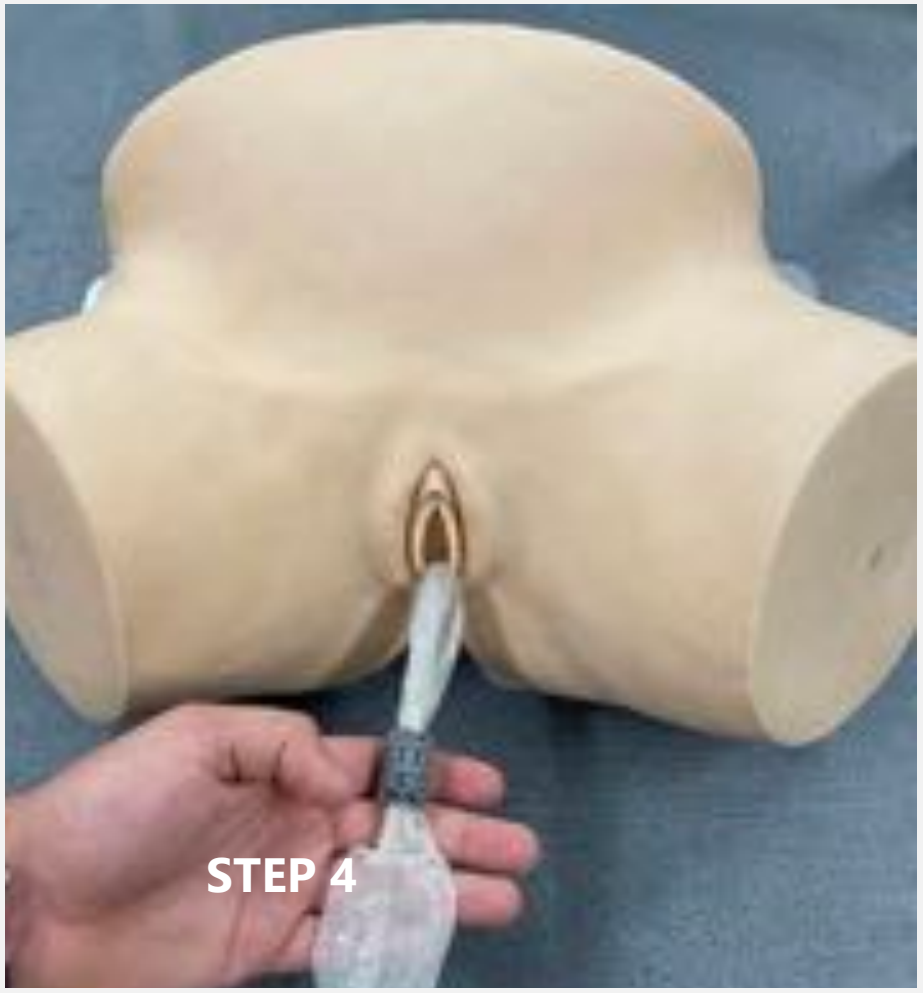

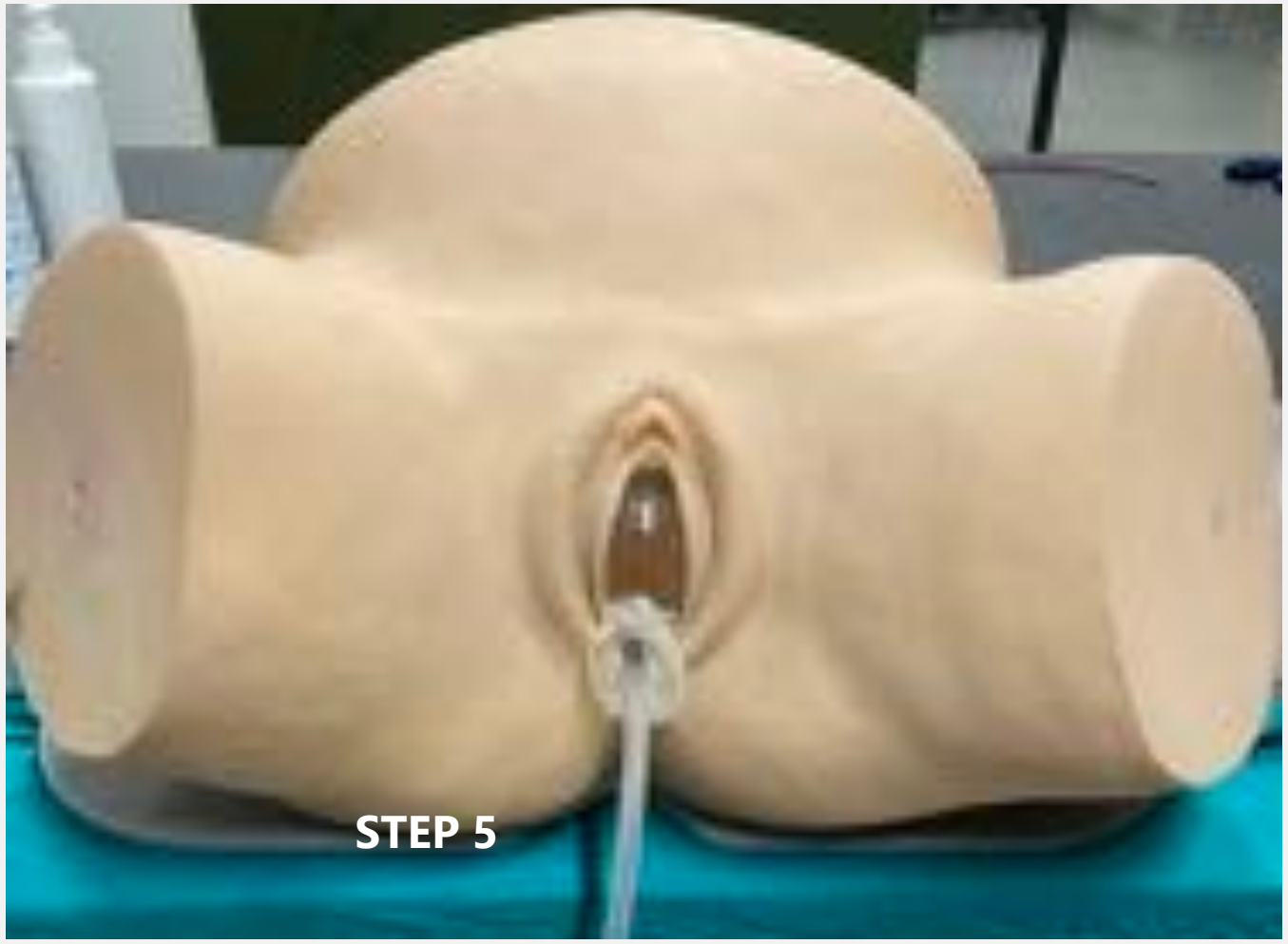

Material

3D printer: Form 3B by formlabs

Material

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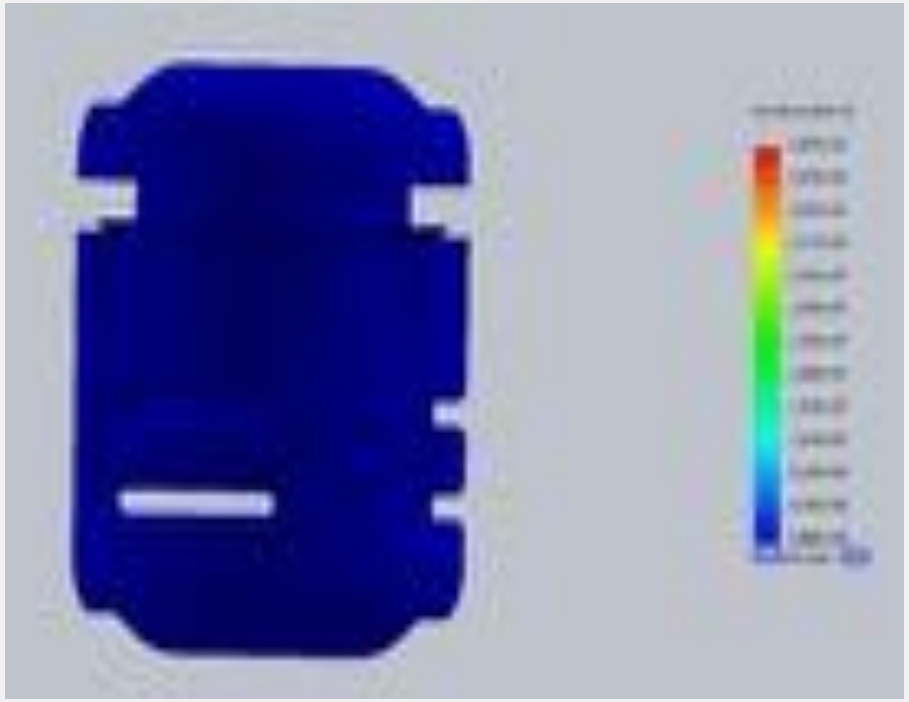
formlabs

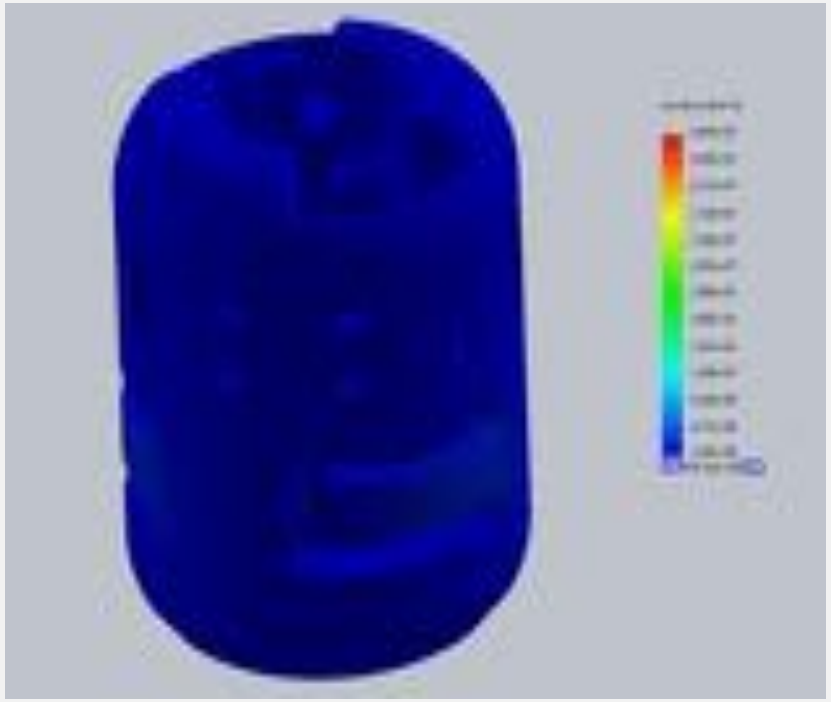
Grey Pro resin

Elastic Modulus: **2 Gpa**

