



# TERM PROJECT - DESIGN BRIEF



**MFA Advanced Product Design**

**Conceptualization and Design of  
A Non-Infective Urinary Catheter**

Umeå Institute of Design

Umeå University

Zihao Wang / China / 1990

APD2 5ID190 Conceptual Product Solution

OCTOBER - DECEMBER 2015

10 weeks

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2015



Introduction

The term project executed by APD 2, will focus on the design challenge of understanding the needs, wishes and opportunities when conceptualizing and designing a non-infective urinary catheter. In collaboration with Madeleine Ramstedt, a researcher at the department of Chemistry at Umeå University, this is the first face of a project funded by Vinnova, a company that supports need-driven research and runs programs to boost innovation in Sweden.

Collaborating partner:  
**Madeleine Ramstedt**  
Researcher at the department of Chemistry.

Contact at UMH's department of Urology:  
**Katarina Günséus**  
Urology therapist (Uroterapeut)

External tutor from Veryday, Stockholm:  
**Anna Carell**  
(7 visits planned at UID, see schedule in the back)  
Senior Designer.

Uminova Holding AB (Umeå University):  
**Stefan Lööw**  
Corporate lawyer and innovation advisor

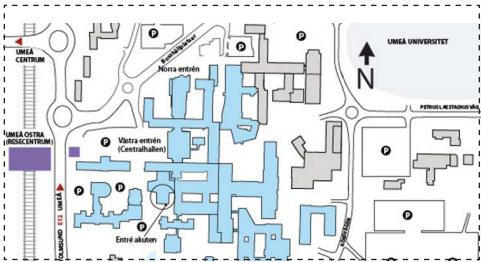
External advisor from Bristol Urological Institute:  
**Roger Feneley**  
Emeritus Consultant Urologist at Bristol Urological Institute.  
Visiting Professor at the University of the West of England.



Background

**Diameters and materials**  
Catheter diameters are sized by the French catheter scale (F). The most common sizes are 10 F (3.3mm) to 28 F (9.3mm). The clinician selects a size large enough to allow free flow of urine, and large enough to control leakage of urine around the catheter. A larger size is necessary when the urine is thick, bloody, or contains large amounts of sediment. Larger catheters, however, are more likely to damage the urethra. Some people develop allergies or sensitivities to latex after long-term latex catheter use making it necessary to use silicone or Teflon types

**Effects of long term use**  
The duration of catheterization can have significance for the patient. Incontinent patients commonly are catheterized to reduce their cost of care. However, long-term catheterization carries a significant risk of urinary tract infection. Because of this risk catheterization is a last resort for the management of incontinence where other measures have proved unsuccessful. Other long term complications may include blood infections (sepsis), urethral injury, skin breakdown, bladder stones, and blood in the urine (hematuria).



**Urinary catheterization**  
In urinary catheterization a latex, polyurethane, or silicone tube known as a urinary catheter is inserted into a patient's bladder via the urethra. Catheterization allows the patient's urine to drain freely from the bladder for collection. It may be used to inject liquids used for treatment or diagnosis of bladder conditions. (A clinician, often a nurse, usually performs the procedure, but self-catheterization is also possible. The catheter may be a permanent one (indwelling catheter), or an intermittent catheter removed after each catheterization.)



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## *Urology Department*

The kick off for the project started with a meeting at the Urology Department at Norrlands University Hospital. Attending the meeting was the 9 design students, Madeleine Ramstedt, Thomas Degn, programme director for APD, Stefan Lööw who is a corporate lawyer and innovation advisor at Uminova Holding, external tutor Anna Carell from Veryday and representatives from the hospital; Katarína Gunséus, Urology therapist and Bengt Friedrich, Physician at the department.

A presentation on the topic was help by Madeleine and after followed a discussion and questions from the students. Katarina Gunséus and Bengt showed a treatment room and displayed the different catheters that are used today, both clean intermittent catheters (CIC) and long-term indwelling catheters.

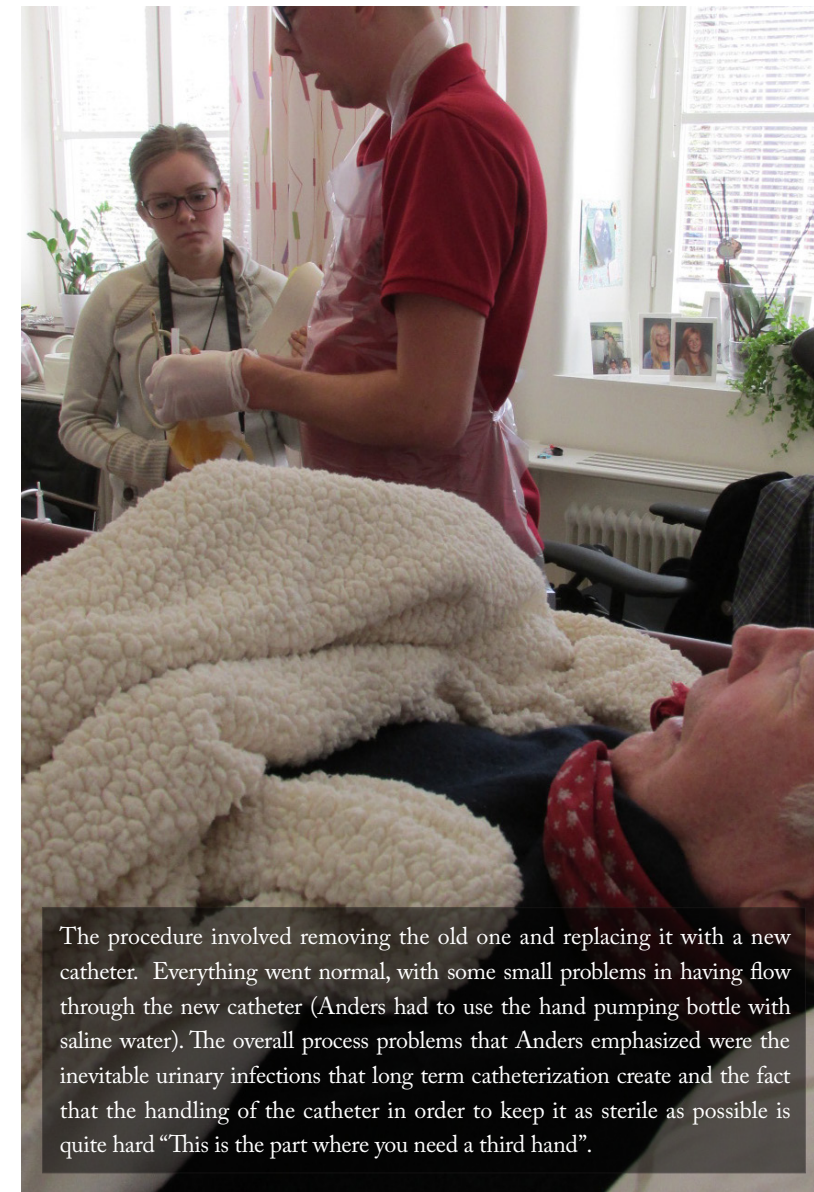


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## *Nursing Home*



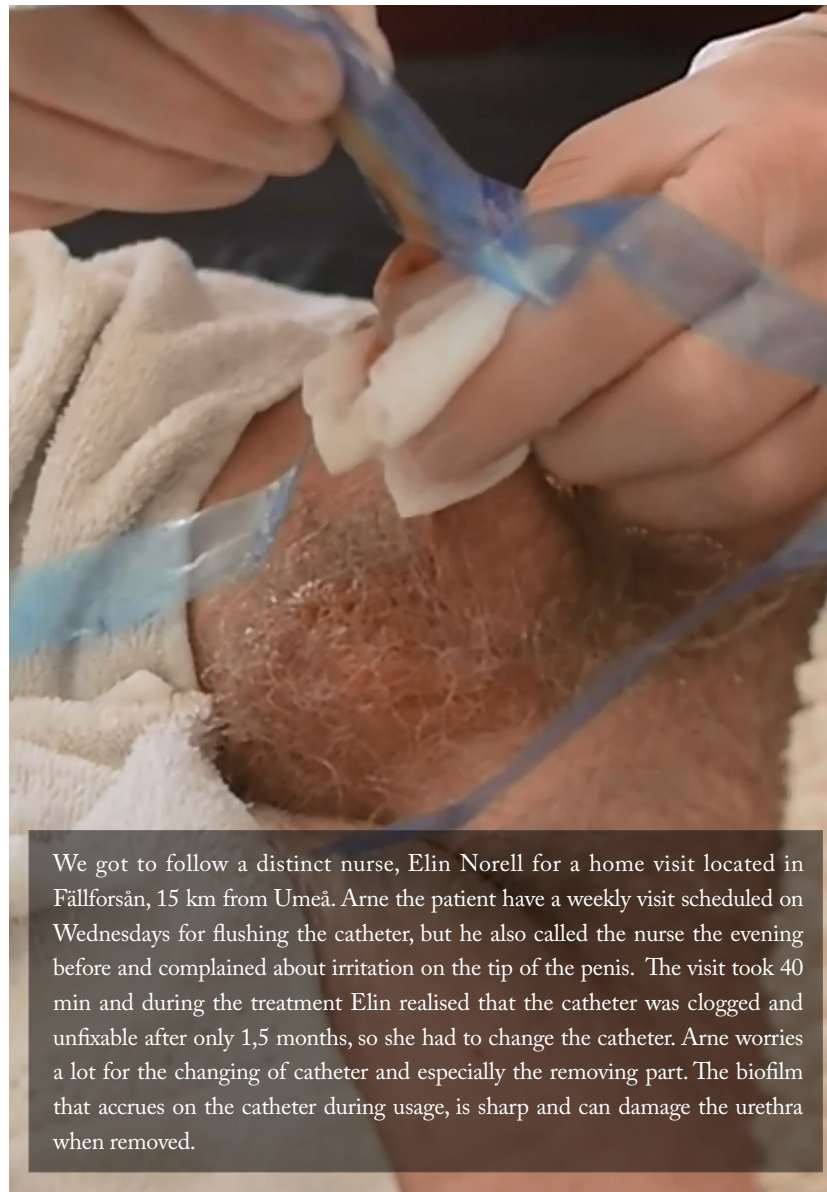
Our host was Anders Persson which works as a nurse in Umedalen, Aktrisens Nursing home. The patient he was taking care of, Lennart, was a 72 year old man, suffering from Alzheimer. He was unable to walk or speak and the only way to get some feedback was to follow his facial expressions. The task that he had to perform, under our observation, was replacing of the long term catheter (after 11 weeks of usage).



The procedure involved removing the old one and replacing it with a new catheter. Everything went normal, with some small problems in having flow through the new catheter (Anders had to use the hand pumping bottle with saline water). The overall process problems that Anders emphasized were the inevitable urinary infections that long term catheterization create and the fact that the handling of the catheter in order to keep it as sterile as possible is quite hard “This is the part where you need a third hand”.

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## *Home Vist*



We got to follow a distinct nurse, Elin Norell for a home visit located in Fällforsån, 15 km from Umeå. Arne the patient have a weekly visit scheduled on Wednesdays for flushing the catheter, but he also called the nurse the evening before and complained about irritation on the tip of the penis. The visit took 40 min and during the treatment Elin realised that the catheter was clogged and unfixable after only 1,5 months, so she had to change the catheter. Arne worries a lot for the changing of catheter and especially the removing part. The biofilm that accrues on the catheter during usage, is sharp and can damage the urethra when removed.

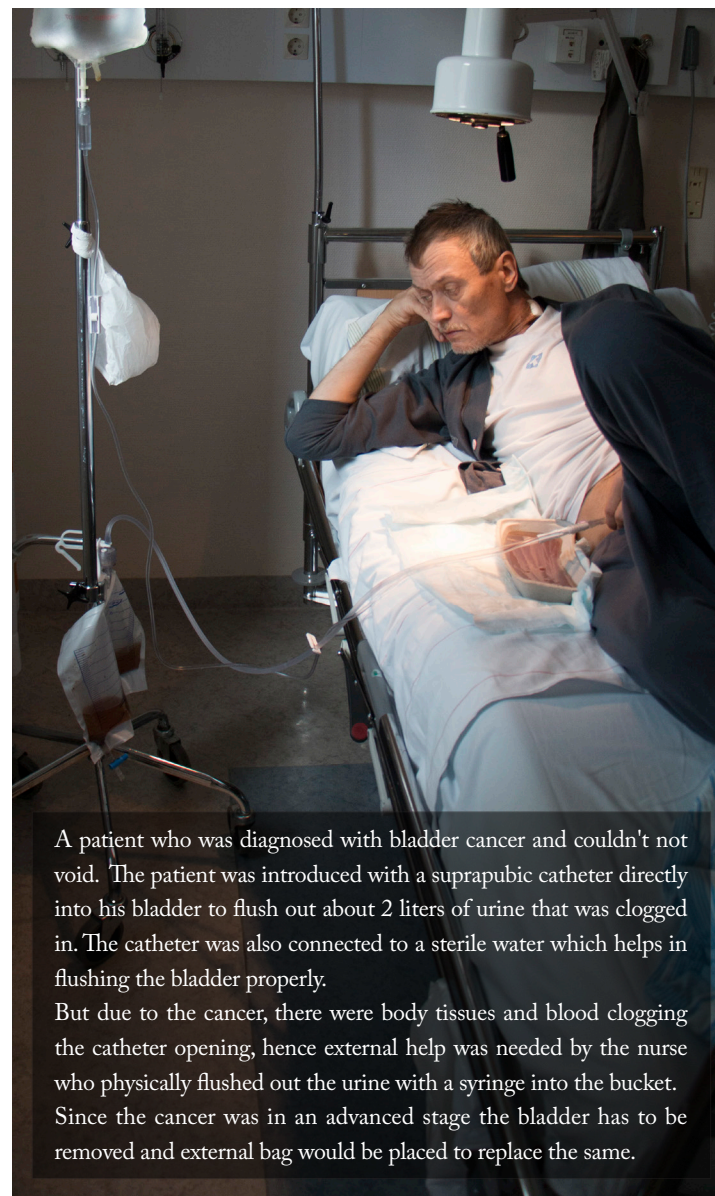


## Catheter Change + Measurements

During the hospital visits, we were able to observe not only the discomfort and pain which the patients are having in different parts of the process depending on their condition, but also the difficulties that the nurses were having while trying to apply the procedure. We've seen that handling the medical equipment during the procedure is flawed and it is done differently by each nurse, and it might cause discomfort and hygiene problems to the patient depending on the patient's case. We also tried the ultrasound device for measuring the bladder size, and the equipment to measure the flushing pressure and rate when urinating. So, having an overview of those devices might inspire us for more holistic solutions.

