



IMPACT Study¹

InterMittent catheters Protective feAtures and miCrobial Transfer

Hollister Incorporated, is a leader in innovation and offers a diverse portfolio of catheter products including VaPro™ No Touch Intermittent Catheters designed with a protective tip and sleeve. The IMPACT laboratory study is part of a larger body of no-touch catheter evidence including laboratory studies and clinical trials.

IMPACT at a Glance

The IMPACT study (InterMittent catheters Protective feAtures and miCrobial Transfer) is the first study demonstrating that VaPro catheters outperform competitive sleeved catheters without a protective tip in preventing microbial contamination, a leading risk factor for urinary tract infections.

The Background

VaPro catheters have been known for years for their 100% No Touch Protection they provide with a protective tip and sleeve. Hollister asked an independent laboratory to investigate the protective effects of VaPro catheters and how they compare directly with catheters from other manufacturers.

The Methodology

For optimal comparability, the researchers

assessed catheters that also have a protective sleeve. Comparative intermittent catheters included SpeediCath Flex™ catheter (Coloplast), Liquick X-treme™ catheter (Teleflex) and IQ Cath™ catheter with sleeve (Manfred Sauer). All comparators have a protective sleeve, but there is none with a protective tip like VaPro catheters. The most relevant uropathogenic microbial species were tested including *Escherichia coli*, *Enterococcus faecium* and *Candida albicans* (a yeast). *Escherichia coli* are a leading cause in urinary tract infections and have a high

propensity for antimicrobial resistance. *Enterococcus faecium* has also been associated with multidrug resistance, including to gentamycin and vancomycin. To simulate the touch contamination, the researchers contaminated gloves with a precisely defined concentration of each microbial strain. With these gloves, the researchers inserted the respective catheter into the urethra of an anatomical penis model. The model was also prepared by contaminating a defined quantity of microbes into the first 15mm of the distal opening to simulate real-world presence in that region. The rest of the model was sterile. Then the researchers pushed the catheter through the model, following the instructions for use of the respective manufacturer. When it came out on the other side they cut off two pieces, each 2 inches (5 centimeters) long. Upon withdrawal of the catheter they also cut two 2 inches (5 centimeters) sections from the protective tip and sleeve. The entire cap of the VaPro catheter was also tested. The researchers counted how many bacteria or yeast adhered on the respective sections. Multiple researchers repeated this process 9 times for each bacterial and yeast strain for each catheter model.

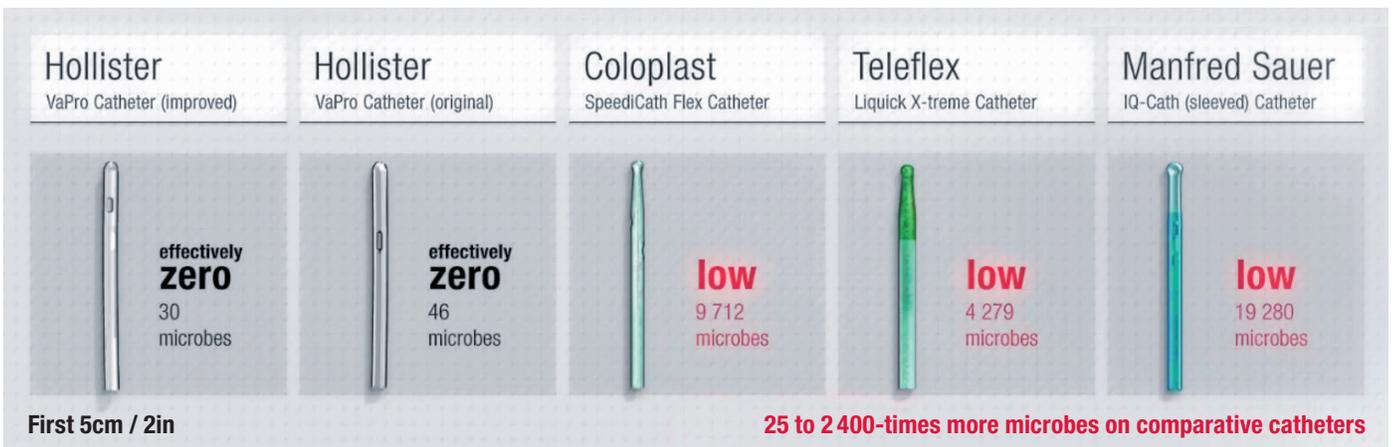
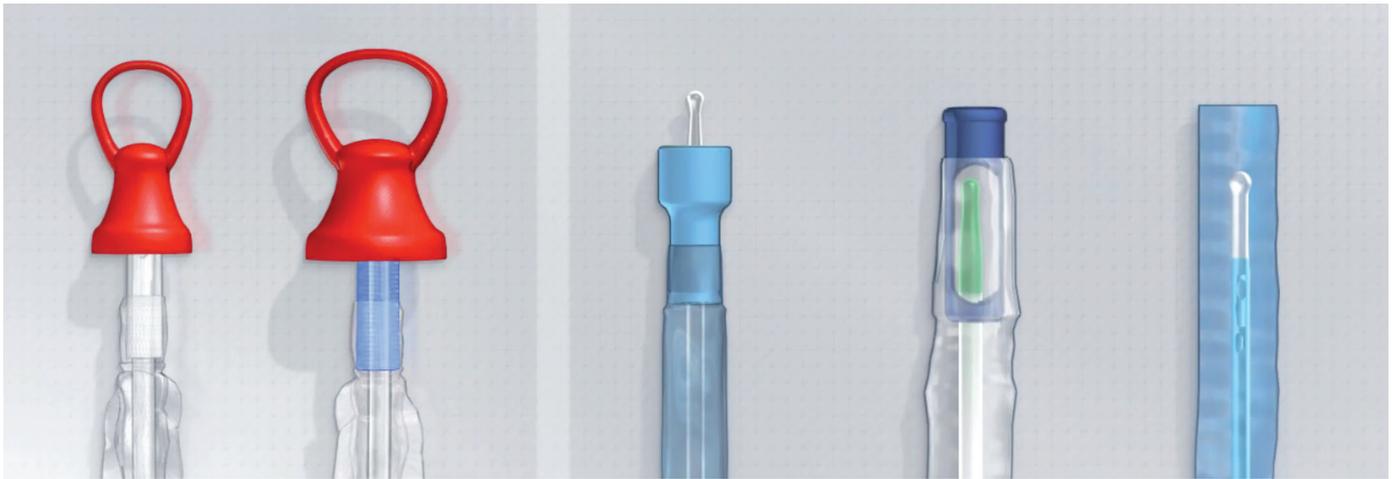
Watch the IMPACT Study Video



A video detailing the study methodology and results is available at www.hollister.ca/continencecare/vapro

Reference: 1. Hollister data on file, TR-00453, 2021

VaPro™
No Touch Intermittent Catheter



The Results

VaPro catheters outperformed SpeediCath Flex catheters, Liquick X-treme catheters and IQ Cath (with sleeve) catheters in preventing touch contamination to the catheter for all three species evaluated. The VaPro catheters provide superior protection in reducing microbial contamination to effectively zero. Comparative catheters resulted in 25 to 2400 times more microbes than on VaPro catheters (p-value of <0.05).

Conclusion

VaPro catheter's combination of protective tip and sleeve demonstrates the best protection against contamination when compared to other sleeved catheters without a protective tip.

Prior to use of VaPro catheters, be sure to read the Instructions for Use for information regarding Intended Use, Contraindications, Warnings, Precautions, and Instructions.

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