Ultimate Strength: **80 MPa**

BAMBI – Connector Design Assessment

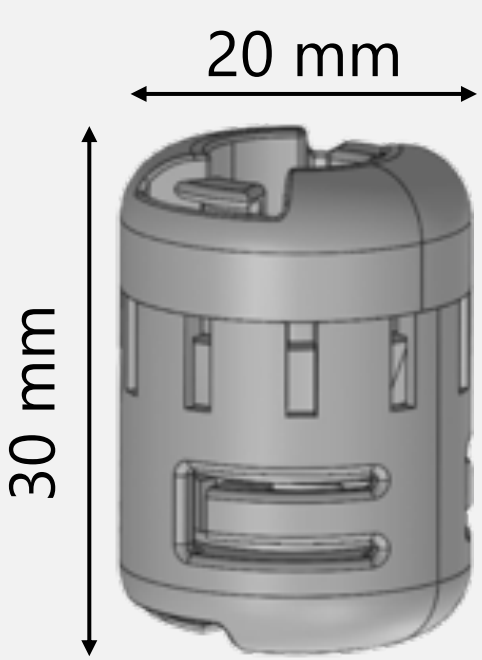




Ultimate Strength: 80 MPa

Max. Stress: 50 MPa

Prototypes



CAD

STL file

Prototypes

Experimental Activities

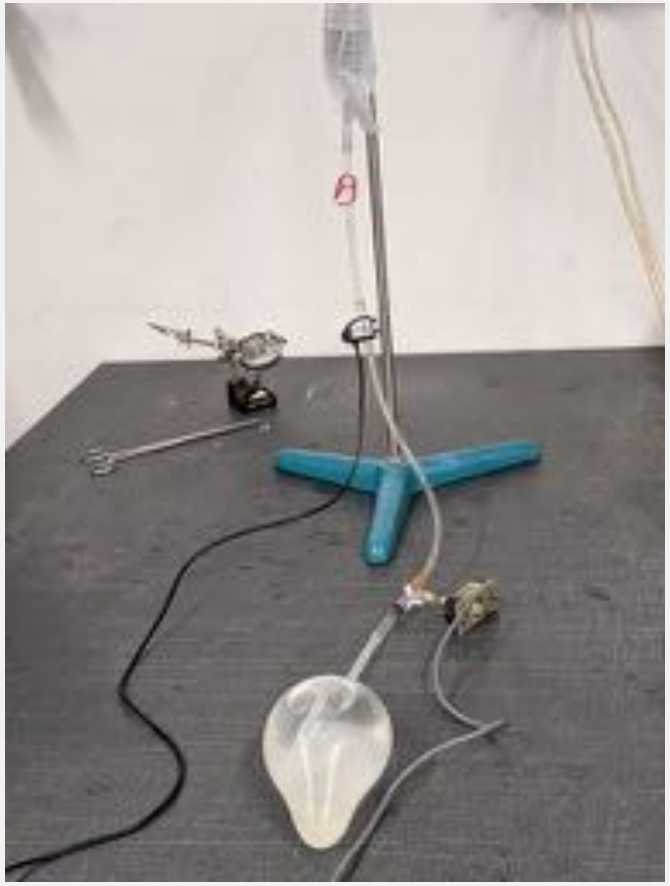
Which kind of test should we perform?