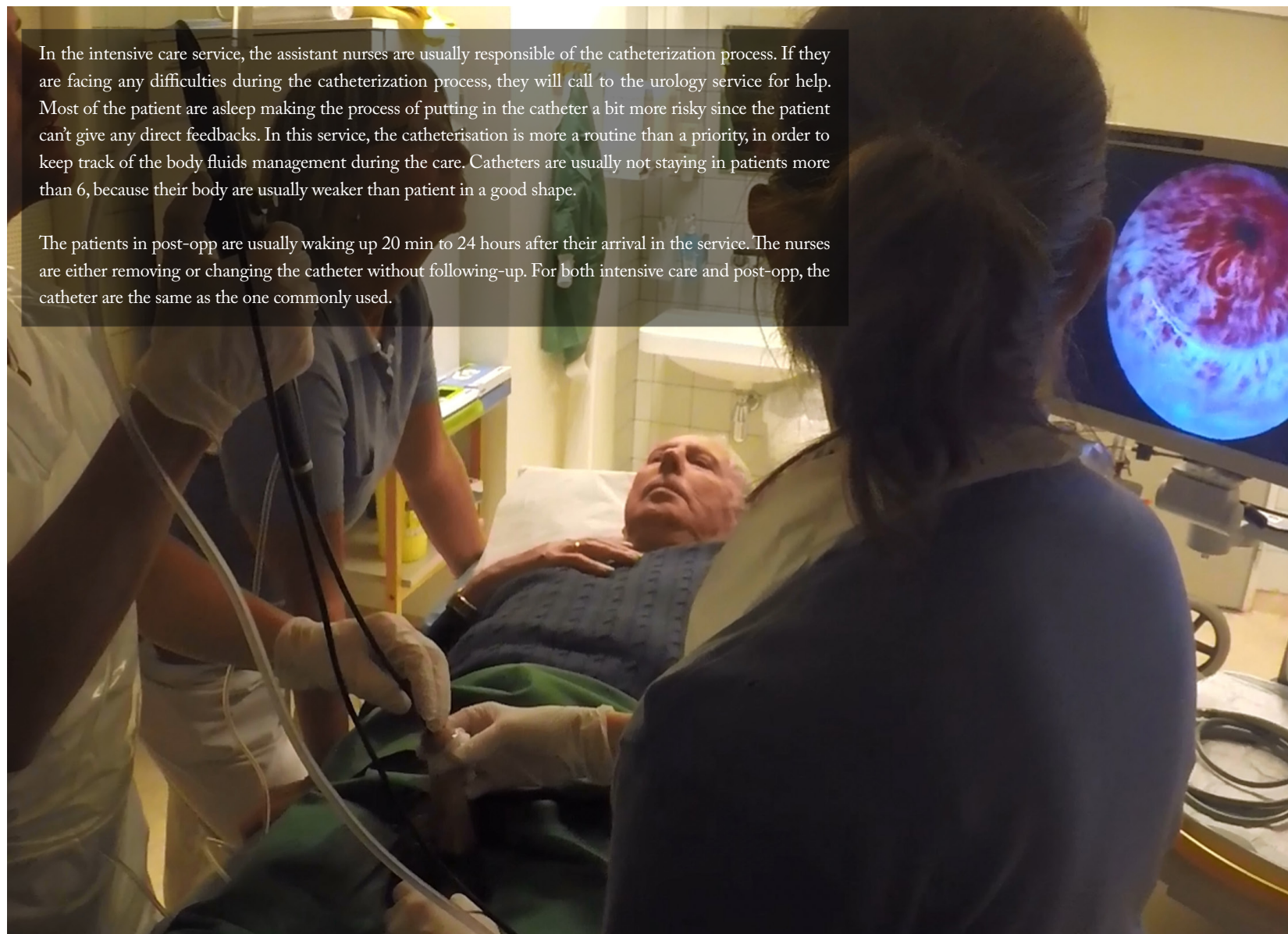


## Bladder Cancer Patient Vist



A patient who was diagnosed with bladder cancer and couldn't void. The patient was introduced with a suprapubic catheter directly into his bladder to flush out about 2 liters of urine that was clogged in. The catheter was also connected to a sterile water which helps in flushing the bladder properly. But due to the cancer, there were body tissues and blood clogging the catheter opening, hence external help was needed by the nurse who physically flushed out the urine with a syringe into the bucket. Since the cancer was in an advanced stage the bladder has to be removed and external bag would be placed to replace the same.

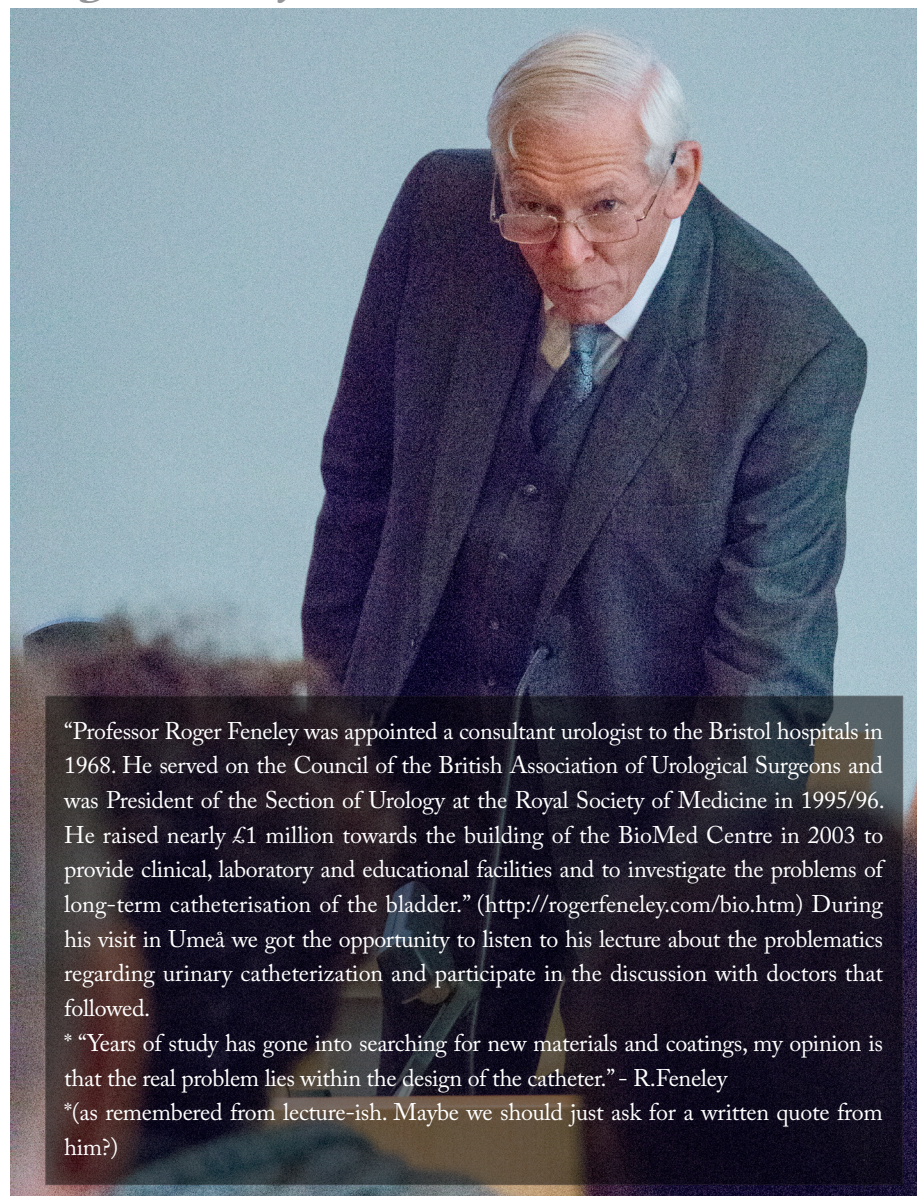
## Intensive care interview



In the intensive care service, the assistant nurses are usually responsible of the catheterization process. If they are facing any difficulties during the catheterization process, they will call to the urology service for help. Most of the patient are asleep making the process of putting in the catheter a bit more risky since the patient can't give any direct feedbacks. In this service, the catheterisation is more a routine than a priority, in order to keep track of the body fluids management during the care. Catheters are usually not staying in patients more than 6, because their body are usually weaker than patient in a good shape.

The patients in post-opp are usually waking up 20 min to 24 hours after their arrival in the service. The nurses are either removing or changing the catheter without following-up. For both intensive care and post-opp, the catheter are the same as the one commonly used.

## Roger Feneley Lecture



"Professor Roger Feneley was appointed a consultant urologist to the Bristol hospitals in 1968. He served on the Council of the British Association of Urological Surgeons and was President of the Section of Urology at the Royal Society of Medicine in 1995/96. He raised nearly £1 million towards the building of the BioMed Centre in 2003 to provide clinical, laboratory and educational facilities and to investigate the problems of long-term catheterisation of the bladder." (<http://rogerfeneley.com/bio.htm>) During his visit in Umeå we got the opportunity to listen to his lecture about the problematics regarding urinary catheterization and participate in the discussion with doctors that followed.

\* "Years of study has gone into searching for new materials and coatings, my opinion is that the real problem lies within the design of the catheter." - R.Feneley  
\*(as remembered from lecture-ish. Maybe we should just ask for a written quote from him?)





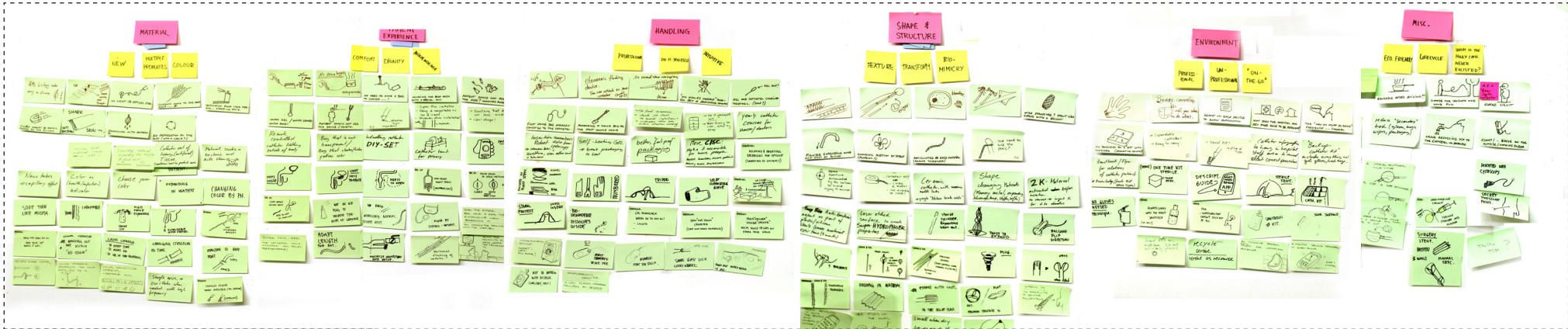
## General

1. Whats the costs of a Catheter kit (Catheter, bag and valve)
2. Why do they not burn the prostata more often?

## Preparation

1. Should you check the ballons condition before inserting it? And how do you do that?
2. Why not use the Luer-lock on the connections?(twist and unlock)
3. Whats the best way to make a sterile environment?

## Ideation Session



## Environment

- Storage and kit and mobility
- Organisation
- Process
- Natural flow
- Work place

## Materials

- |                |               |
|----------------|---------------|
| Infection      | Structure     |
| Handling       | Work place    |
| Confort        | Easy cleaning |
| Reminder/Guide | Confort Nurse |

## Handling

- Material innovation
- Hygiene
- Infection

## Shape & Structure

- |              |                   |
|--------------|-------------------|
| Tip redesign | Confort           |
| Product      | Product           |
| Leakage      | Defect of product |
| Shape        | Mel injuries      |

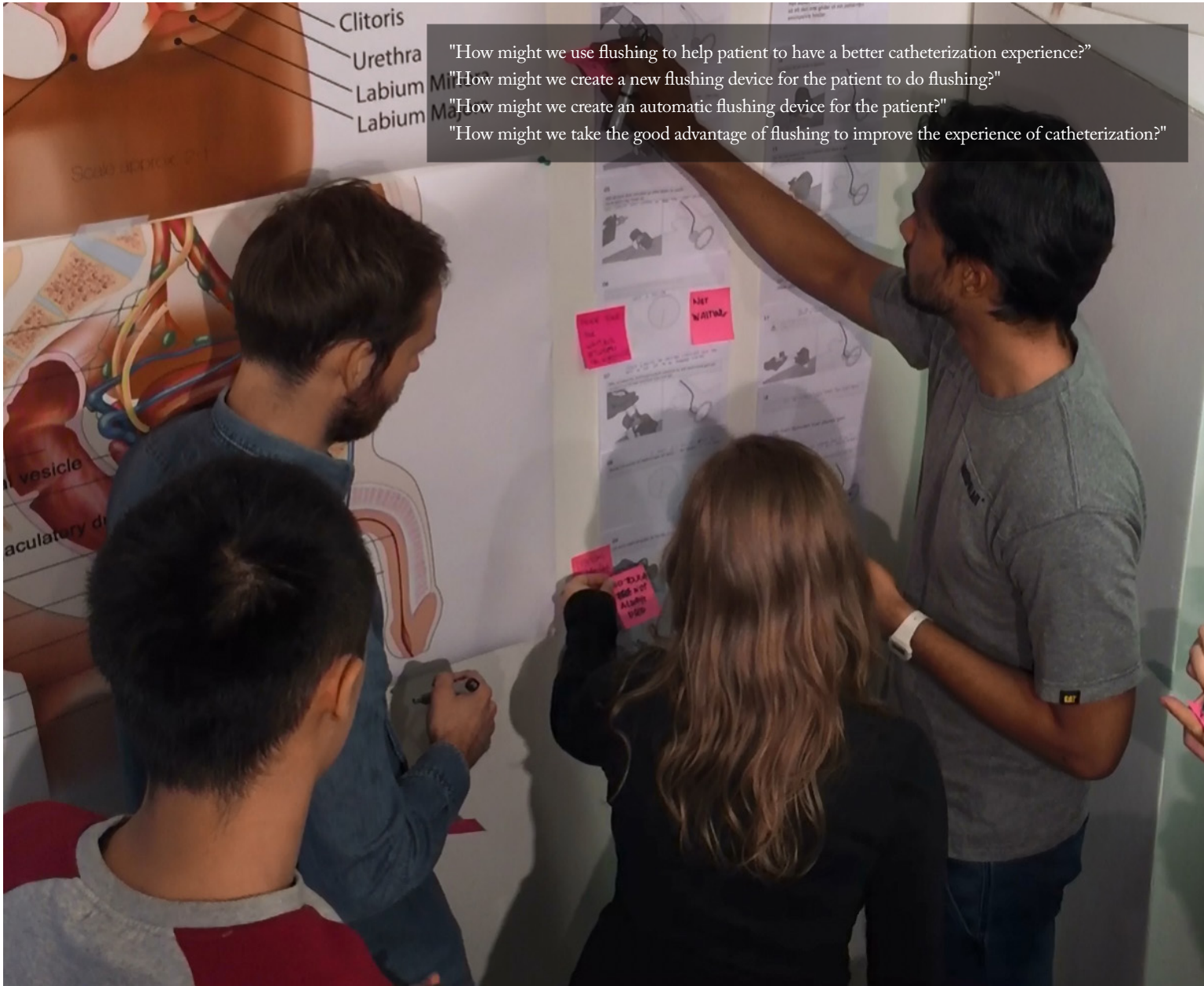
## Patient experience

- Stigma
- Holistic experience
- Life quality

## Misc

- Lifecycle
- Eco-friendly

## H.M.W. Session





Important Quotes regarding Flushing from



Katarina Gunséus :

“You use the flushing tool to do the flushing, and push the salt water into the patient’s blader and drain the water back within urine and bactateria left insde of blader. And you normally do it again by pushing the contagious water into the blader again in order to have enough flush.”

“Flushing is not bad, always good.”  
“Normally once a week to do the flushing by using salt water,but it depens on the patient, it is not necessary.”

"Long-term catheterization carries a significant risk of urinary tract infection. "

“The urine left inside of your blader because of the design problem of current catheter creates perfect condition for bacteria to grow into biofilm and result in infection during long-term use.”

“The patient come to the hospital to change their catheter normally after 11-12 weeks depends on different situations. Some of the catheter are cleanner than others, we do not know why.”

Bengc :

“The flushing is just to flush the remaining stones and bad bacteria out of your body to get rid of the clogg. And it’s more about get through the prostate. I have never seen the flushing will solve the catheterization infection and I dont think it is a good idea.”

“The flushing may also flush the good bacteria out of your urine system, too often is not good.”

“Continues flushing is not possible and not good for your blader, because you have to imitate/mimic the expand and shrink of your blader original function.”

“If you increase the times of flushing, you will also increase the chances of get infected.”

“The only reason to do the flushing is to get rid of the clogg.”

"The keeping of nature flow function of your blader is more importatnt than flushing."

Practical Bible

“You shouldn't do the flushing unlesvs you really need to.”



Q

“Will it be more effecient if we flush more times?”

A

“It could be a good way. We dont know, but it could be good.”

Q

“Will it be more effecient if we flush more times?”

A

“It could be a good way. We dont know, but it could be good.”

Q

"If they can D.I.Y, will it be better?"

A

“They should be able to do the flushing by them selfs.”

Advantage

Flushing

Disadvantage

- ①

Reduce infection risks by clean the left urine inside of the blader which creates perfect condition for bacteira to grow.
- ②

Catheter may be uesd longer before 12 weeks.
- ③

Get rid of clogg possibility can also reduce infection risks.
- ④

Patient should be able to do it by themself to keep flushing once a week.
- ⑤

Improve catheter duration before 12 weeks
- ⑥

The keeping of nature flow function of your blader is more importatnt than flushing.
- ①

You may also take good bacterias out of your body.
- ②

Flushing processure handling may increase infection chances.
- ③

Bring in bad bacterias along the cathether into blader.
- ④

Second-contagious salty water goes into blader due to normal process routine.
- ⑤

It is not mandatarly, so few people can keep going to hospital once a week to do the flushing.
- ⑥

Continues flushing is impossible and not good for your blader, because you have to imitate/mimic the expand and shrink of your blader original function.



Goals

- Using flushing feature to decrease the infection risk.
- Make flushing feature accessible for patient to process.
- Prevent second time water-contagious for present flushing tool.
- Help patients to form habit of flushing once a week.( whenever needed.)
- Get rid of infection possibility while changing urine bag to flushing tool.

