Balloon-Stent Endovascular Device for the Treatment of Intracranial Aneurysms

Final Proposal

Team Number: 21Spr02

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2021

Project Sponsor: Bioengineering Devices Laboratory (BDL)

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DISCLAIMER

This report was prepared by students as part of a university course requirement. While considerable effort has been put into the project, it is not the work of licensed engineers and has not undergone the extensive verification that is common in the profession. The information, data, conclusions, and content of this report should not be relied on or utilized without thorough, independent testing and verification. University faculty members may have been associated with this project as advisors, sponsors, or course instructors, but as such they are not responsible for the accuracy of results or conclusions.

EXECUTIVE SUMMARY

The following report contains the design description, requirements, testing procedures, and risk analysis for the balloon-stent medical device that will be used to treat intracranial, saccular aneurysms. The design consists of a cylindrical balloon surrounding a cylindrical stent; the balloon acts to occlude blood flow into the aneurysm and the stent acts to maintain sufficient blood flow in the parent artery. Our design is constrained by nine customer and engineering requirements that ultimately determine whether our device is successful or not. The testing procedures for this device include computational fluid modeling, experimental in vitro testing, and material property testing.

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1 BACKGROUND

1.1 Introduction

Brain aneurysms can be defined as an abnormal bulge on blood vessels within the cranium. Intracranial aneurysms affect approximately 2-3% of the general population [7]. The main concern with brain aneurysms is that they are prone to rupture which results in hemorrhage into the subarachnoid space. The mortality rate due to aneurysm rupture is 20-40%, where 50% of survivors face other health complications such as permanent brain damage [2]. Neurosurgeons attempt to reduce the risk of mortality and morbidity by treating unruptured aneurysms through coiling, liquid embolics, flow diverters and flow disruptors. The commonality between the treatments is that they either disrupt blood flow into the aneurysm or maintain normal blood flow in the parent vessel. The purpose of this project is to develop a balloon-stent endovascular device that isolates the aneurysm and provides parent vessel flow while the surgeon operates.

This capstone project is sponsored by the Bioengineering Devices Lab (BDL) directed by Dr. Timothy Becker. The Bioengineering Devices Lab is a translational research lab at Northern Arizona University (NAU) that focuses on developing biomedical devices and biomaterials that help improve the treatment of brain aneurysms. Any accomplishments in the BDL and capstone project bring NAU more recognition and funding for future research. Our client, Timothy Becker, and the graduate students working in the BDL benefit from success in the capstone project because any research conducted is relevant to their projects. Our primary stakeholders, physicians, benefit from this project because it gives them more time to operate increasing the success rate of the surgery. The team recognizes the importance of the project and aims to produce meaningful work that will help our client, stakeholders, and patients.

1.2 Project Description

According to the project proposal, the capstone team is to design, analyze and prototype a novel balloon-stent endovascular medical device. The project description provided by the BDL is found below.

> The scope of this project is to design, model, and analyze (CFD) a prototype endovascular device that improves aneurysm neck protection during embolic device placement, while reducing blood flow obstruction in the parent artery thus minimizing ischemic risk.

2 REQUIREMENTS

As the purpose of this device is to treat the aneurysm while maintaining proper blood flow, certain requirements must be met to ensure the device works properly. The following chapter describes the customer and engineering requirements for a functional balloon-stent device.

2.1 Customer Requirements (CRs)

Customer requirements (CRs) are aspects of the design important to the customer, which in this case would be a surgeon or a medical clinic. The requirements were set based on research and discussion with our client. The most important CRs are weighted the highest, and for the balloon-stent these are: must be safe on the human body, must prevent occlusion of the parent artery (to avoid brain ischemia), must prevent embolics from travelling downstream (can cause clotting outside of aneurysm), must fit in blood vessel, must block flow into aneurysm (to allow surgeon to embolize blood in aneurysm), must be maneuverable by surgeons, and must not cause turbulent blood flow (can cause clots in the parent artery). These CRs were weighted on a scale of 1 to 5 as a 5. While this is a large number of requirements weighted as a 5, they are all critical to the success of the surgery and safety of the patient. Additional, less crucial, requirements are: must have a smooth surface at the neck of the aneurysm, and must be within budget. All the nine CRs and their respective weights can be found on the House of Quality diagram in Figure 1.

2.2 Engineering Requirements (ERs)

The nine customer requirements are then translated to nine engineering requirements (ERs). ERs are technical aspects of the design that would satisfy the customer requirements. The requirements formulated for the balloon-stent device are: inflated balloon diameter (mm), deflated balloon diameter (mm), stent minimum diameter (mm), stent wall thickness (mm), device length (mm), Rigidity (unitless), durability (stress-life cycles), friction (unitless), and cost (USD). These ERs can also be found on Figure 1.