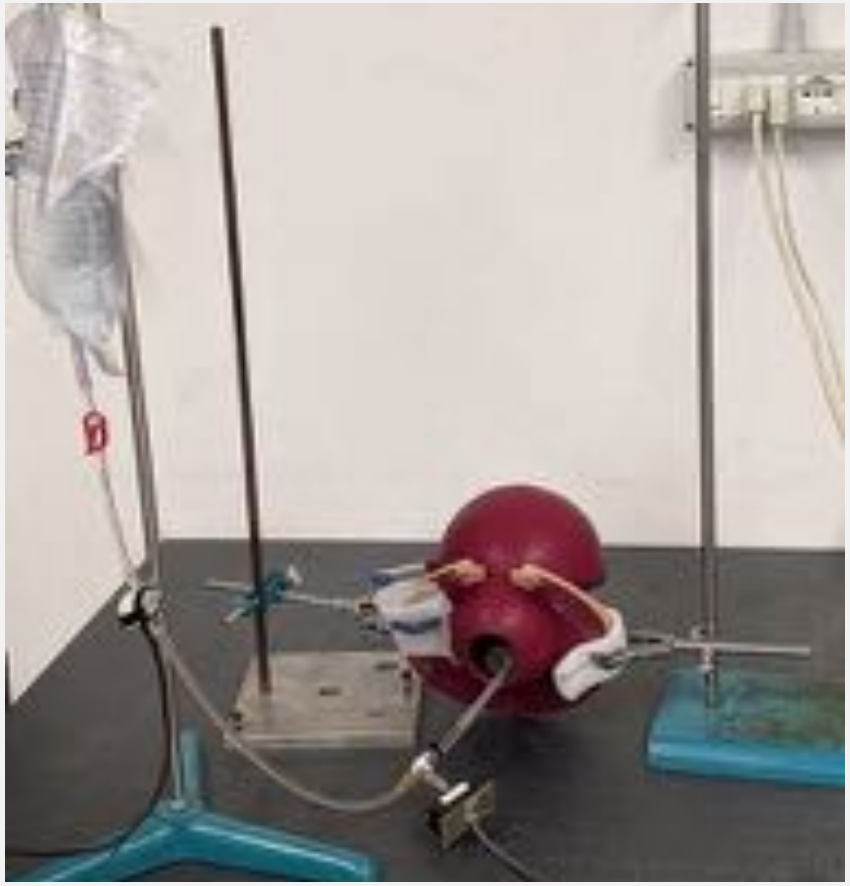
Experimental Activities

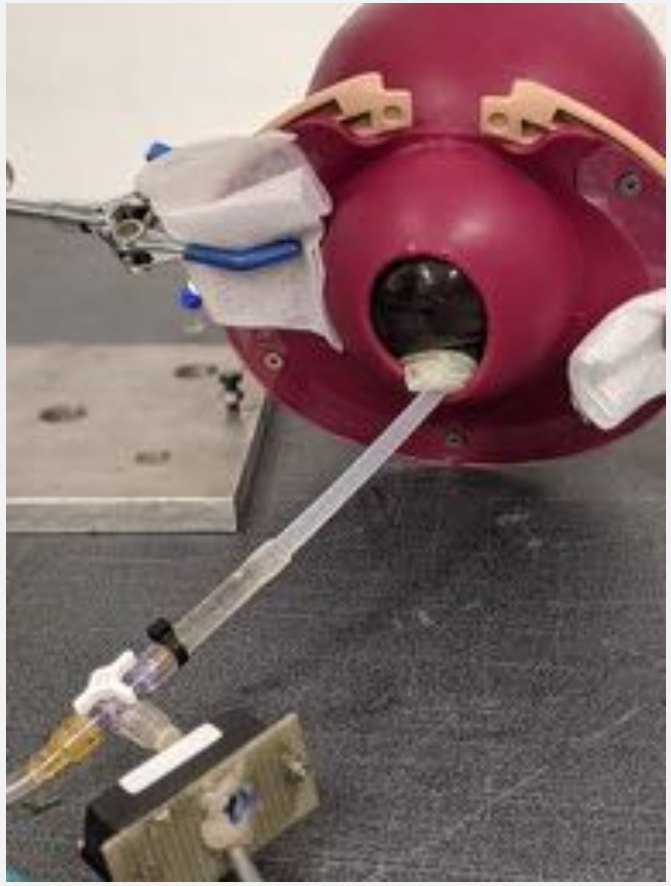
Safety and Mechanical **Performance Assessment**

1. Intraluminal Pressure (ILP) Measurement: Open Air and *in-situ*
2. Evaluation of the connector and the balloon-catheter attachment: Tensile tests
3. Usability tests