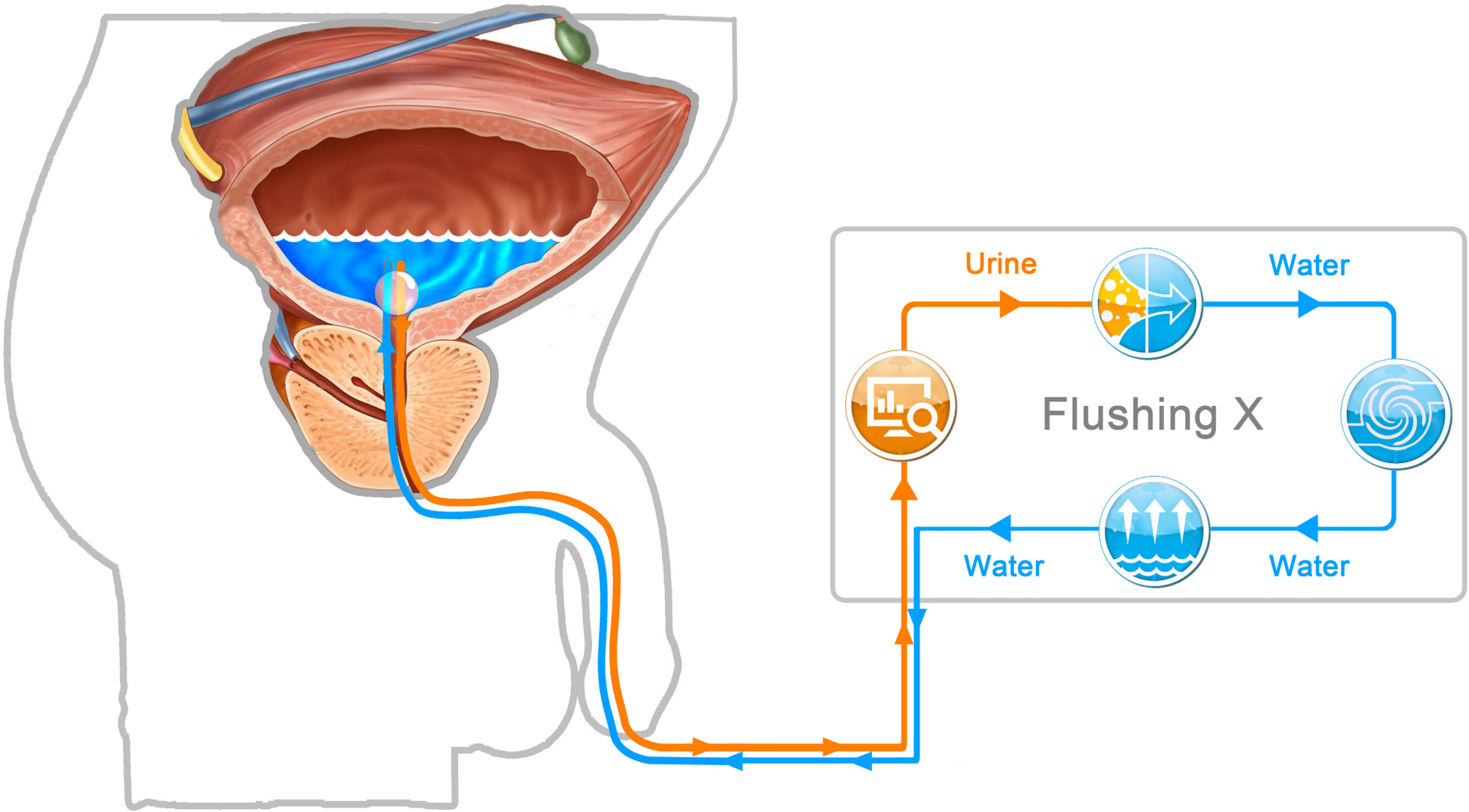
Wishes

- Keep the expand and shrink blader function while flushing.
- Do not disterb the original function while flushing.
- Make it possible for patient to do it by themself.
- Thinking from advantages of flushing to Improve catheteriazation experience for patient.
- Get rid of urine bag changing.







Flushing - X system flow

- ① Intelligent-sensor at the catheter tip tests the PH level of the urine in the bladder, and transfer that information to the Control center for processing to decide flushing or not.
- ② Once the PH level is not normal, the flushing starts.
- ③ First, urine comes to the Control center and stored at there till the volume is enough for flushing.
- ④ Then the Pump system starts working, and the Control center realeases the urine which goes to the Filtration system.
- ⑤ After the urine is filtered into "Ideal water", the Pump system pushing the "Ideal water" into bladder to do the flushing, as commanded from the Control center till the PH level is right.
- ⑥ Evaperation system is used for evaperating the unnecessary liquid in the circulation system, so the "Flushing - X" system can work as a normal catheter but without urine bag.

Flushing X



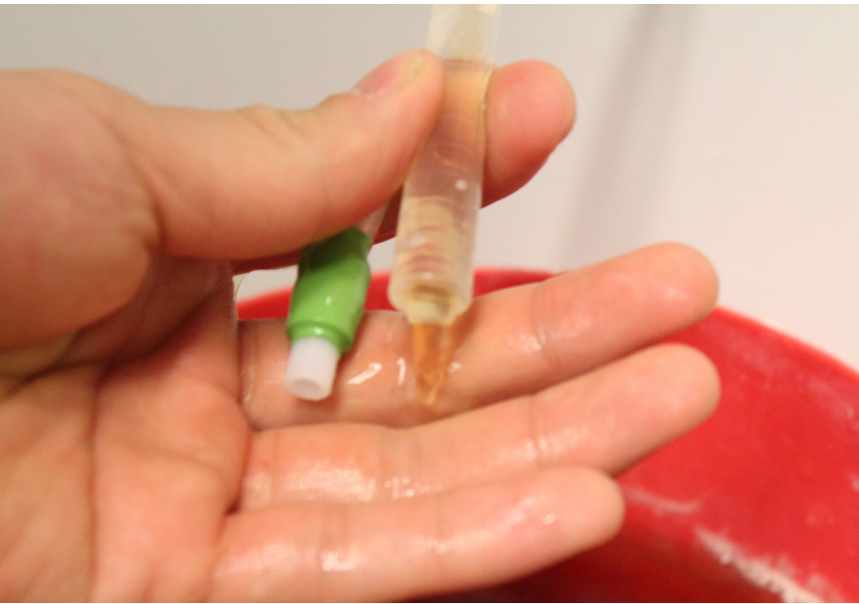
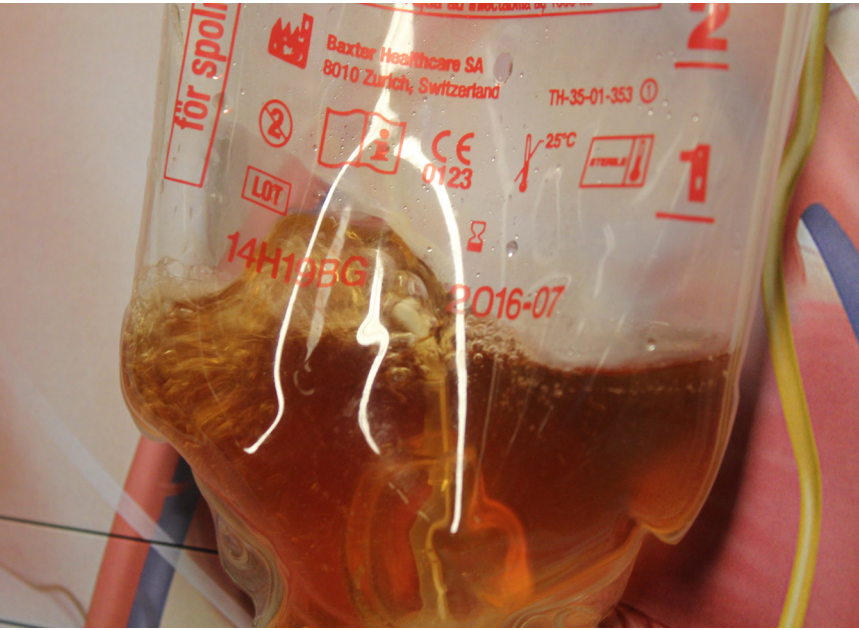
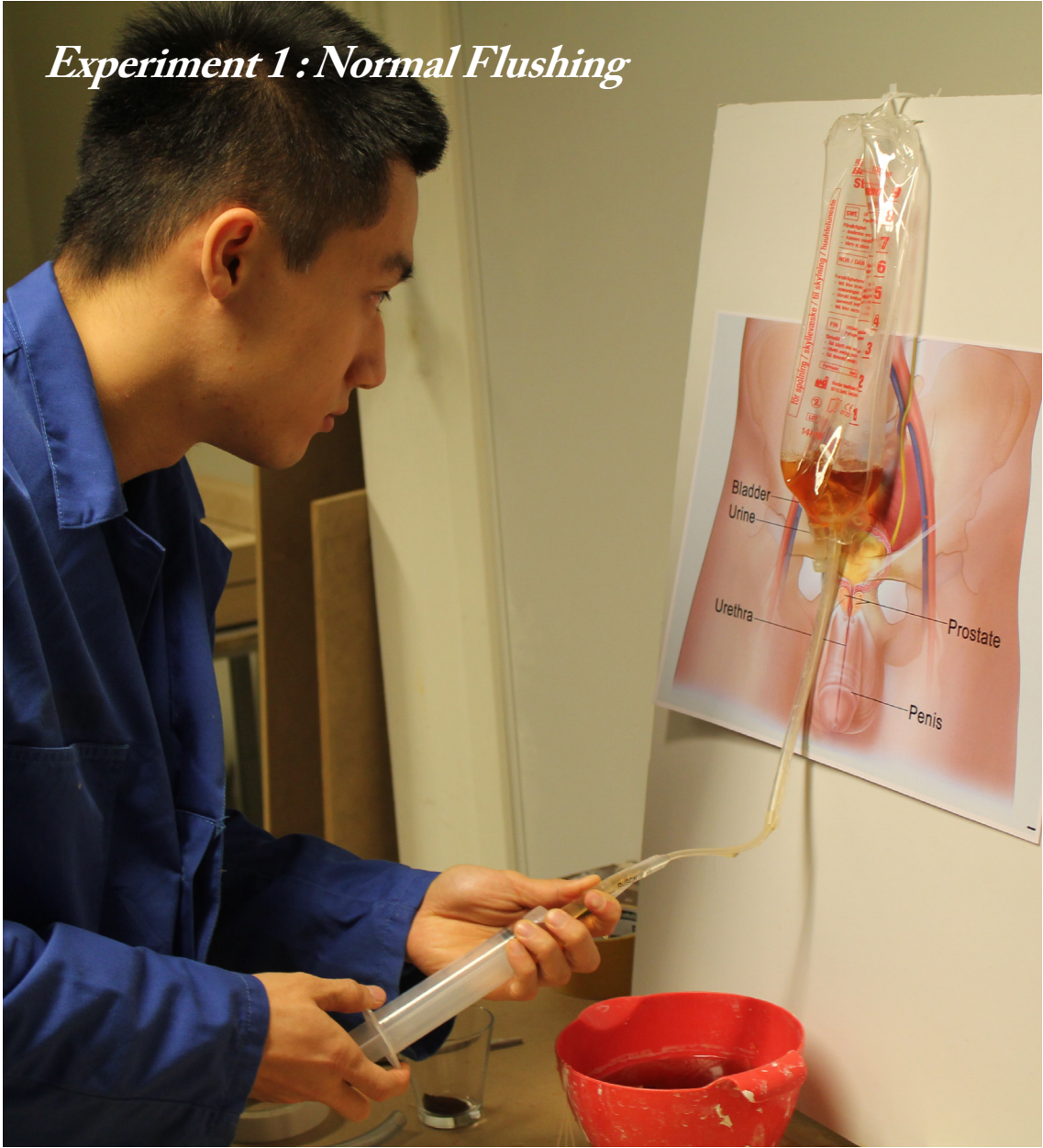
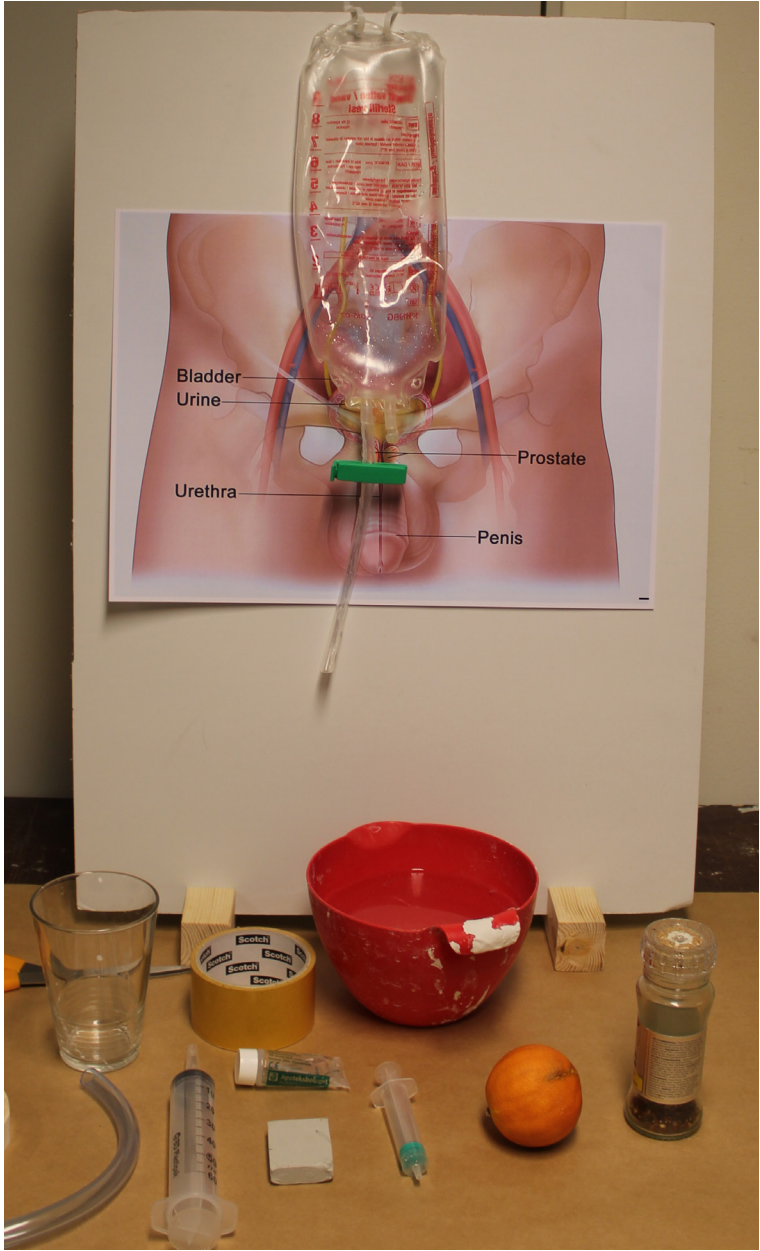
Details

-  **Water**  
"Ideal water" filtered from urine, which is perfect for flushing ues.
-  **Urine**  
Patient's urine.
-  **Control Center**  
Information center which controls all other units in the Flushing X device, responsible for creating a healthy catheterization flushing-circulation for patient.
-  **Filter**  
Undefined urine filtration, could filter urine to "Ideal water", not decided yet.
-  **Pump**  
Used as power system of the whole circulation.
-  **Evaperator**  
Evaperation system used for evaperating unnecessary liquid in the circulation system.

