Deliverable 4: Design Input

Team 12: OBGYN
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1 Purpose

This document outlines the specifications for the Aspiration Containment System (ACS).

2 Scope

Focusing on the performance, interface, human factors, biological, energy, and packaging requirements.

3 Product Description

This device is intended to be used by oncological OB GYN surgeons in a minilaparotomy for the contained drainage and subsequent removal of large ovarian cysts.

4 Definitions

Autoclave: *machine used to carry out industrial and scientific processes requiring elevated temperature and pressure in relation to ambient pressure.*

Biocompatibility: *the ability of a device material to perform with an appropriate host response in a specific situation*

Degradation: *decomposition of the device, possibly through the generation of new chemicals or absorption of the material, leading to loss of mechanical and/or physical properties of the device (device function) over time*

Extractables: *substances that can be released from a medical device or material using extraction solvents and/or extraction conditions that are expected to be at least as aggressive as the conditions of clinical use*

IFU: *Instructions for Use*

In-Parallel: *connected to common points at each end*

Intracutaneous: *Within the skin*

Leachables: *substances that can be released from a medical device or material during clinical use*

Minilapatoromy: *A surgical incision into the abdominal cavity that is limited in size.*

Neptune 3: *Stryker Neptune 3 Waste Management System is a medical device that is used to remove cyst contents during cyst removal surgery.*

Sensitization: *The process by which your body becomes sensitive to—and allergic to—a particular substance*

Short Circuit: *an unintended electrical connection between two current carrying parts, resulting in damage to the overall circuit*

Stratasys: *3D-printing company based in Eden Prairie, MN that owns the trademark to* PolyJet™ *printers and materials*

Subcutaneous: *Under the skin*

Yankauer: *oral suctioning tool used in medical procedures, typically a firm plastic suction tip with a large opening surrounded by a bulbous head and is designed to allow effective suction without damaging surrounding tissue.*

5 Reference Documents

Table 1: Reference Documents

Document Number	Revision	Description
Applicable Standards		
ISO 14971	2019	International Standards for risk management of medical devices.
ISO 10993	2018	Document specifying general principles governing the biological evaluation of medical devices within a risk management process
21 CFR Part 801	2022	This regulation set forth by the United States Food and Drug Administration (FDA) outlines the information that must be included on the label of a medical device.
ISO 20484	2017	Document specifies leak tests.
ISO 10012	2003	Document specifies requirements for the measurement process and measuring equipment.
ISO 20457	2018	Document specifying the requirements for tolerances of plastic molded parts.

6 Functional & Performance Requirements

6.1 Performance Characteristics

6.1.1 Maximum strength

Requirement: 520 mmHg

Requirement Source: The device components should not deform under the maximum suction that the Neptune 3 suction system can provide.

Test Method: This will be tested through the back-pressurizing test as described in ISO 20484. This is not currently feasible so a bubble leak test can be performed instead.

6.1.2 Containment and vacuum tubing airtight

Requirement: Containment device and vacuum tubing cannot leak air

Requirement Source: The device needs to be able to maintain pressure within in order to function properly. User needs require that the device does not leak cyst contents into the abdomen, requiring the device to maintain pressure in the containment system and tubing.

Test Method: This will be tested through the bubble leak test as described in ISO 20484 as micro-holes are not required to be detected.

6.2 Physical Dimensions

6.2.1 Vacuum tubing diameter

Requirement: 5/16 in. ± tolerance of inner diameter of suction tubing

Requirement Source: From VOC feedback, the device should be compatible with the Neptune 3 suction system that is used in the OR.

Test Method: This could be done using a 3D viewer, like a MicroVu, which would allow for precise measurements of the diameter of the internal tube diameter. Tolerance will be determined through a bubble test ISO 20484. Since we do not have access to a 3D viewer, we will measure with a caliper.

6.2.2 Containment System Diameter

Requirement: $< 4.8^{+0.2}_{-0.2}$ cm

Requirement Source: During VOC process, the device needs to be compatible with a minilaparotomy. Requiring the device to be less than 5 cm.

Test Method: This could be done using a 3D viewer, like a MicroVu, which would allow for precise measurements of the device's diameter as described in ISO 10012. Since we do not have access to a 3D viewer, we will measure with a caliper.

7 Device/System Interface

7.1 Facilities and Operating Room Interface

7.1.1 Suction required for functioning is drawn from Operating Room Suction System

Requirement: 50-520 mmHg

Requirement Source: From VOC feedback, the device should not require any additional plugins for ease of use and feasibility. Its functioning should use the pressure ranges supplied by the Neptune 3 suction system that is used in the OR.

Test Method: The containment ability of the device will be examined with pressures on the range of the Neptune 3 system using an adjustable pressure source.