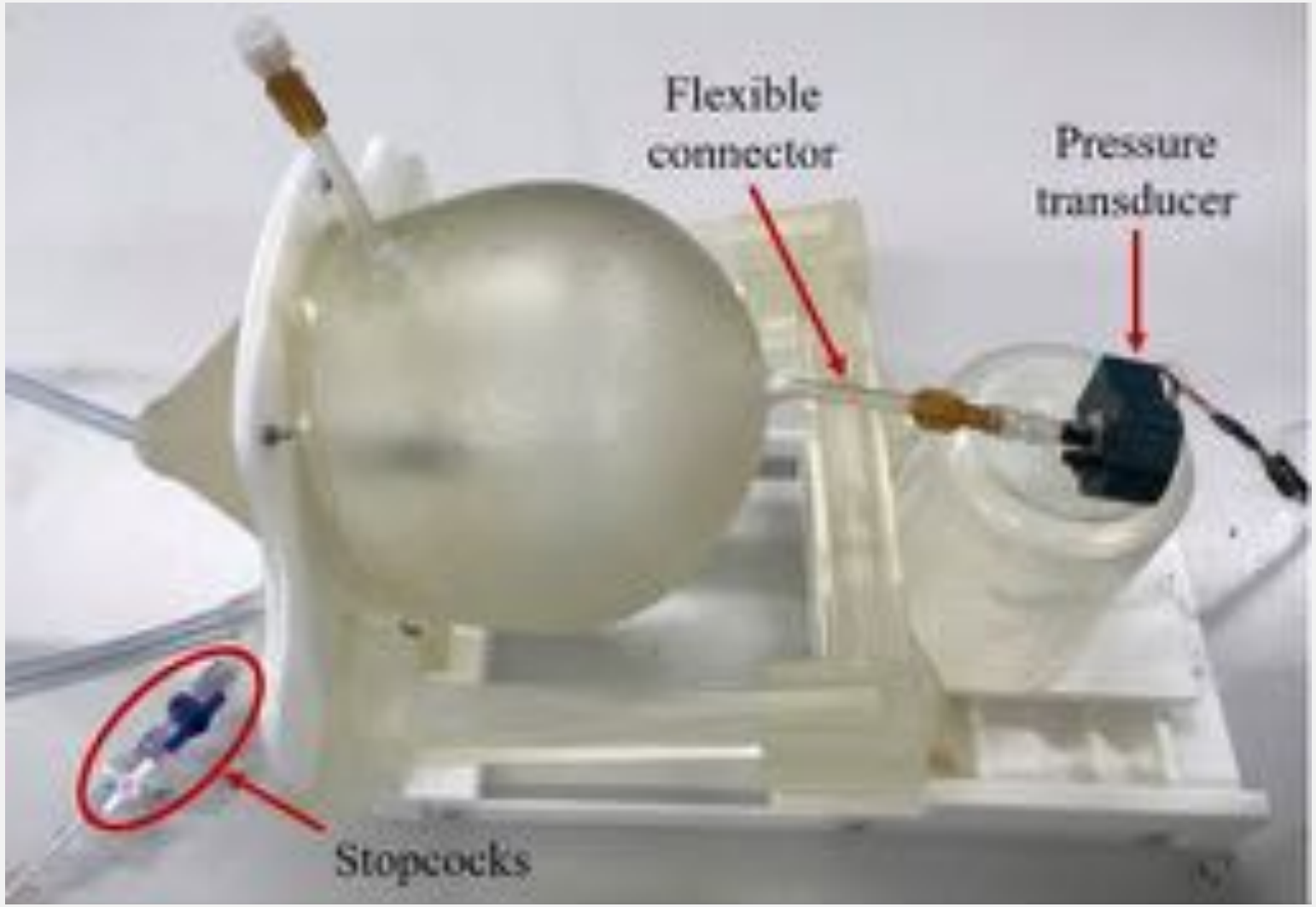
ILP Measurement: Open Air and *in-situ*





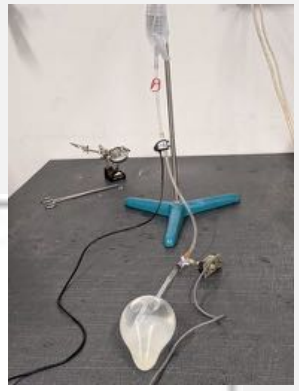


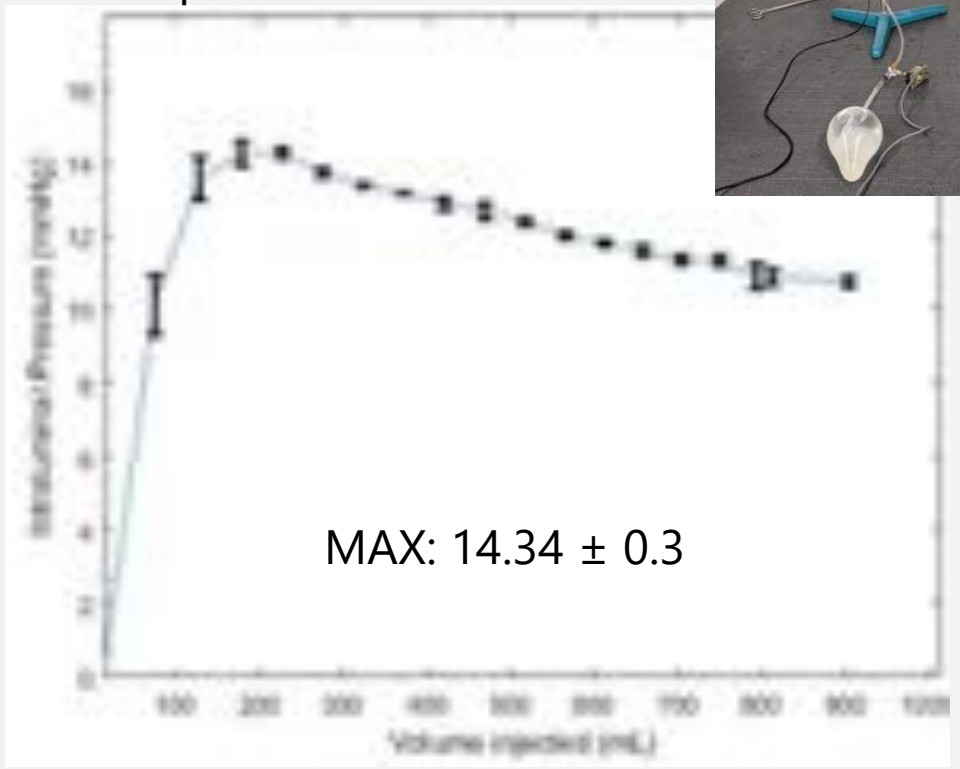
ILP Measurement: Open Air and *in-situ*



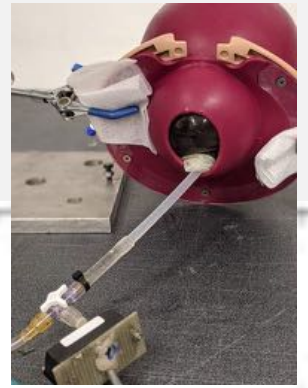
Results: Intraluminal Pressure

