

Prototyping JSTOP Medical Device for Controlling Severe Nosebleeds

Tanveer Janjua, MD^{1,6}, Dan Weiner, MD², John Rutledge, Jr³, Martin 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; ⁴The University of Health Science Center at Houston, Houston, TX; ⁵AzTech Regulatory and Quality, LLC, Shelton, CT; ⁶Janjua Facial Surgery, Bedminster, NJ

INTRODUCTION

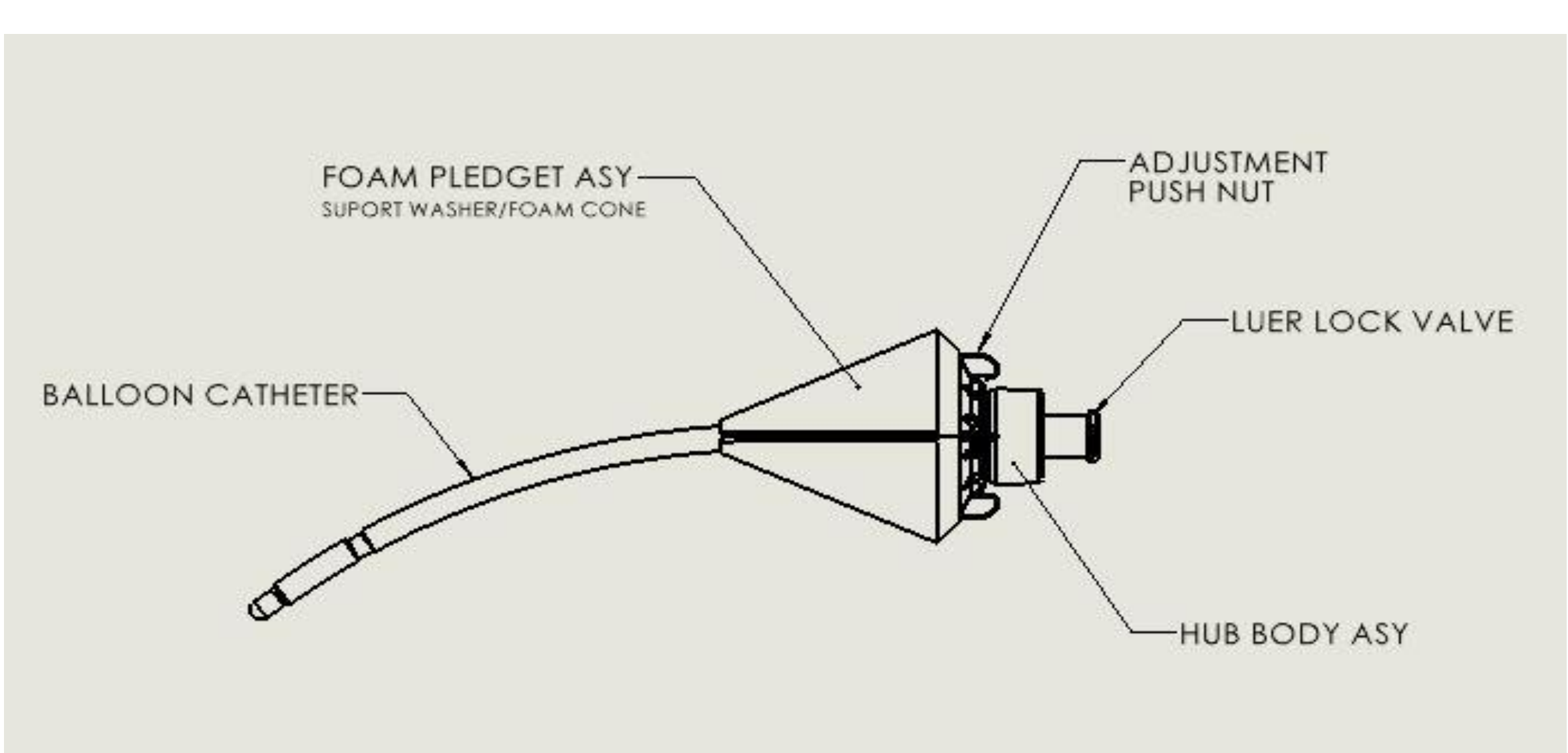
Epistaxis (or nosebleeds) can have a significant yet understated impact on US military personnel. Deployment hazards such as those acquired from chronic exposures to open burn pits can predispose military personnel towards respiratory track illnesses particularly severe sinus and nasal diseases, which is one of the known causes for nosebleeds¹⁻². Frequent nosebleeds have been reported by several US veterans during their active military service³⁻⁵ and by soldiers residing in moldy barracks in some US military stations⁶. Given the 732,000 veterans exposed to burn pits between 1990 and 2021⁷ who are claiming benefits for nasal illnesses and with 1000 more possibly exposed to black molds⁸, the frequency of nosebleeds is certainly undermining US troop readiness for combat operations. Currently, the military has no existing medical control device for severe nosebleeds in its emergency packets for soldiers. Hence, there is a significant unmet need for a simple and easy-to-use device to quickly control severe epistaxis.

