



**Coloplast**



Interpreting the evidence....  
***more than meets the eye***

# Michael Kennelly, MD, FACS, FPMRS

Professor of Urology and Obstetrics & Gynecology  
Female Pelvic Medicine and Reconstructive Surgery  
Director, Charlotte Continence Center  
Co-Director, Women's Center For Pelvic Health  
Director of Urology, Carolinas Rehabilitation

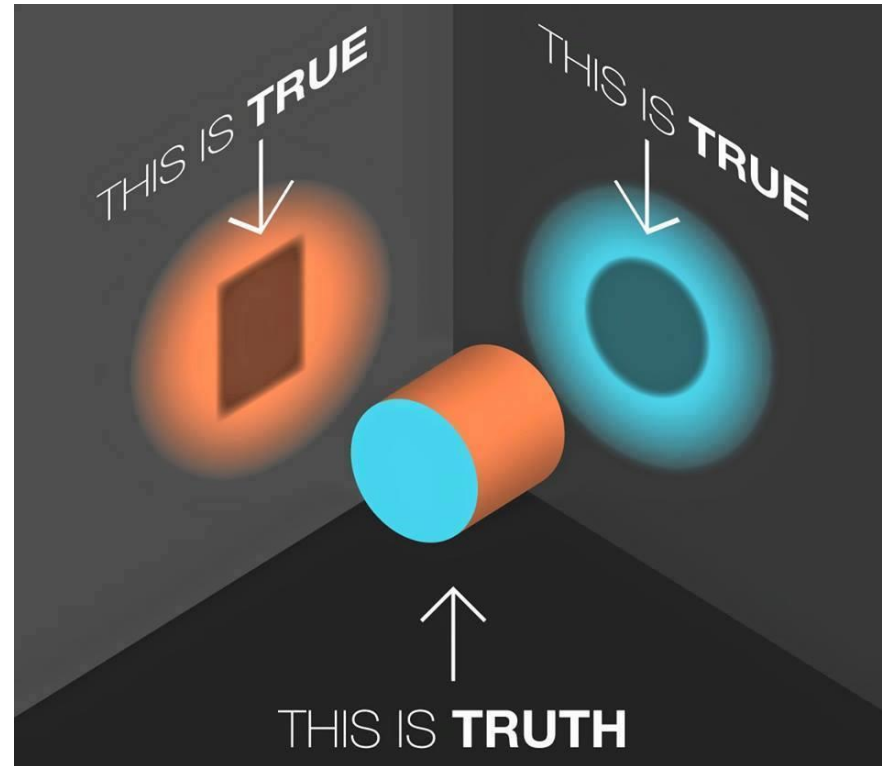


US representative Coloplast Global Urology Advisory Board  
*Paid Coloplast Consultant*

# Agenda

- The withdrawal of the 2014 Cochrane review on IC and a new recommendation
- Invisible insertion difficulties

# Knowledge as a matter of perspective





---

Social Science & Medicine. Part A: Medical Psychology &  
Medical Sociology

Volume 14, Issue 1, 1980, Pages 81-83



---

Research note

## Beautiful patients are good patients: evidence for the physical attractiveness stereotype in first impressions of patients

Lena A. Nordholm

Cognitive bias: Physicians

# How do we learn?

- We read
- We do what we have learned
- We try to teach someone
- “See One, Do One, Teach One”
- You do not see what you do not know...



# What are our educational tools?



- Textbook – a book used as a standard work for the study of a particular subject



- Cochrane Reviews are systematic reviews of primary research in human healthcare and health policy, and are internationally recognized as the highest standard in evidence-based healthcare resources. They investigate the effects of interventions for prevention, treatment, and rehabilitation.

# Should we trust all literature evidence?



**Scientists have  
discovered  
that people will  
believe anything  
when you claim  
scientists have  
discovered it!**





**Cochrane**  
**Library**

Cochrane Database of Systematic Reviews

Prieto J, Murphy CL, Moore KN, Fader M.