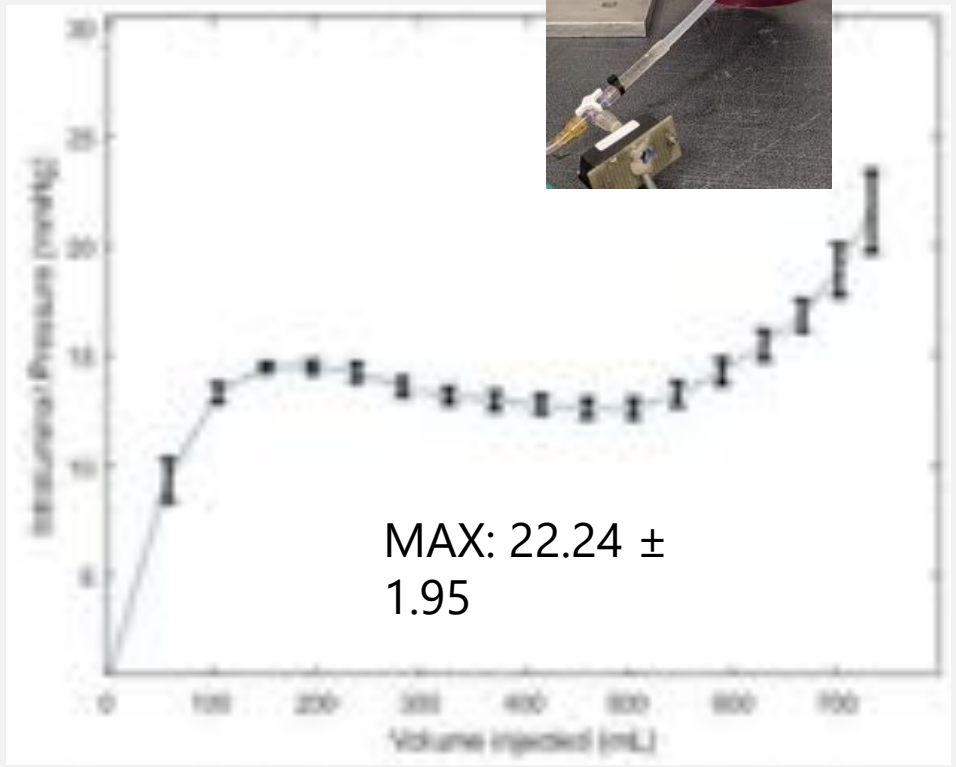
Open Air



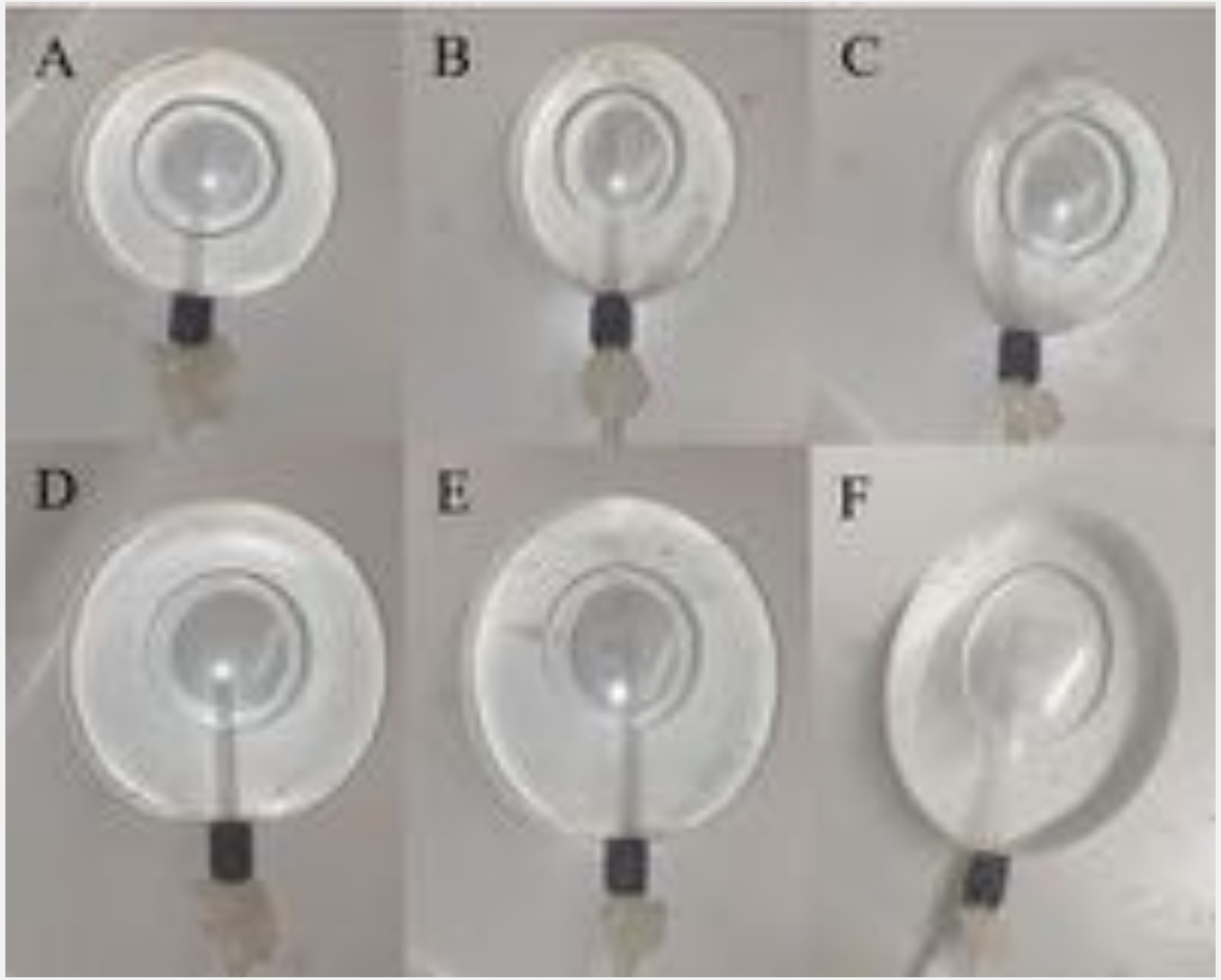


in-situ





Results: Shape differences

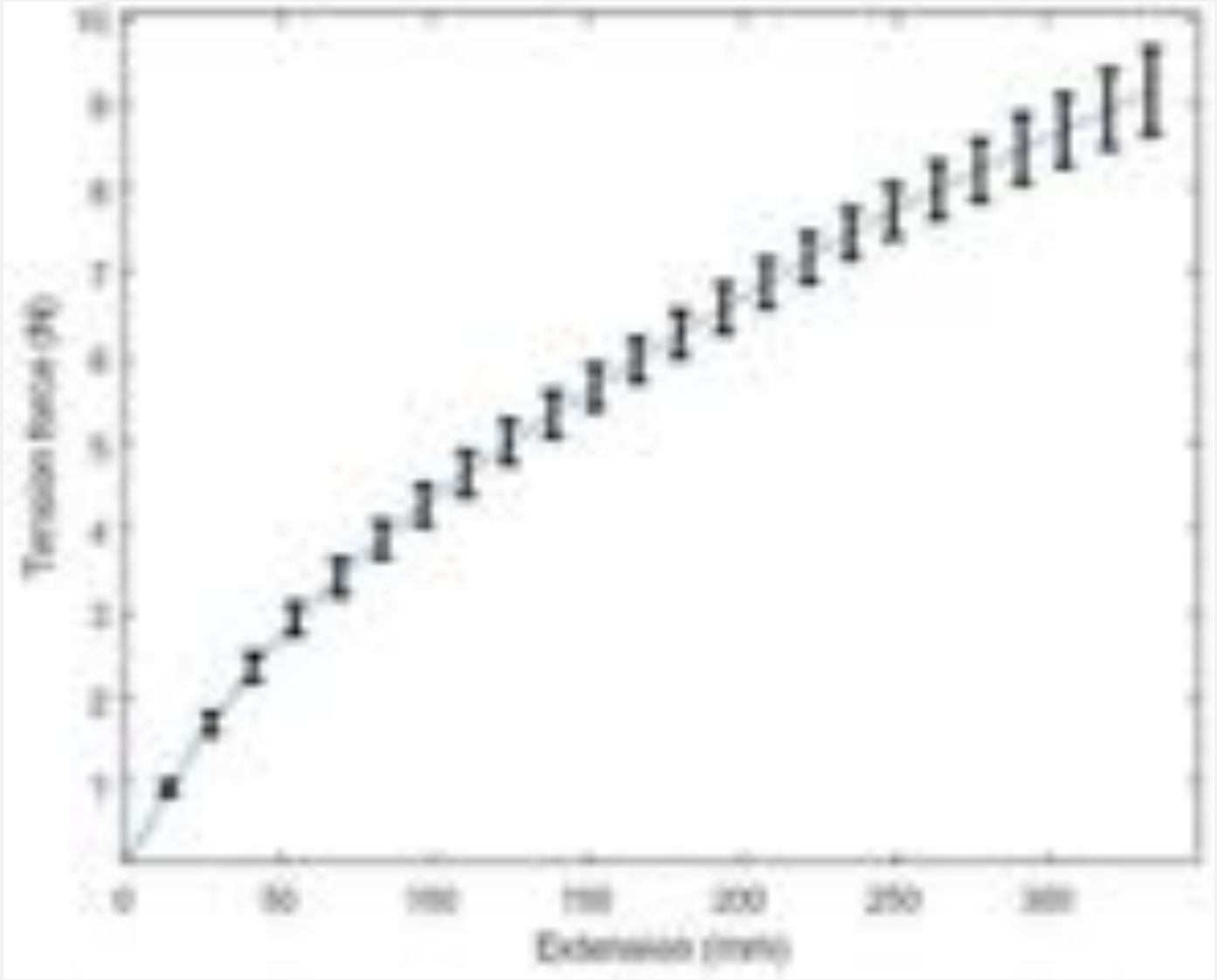


A, B and C show the shape of the balloon after being filled by **700 ml of water for 10, 7.5 and 5 cm configurations,** respectively. **D,E