2.3 Functional Decomposition

This purpose of this section is to illustrate what the endovascular device must accomplish. This is done by defining the inputs and outputs through a black box model. The functions and sub-functions are illustrated using a functional model. The functional decomposition creates a clear outline that helps generate feasible concepts for the project.

2.3.1 Black Box Model

The purpose of the black model is to illustrate the inputs and outputs. This helps the team have a good understanding of specific components that the device must have. Figure 5 shows the black box model diagram. The goal for the endovascular device is found in the middle of the box in its simplest form. The material, energy and signal inputs and outputs are shown from top to bottom, respectively. Because the balloon-stent device is meant to be removeable, it is observed that the inputs and outputs are roughly the same.

Figure 1: Black Box model

2.3.2 Functional Model

The functional model illustrates the main purpose of the project, sub-functions, and how the sub-functions could potentially be accomplished. The diagram shown in Figure 6 shows the functional model. The team benefits from this diagram as it provides a more detailed description of the project objectives.

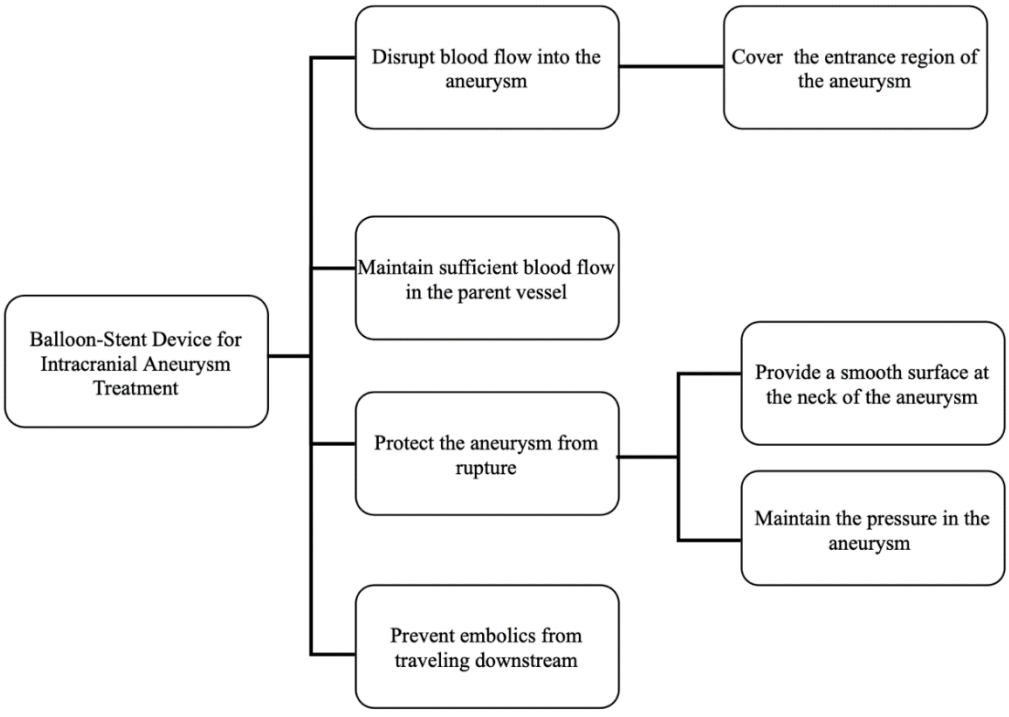


Figure 2: Function decomposition model

2.4 House of Quality (HoQ)

The House of Quality diagram (Figure 3) is a design approach that relates CRs to each ER; by doing this, we are able to rank the technical importance of each engineering requirement. Observe that the most important ER is the stent wall thickness (mm). This is due to the stent wall thickness having a strong correlation to the two highly weighted CNs, a moderate correlation to one highly weighted CN, and weak correlations to two more highly weight CNs. Taking the weights and correlations into account, it is calculated that the stent wall thickness has an Absolute Technical Importance (ATI) of 115, which ranks it first in terms of Relative Technical Importance (RTI). Contrary to this, the least important ER is cost (USD), as it only correlates to one low ranked CR. Each ER is also given a target value with tolerance based on common Circle of Willis artery geometry and other knowledge gained by research. Furthermore, each engineering requirement corresponds to one of the three testing procedures stated in section 3 of this document.

