

Smart catheter system: A new bladder control management solution

With component sourcing and supply chain management support from Trelleborg, Spinal Singularity developed the Connected Catheter to offer improved quality for users.

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A fully internal, extended use smart catheter system could provide control for men who face daily challenges of living with a neurogenic bladder – the inability to feel the fullness of their bladder or control their bladder to urinate, leading to chronic urinary retention (CUR). The Connected Catheter, developed by a team at Spinal Singularity and supported with component sourcing and final assembly from Trelleborg, is an approach to overcome the risks and nuances that current bladder management methods present.



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“With today’s standard of care, people use a disposable, intermittent catheter that requires them to insert the plastic tubes into their bladder every time they go to the bathroom,” explains Derek Herrera, CTO and founder of **Spinal Singularity**. “That could be 8 to 10 times a day or 100 times a month. Throughout a lifetime, it becomes a very daunting task.”

An internal, extended use catheter “could potentially replace 50 catheters because our device can safely stay in the body for up to seven days,” Herrera adds. “Instead of having to insert a new catheter every time you go to the bathroom, you can use our device and just open and close a valve to empty the bladder.”

Those using standard catheter devices often get infections or face urethra trauma. Unable to control their bladders, individuals may dehydrate themselves to avoid having accidents in public.

HOW IT WORKS

The user places the magnet on the controller next to the valve (in the inserted catheter) and activates the controller’s motor. When the valve is opened and the motor is activated, the titanium pin spins forward, actively propelling urine out of the bladder. This allows for a more complete emptying of bladder and expulsion of residual urine from the urethra.

When the cycle is complete the pin is activated again, spinning in reverse to close the valve. A weekly exchange of a sterile catheter, as opposed to multiple daily insertions, decreases the likelihood of bacteria being transmitted.

The design process

Because the catheter needed to be used as a long-term device, it required a biocompatible material. To meet this standard, the Spinal Singularity team partnered with polymer engineers at Trelleborg Healthcare & Medical for the device’s critical, molded silicone parts and tubing.

“Often, silicone components, whether they are injection molded or extruded components, are chosen because the material attributes provide clinical and design benefits,” says Sean McPherson, sales engineer at **Trelleborg Healthcare & Medical**. “Silicone is known for long-term stability, is very inert, and can be used and stored under a wide range of temperatures and humidity.”

Medical device makers often use silicone rather than a thermoplastic elastomer (TPE) due to its stability and because it is not affected during sterilization and aging.

Trelleborg was able to manufacture the components in-house and complete final assembly at its Tustin, California facility, streamlining the transition from component manufacturing to final assembly.

An extension of Spinal Singularity’s project team, Trelleborg’s engineers provided design for manufacturability support, demonstrating the risks of bonding silicone materials.

The team used an overmold process that was shorter, less costly, and reduced the likelihood of device failure. Additionally, the Trelleborg team supplied finished product packaging and labeling support.

“Labeling is often looked at as something that can be done last-minute. Because of unique device identifiers, batch numbers, traceability, and other factors, this is not the case,” McPherson says. “Labeling is key because if any part of it is off, then the device will be off.”

The partnership provided Spinal Singularity with rapid prototyping, full component manufacturing, and ultimately full device assembly scale-up and finished device manufacturing.

A NEED TO SERVE

While serving in Afghanistan, Derek Herrera suffered injuries after being shot by a sniper, which left him paralyzed from the neck down. Although he could no longer serve in the military, Herrera still wanted to do his part to assist others. Despite the new reality he faced with the daily hardships of paralysis, Herrera went on to continue his studies to find a new solution for others who face the outcomes of spinal injuries. After earning a Master of Business Administration degree, Herrera launched his own medical device company – Spinal Singularity.

“How we initially envisioned it, it was designed to create products to improve the quality of life for people with spinal injury,” Herrera says. “So, the first product we decided to work on was this bladder management system Connected Catheter.”

Spinal Singularity is a seed stage, venture-backed medical device company located in San Clemente, California.

Company timeline:

- 2015:** Spinal Singularity launched
- 2016:** Acceleration – The company completes MedTech Innovator, YCombinator, HealthBox LA
- 2017:** Equity investment secured
- 2018:** First-in-man clinical studies and Clinical Feasibility study
- 2019:** Launches clinical validation study and CE regulatory submission

A smart catheter

The Connected Catheter is fully internal to the male anatomy. The Catheter tip incorporates a magnetic valve-pump, which opens and closes via remote control and enables the bladder to fill naturally. The catheter enables users to empty their bladders comfortably and conveniently without frequent catheterization or an external bag attached to the body to collect urine.

Spinal Singularity

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