and F** show the same balloons filled until **1500 ml.**

Connector's Strength Evaluation: Tensile Test

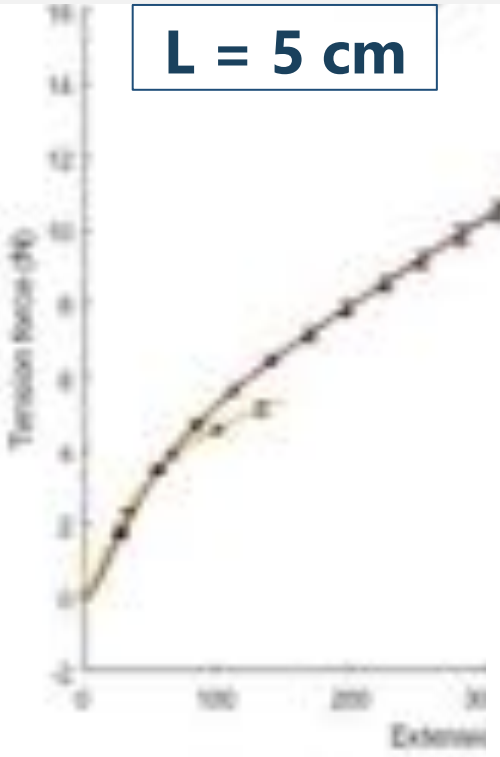
- Electromechanical test system: MTS Synergie 200H (100N load cell)
- Crosshead Velocity: 1 mm/s
- Crosshead Displacement: 400 mm