Customer Requirement	**Weight**	**Engineering Requirement**	Balloon diameter- inflated (mm)	Balloon diameter- deflated (mm)	Stent minimum diameter (mm)	Stent wall thickness (mm)	Device length (mm)	Rigidity, Young's Modulus (unitless)	Durability (functioning life span)(min)	Friction (unitless)	Cost (USD)
1. Must be safe to use on the human body	5					1			9		
2. Must prevent occlusion of the parent artery	5		9		9	1		9	3		
3. Must prevent embolics from traveling downstream	5		1		1					9	
4. Must have a smooth surface at the neck	2									3	
5. Must fit in the blood vessel	5		3	9	9	9	3				
6. Must block blood flow into aneurysm	5				3	3				1	
7. Must allow surgeons to deploy and maneuver the device	5			9			9	9	9	1	
8. Must be within budget	2							3			9
9. Must not cause turbulence in blood flow	5					9					
Absolute Technical Importance (ATI)			65	90	110	115	60	90	105	61	18
Relative Technical Importance (RTI)			5	4	2	1	7	4	3	6	8
Target ER values			**3**	**0.4**	**1**	**0.05**	**25**	**200**	**15**	**3**	**2000**
Tolerances of ERs			± 0.2	± 0.2	(+) 5	(+) 0.3	± 10	± 20	± 5	± 1	± 1000
Testing Procedure (TP#)			2	2	2	1	1	3	3	3	3

Figure 3: latest version of the House of Quality diagram

2.5 Standards, Codes, and Regulations

The standard that we will abide by will be the Human Factors Design Process for Medical Devices standard. This will ensure that the medical device we comply with known safety regulations for the human body.

Table 1: Standards of Practice as Applied to this Project

Standard	**Title of Standard**	**How it applies to Project**

Number or Code		
ASNI/AAMI HE 74:2001	Human Factors Design Process for Medical Devices	Helps in the design of how the device with interface with the user in a safe manner.

3 Testing Procedures (TPs)

Once a prototype has been created, we will conduct tests to validate our design against the engineering requirements. These tests will consist of both physical, laboratory-based tests as well as computational, software-based tests. The software-based testing will provide useful data about the pressure changes between the inlet and outlet of the balloon-stent, while the laboratory-based testing will allow us to examine the functionality and the maneuverability of our design in a life-like scenario.

3.1 Testing Procedure 1: Computational Fluid Dynamics (CFD)

In order to computationally validate our design, the final version will be examined using ANSYS Fluent of a blood flow simulation.

The mesh for these simulations will consist of the balloon-stent assembly within a cylindrically modelled artery. One entrance of the artery will be set as an inlet and the other will be set as an outlet. As blood is an incompressible, non-Newtonian (varying viscosity) fluid, the fluid properties will correspond to that of blood modelled using the Carreau model for blood viscosity [12].

3.1.1 Testing Procedure 1: Objective

The objective of this simulation is to find the change in pressure between the inlet and outlet of the balloon-stent. This pressure difference will be used to dictate the geometry of the balloon-stent, as the Fractional Pressure Ratio (FPR) must be above 0.75 ($\frac{Pressure\ In}{Pressure\ Out} \geq 0.75$) to avoid ischemia. If the design results in a suitable pressure ratio, then it can be manufactured and tested in the BDL. The results of these tests will determine suitable values for the engineering requirements stent wall thickness and device length, as seen on the House of Quality diagram (Figure 3).

3.1.2 Testing Procedure 1: Resources Required

The only resources required for these computational fluids tests are CFD software and computer aided design (CAD) software. The CAD software that is currently being used is SolidWorks, and will likely continue to be used through out the remainder of the project. The CFD software used will be ANSYS fluent, as this is a powerful software to model fluid flow. However, other CFD software may be considered if problem arise with ANSYS Fluent. The CAD software will be used to create the geometry and can be inputted into ANSYS Fluent to be turned into a mesh. Both of these programs are made available to the engineering students of Northern Arizona University for no charge.

3.1.3 Testing Procedure 1: Schedule

The scheduling of these CFD simulations are not firm, as in, each iteration of the final design will be evaluated with ANSYS Fluent. The first CFD simulations will be simplified to the bare essentials, the balloon-stent in an artery. Once a final design and geometry are reached, future CFD analyses will account for the actual aneurysm and possibly bifurcation cases. By implementing computational fluid analysis, our design can be theoretically validated before it is experimentally validated within the Bioengineering Devices Laboratory (BDL)

3.2 Testing Procedure 2: BDL Blood Flow Simulator

After being computationally validated, the balloon-stent protype will be tested experimentally using an in vitro method of simulating blood flow through a 3D printed Circle of Willis.

3.2.1 Testing Procedure 2: Objective

The objective of this testing procedure is to determine the maneuverability and functionality of the balloon-stent within an in vitro model. Being able to successfully deploy the device is obviously very important ant, therefor it is here where we will test the device's compatibility with the catheter and being able to position the device correctly. Additionally, we will be able to test our device on the in vitro Circle of Willis to determine if it is expanding enough to block blood flow into an aneurysm. These tests will help determine suitable values for the engineering requirements balloon inflated diameter, balloon deflated diameter, and stent minimum diameter as seen on the House of Quality diagram (Figure 3).

