Center for Rural Affairs REAP Women's Business Center (Nebraska) InnovateHER Challenge Submission

Sonia Rocha-Sanchez (Lead)

Michael Feloney, MD
F&S Medical Solutions, LLC
SimplCath – female catheterization assisting device
10221 Woodridge Lane
Omaha NE 68124
402-871-6135
fsmedicalsolutions@gmail.com

Center for Rural Affairs REAP Women's Business Center P O Box 136 145 Main Street, Lyons NE 68038 cfra.org/reap/wbc

POC:

Monica Braun, REAP WBC Director

402.643.2673 monicab@cfra.org

Joinder Agreement: A-53

F&S Medical Solutions has created SimplCath — a unique medical device that assists with helping catheterize the female uretha. In addition to simplifying the female catheterization process by providing a product designed only for female use, this device greatly decreases the risk of urinary tract infections caused by contamination of the catheter, reduces the number of staff required for catheterization and can be widely utilized in hospitals, other medical settings, and at home.

Three total applicants participated in the Center for Rural Affairs REAP WBC InnovateHER Challenge Submission:

- F&S Medical Solutions, LLC
- Ace Empire
- Third Space Coworking & Childcare

STATEMENT OF SUPPORT

Center for Rural Affairs REAP WBC InnovateHER Challenge

F&S Medical Solutions was the clear winner in the InnovateHER Challenge competition held on June 2nd, 2017. Three individuals competed in total, and F&S Medical Solutions, LLC most clearly met the three challenge objectives in the following ways:

Has a measurable impact on the lives of women and families: The impact of the SimplCath product is enormous in that it can potentially assist each and every woman at some point in her life. Currently the same catheterization process is used for both men and women, despite the fact that the anatomy is clearly different. This product is designed specifically for women and greatly assists with the catheterization process in that it provides a guide for catheter insertion into a woman. This makes the process far simpler and therefore less traumatic for a woman being catheterized. The product also decreases urinary tract infection rates which not only makes the catheterization process safer, but it also provides peace of mind for women either as patients or family/friends of a patient. The product is also simple to use, which greatly impacts females who need to self-catheterize at home. Lastly, medical visits, especially ones involving this type of intimate procedure can be difficult at best and traumatic at worst for women. Many clinical catheterizations involve two nurses, but this product can be used by only one nurse, which can have a psychological benefit to the patient as well as labor cost-savings to institutions.

The other two competitors did not as clearly demonstrate an impact on the lives of women and families. Ace Empire's product, while very interesting, did not have a big impact on the lives of women and families because similar products already exist. Ace Empire's unique factor was to add in entrepreneurial content to a digital/print magazine. While this is noteworthy, it does not have the same level of impact on women that SimplCath does. Ace Empire also did not clearly demonstrate the impact on women during the business pitch. Third Space definitely provides a valuable service to women who have infants and want a transitional day care option; however, the cost of service is relatively high and limited to urban communities which means not all women would have access to the service. F&S Medical Solutions' product is applicable to literally all women in all medical settings.

Has the potential for commercialization: SimplCath is highly commercializable and has a low cost/high return. It is inexpensive to produce and can be used in all manner of medical settings from hospitals to clinics to at home. It is accessible to women of all income levels living in either rural or urban settings. There are multiple benefits to this product that will be very attractive to medical professionals — it greatly decreases urinary tract infection rates, it reduces staff requirements in half by requiring one nurse instead of two for the catheterization procedure, it can be utilized in virtually every medical setting and can easily be used by patients self-catheterizing at home. This product can also be either disposable (hospital use) or reusable (home use). It is currently the only product on the market to assist female catheterization in any setting.

Ace Empire's product is commercializable in that many women would be interested in a digital/print magazine that combined business with personal interests. However, as noted before, many magazines

already exist in both of those realms – though Ace Empire strives to combine the two which would be attractive to women. Ace Empire also did not demonstrate a firm grasp of scale up numbers, monthly expenses, etc. in the business pitch. Third Space is commercializable in that many women are struggling with the concept of putting infants in daycare when they must go back to work. The business idea would be popular, however, the high cost does not make the product marketable across all income levels and would exist solely in urban communities

Fills a need in the marketplace: There is no question that F&S Medical Solutions, LLC's product fulfills a need in the marketplace. There is no other female-specific catheterization assistance device currently on the market but the medical need for such a product clearly exists. This pitch included a variety of statistical evidence and a video testimonial that clearly depicted the need for this product. Market research done by F&S Medical Solutions determined that the US market size for adult female urethral catheterization is approximately 20M patients annually, and the market for in home use is approximately 3M patients per year (based on 2010 CDC data). None of the other competitors could demonstrate this level of need in the marketplace.

The other two competitors did not as strongly demonstrate filling critical need in the marketplace. As mentioned before, Ace Empire's magazine makes only one distinction in an otherwise fairly saturated market. Third Space has a definite marketable and unique idea with their concept of a day care combined with a teleworking/communal workspace, but other, more affordable options already exist for women.

I support F&S Medical Solutions, LLC as the Nebraska winner and hope that they will be selected as a national finalist.

Monica Braun, Director

REAP Women's Business Center