

**Problem and Need**

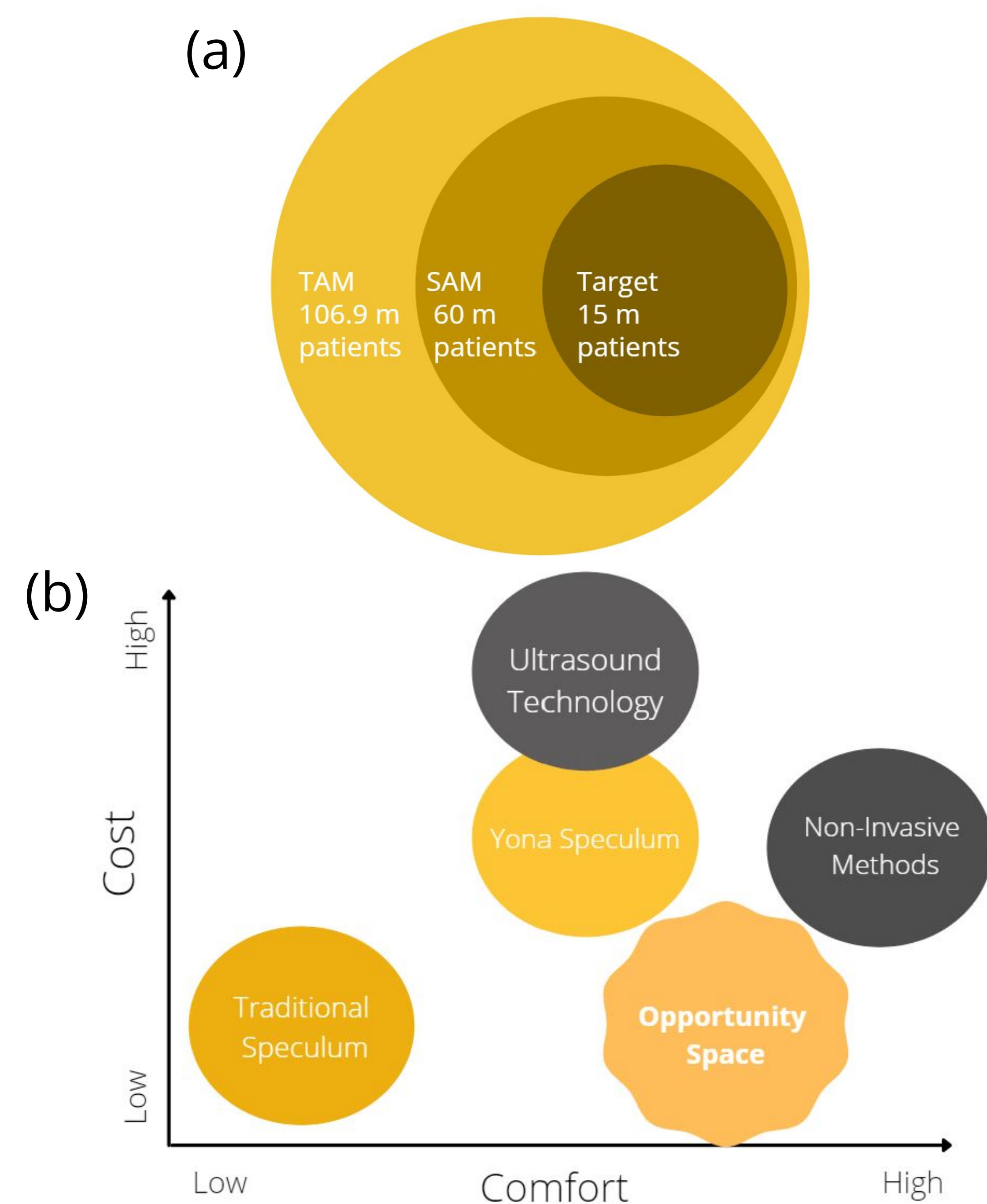
Of 79 surveyed patients, 25.9% attributed avoiding pelvic procedures due to concerns about the speculum, leading to increased risk of developing reproductive health issues.

**Pain Points:**

- Discomfort and pain
- Cold metal speculums
- Tissue pinching during opening
- Unpleasant clicking
- Non-Universal design

There is a need for a **redesigned speculum to decrease the percentage of women aged 15-65 years who avoid getting speculum procedures** due to fear of discomfort.