3.2.2 Testing Procedure 2: Resources Required

The resources required for this testing procedure will be made available to the team by the BDL where they have 3D printed Circle of Willis as well as a digitally controlled hydraulic pulsatile pump that is used to simulate blood flow. Possible resources may also include different brands of microcatheters, as it is not yet known which will work best for our design.

3.2.3 Testing Procedure 2: Schedule

These experimental tests will begin during the Fall 2021 semester and once a prototype has successfully been made. Similar to the CFD testing procedure each additional prototype iteration will also be tested.

3.3 Testing Procedure 3: Material testing procedure

The third testing procedure will evaluate the success of the selected material. Testing material properties experimentally will help determine the safety of the device. Additionally, the material data collected will be useful in predicting the behavior of the device.

3.3.1 Testing Procedure 3: Objective

The objective for testing procedure 3 is to measure material properties of the materials used for the device. The material properties that will be tested include, but are not limited to: deformation, stress-strain behavior and fatigue. The deformation of the material will help determine the reach of the device in the case of overloading. Due to the proximity of the blood vessels within the CoW, the device could potentially over-expand and cover the entrance region of another vessel. Studying the stress-strain behavior of each material will aid in predicting critical points of failure. Essential material properties can be determined such as: yielding point, modulus of elasticity and elastic and plastic deformation regions. Lastly, the fatigue due to pulsatile flow and irregular flow patterns of each material can be quantified to determine the durability of the device. This property will also provide an estimate of the time that the surgeon will have to perform the surgery.

3.3.2 Testing Procedure 3: Resources Required

The instrument that will be used to evaluate material properties is a rheometer. A rheometer is a device that accepts various material samples and has the capabilities of measuring with high precision. In addition to testing several material properties, the rheometer has a camera that shows the physical behavior of the material under different applied stresses. The team has completed rheometer training in the BDL and is allowed to use the device. The software that reports the data is also accessible though the BDL.

3.3.3 Testing Procedure 3: Schedule

The rheometer testing can be completed at any point throughout the experiment for materials in question. The goal is to begin testing prior to the development of a promising prototype. Obtaining material property data will help the team make better decisions to avoid unnecessary expenses.

4 Risk Analysis and Mitigation

This section will discuss the risk analysis of the device. Establishing potential failures methods helps the team prevent failure of the device before it occurs. In specific to this capstone project, the medical device directly affects patients' health and physicians' liability. The success of the device depends on the physicians' faith in the device.

4.1 Critical Failures

To date, the team has considered three subcomponents of the device to evaluate. The components in consideration include the: balloon, stent, and microcatheter. While the design components only consist of the balloon and the stent, the microcatheter enables the placement of the device.

4.1.1 Potential Critical Failure 1: Stress corrosion on the balloon

Shear force caused by blood can possibly cause the corrosion of the balloon-stent, however it is unlikely that this could occur during the 15 minute surgery.

4.1.2 Potential Critical Failure 2: Over inflation of the balloon

Over inflation of the balloon can cause it to rupture, which in turn caused the failure of the surgery and the possible release of embolics into the blood stream. This risk can be mitigated with automated balloon inflating as to make sure the maximum inflation point is not reached.

4.1.3 Potential Critical Failure 3: Low cycle fatigue on the balloon-stent

Caused by the balloon being used, will likely not be an issue if a new balloon-stent is used after each operation.

5 DESIGN SELECTED – First Semester

The following section details the latest version, Version 3, of the balloon-stent design. The design consists of two parts, the balloon and the stent, with the balloon surrounding the outside of the stent. It is worth mentioning that the team does not yet have a physical prototype as variations of the design are still to be tested computationally, which will determine whether we would like to spend the money to get it manufactured.

5.1 Design Description

5.1.1 Stent

The stent (Figure 4) consists of a cylindrical grid of intersecting rods. It was created by implementing circular sweeps about two helical spirals of 180 degrees going in opposite directions. The sweeps are then made into a circular pattern creating the grid for the stent. Compared to the preliminary design, this version of the stent does not have the extruded circular component used to create the circular pattern, which is not needed in the actual design. Simply deleting this component caused errors as the circular pattern becomes undefined, but by intersecting the front plane with the circular pattern, then excluding the extruded circle, the stent was able to remove the extruded circle while maintaining the circular pattern it governed. The stent is to be made of nitinol due to it's thermally expanding properties, and will act as scaffolding for the balloon to ensure that there is sufficient blood flow in the parent artery.