7.1.2 Sterilization Compatibility

Requirement: Device must be able to withstand autoclave steam sterilization

Requirement Source: Surgery is performed in a sterile environment and it would be unacceptable for the device to break such sterility. Most surgical tools are sterilized by the application of intense pressure and heat by an autoclave. Many polymer-based instruments are known not to be able to withstand such conditions.

Test Method: Device sample will be subjected to sterilization in an autoclave using autoclave indicator tape to indicate completion of the

sterilization process. Device condition will be evaluated subsequently.

7.2 Other Interfacing Devices

7.2.1 Scalpel Handle

Requirement: ≥ 10.00cm

Requirement Source: Scalpel must be long enough to extend to the cyst through the device with some extra handling length, to allow surgeons comfortably hold it and make an incision.

Test Method: The device is intended to be used with standard-length scalpel handles which are commonly known to be of length 12.45cm. Voice of Customer feedback will be collected from surgeons on the ease of use of commonly used scalpel handles with the device. The scalpels will be measured using a caliper. If resources are present, it could be done using a 3D viewer, like a MicroView, which would allow for precise measurements of the scalpel as described in ISO 10012.

7.2.2 Suction Tip Diameter

Requirement: $\leq 2.0^{+0}_{-0.1}$ cm

Requirement Source: The suction tip should ideally be small enough to fit within the device cavity for clean suction of fluid.

Test Method: The tools commonly used in this surgery will be placed inside the inner chamber of the device to ensure it fits and can be used for suction. It will also be measured with a caliper. If resources are present, it could be done using a 3D viewer, like a MicroView, which would allow for precise measurements of the suction tip as described in ISO 10012.

8 Human Factors/User Interface

8.1 Handheld Device

8.1.1 Outer Tube Diameter

Requirement: $< 4.8^{+0}_{-0.2}$ cm

Requirement Source: During the VOC process, a desire for the device to be a handheld device that fits in a 5 cm incision was expressed. It should be small enough to be held in the surgeon's/nurse's hand for the duration of the surgery.

Test Method: This requirement will be measured with a caliper. If resources are present, it could be done using a 3D viewer, like a MicroView, which would allow for precise measurements of the outer tube's external diameter as described in ISO 10012.

8.1.2 Cordless

Requirement: Device is hooked up to a suction machine already in OR.

Requirement Source: Several doctors noted the lack of available plugs in the operating room during the procedure, and suggested the device be cordless. The device should have an internal power supply or work with something already present in the OR.

Test Method: Device should be examined to ensure there are no power cords. The tube that hooks up to the suction machine should be measured with a caliper and tested with a machine to ensure proper fit.

8.2 Current technique performance and interfacing

8.2.1 Inner Tube Diameter

Requirement: 3.0 ± 0.1 cm

Requirement Source: VOC and assessment of current OR practices showed it was essential to change as little of the current procedure as possible. The tools currently used in the surgery should be usable with the device, and thus fit inside the inner tube. Additionally, the inner tube must be large enough to create an incision on the cyst.

Test Method: This requirement will be measured with a caliper. If resources are present, it could be done using a 3D viewer, like a MicroView, which would allow for precise measurements of the inner tube's external diameter as described in ISO 10012.The incision size will be determined with VOC.

8.2.2 Size Adaptability

Requirement: Device is one-size-fits-all.

Requirement Source: In the VOC the doctors mentioned how because every patient is differently sized, and every cyst is different, it would be nice to have a device that did not need to be sized for the patient. Using the containment bag on the proximal end of the device that can be pulled outside of the incision creates size adaptability.

Test Method: Using the sizing standards in the medical device community (smallest women to largest men averages) and in ovarian cyst history, ensure the containment bag extends out of the patient by 5 cms, testing about 5 different size people (using extremes) and 5 different cyst sizes (using extremes).

8.2.3 Clear Visualization

Requirement: Device is see through

Requirement Source: Doctors noted it was important for them to be able to see the surgery, as well as determine if any of the contents of the cyst had

escaped. A clear/see through device is needed to ensure surgeon line of sight.

Test Method: This can be done by shining a light through the material being used in the device as well as through the device and using a sensor on the other side to determine how much light is passing through the device.

8.2.4 Skill Level Required

Requirement: Oncologic OBGYN Certification

Requirement Source: VOC noted that those using the device should be experienced with the surgery.

Test Method: Certification will be checked to ensure surgeon in oncologic OBGYN.

9 Biological Requirements

9.1 Biocompatibility

9.1.1 Irritation or Intracutaneous Reactivity

Requirement: Device must not introduce chemical leachables or extractables during its clinical use that may be irritants.