Results: Tensile Tests

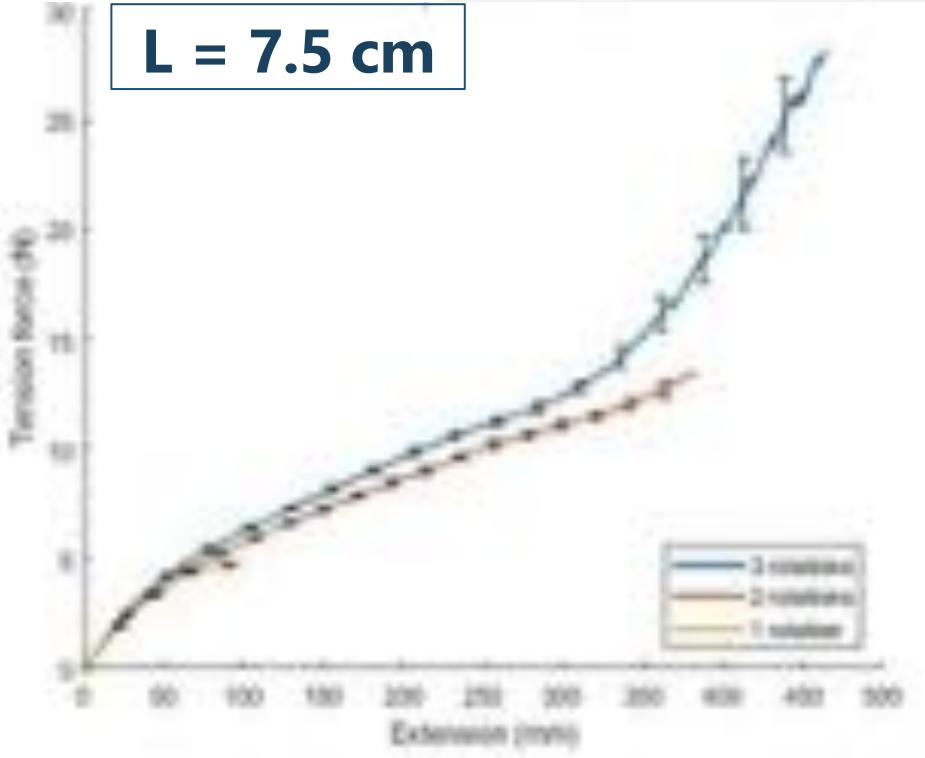


Results: Tensile Tests

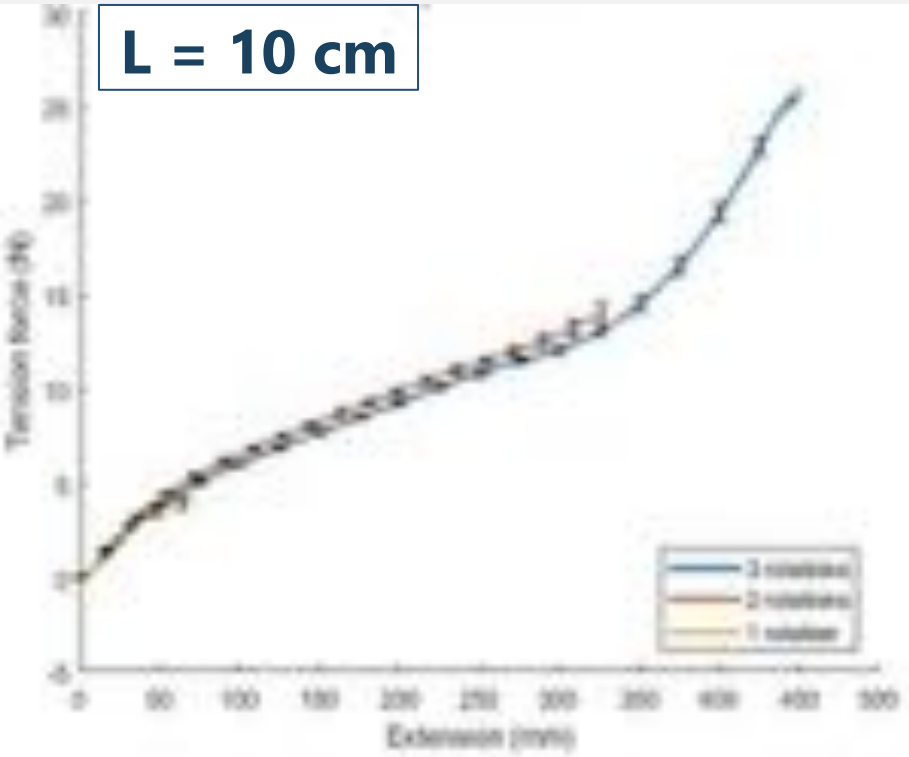
L = 5 cm



L = 7.5 cm



L = 10 cm



Preliminary Usability Test

Participants: 5 researchers with no experience with the uterine tamponade technique.

Training: Participants were given an overview of the practical instructions on the correct techniques for assembling the devices.

Experiments: The participants were required to complete the assembly, inflation of the device and insertion into the uterus model. This procedure was repeated for both devices.

Survey: After the completion of the experimental test, the session concluded with a survey regarding the participant's preferences in using the devices.

Results: Preliminary Usability Tests

BAMBI DEVICE	EMERGENCY DEVICE
30 s	60 s

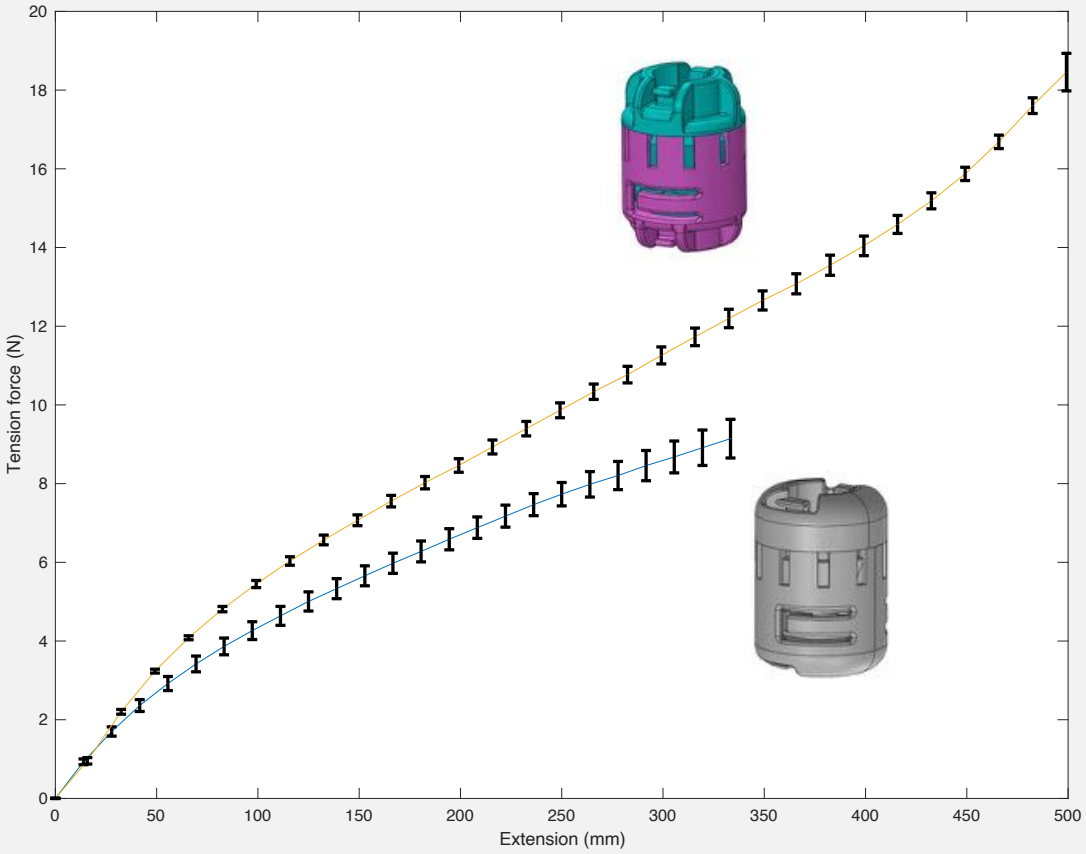
Failed tie using manually twisted elastic rings

Improvement for Mass production

PRE

POST

MTTS



Beneficiaries and Partners

Alberto Zanini, MD
Past Head of the Dep. of Obstetrics and Gynaecology (Erba Hospital)

MEDICI CON L'AFRICA CUAMM

soleterre

Amici della Neonatologia Trentina - onlus -

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Amici della Neonatologia Trentina - onlus -