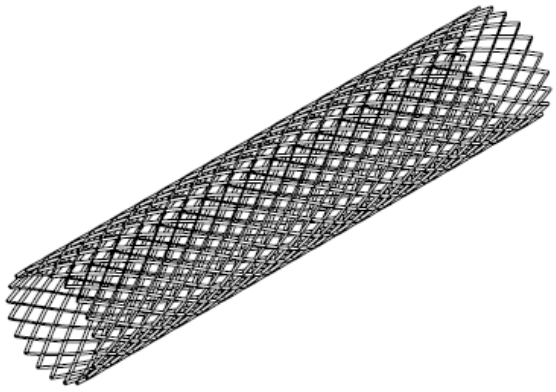


Figure 4: Stent, isometric view

5.1.2 Balloon

The balloon (Figure) consists of a cylindrical tube that has inflating walls meant to block blood flow into the aneurysm. The design has changed only slightly compared to the preliminary design, with modifications to the overall shape. The balloon will consist of two materials, one of high compliance and one of low compliance. The material on the outside of the balloon is to be made of a highly compliant material, such as polyurethane or silicon, while the interior material will be made of a lesser compliant material such as nylon. This is to ensure that the balloon expands mostly outwards when inflated, because if the balloon expands too much inwards, there will not be sufficient blood flow within the parent artery. This is important in order to keep the Fractional Pressure Ratio above 0.75($\frac{Pressure\ In}{Pressure\ Out} \geq 0.75$), which is the minimum ratio to avoid ischemia. The entire CAD drawing package can be found in Appendix B of this document.

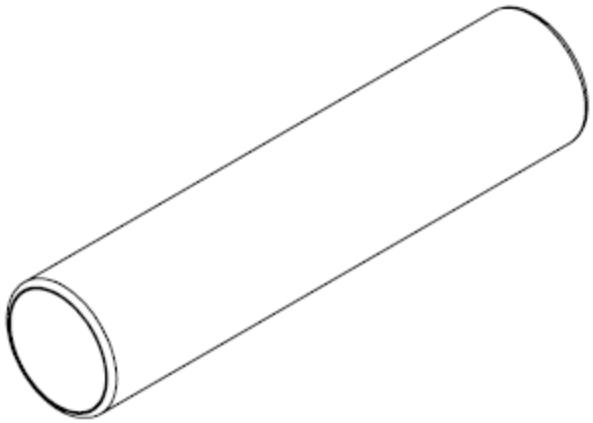


Figure 5: Balloon, isometric view

5.2 Implementation Plan

The design's assembly view as well as the exploded view/ bill of materials can be found in Figure 6 and 7, respectively.

The team plans to implement the design both by computational and experimental means. The design is to be analyzed using ANSYS Fluent CFD simulation to model blood flow. Once a suitable design and results are reached, a prototype will be made and tested using the in vitro methods described in section 3.2. The resources needed will be ANSYS Fluent, SolidWorks, digitally controlled hydraulic pulsatile pump (BDL), 3D printed Circle of Willis (BDL), and microcatheters (BDL). Our clients, Dr. Timothy Becker, as well as PhD student, Omid Asgari, will help to guide us through our testing in the BDL. Manufacturing of prototypes will be outsourced to POBA Medical, a medical device manufacturer in Flagstaff, AZ.

It is expected to have a final design and successful CFD simulation by the end of the Spring 2021 semester (April 30th) so that soon after the Fall 2021 semester begins (August 23rd) the design can be manufactured by POBA Medial to then begin experimental validation.

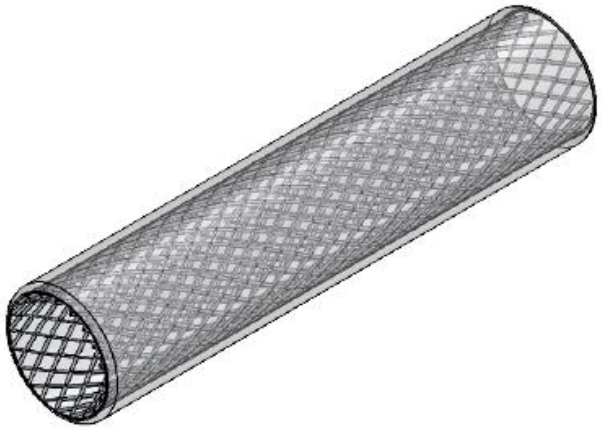
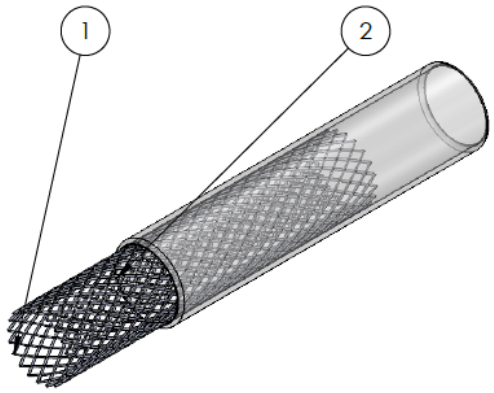


