

BCIT MAKE+ collaborates with one of 20 Most Innovative Companies to Watch

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Urinary incontinence (UI) occurs when an individual loses or has weakened control over the urinary sphincter. Although not a life-threatening condition, losing control of one's bladder is an embarrassing, inconvenient, and common problem that affects as many as 3.5 million Canadians, and of which 1.2 million are men. This medical problem also significantly affects one's quality of life including physical, psychological and sexual.

A solution for urinary incontinent men

With limited treatment options available for urinary incontinent men, Life360 Innovations Inc. (Life360) collaborated with MAKE+ to innovate and research on a device that would serve as a treatment option.

After more than eight years of extensive research, including a five-year, multi-site Canadian clinical study, Life360 finally received Health Canada approval for its Contino® urethral insert, a licensed, self-administered medical device that controls bladder leakage in men.

As the first of its kind, this device is an integrated solution that includes personalized fitting and support from incontinence specialists to provide self-managed bladder leakage solution for men.

Robert Orr, President and CEO of Life360 said, "We are very pleased that Contino® is now available. There are limited treatment options available and the Contino® is a clear

alternative to the existing treatments as it is the first of its kind in the world. We believe Contino® has the potential to transform the lives of many Canadian incontinent men."

As the creator of Contino®, Life360 Innovations received recognition from Business Worldwide Magazine as one of the 20 Most Innovative Companies to Watch, 2020. "This recognition will improve our opportunity to positively impact the lives of UI sufferers around the world, which has been the central motivation behind our innovative design and approach to disrupting the growing multi-billion dollar urinary incontinence market," added Robert.

Where the story begins for the BCIT MAKE+ team

Contino® was inspired by Ken Kunz, a Mr. Fix-It and a prostate cancer survivor who was incontinent and frustrated with the existing treatment options: invasive surgery or medication with significant side effects; bulky pads that leaked and smelled; unwieldy external catheters that had to be continually emptied; or penile clamps that caused swelling, circulatory issues, skin rashes and urethral scarring.

Ken wanted to get on with life without the worry of UI being the main focus of his day, so he eventually created a device to treat his urinary incontinence.

The success of Ken's story led Robert Orr to approach MAKE+ in 2011 to redevelop the "proof of principle" prototype. Although the device showed promise, it was far from something that could be considered ready for a clinical trial and ultimately the consumer market. The BCIT MAKE+ team was tasked to further develop the concept into a functional clinically ready prototype using their ISO 13485 Certified medical device development process.

During the course of the project the MAKE+ team produced over 20 different variations of the initial design with more than one hundred different design requirements needed to be evaluated, tested and verified. This extensive design work is the basis of approximately 45 design patents and 20 utility patents registered in 15 countries.

One challenge the team encountered was the type of material to use. Silicone was the first choice as it was considered to be the "gold standard" for similar applications such as urinary catheters and the bio-compatibility requirements. After many testing failures, the research team couldn't understand why such an "ideal" material didn't seem to work as intended. Surprisingly, extensive research and consultation with physicians, engineers, and materials scientists determined that the properties that made silicone a great material for catheters were not favourable in LIFE360's application. Additional research eventually found a new material that satisfied the performance requirements and met the ISO 10993

bio-compatibility requirements. The next task was to create a prototype mold in order to evaluate the performance of the new material.

Verification testing

Once the mold was completed, the next phase was verification testing. As the product continued to develop, it would need to be tested for durability based on the anticipated useful life of the commercial product. Not a simple task – the MAKE+ team designed a cyclic load test machine that greatly improved the efficiency of accelerated lifespan tests for the device. The test machine was simple, cost effective and most importantly it worked and reduced the time for each test by a factor of sixteen.

Commercialization

The commercialization process continues as Life360 has recently opened their first Contino® Authorized Clinic and plans to opened many additional partner sites across Canada in 2019/2020.

"The receipt of our Health Canada licenses combined with the opening of our first Contino® Authorized Clinic are major milestones which could not have been achieved without the contribution from the Make+ team." Robert Orr, President and CEO of Life360. "In particular, the Make+ team was incredibly committed to our success, which enable us to collectively overcome the many challenges we faced together."

Contino® is now available at the Dayan Physiotherapy and Pelvic Floor Clinic in Vancouver. To book a consultation, please call the clinic at 604-739-3133 or email info@dayanphysio.com or contact Life360 at 604-653-0360 or email support@life360innovations.com.

MAKE+ Team Participants

Nigel Halsted, Thom Bellaire, Ernie Janzen, Judy Findlay, and Johanne Mattie.

Life360 Innovations Inc.

Life360 Innovations Inc. is a Vancouver-based private company dedicated to creating products which create "well-being by design™." Learn more about Contino®.