

NOVEL DEVICE FOR MANAGEMENT OF SEVERE EPISTAXIS (Prototyping JSTOP Medical Device for Controlling Severe Nosebleeds)

Tanveer Janjua, MD^{1,6}, Dan Weiner, MD², John Rutledge, Jr³, Martin J. Citardi, MD⁴, Joseph Michael Azary III⁵, Kim Hughes⁶

¹JSTOP LLC, Bedminster, NJ; ²Morristown Medical Center, Morristown, NJ; ³Atlantic Center for Research, Atlantic Health System Morristown, NJ; ⁴McGovern Medical School, The University of Texas Health Science Center at Houston; ⁵AzTech Regulatory and Quality, LLC, Shelton, CT; ⁶Janjua Facial Surgery, Bedminster, NJ

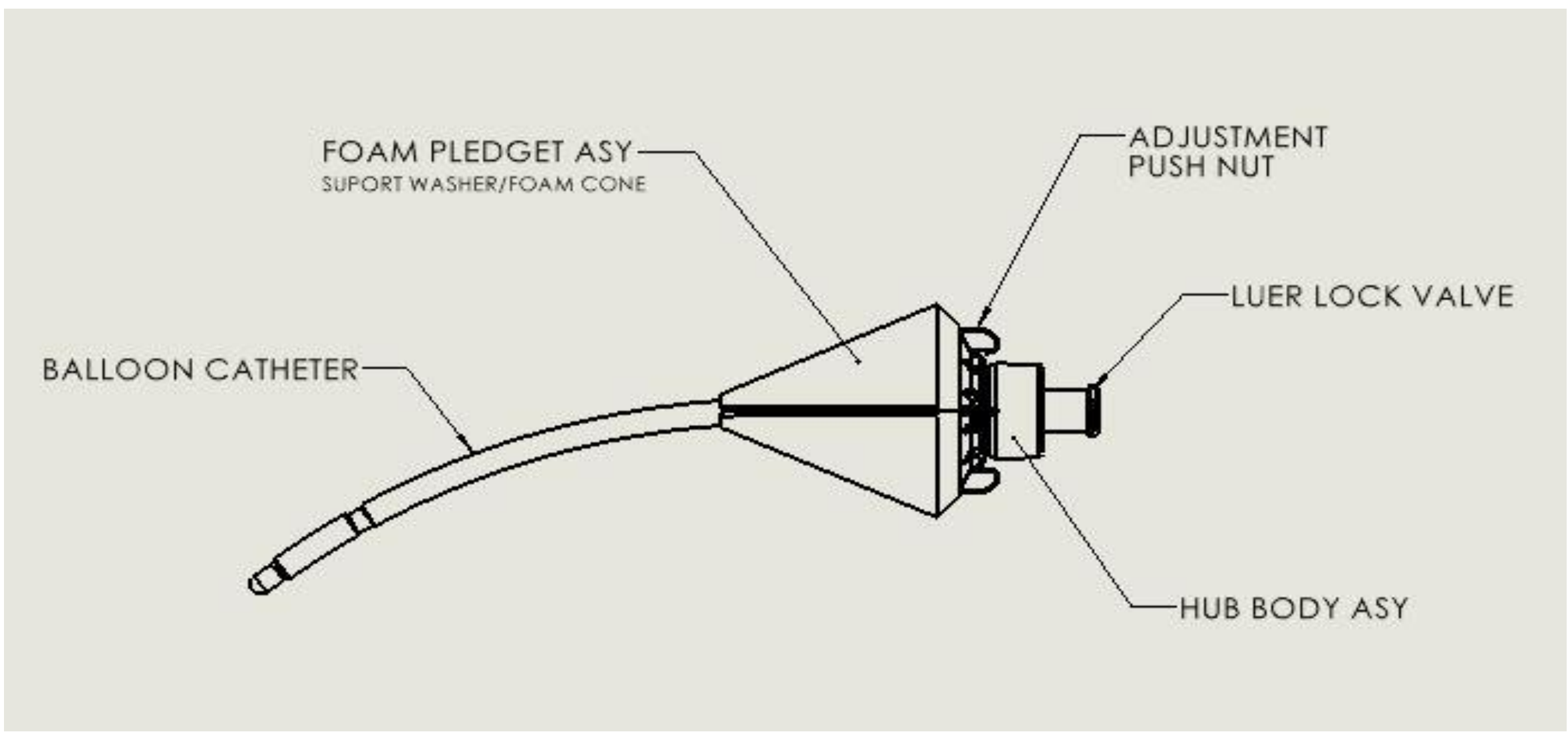
INTRODUCTION

Epistaxis is one of the most frequently encountered otolaryngologic emergencies with a lifetime incidence of up to 60%¹. The incidence of epistaxis is a bimodal distribution, primarily affecting children under 10 years of age and adults between 45-65 years old². The etiology includes factors that damage the nasal mucosal lining, induce trauma to the vessel walls, or alter the coagulability of the blood, which have environmental, local, systemic, or medication-related origins^{3,4}. Epistaxis accounts for one-third of all emergency admissions for ear, nose, and throat conditions, with a median age of hospitalization being 70¹. As-, excessive blood loss can result in pneumonia, heart attack, stroke, and even death^{5,6}, timely management of epistaxis is critical. Conventional balloon catheters may require specialized training and can be difficult to use. This leads to the use of Foley Catheter for severe epistaxis. Hence, there is a significant unmet need for a simple and easy-to-use approach to quickly control posterior epistaxis. JStop (from JSTOP, LLC) is a novel balloon tamponade catheter device for severe epistaxis. Its simple means of deployment will allow placement by health care providers without specific ENT training.