Figure 7 : Balloon-Stent assembly, isometric view



ITEM NO.	PART NUMBER	Material	QTY.	Estimated cost
1	stentv2	Nitinol	1	$250
2	balloon	Urethane	1	$100

Figure 8: Balloon-Stent exploded view with BOM

6 CONCLUSIONS

The contents in this report help determine the progress that the team has made in the first semester of capstone. This capstone project is unique to mechanical engineering students because it requires the knowledge of medical phenomena. The team spent a vast amount of time researching, understanding and learning about the problem. Next semester, the team will apply their engineering knowledge in the development of the device.

7 REFERENCES

[1] A. Bose, M. Hartmann, H. Henkes, H. M. Liu, M. Teng, and I. Szikora, “A Novel, Self-Expanding, Nitinol Stent in Medically Refractory Intracranial Atherosclerotic Stenoses : The Wingspan Study,” *Stroke*, vol. 38, no. 5, Nov. 2006.

[2] A. Manhas et al., "Comprehensive Overview of Contemporary Management Strategies for Cerebral Aneurysms," in *World Neurosurgery*, Oct. 2015. [Online]. Available: https://pubmed.ncbi.nlm.nih.gov/26072457/#affiliation-1

[3] B. J. Sudhir, G. Menon, J. B. Reddy, T. Jayachandran, H. K. Jha, and C. Kesavadas, “The Big Bang Theory of Intracranial Aneurysm Rupture: Gazing Through the Computational Fluid Dynamics Telescope,” *2018 International Conference on Intelligent Informatics and Biomedical Sciences (ICIIBMS)*, 2018.

[4] C.-ho Yu, S. Shida, K. Mmatsumoto, D.-J. Kim, and M. Ohta, “EXPERIMENTAL HEMODYNAMIC STUDY WITH SEVERAL STENTS IN CEREBRAL ANEURYSM MODEL USING PIV,” *Nano-Biomedical Engineering 2012*, Oct. 2012.

[5] Center for Devices and Radiological Health, “Woven EndoBridge (WEB) Aneurysm Embolization System - P170032,” *U.S. Food and Drug Administration*, 28-Jan-2019. [Online]. Available: https://www.fda.gov/medical-devices/recently-approved-devices/woven-endobridge-web-aneurysm-embolization-system-p170032. [Accessed: 28-Feb-2021].

[6] “FDA Executive Summary General Issues: Meeting to Discuss the Evaluation of Safety and Effectiveness of Endovascular Medical Devices Intended to Treat Intracranial Aneurysms,” *FDA.gov*. [Online]. Available: https://www.fda.gov/media/111329/download.

[7] https://www.scopus.com/record/display.uri?eid=2-s2.0-0031984850&origin=inward

[8] J. Inoue, A. Shiraishi, A. Yoshiyuki, K. Haruta, H. Matsui, and Y. Otomo, “Resuscitative endovascular balloon occlusion of the aorta might be dangerous in patients with severe torso trauma,” *Journal of Trauma and Acute Care Surgery*, vol. 80, no. 4, pp. 559–567, 2016.

[9] M. S. Park, P. Taussky, F. C. Albuquerque, and C. G. McDougall, *Flow diversion of cerebral aneurysms*. New York: Thieme, 2018.

[10] Medtronic, “Pipeline Flex - Aneurysm Treatment Products,” *Medtronic*. [Online]. Available: https://www.medtronic.com/us-en/healthcare-professionals/products/neurological/aneurysm-treatment/pipeline.html. [Accessed: 28-Feb-2021].

[11] “MicroVention,” *Microvention*. [Online]. Available: https://www.microvention.com/product/scepter. [Accessed: 01-Mar-2021].

[12] R. Bhaskaran, “3D Bifurcating Artery,” *ANSYS*. [Online]. Available: https://courses.ansys.com/index.php/courses/fluent-3d-bifurcating-artery/. [Accessed: 15-Mar-2021].

[13] S. Kieffer, “Endovascular Coiling for Brain Aneurysms: Treatment: Johns Hopkins Aneurysm Center,” *Treatment | Johns Hopkins Aneurysm Center*, 08-Dec-2017. [Online]. Available: https://www.hopkinsmedicine.org/neurology_neurosurgery/centers_clinics/aneurysm/treatment/aneurysm_endovascular_coiling.html. [Accessed: 01-Mar-2021].