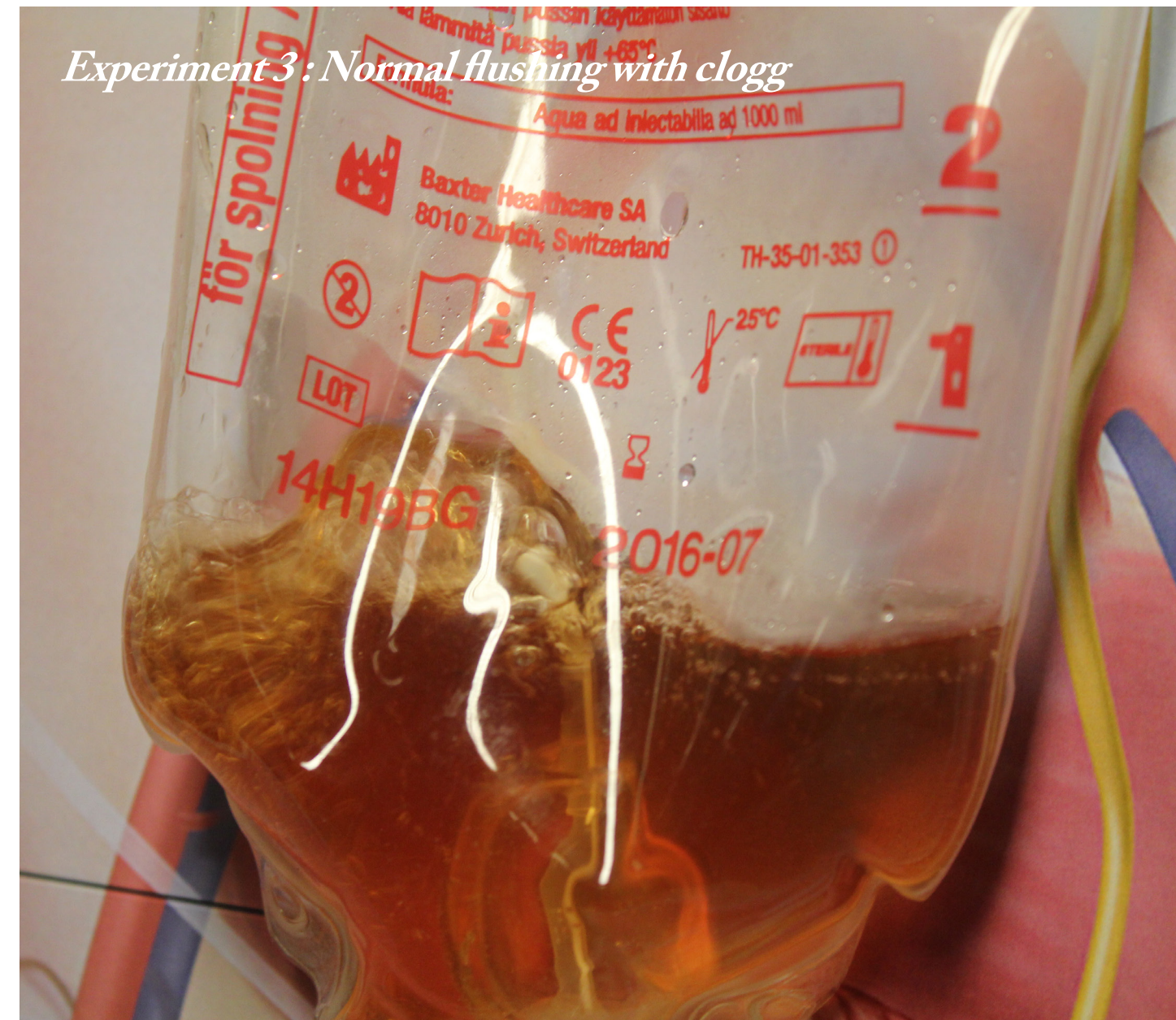
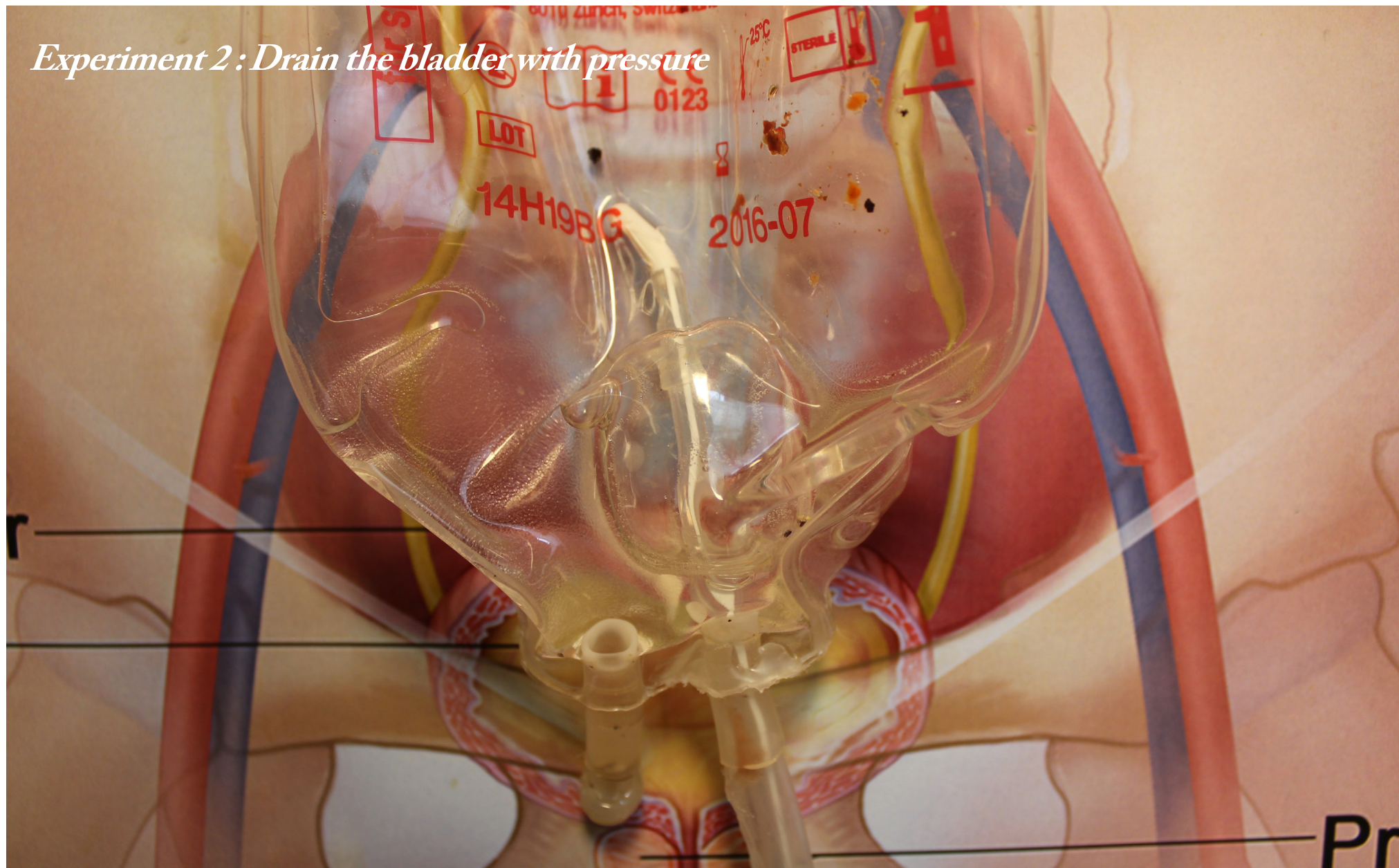


After I build up a moucup to test each of my qestion.

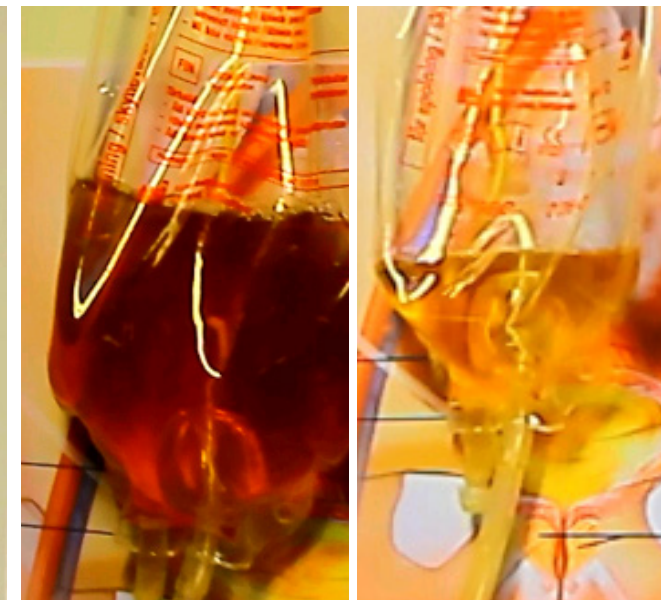
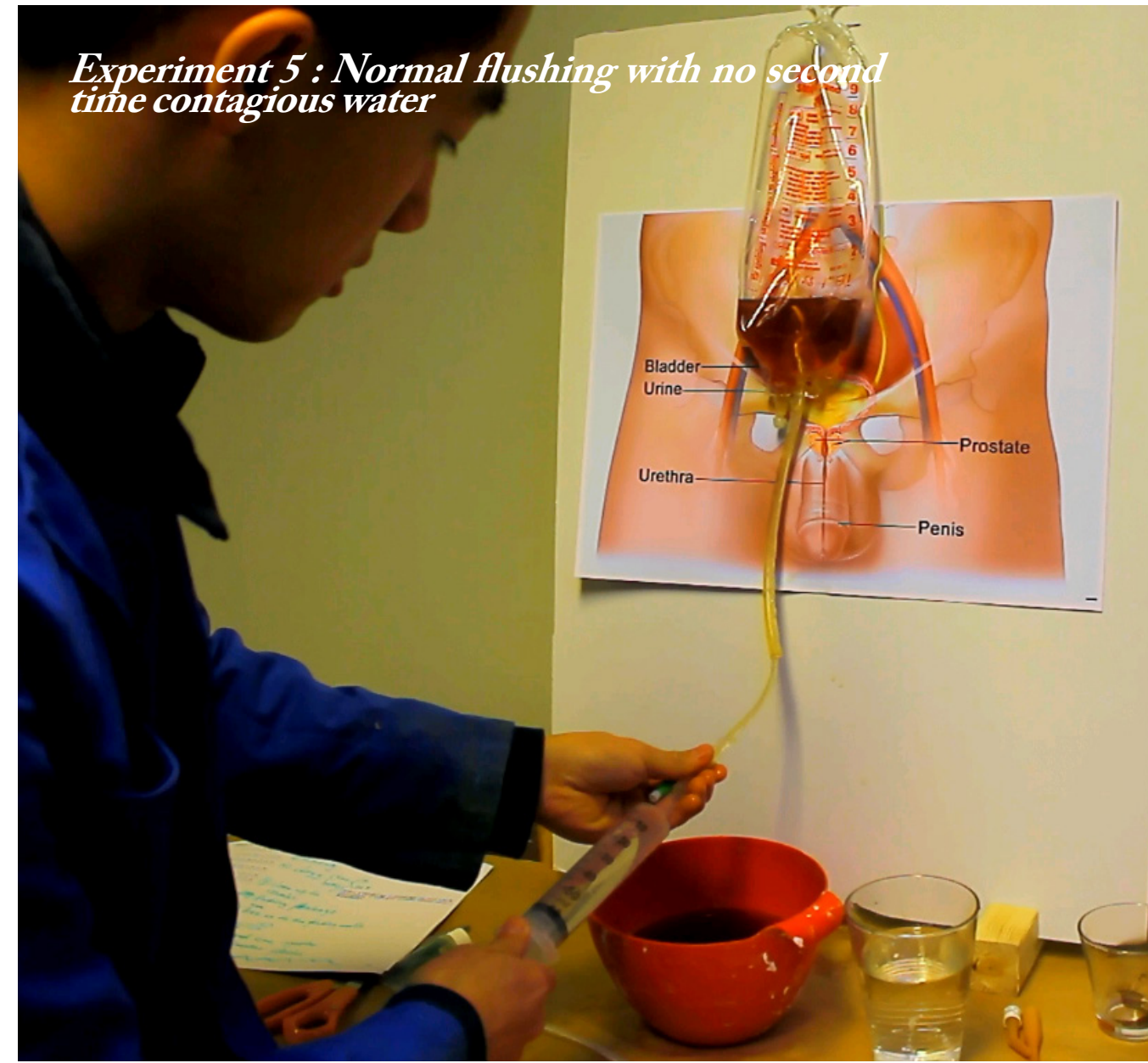
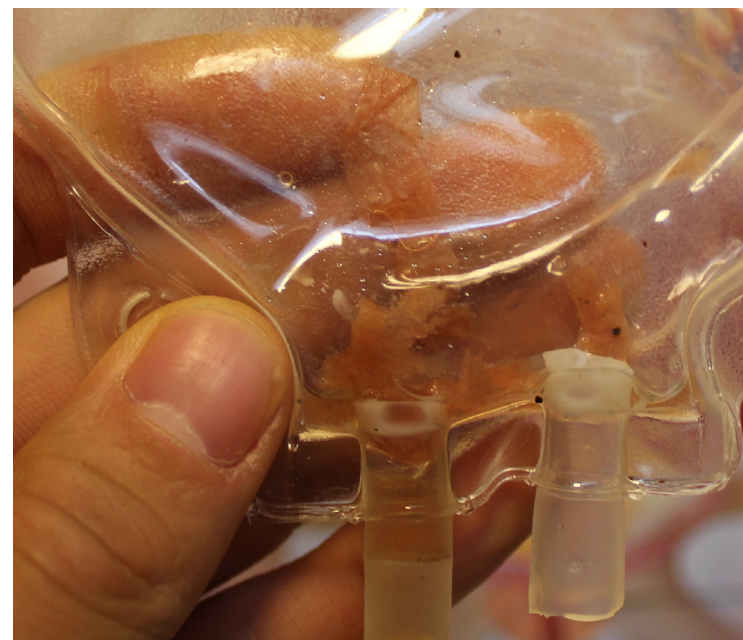
- ① Normal catheterization
- ② Drain the water with pressure
- ③ Normal flushing process (with clogg)
- ④ Normal flushing with old second time contagious water
- ⑤ New flushing with no second time contagious water.
- ⑥ Crazy!!!!!!!!!!!!!!!!!!!!!! Push forward and backward!!!













Conclusion

- ①
- Without considering the tissure damage (aperture) ,draining with pressure can empty the bladder fully. We do not need the drainage aperture to be as low as possible, we just need to make sure we do not damage the tissure.
- ②
- If we use clean water to do the second time injection while flushing, the bladder will be much cleaner than the other exp, the more the urine inside is diluted, the better flushing result will be. (No crunmbs left.)



WHAT IF session after experiment

- Experiment ①
- Normal catheterization  
● What if control the PH level in the bladder to decrease the risks of infection??
- Experiment ②
- Drain the bladder with pressure  
● For people who can not void, what if drain thei bladder with pressure? Then we do not need the drainage entrance to be as low as possible, we just need to make sure we do not suck the tissure.
- Experiment ③
- Normal flushing process (with clogg)  
● Will there be more way to get rid of the clogg? Once a week?
- Experiment ④
- Normal flushing with old second time contagious water  
● After flushing, how does the crumbs come out?
- Experiment ⑤
- New flushing with no second time contagious water.  
● What if we can prevent the second time contagious water by a new flushing tool?  
  
Crazy!!!!!!!!!!!!!! Push forward and backward!!!

IDEA 1: Power Drainage

1, Feel full, push "drainage" button.

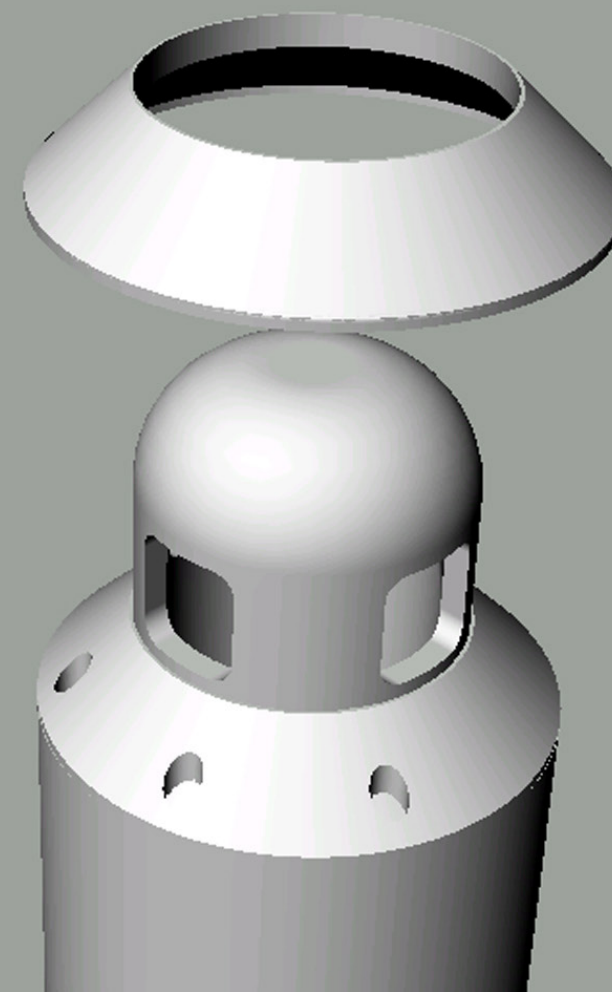
2, Clogg light flashes, DIY.