Funding and Grants

Switch To Product 2019

PoliSocial Award 2020

Activities and expected outcomes

and
Social Patents Submission
2019-20

Partnership
06/2020

Concept Design
08/2021

Prototyping
12/2021

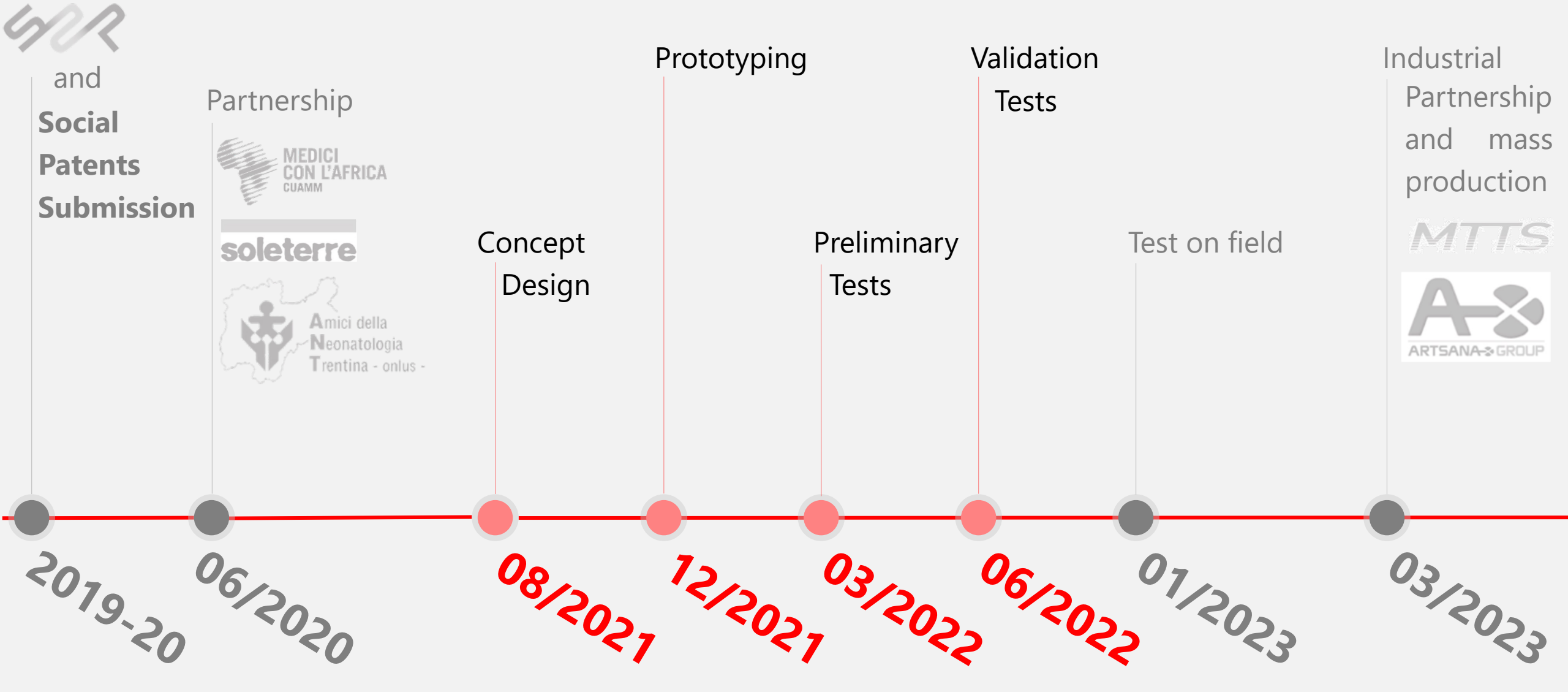
Preliminary test
03/2022

Validation Tests
06/2022

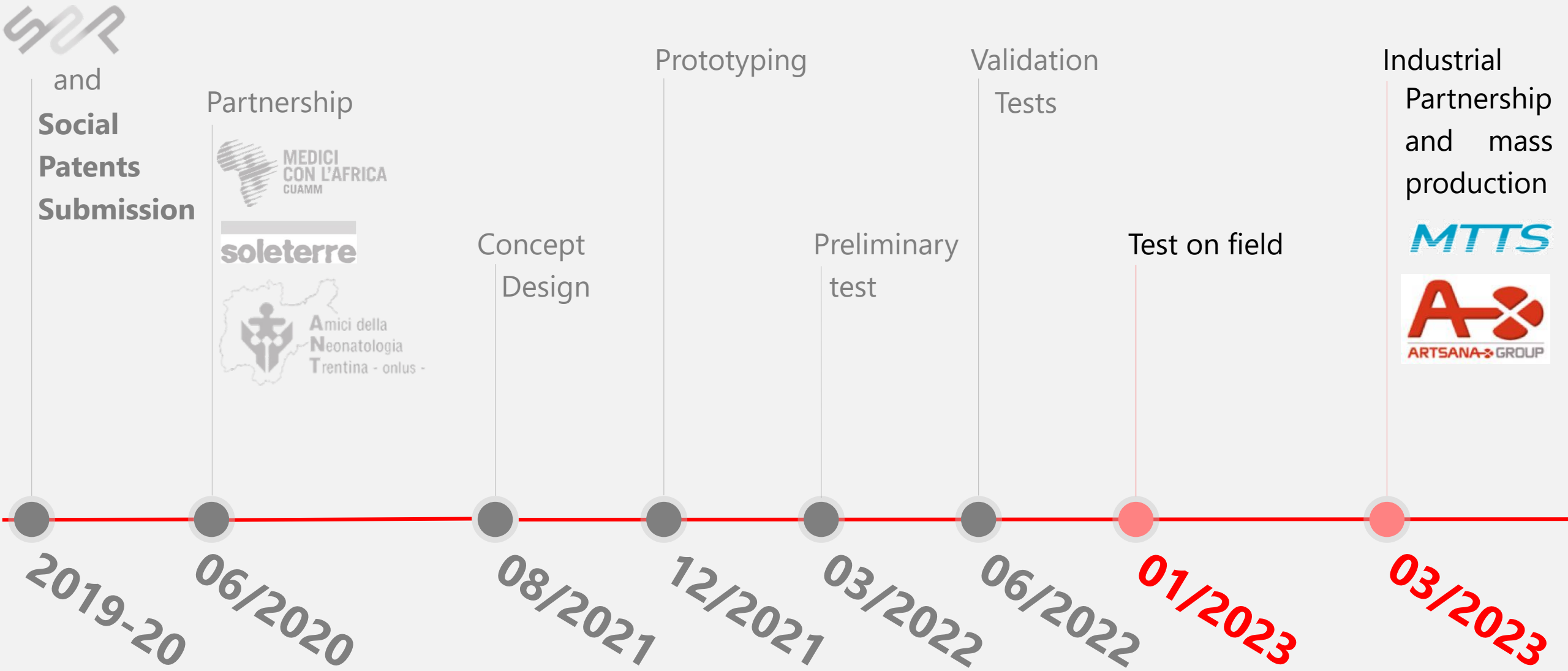
Test on field
01/2023

Industrial Partnership and mass production
03/2023

Activities and expected outcomes



Activities and expected outcomes



The TEAM

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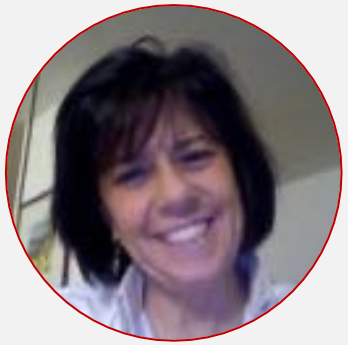
Chemistry, Material and Chemical Eng.



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Mechanical Engineering

Sara Candidori
PhD Student in Mechanical Eng.
Mechanical Engineering

Anna Plebani
Responsible for IP Protection and Technology transfer
Technology Transfert Office

B.A.M.BI

Balloon Against Maternal BleedIng

Let's make B.A.M.BI to change the Tale: Save the Mother!

Dr. A. Zanini during a mission with the Rava Foundation (Corriere.it)