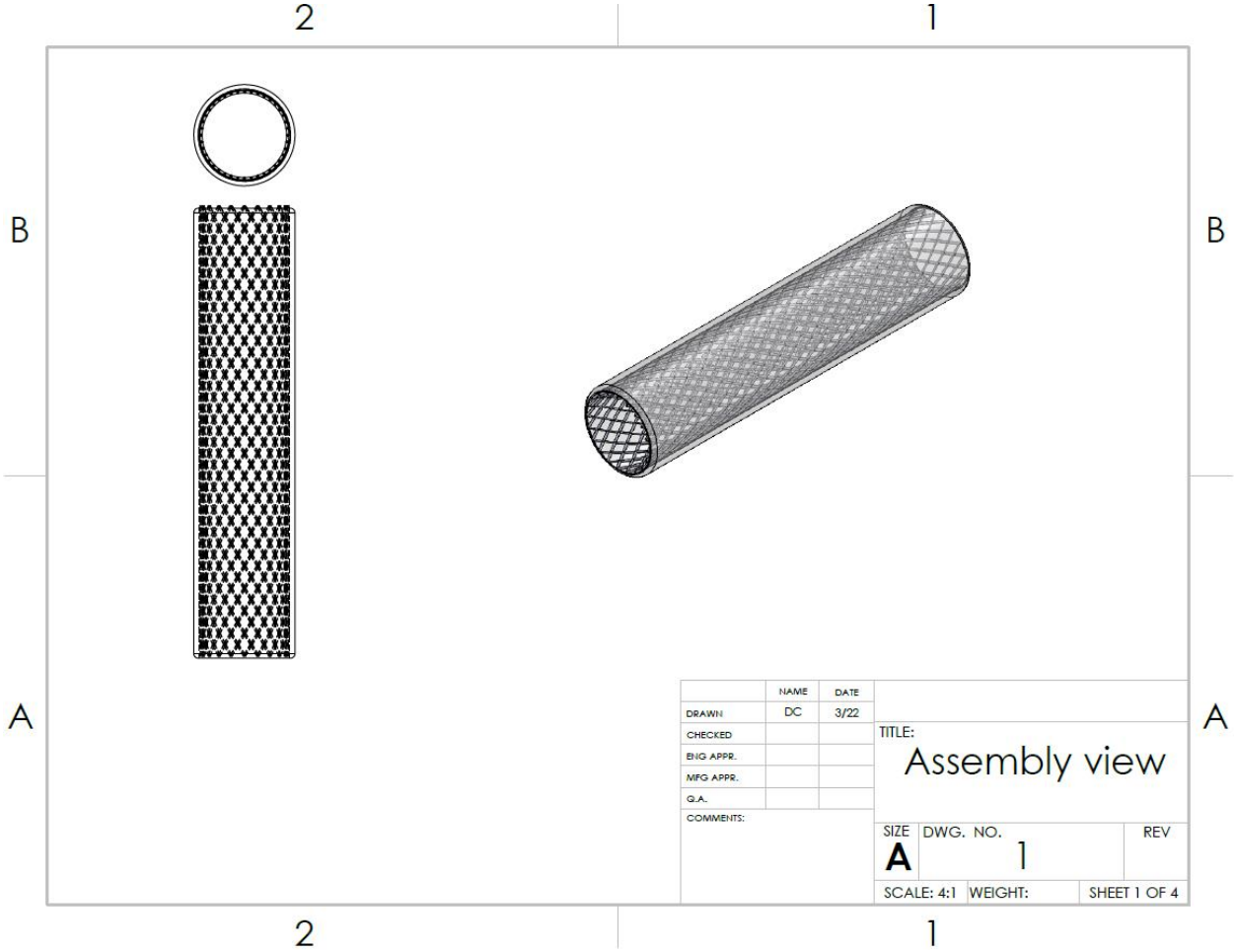
[13] “Statistics and Facts,” *Brain Aneurysm Foundation*, 17-Nov-2020. [Online]. Available: https://bafound.org/about-brain-aneurysms/brain-aneurysm-basics/brain-aneurysm-statistics-and-facts/. [Accessed: 05-Feb-2021].

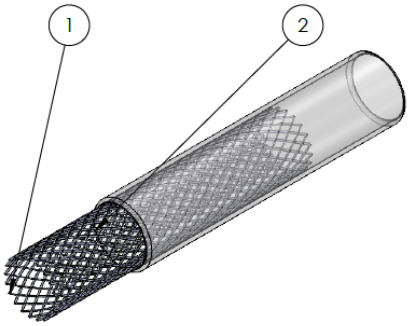
8 APPENDICES

[Use Appendices to include lengthy technical details or other content that would otherwise break up the text of the main body of the report. These can contain engineering calculations, engineering drawings, bills of materials, current system analyses, and surveys or questionnaires. Letter the Appendices and provide descriptive titles. For example: Appendix A-House of Quality, Appendix B- Budget Analysis, etc.]