3, PH level, Injection other medicine / Changing

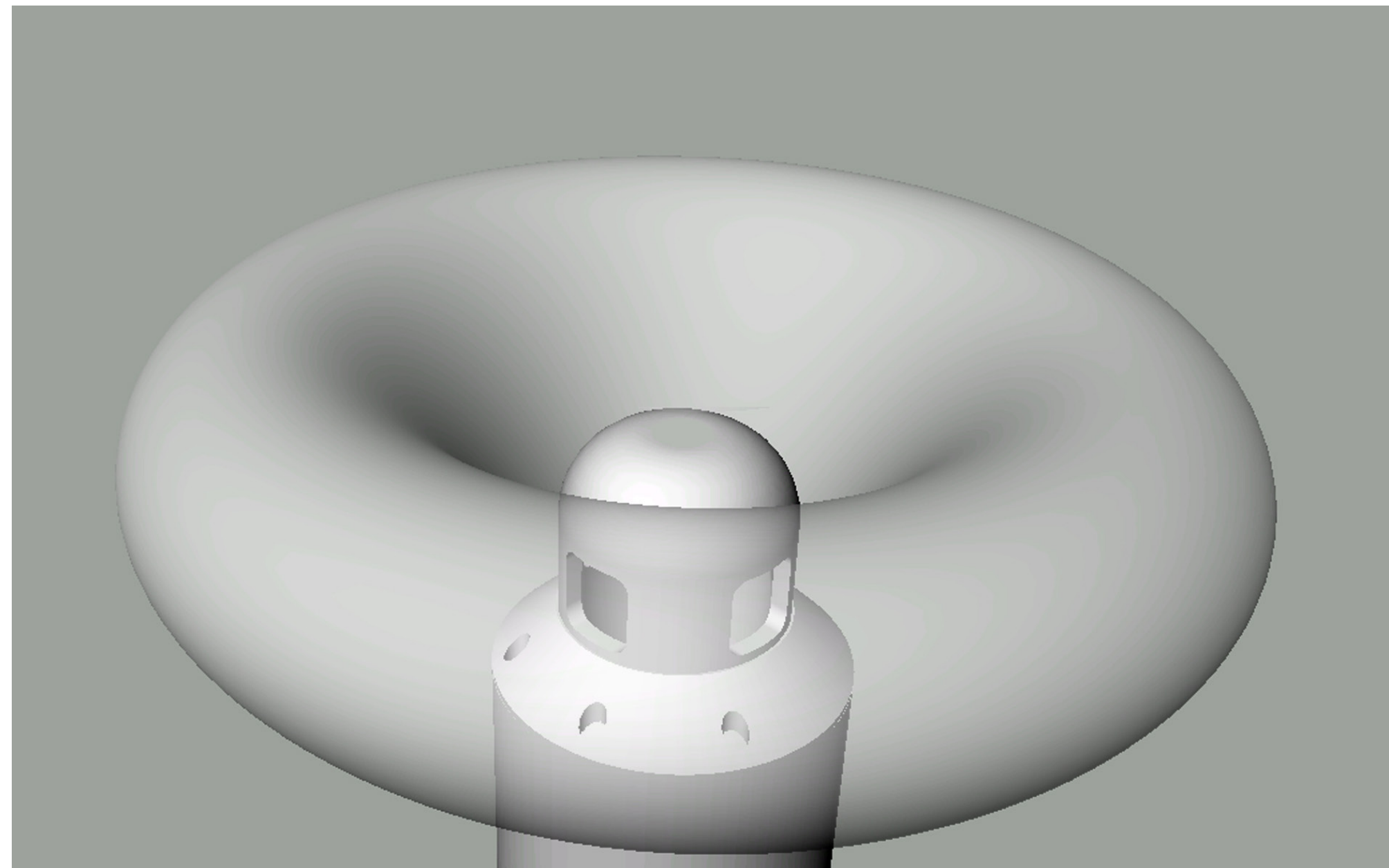
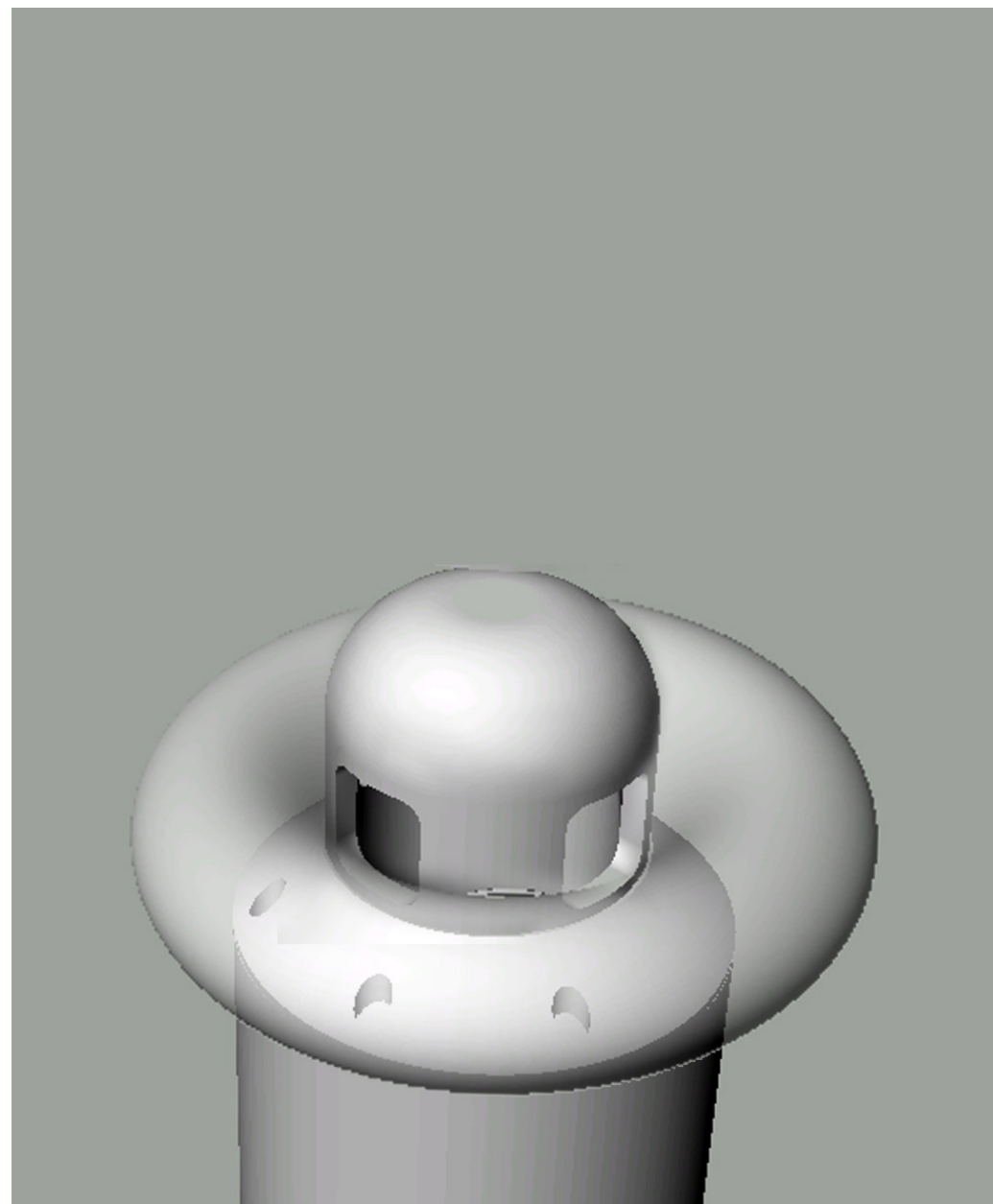
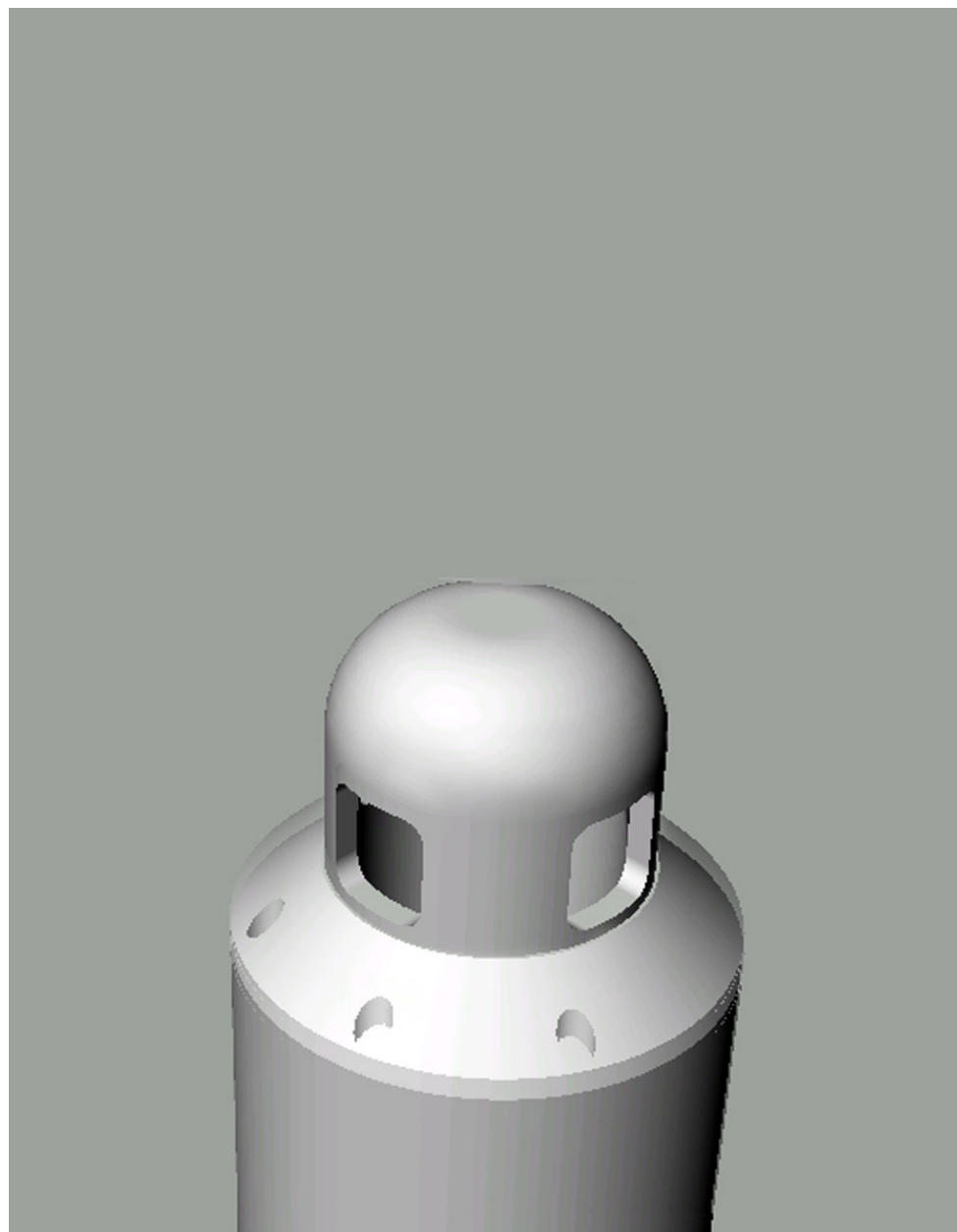




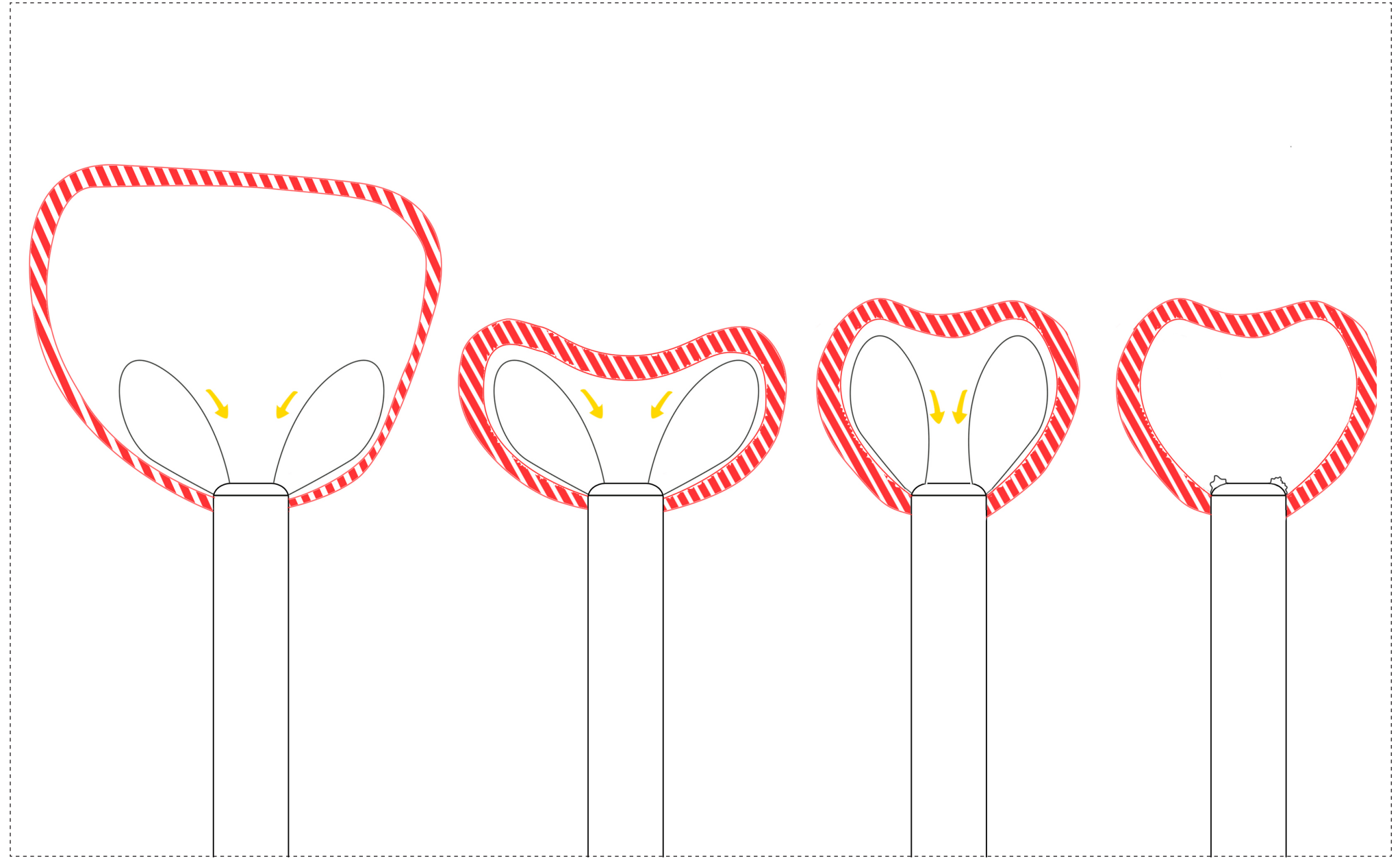
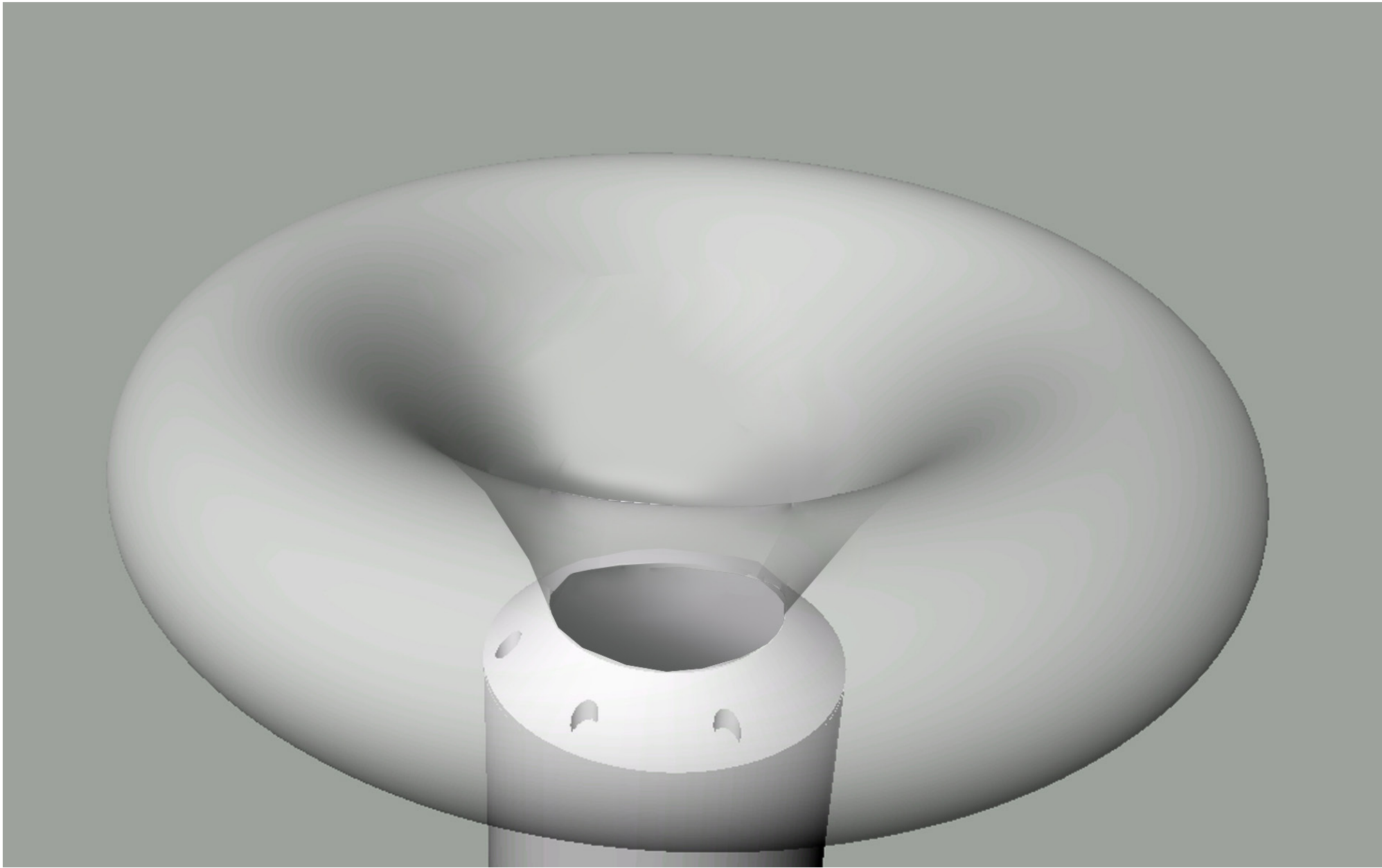
## IDEA 2: Bowl