Requirement Source: Intracutaneous reactions may lead to longer healing times which defeats the purpose of the use of the device.

Test Method: According to Stratasys reports, medical grade PolyJet™ printed materials like the Bio-compatible (MED610), which is to be used for this device's rendering, are scaled to meet medical approvals of irritation in line with guidelines outlined in ISO 10993-10:2013.

9.1.2 Mechanical Damage to Tissue

Requirement: The surface properties of the device and components of its operation should not confer any additional damage to the cutaneous and subcutaneous tissue that it is used adjacent to as well as the cyst wall, which it comes in contact with at its distal end.

Requirement Source: In order to proffer minimal interference to current methods and to minimize the chance for immune reaction and sensitization, it would be ideal for the device's mechanical interface not to cause any damage to the tissues it comes in contact with.

Test Method: The device body will be made with a smooth material such as the PolyJet™ material, Bio-compatible (MED610). Stratasys has reported this material to be sufficiently smooth as implemented in medical devices on the market such as Coloplast's Self-Cath®. If resources permit, this smoothness will be tested according to ISO 20457 standards. The effect of the device's end on the cyst wall will be examined during surgical simulations with a ballistics gel cyst

model. If needed, varying end attachments will be tested to determine an optimal set-up for the device's use. The amount of pressure with which the device is operated will be optimized to ensure that it is high enough to create a non-leaking seal but not so high such that it elicits a damaging pulling force on the cyst wall.

9.2 Toxicity

9.2.1 Cytotoxicity

Requirement: Device material must not be toxic to cells.

Requirement Source: The material of the device body should not effect cytotoxicity which is known to cause apoptosis, cell membrane disruption, inflammation, and oxidative stress at the incision site so that healing times stay at minimum.

Test Method: According to Stratasys reports, medical grade PolyJet™ printed materials like the Bio-compatible (MED610), which is to be used for this device's rendering, are scaled to meet medical approvals of cytotoxicity in line with guidelines outlined in ISO 10993-5:2009.

10 Energy Requirements

10.1 Voltage Source

10.1.1 Externally Powered

Requirement: Device does not contain an embedded power supply.

Requirement Source: Bodily fluids must not come into contact with the power supply, as this could cause a short circuit and subsequent device failure.

Test Method: A visual inspection of the clear device should be conducted to ensure there is no internal power source. Upon completion, the device should be connected via the provided surgical tubing to the Neptune 3 Waste Management System. An airtight connection between the two should be confirmed by placing a hand around the joint, turning the waste management device on, and feeling for air.

10.1.2 Cordless

Requirement: Device must utilize power cord of suction machine already in OR.

Requirement Source: Several doctors noted the lack of available plugs in the operating room during the procedure, and suggested the device be cordless.

Test Method: Device should be visually examined to ensure there are no power cords. The tube that hooks the device up to the suction machine should be measured with a MicroView and tested with a machine to ensure proper fit.

10.2 Power Source Adaptability

10.2.1 Multiple Power Sources

Requirement: Capable of being connected in-parallel to multiple suction systems.

Requirement Source: To increase vacuum pressure and decrease drainage time, the device should be able to connect in-parallel with multiple independently powered Neptune Waste Management Systems.

Test Method: A Y-shaped connector will be connected to the proximal end of the surgical tubing exiting from the device. The two branches on the connector will lead to two independently powered suction systems. Again, an airtight connection should be confirmed by placing a hand around all joints one-at-a-time, turning the respective waste management device on, and feeling for air.

11 Labeling Requirements

11.1 United States IFU Regulations

11.1.1 Date Formats

Requirement: All labels on the device should follow the YYYY-MM-DD format

Requirement Source: 21 CFR Part 801 requires expiration and production dates to be in the approved format: YYYY-MM-DD.

Test Method: All technical writers will be notified of the required FDA standards, and date formats will be peer-reviewed by redlining and queuing for revision.

11.1.2 Designated Use and Contradictions

Requirement: Designated use and contradictions must be included in the intended use

Requirement Source: 21 CFR Part 801 requires device manufacturers to analyze potential applications of the device and advise on how the alternative might affect the outcome.

Test Method: To test all contradictions to the intended use of the device, the team will perform a cognitive walkthrough and use the data to enhance user experience.

11.2 Sterilization Protocol

11.2 Sterilization Protocol Documentation

Requirement: The device labeling must contain a sterilization protocol that optimizes the completion rate of the task- sterilize the device.

Requirement Source: The device will undergo autoclave steam sterilization before every subsequent use to be in accordance with the sterility requirements in the OR.

Test Method: The team will run a heuristic evaluation to analyze the ease of use of these documents and will follow the plan-test-modify approach to iterate till all participants can complete the task by following the documentation.