

Prospective Analysis of Cultures From the Furlow Insertion Tool: A Possible Etiology for Penile Prosthesis Infections

Faysal A. Yafi,^a James Furr,^b Farouk M. El-Khatib,^a Koenraad van Renterghem,^c Luca Venturino,^d Robert Andrianne,^e Daniar Osmonov,^f David Ralph,^d Javier Romero Otero,^g Maxime Sempels,^e Georgios Hatzichristodoulou,^h Aaron Lentz,ⁱ Steven K. Wilson,^j



Highlights:

- A total of 83 Furlow devices were cultured. Median age of surgical instrument was 4 years (2–10 years).
- Methods of sterilization included autoclave, wet autoclave, steam and STERAD. Median time from sterilization was 3 days (1–22).
- The internal component (obturator) was swabbed.
- 2/83 (2.4%) devices revealed positive swab cultures for *Staphylococcus epidermidis* (<10,000 colonies).
- Both of these devices presented disassembled and did not demonstrate any stains or discoloration.
- Both of these devices were sterilized using autoclave.
- No implant from this cohort has become infected to date as contaminated Furlows were discarded.

Potential Limitations:

- One potential limitation is that the contaminated instruments were simply the result of the microbiology lab causing contamination.
- Other limitations include the relatively small sample size (n=83) and lack of standardization regarding sterilization protocols across centers.
- The data presented does uniquely highlight a problem with sterilization protocols that was seen across multiple centers.

Yafi FA, Furr J, El-Khatib FM, et al. Prospective analysis of cultures from the Furlow insertion tool: a possible etiology for penile prosthesis infections. *Int J Impot Res.* 2021 Apr;33(3):291-5.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.

All images are the property of Boston Scientific. All trademarks are the property of their respective owners.

© 2022 Boston Scientific Corporation or its affiliates. All rights reserved. MH-1243408-AA MAR 2022

The purpose of this study was to assess whether inadequate cleaning and sterilization of the reusable Furlow inserter may represent one of the last etiologies of infection in patients undergoing penile prosthesis implantation. The study included a prospective analysis of cultures of the Furlow inserter used for PP surgeries from seven centers (multiple high-volume) in the USA, Germany, Belgium, the United Kingdom, and Spain between May 1 and June 30, 2019.

Once the Furlow was received for surgery, the surgical team inspected the device for assembly status (disassembled or not) and the presence of visible stains, pieces of tissue or discoloration on either the interior of the barrel or the plunger. Swab aerobic and anaerobic bacterial and fungal cultures were then obtained from the internal component, after removal from the external component if assembled, and after introduction and immediate removal from the external component if disassembled. On initial presentation, 79 devices were disassembled (95.1%) and 4 devices were still assembled (4.9%). Three external components were discolored (3.6%), while internal components demonstrated two stains (2.4%) indicative of improper cleaning which were thought to be residual blood products. (Table 1).

2/83 (2.4%) of devices revealed positive swab cultures for *Staphylococcus epidermidis*. Swab cultures were negative for fungi and anaerobic bacteria.

Conclusion: Improper handling, cleaning and/or sterilization of the Furlow insertion instrument may represent a source of infection for patients undergoing PP implantation. The authors suggest a disposable Furlow inserter might offer the opportunity to reduce the risks of contamination associated with improper instrument handling and impact the rate of device infection. Both of these devices presented disassembled, did not demonstrate any stains or discoloration, and were sterilized using autoclave.

“The results also highlight the importance of developing novel single use, i.e., disposable, instruments (e.g., Furlow) to potentially reduce the risks of contamination associated with improper instrument handling.”

Link to full article: <https://doi.org/10.1038/s41443-020-0256-2>

a University of California Irvine, Irvine, CA, USA; **b** University of Oklahoma, Oklahoma City, OK, USA; **c** Jessa Hospital, Hasselt, Belgium; **d** University College London Hospital, London, England; **e** University Hospital of Liège, Liège, Belgium; **f** University Hospital Schleswig-Holstein, Kiel, Germany; **g** Hospital Universitario 12 de Octubre, Madrid, Spain; **h** Martha-Maria Hospital, University of Erlangen-Nuremberg, Nuremberg, Germany; **i** Duke Raleigh Hospital, Raleigh, NC, USA; **j** Institute for Urologic Excellence, La Quinta, CA, USA

Conflict of interest: FAY reports associations with Endo Pharmaceuticals as consultant and speaker; Antares Pharma as consultant and speaker; Coloplast as speaker and advisory board; and Viome Inc. as trial primary investigator. All other authors declare that they have no conflict of interest.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

The content of this article/publication is under the sole responsibility of its author/publisher and does not represent the opinion of BSC.

Table 1: Instrument and culture information from 83 cultured Furlow inserters

Time of surgery	
First case	67 (80.7%)
Not first case	16 (19.3%)
Location of surgery	
Academic	62 (74.7%)
Nonacademic	21 (25.3%)
Sterilization technique	
Autoclave	62 (74.7%)
STERAD (dry heat sterilization)	21 (25.3%)
Median time from sterilization (range)	
	3 days (1–22)
Median age of device (range)	
	4 years (2–10)
Device presentation	
Assembled	4 (4.9%)
Disassembled	79 (95.1%)
External component inspection	
Clean	80 (96.4%)
Discolored/stains	3 (3.6%)
Internal component inspection	
Clean	81 (97.6%)
Discolored/stains	2 (2.4%)
Positive cultures	
Aerobic	2 (2.4%)
Anaerobic	0
Fungal	0