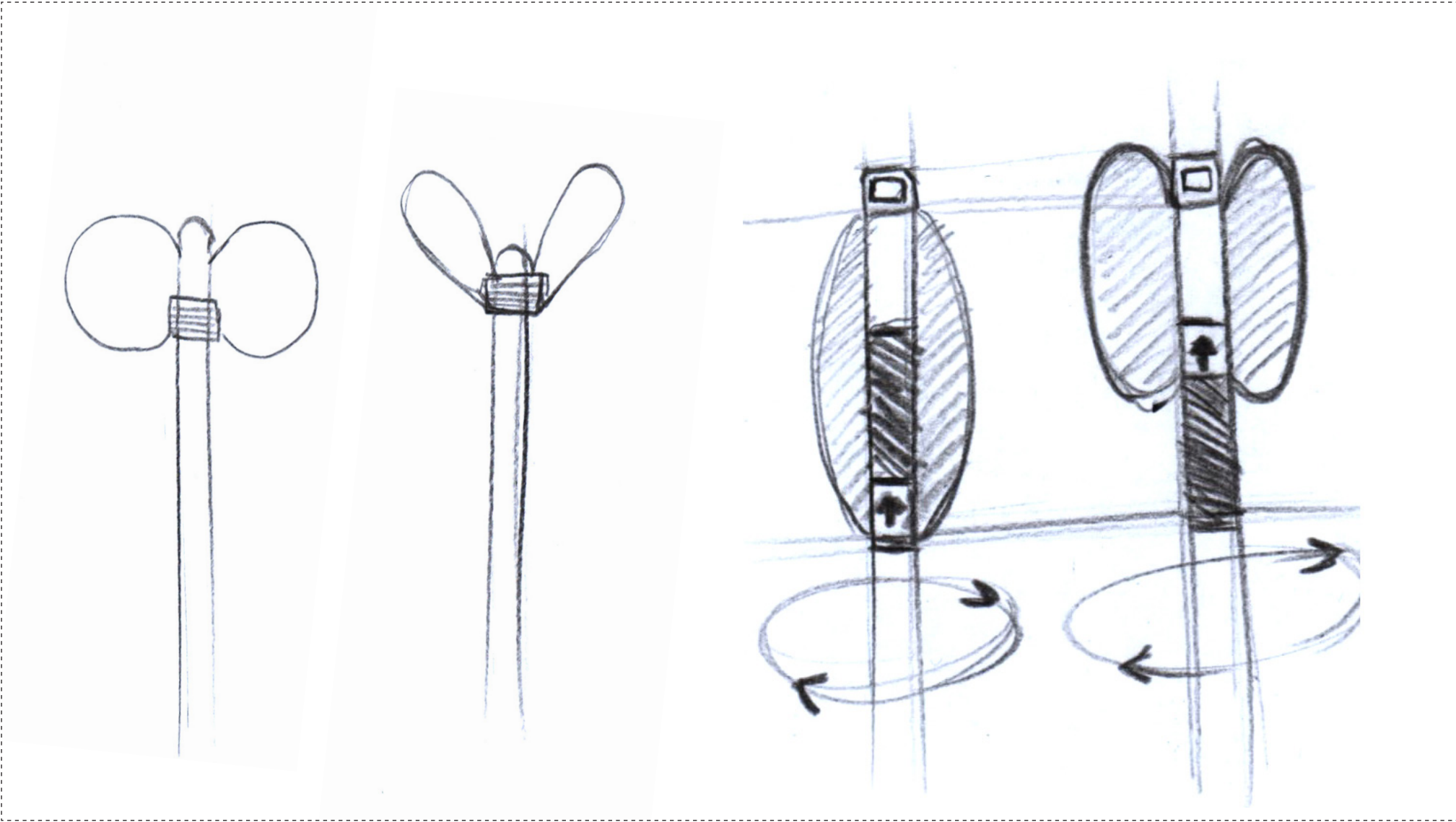






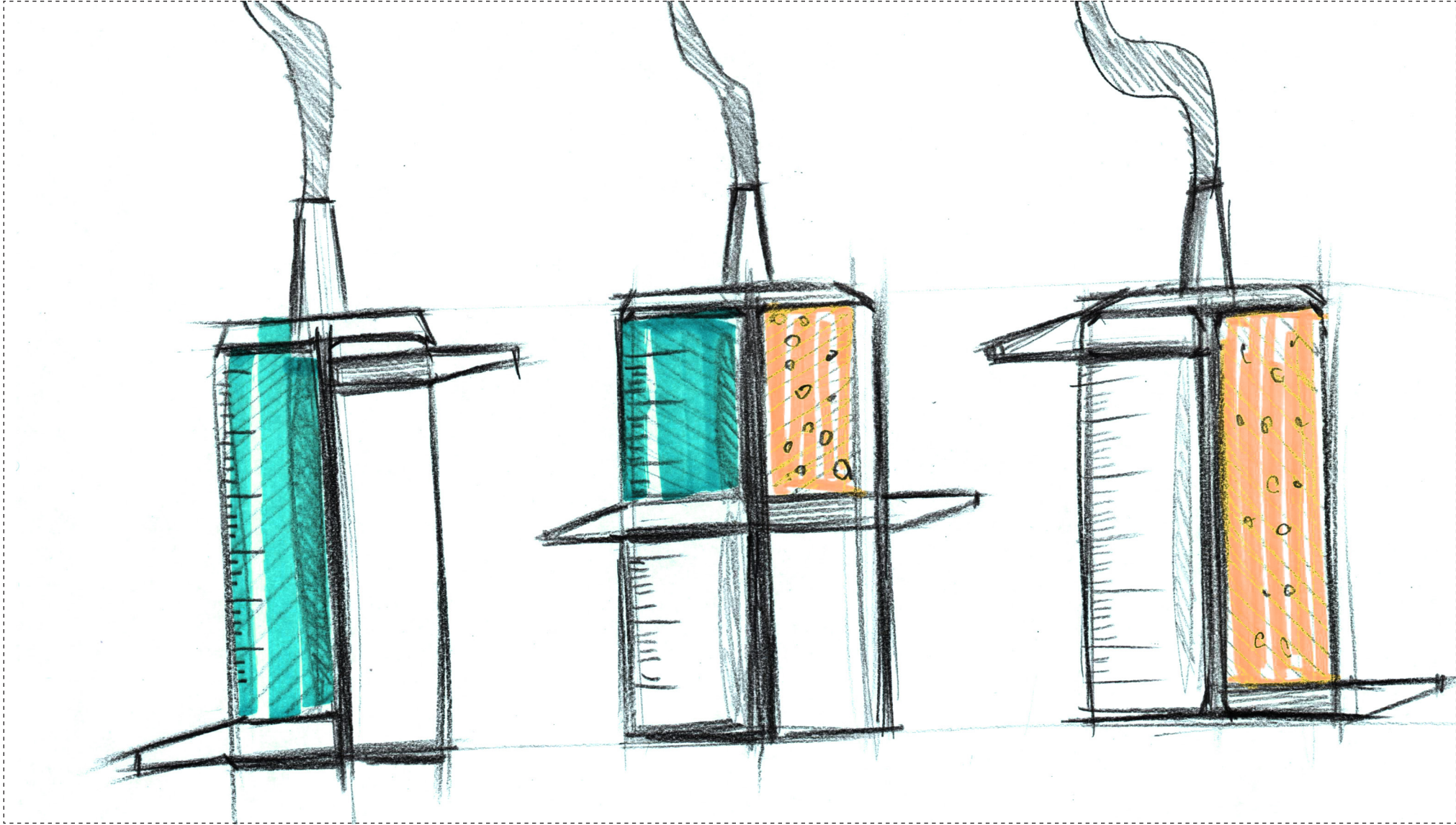


IDEA 4: Cage

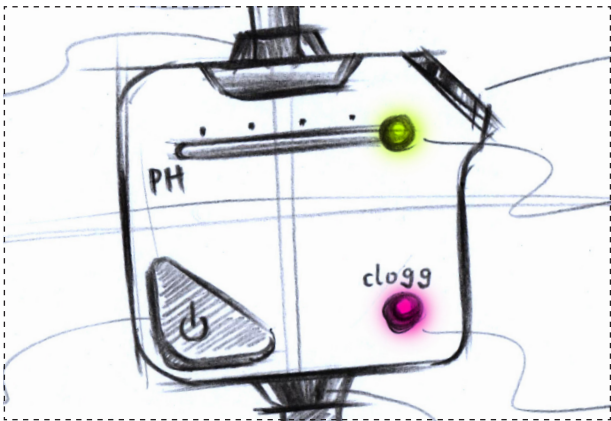




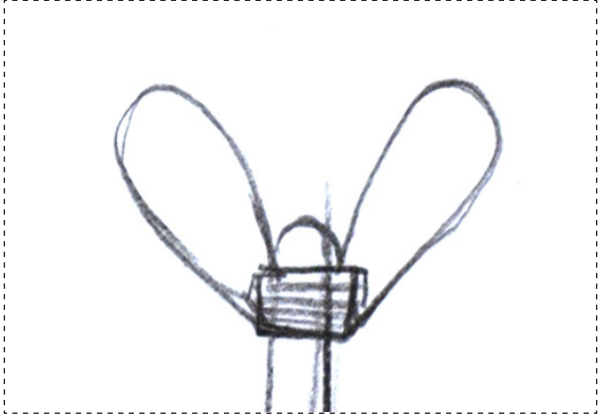
IDEA 5: New flushing



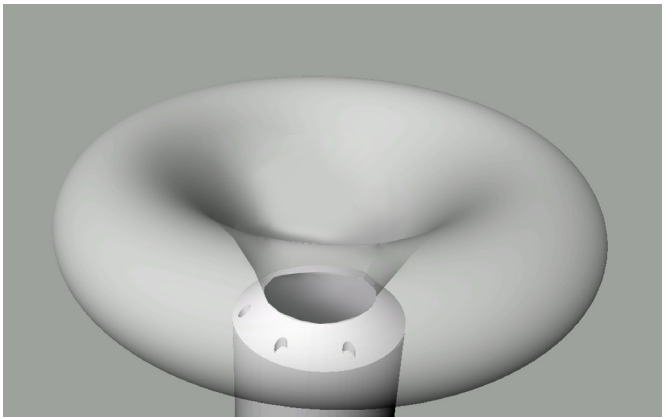
IDEA 1: Power Drainage



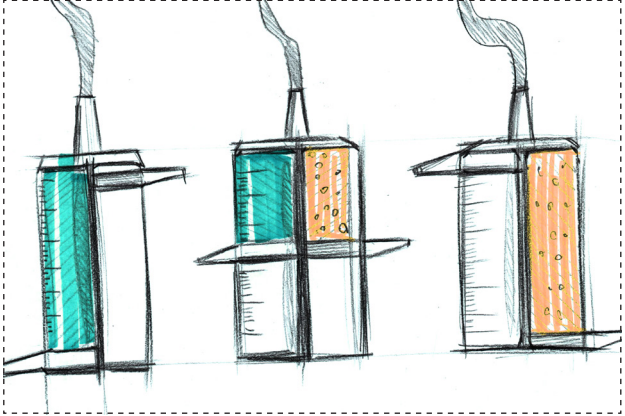
IDEA 4: Cage



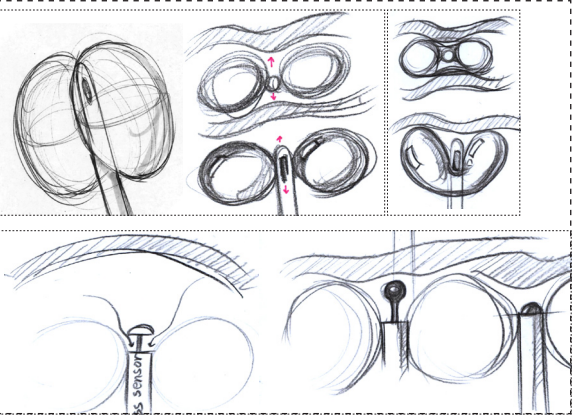
IDEA 2: Bowl