8.1 Appendix A: FMEA

8.2 Appendix B: CAD Drawings





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2	balloon	Urethane	1	$100

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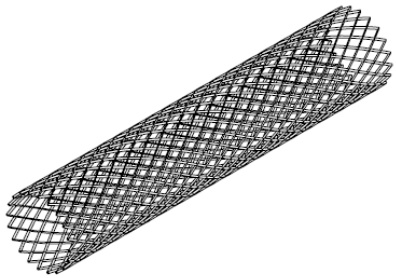

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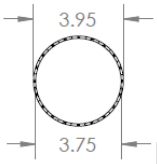

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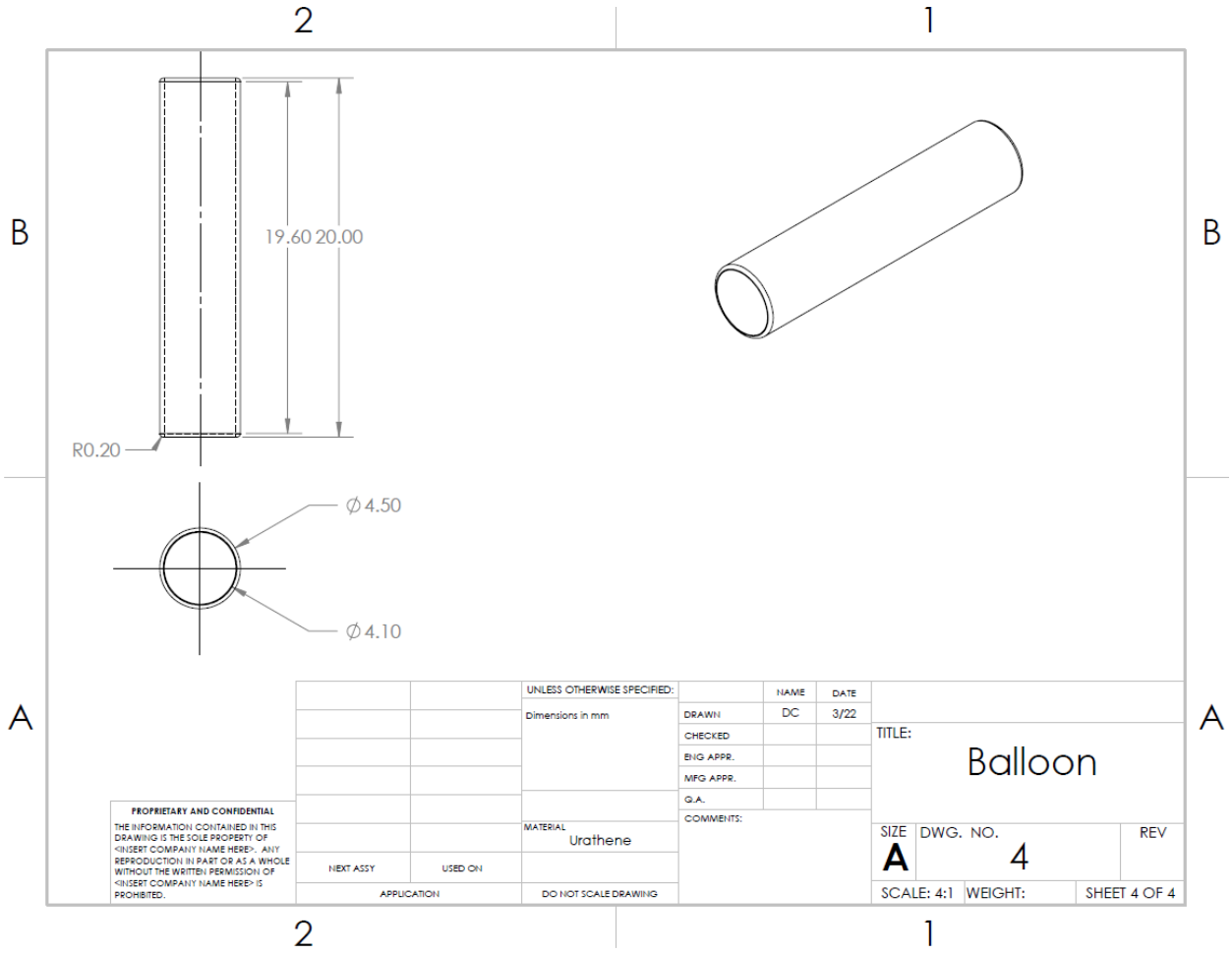
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