Solution: JSTOP, LLC is developing a user-friendly device to control severe epistaxis called JStop. It is a portable balloon tamponade catheter designed to be readily deployed by medics to swiftly triage affected soldiers.

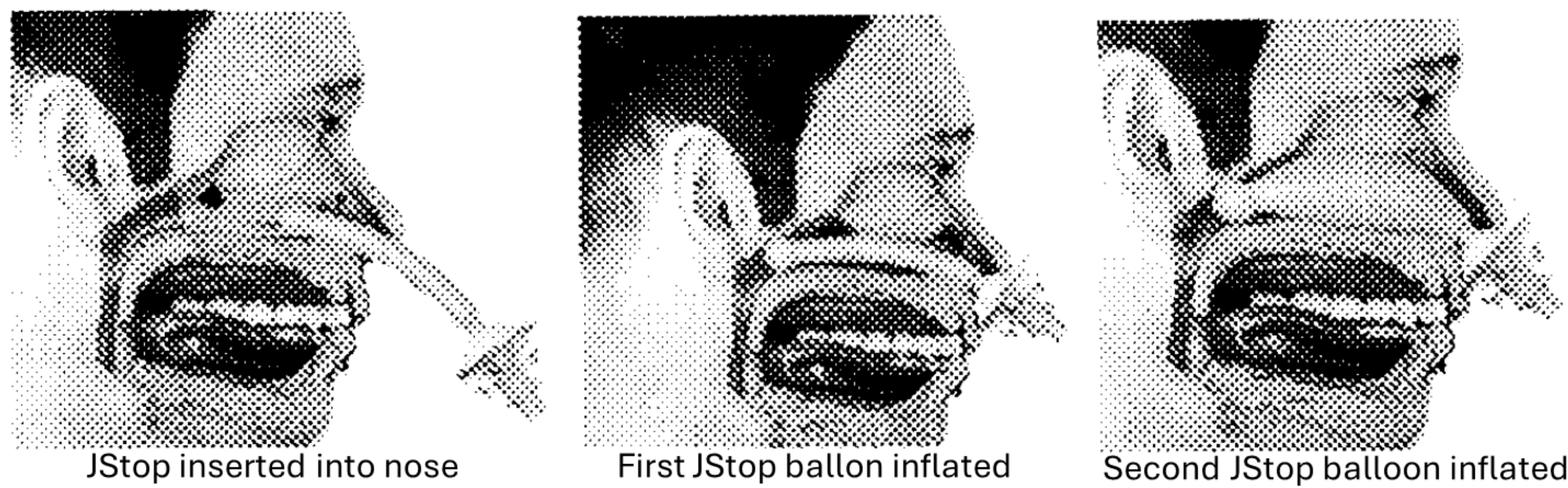
OBJECTIVES

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

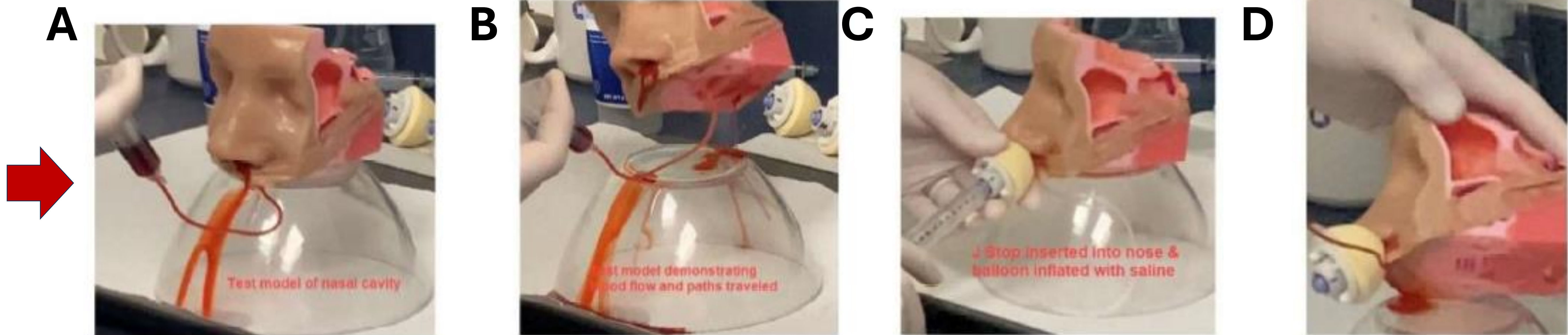
METHODS



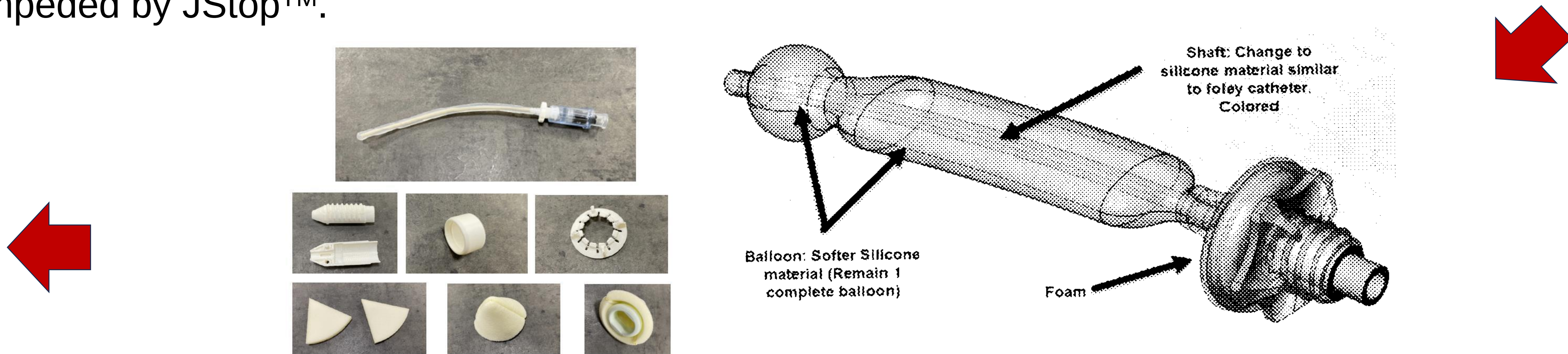
Step 1: A Computer Aided Design (CAD) diagram was created and formed the basis for the 1st generation JSTOP™ prototype fabrication.



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



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™.



Step 3: Next, the prototype was reengineered 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).

COMPETITIVE ADVANTAGE OF JSTOP™

	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 in the future 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: ¹Elam, T., et al., Air Pollution Exposure and the Development of Chronic Rhinosinusitis in the Active Duty Population. Mil Med, 2022. ²Hill, C.J., et al., Burn Pit Exposure Is Associated With Increased Sinonasal Disease. J Occup Environ Med, 2022. 64(8): p. 629-634. ³On appeal from the Department of Veterans Affairs Regional Office in Winston-Salem, North Carolina. 4 Sep 2015; <https://www.va.gov/vetapp15/Files4/1537206.txt>. ⁴On appeal from the Department of Veterans Affairs Regional Office in Muskogee, Oklahoma. 15 Apr 2014; <https://www.va.gov/vetapp14/Files2/1415412.txt>. ⁵On appeal from the Department of Veterans Affairs Regional Office in Reno, Nevada. 27 Jan 2016; <https://www.va.gov/vetapp16/Files1/1602248.txt>. ⁶Baynon, S., These soldiers say mold in barracks isn't just disgusting, it's making them sick. (April 24, 2023). ⁷Sagaly, D., VA will now recognize some veteran's illnesses associated with exposure to burn pits, in PBS News Hour. PBS.org. ⁸Military barracks poor living conditions undermine quality of life and readiness. September 2023; Report to Congressional Committees]. <https://www.gao.gov/assets/gao-23-105797.pdf>.