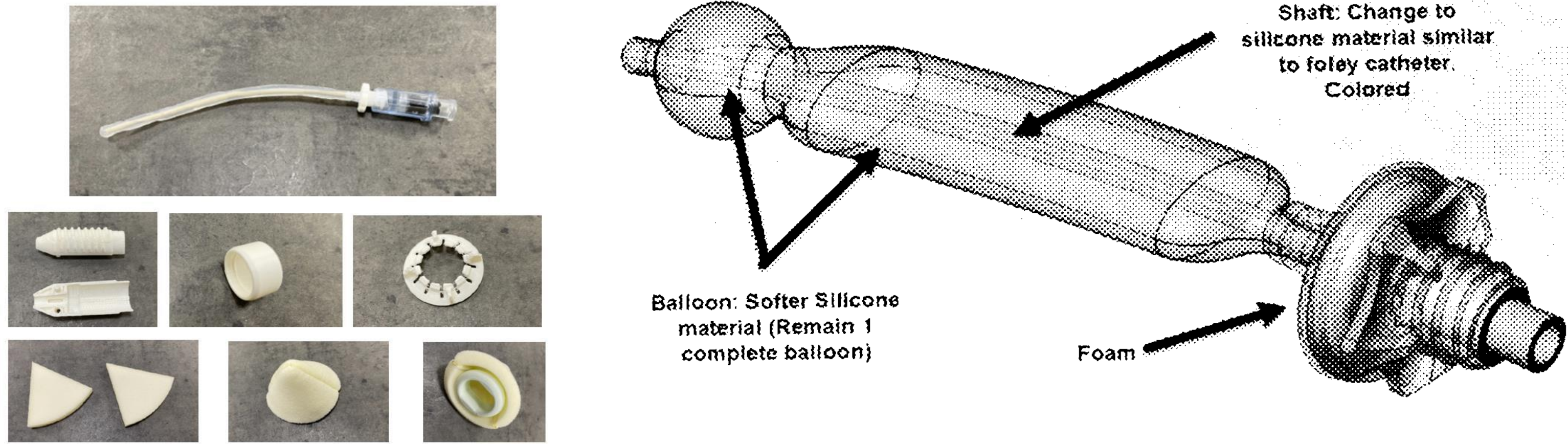
OBJECTIVES

- a) To complete the JSTOP™ prototype development
- b) To validate and test device efficacy and safety in a clinical study

METHODS



Step 1: A Computer Aided Design (CAD) diagram formed the basis for the 1st generation JSTOP™ prototype fabrication.



Step 3: Next, the prototype was re-engineered based on the above model study (e.g., balloon and shaft materials, resizing of the washer, addition of a stylet and a hole in the style for faster balloon inflation).

A



Step 2: A human head model study of the 1st JStop™ prototype was conducted. A. Test model of nasal cavity. B. Test model demonstrating blood flow and paths traveled during severe anterior and posterior epistaxis. C. JStop inserted into nose and balloon inflated with saline. D. Flow of blood simulant fluid from the test model impeded by JStop™.

B



C



D



ACTUAL JSTOP PROTOTYPE
For more information visit
www.JSTOP.COM
US Patent #10154850



Step 4: Validation and quality testing of the JSTOP™ prototype will be performed to ensure readiness for clinical testing phase.

COMPARISON OF JSTOP™ vs OTHER NASAL PACKING DEVICES

	RhinoRocket®	Merocel®	EpiStat®	EpiStax™	Ultra-Stat™	JStop™
Ease of Use	Easy	Easy	Difficult	Difficult	Difficult	Easy
Epistaxis	Mild	Mild	Moderate	Moderate	Moderate	Severe
Rapidity	1 min	1 min	5 min	5 min	5 min	1 min
Specialist?	No	No	Yes	Yes	Yes	No

OUTLOOK FOR JSTOP™

Successful prototyping of JStop™ will ensure its robust, safe operation and optimal performance. The establishment of proof-of-feasibility through this work will inform its evaluation in a first-in-human clinical trial which will enable compliance with the FDA's registration process for epistaxis balloons (Class I devices exempt from premarket notification requirements) and subsequent market entry.

References: ¹Morgan DJ, Kellerman R. Epistaxis: evaluation and treatment. Prim Care. 2014;41(1):63-73. Epub 2014/01/21. PubMed PMID: 24439881. ²Pope LE, Hobbs CG. Epistaxis: an update on current management. Postgrad Med J. 2005;81(955):309-14. Epub 2005/05/10. PubMed PMID: 15879044; PMCID:PMC1743269. ³Kasperek ZA, Pollock GF. Epistaxis: an overview. Emerg Med Clin North Am. 2013;31(2):443-54. Epub 2013/04/23. PubMed PMID: 23601481. ⁴McLarnon CM, Carrie S. Epistaxis. Surgery - Oxford International Edition. 2012;30(11):584-9. ⁵Grossmann I, Rodriguez K, Soni M, Joshi PK, Patel SC, Shreya D, Zamora DI, Patel GS, Sange I. Stroke and Pneumonia: Mechanisms, Risk Factors, Management, and Prevention. Cureus.2021;13(11):e19912. Epub 2022/01/06. PubMed PMID: 34984111; MCID:PMC8713735. ⁶Faria I, Thivalapill N, Makin J, Puyana JC, Raykar N. Bleeding, Hemorrhagic Shock, and the Global Blood Supply. Crit Care Clin. 2022;38(4):775-93. Epub 2022/09/27. PubMed PMID: 36162910.