Reusable Catheter Analysis

Competitive Landscape:
1. **Non-Invasive** - Includes: pelvic floor exercises and training, diapers, and pads (2).
   - **Strengths**: Natural and least harmful on body. Muscle rehabilitation has long-term benefits. **Weaknesses**: Training/exercise requires time and does not guarantee success. Diapers and pads are non-reusable and can be expensive to purchase frequently.

2. **Devices** - Includes: plugs, bulking agents, and valve based devices.
   - **Strengths**: More reliable and long-term solution than non-invasive and less risky than surgery. Allows controlled usage. **Weaknesses**: requires education on usage. Must clean repeatedly and fixing if damaged. Price and maintenance is expensive. Users susceptible to infection.

3. **Pharmaceuticals** - Includes: restorative creams, pills, and injections.
   - **Strengths**: Quickest and most convenient compared to non-invasive and devices. Doesn’t require cleaning or timely training. **Weaknesses**: Potentially requires prescription from a doctor. Modest efficacy rates and irritating side-effects are tradeoffs. Chemical solution not effective for mainly physical challenge.

4. **Surgery** - For example, a Urethral Sling procedure.
   - **Strengths**: Potentially long-term solution to repairing muscles. **Weaknesses**: Cost is expensive considering low success rates and inherent pain of procedure.

Unmet Medical Need: Many that experience SUI require more than exercise or non-invasive products to treat their condition but do not require intensive surgery or drugs. The SUI market needs a short-term, simple, effective device that integrates conveniently into daily life and provides bladder control.

Market Segmentation
a. **Patients** can experience three types of Urinary Incontinence: Urge Incontinence, Stress Urinary Incontinence, and Mixed Incontinence (1). Urge Incontinence affects men and women and involves psychological urge to go to the bathroom. Mixed Incontinence is a combination of UI and SUI. This product targets SUI patients specifically because it allows users to control their bladders physically. Women, in particular, are at risk for SUI due to weakening pelvic floor muscles and intrinsic sphincter deficiency associated with natural aging, pregnancy, menopause, and childbirth; in fact, SUI affects approximately 15 million women in the U.S. This device is designed for, and can help, women regardless of age, as one-third of female SUI patients are younger than 35 and many elderly women also experience SUI.

b. **Other customers** - Hospitals may consider the device temporarily for women who have recently delivered a child vaginally, as the act weakens pelvic floor muscles. Assisted-living homes may consider the device as an alternative to pads and diapers, empowering residents to take control and alleviating attendants from cleaning up accidents. Urologists can consider the device as an alternative to patients who are opposed to taking pharmaceuticals or undergoing surgery.

Value Proposition
SUI patients cannot control leakage and may have embarrassing accidents frequently, making daily functions like working and exercising stressful and fear-inducing. Medici’s device, which resembles a self-catheter, utilizes physiologically-triggered valves that open under low abdomen pressure and close under high pressure bursts correlated to SUI. Simple to insert and remove once a week, Medici’s device offers a convenient alternative to other treatments that require constant replacements at inopportune times, making it effective for women during the workweek. Cheaper and less invasive than surgery, Medici’s device is a low-risk, effective solution to SUI that does not simply quell symptoms like diapers or pads, but allows users to regain muscle control, enhancing confidence and physical well-being. Alternatively, Medici’s device can function excellently for patients in assisted-living homes, allowing residents void without aid of diapers or pads, fostering autonomy and allowing nurses to focus on other areas.

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<th>Target Product Profile</th>
<th>Needs</th>
<th>Wants</th>
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| **Patient Population** | - Ability to insert and remove device independently  
- Universal body compatibility | |
| **Efficacy** | - Average body compatibility  
- Prevents Accidents/Leakage  
- Self-Control during Voiding | - Lower accident rate compared to plugs or buffers |
| **Safety** | - Satisfies FDA Regulations | - Mitigate discomfort for user  
- Less risk for infection than plugs or buffers |
| **Convenience** | - Bi-weekly replacement  
- Shorter replacement time compared to diapers/pads | - Functions completely during vigorous exercise  
- Max ease of learning |

**Development** - According to this TPP, testing must confirm bi-weekly usage does not have adverse side-effects. A tradeoff to testing bi-weekly efficacy is slow data collection and potentially delaying FDA approval. The TPP aims to develop the device as a longterm solution; however, this approach may have tradeoffs. The average human urinates 6-7 times per 24 hour span (3), and over the course of two weeks, undergoing 64-98 high-pressure applied voidings and withstanding the wear of young women’s active lifestyles will test the device’s durability. Developing and testing the device’s performance over extended time will be crucial, according to this TPP. Funding-wise, acquiring investments to support medical devices is difficult: venture capital works for 1-2 rounds of prototyping but is insufficient for large scale manufacturing. Partnering with a large maternity, pregnancy, or elderly care oriented companies could help secure funds and aid with growing commercial potential.

**Regulatory Pathway**

Medici’s device is relatively low-risk and manages a non-life-threatening condition, so it would likely be classified as Class II like many other types of urological catheters (4). Medici’s would
likely be approved through the 510(k) pathway by proving substantial equivalence to a similar device through trials. Similar intraurethral devices like Reliance VIVA, and FemSoft (5) function similarly to Medici’s proposed device, so obtaining clearance would be a matter of proving efficacy in objective and subjective tests.

**Market Size**
On a global scale, urinary Incontinence affects 200 million people worldwide. Specifically, stress urinary incontinence affects 15 million adult women in the U.S. According to its statistical study (9), Phoenix Physical Therapy concludes about 1-in-4 women experience UI in some capacity - 24% of women between the ages 18-44 experience incontinence or episodes of leaking urine involuntarily, and 23% of women over 60 also deal with the condition. The market for incontinence is prevalent, and will likely continue growing as the baby boomer population ages into assisted-living conditions. A portion of the market is also unknown considering women often wait an average of 6.5 years before considering treatment as the condition can be uncertain. FemSoft, the current leader in the market, is applicable to about 5% of the 15 million women who experience SUI, an estimated $1 billion market (7).

**Price**
Compared to other devices and non-invasive remedies, Medici’s device is more long-term. FemSoft, the leading intraurethral device, is single-use with an estimated cost of $2 per device and is mainly sold in $72.95 packs (8). A yearly supply of FemSoft would likely likely cost over $1000 for a daily user. According to this article from Post-Bulletin, FemSoft is rewarding for “women who pay full cost for the product,” which can be understood as an expensive decision. Assuming a user would use Medici’s device 25 times annually, each device would cost $40 to equal the same cost as FemSoft; therefore, to make Medici’s device more profitable, it would need to cost less than $40 and optimally above the cost of manufacturing to be considered a cheap and efficient alternative to the leading brand.

**Overall Assessment**
- Easy regulation route and passing FDA (510(k))
- Growing Market (Baby Boomers and elderly)
- Innovative Design (unique)

**BUT…**
- SUI ranges in severity. Patients will opt for exercise therapy to control before purchasing a device to be inserted into their body. There are many simple, common methods of treating what is not a life-threatening condition. Medici’s device would need to be significantly more convenient and effective than other alternatives, which is difficult to imagine for a device meant to undergo wear-and-tear inside a person’s body for two
weeks. It is also concerning that FemSoft is the only discernable device in the market and that other intraurethral devices are no longer sold. The market is not overwhelming and it seems neither is demand. I wouldn't consider a job at Medici because the company will likely only be successful if it is extremely disruptive to the market, which will be a matter of luck.

References

Note: the sources listed below are referenced in the main body using endnote citation.

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