**Market Size & Opportunity Space**

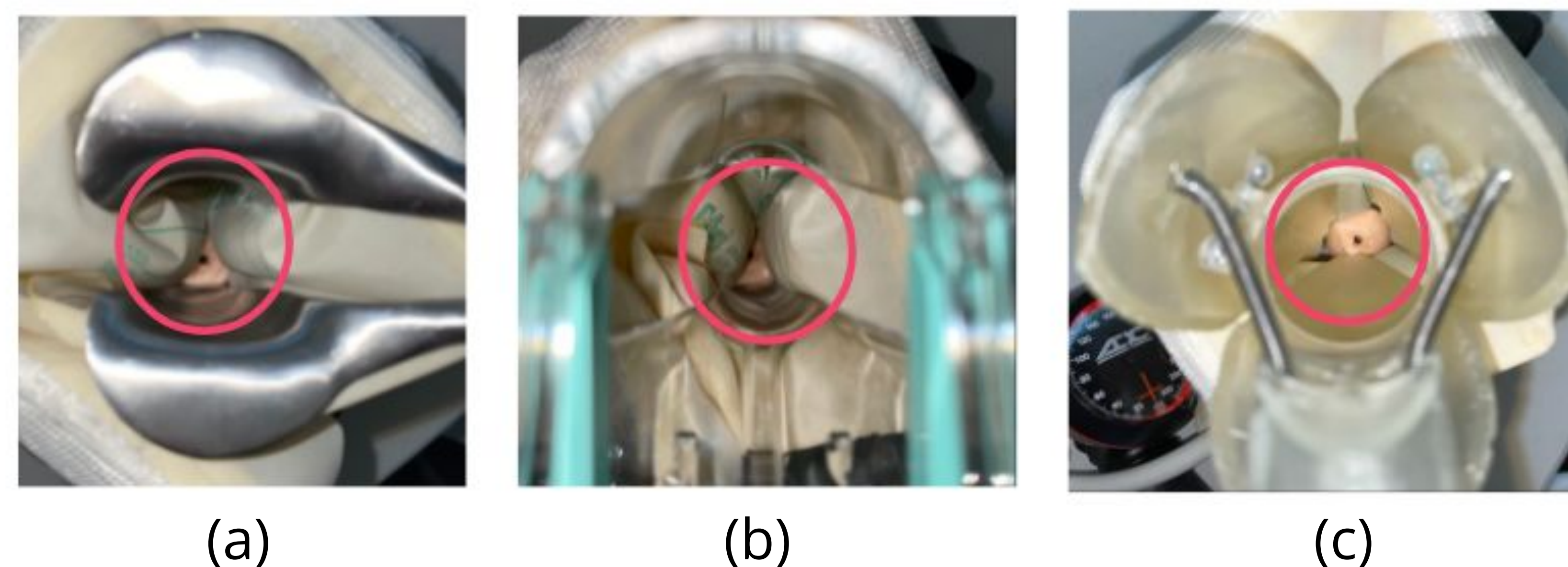


**Figure 1.** (a) Market Size (b) Opportunity Space

**Design Specifications**

User Need	Design Input Requirements	Weight
Able to open the walls of the vaginal canal	The device shall be able to withstand a contraction force of greater than 3.2 N [25]	3
Able to be inserted easily	The device shall have an insertion force less than 50 N, which is our upper bound for insertion force found by preliminary testing	3
Must accommodate different vaginal sizes	The device shall have a minimum working length of 40.9 mm and a maximum working length of 147.3 mm [26][27]	3
Must allow for a clear view of the cervix	The device shall have a maximum opening diameter of 35.0 mm to allow for a clear view of the cervix [28]	3
Must be compatible with all other current examination instruments	The device shall have a yoke greater than 25 mm in order to be compatible with the largest pelvic procedure instrument, a cytobrush	3
Able to be used with a single hand (left or right)	The device shall have a blade deployment/opening force of less than 45 N [29]	2
Able to be comfortably held by physicians with varied hand sizes	Largest handle diameter ranges between 31.1 mm and 40.6 mm (i.e. 19.7 percent of the hand length of the 5th percentile of females and 95th percentile of males) [30][31]	2
Handle length must be within the OSHA ergonomic recommendations	Handle length must be between 100 mm and 120 mm [32]	2
Must weigh less than current metal speculums (upper range)	The mass of the device shall be less than 454 g (i.e., the mass value corresponding to a 1 lb weight) [33]	2
Device must not interfere with patient's body, excluding the vaginal canal	The handle shall be angled approximately 130° away from the base of the blades	2
Able to be inserted in less than or equal amount of time than current speculums	The device shall be able to be inserted and expanded in less than 20 seconds, found from preliminary testing	1