IDEA 5: New flushing

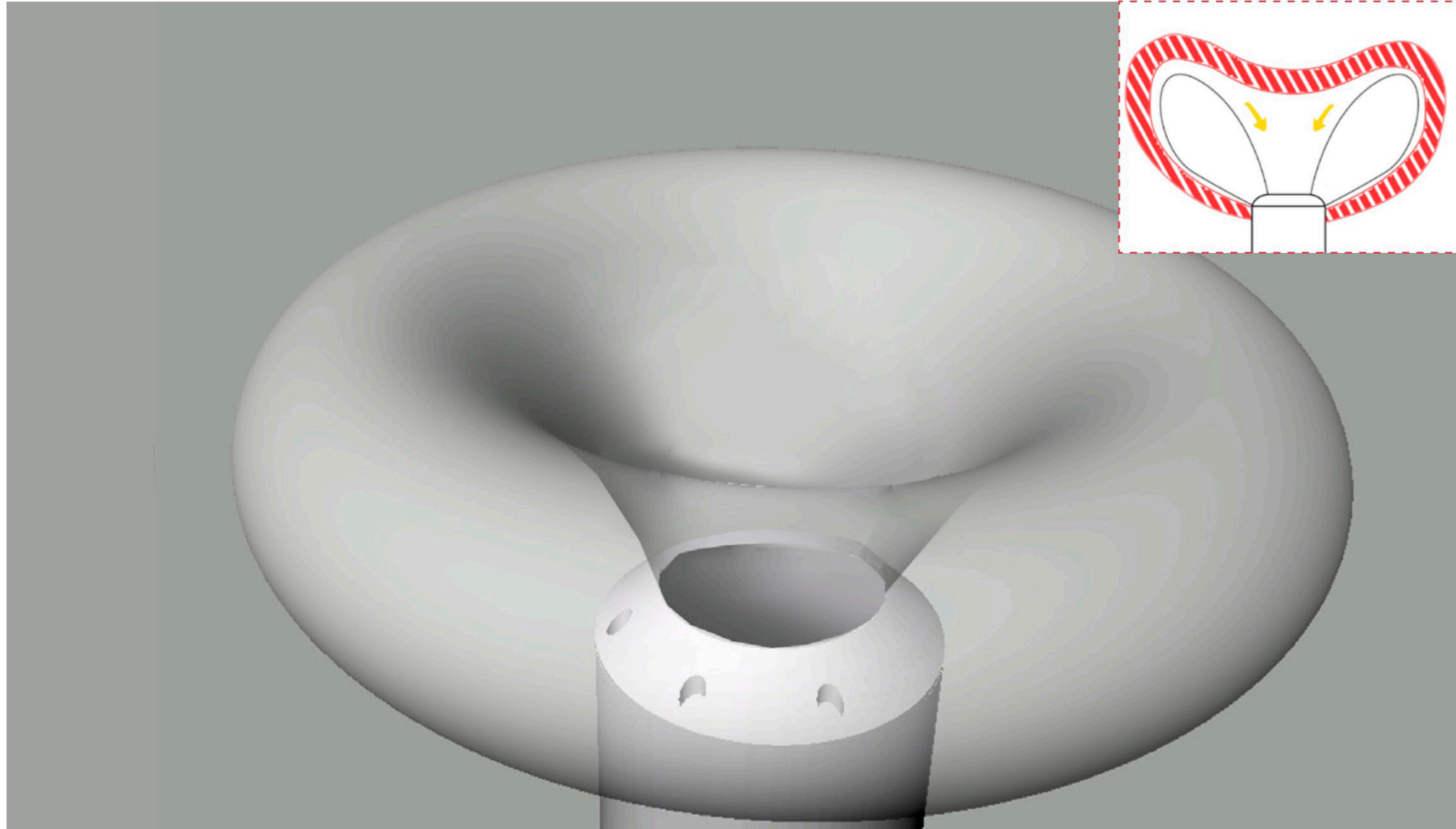


IDEA 3: Before Bowl

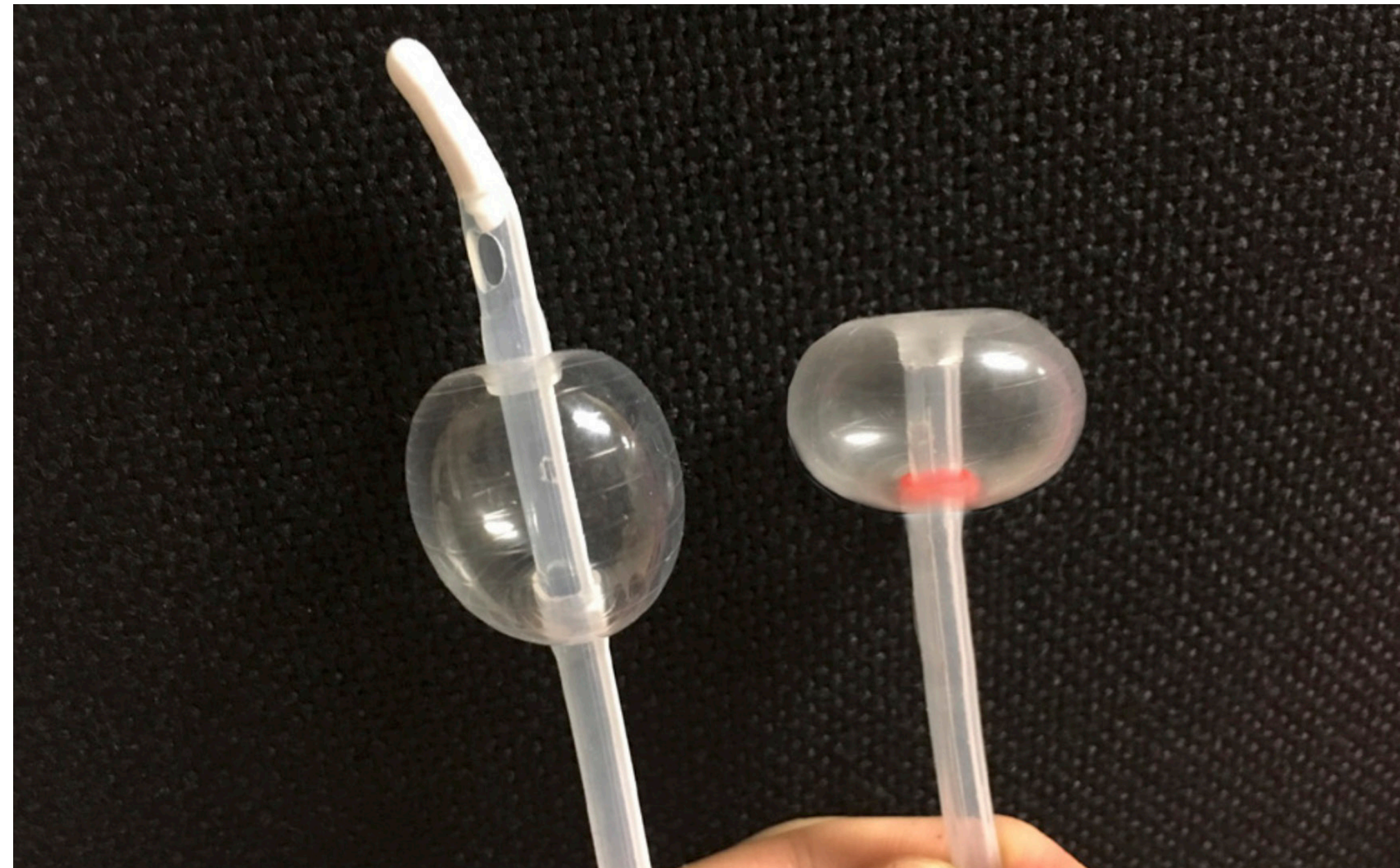




## Concept Refinement

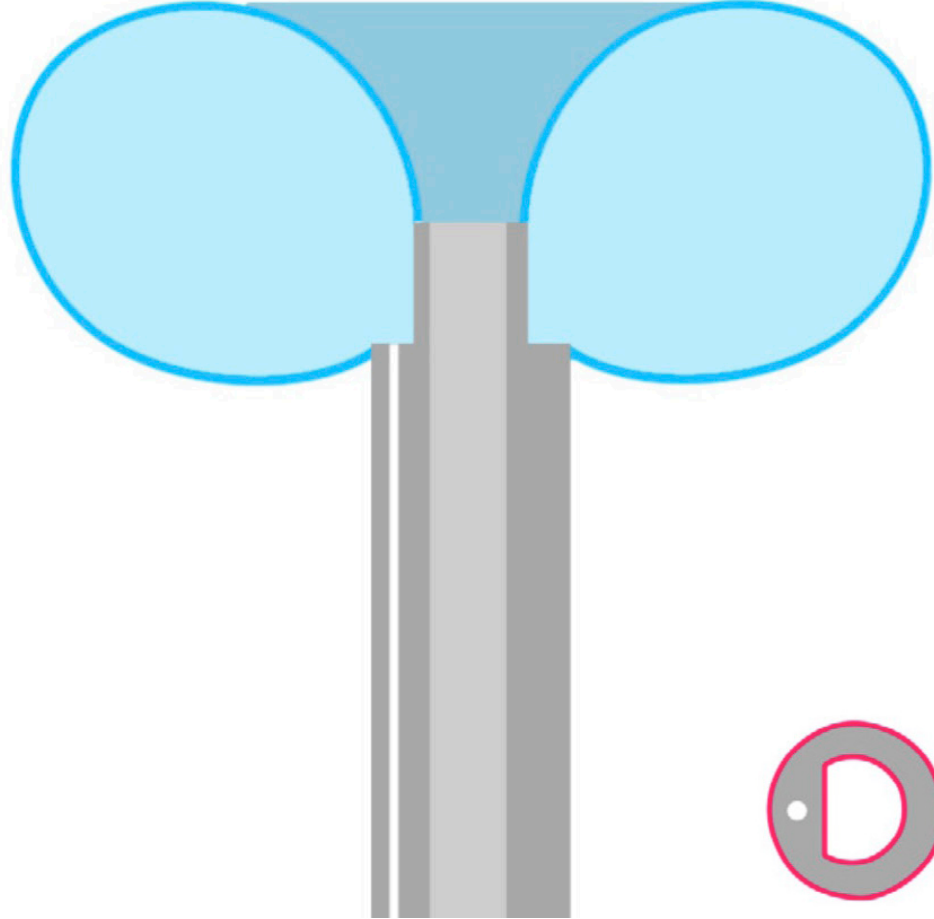
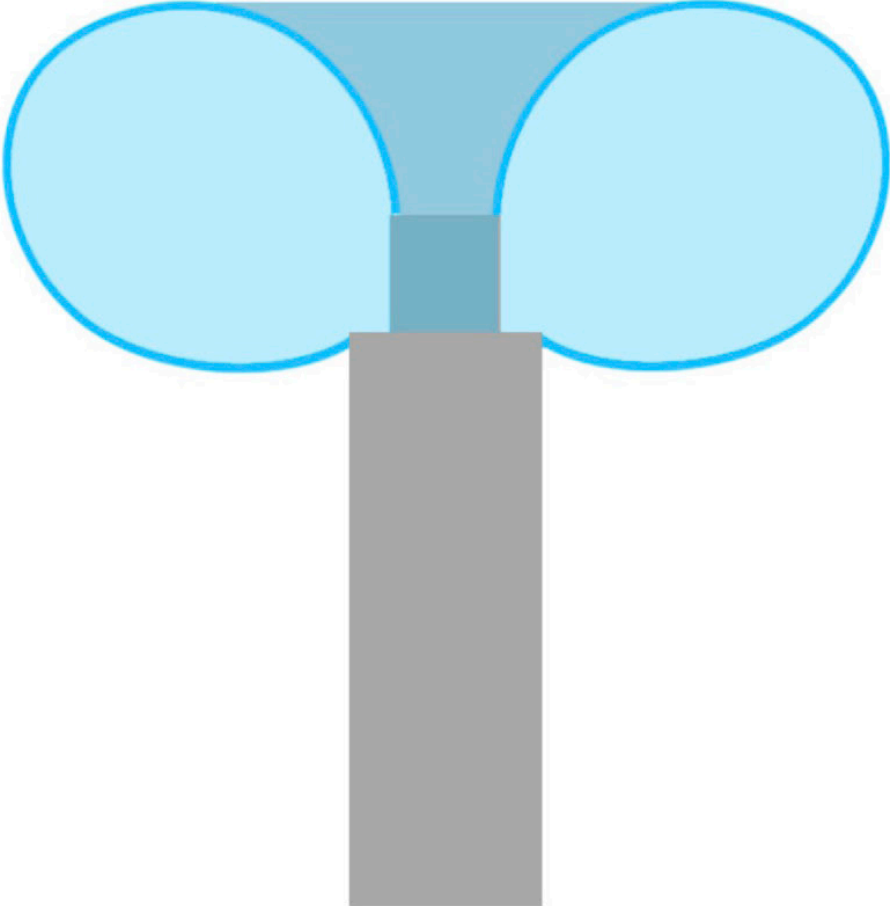






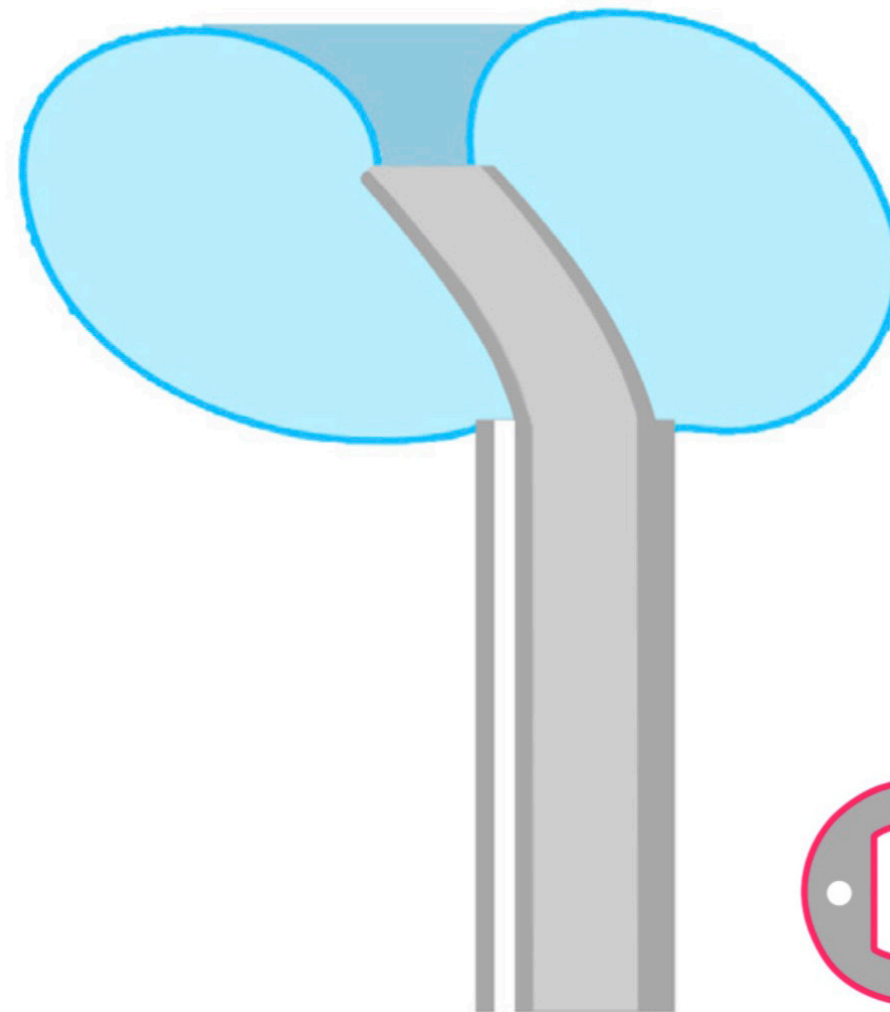
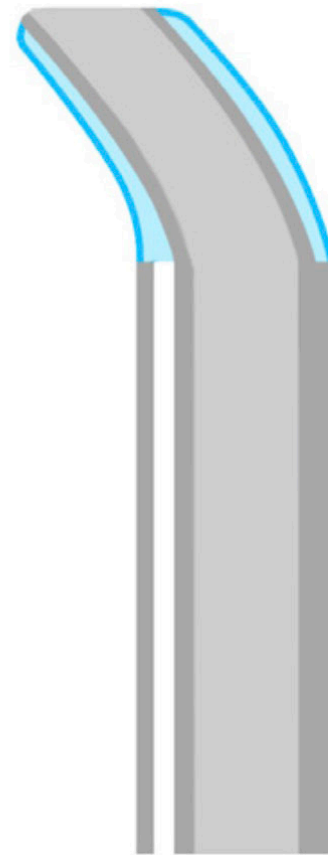
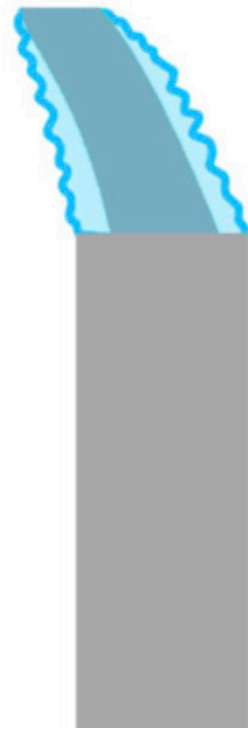
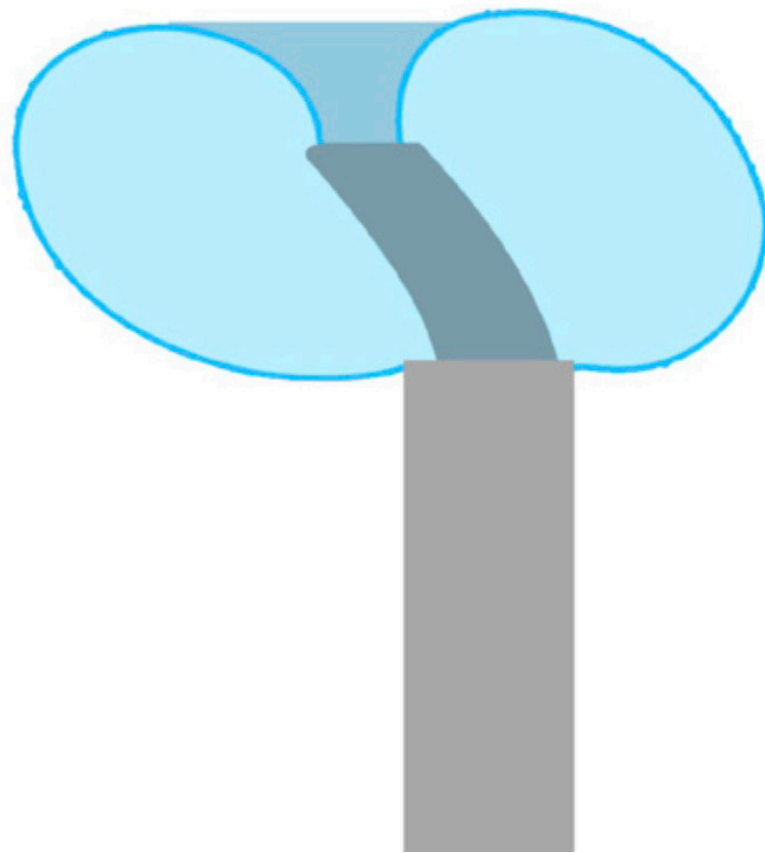


