

FDA clears SMD's innovative new urinary catheter design

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Safe Medical Design, Inc. (SMD), a medical device company dedicated to developing safe and cost-effective solutions in urology has announced that the U.S. Food and Drug Administration (FDA) cleared the Signal Catheter for commercialization in the United States.

A urinary catheter is a flexible tube passed through the urethra and into the bladder to drain urine. Each year in the United States there are as many as 500,000 interventions due to trauma from catheter placement. SMD's Signal Catheter features a novel design and has the potential to reduce urethral trauma as a result of premature balloon inflation during placement.

"This is a monumental shift in a field that has changed very little for the better part of 25 years, despite the over 20 million catheter placements annually in the United States alone," said CEO Dr. David Aaronson, M.D. "Our device, the Signal Catheter, has the potential to protect patients from unnecessary pain and other complications, while also addressing an issue that costs hospitals \$184M annually."

30 million urethral catheters are placed annually in the United States. While over 200,000 incidences of urethral trauma during catheter insertion were officially reported in 2012, catheter complications are often underreported with some publications estimating there are closer to 500k incidences.

"The accidental inflation of a traditional catheter in the urethra can cause painful, long-lasting and costly damage to patients," said Dr. Maurice Garcia, Safe Medical Design, Inc. Founder and Cedars-Sinai Medical Center urologist. "The data we presented at the 2018 American Urological Association (AUA) annual meeting demonstrates that accidental inflation of the catheter's balloon within the urethra using SMD's Signal Catheter results in significantly lower intraurethral balloon pressures when compared to the market leading urethral catheter."

SMD was founded by a team of urologists and engineers in 2012. Funded in part by the National Institute of Health and private financing, SMD is focused on addressing complications in the urology market while reducing overall healthcare costs.