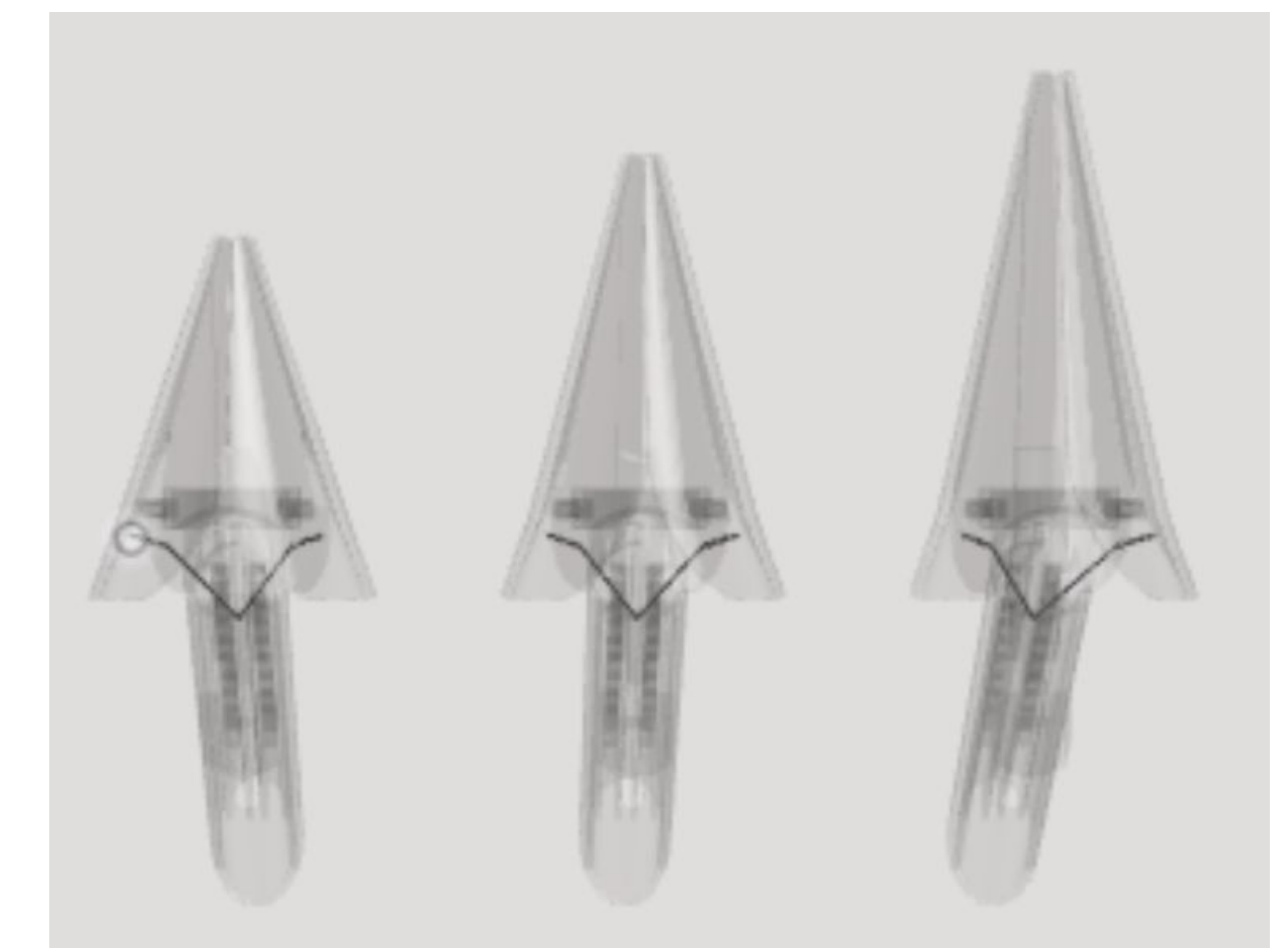
**Preliminary Testing Results**



**Figure 2.** Images of lateral wall support for (a) Collins Speculum, (b) Welch Allyn speculum, and (c) SAZER speculum

**Key Features**

- Tri-valve design
- Conical design, with tip circumference equal to that of a tampon
- Transparent blades
- Range of blade sizes
- Quiet locking
- Angled handle



**Figure 3.** 3D render of small, medium, and large sizes of the SAZER speculum

**Future Work**

Based on customer feedback, future design and validation plans include:

- Light implementation
- Interchangeable blade design
- Extensive force testing
- Animal studies
- Clinical studies of pain thresholds
- Patent filing

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