Concept (1)



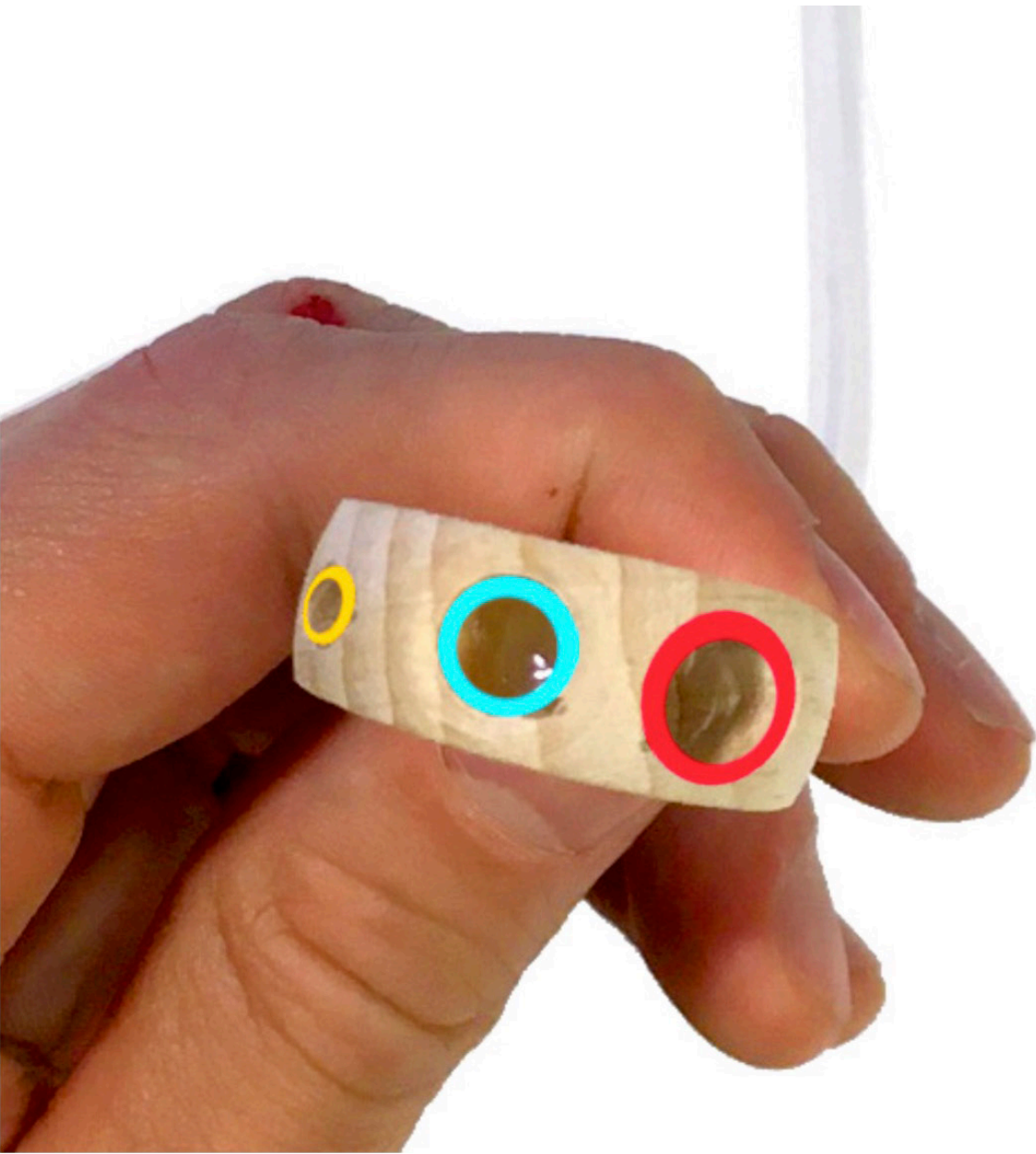


Concept (2)





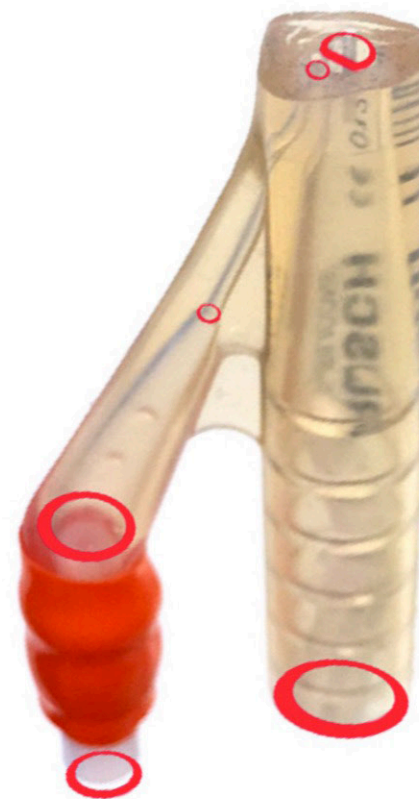
Concept Refinement



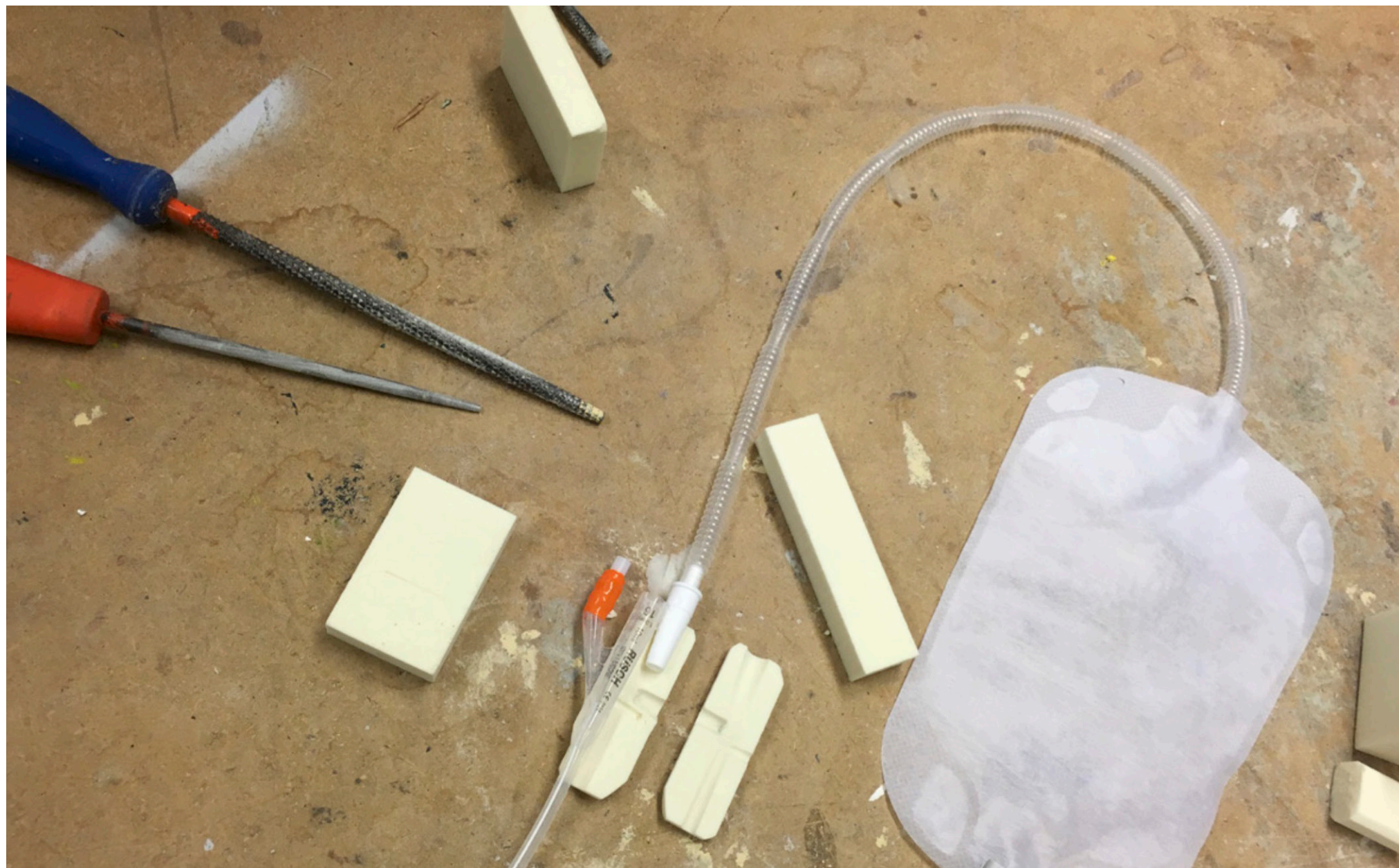














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## Concept (3)

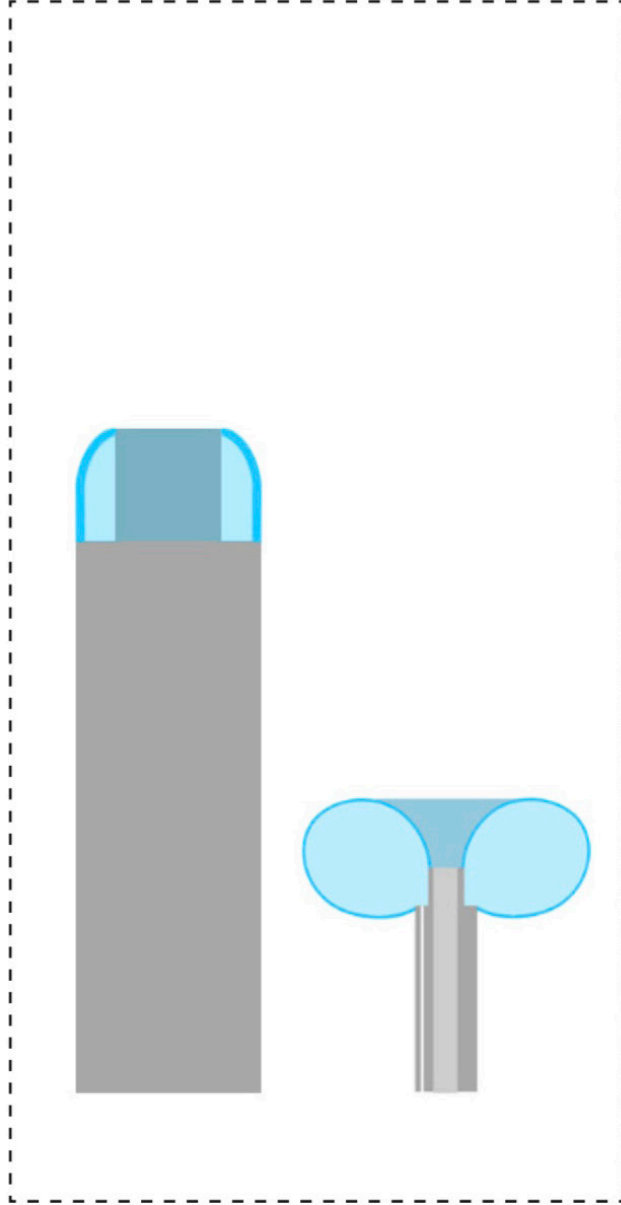


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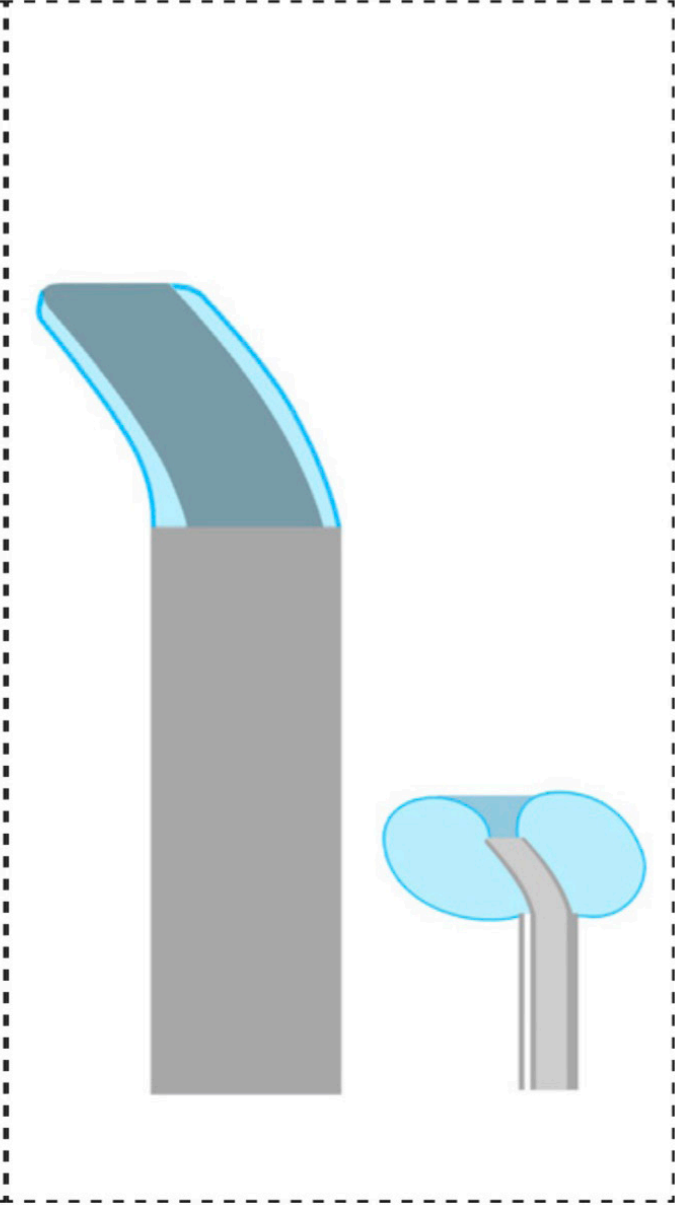
## Concept (4)



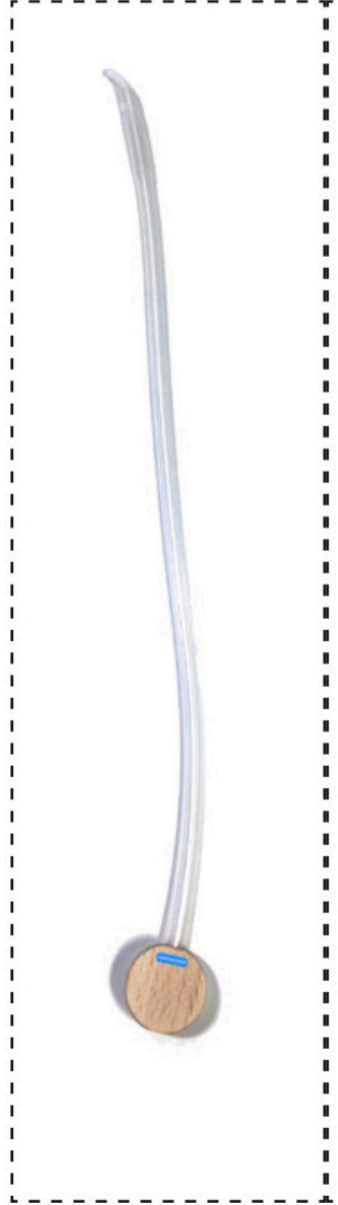




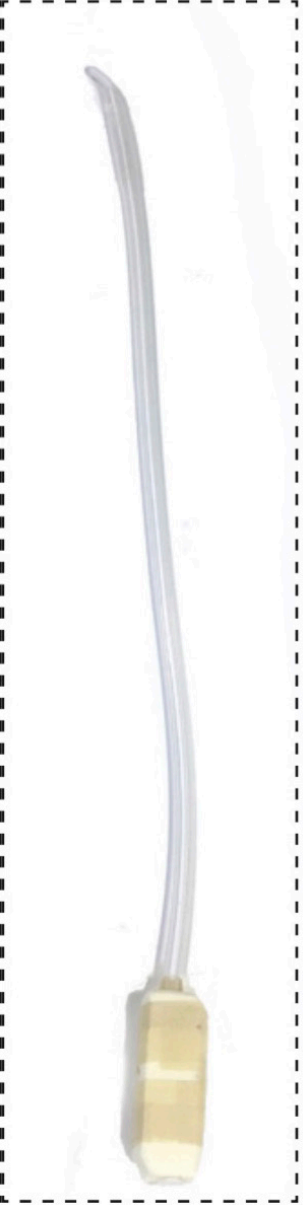
**Concept (1)**



**Concept (2)**



**Concept (3)**



**Concept(4)**

# ***EZ Care Catheter***

A Urinary Catheter designed for easy self-care and avoiding damage to the mucosa.