***Intermittent catheterization for long term bladder management.***

Cochrane Database of Systematic Reviews 2014, Issue 9.

## Background:

The most frequent complication of intermittent catheterization is urinary tract infection (UTI), but satisfaction, preference and ease of use are also important to users.

It is unclear which catheter designs, techniques or strategies affect the incidence of UTI, which are preferable to users and which are most cost effective.



**Cochrane**  
**Library**

Cochrane Database of Systematic Reviews

Prieto J, Murphy CL, Moore KN, Fader M.

***Intermittent catheterization for long term bladder management.***

Cochrane Database of Systematic Reviews 2014, Issue 9.

## Authors' conclusions:

Despite a total of 31 trials, ***there is still no convincing evidence*** that the incidence of UTI is affected by use of aseptic or clean technique, coated or uncoated catheters, ***single (sterile) or multiple-use (clean) catheters***, self-catheterisation or catheterisation by others, or by any other strategy.

# Intermittent catheterization: The devil is in the details

Christison, K; Walter, M; Wyndaele, JJ; Kennelly, M; Kessler, T; Noonan, V; Fallah, N; Krassioukov A .

J. Neurotrauma October , 2017 Accepted for publication

## 1. Data selection

Out of the 31 trials included in the 2014 Cochrane review,  
two were only published as conference abstracts

## 2. Data extraction

Five types of disagreements were observed:

- a. Data was mislabeled
- b. Extracted data did not match data from original trial
- c. Data was extracted in a method not consistent with convention
- d. Data was in a form that could not be used in meta-analyses
- e. Data was not originally extracted, although eligible



# 3. Symptomatic UTI definition

- Cochrane 2014 UTI definition - was taken from an outdated 1992 National Institute on Disability and Rehabilitation Research (NIDRR) consensus statement.
- Infectious Diseases Society of America (IDSA) 2009 consensus statement already provided the most up-to-date and comprehensive definition of UTI, which specifically covered catheter-associated UTI.

# 4. Data analysis

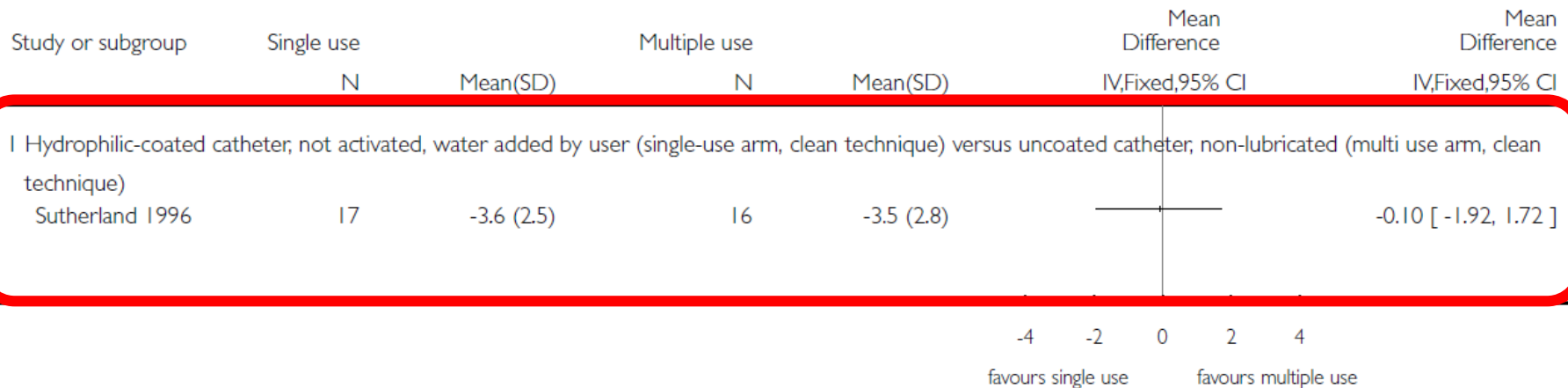
20 of all 39 analyses from the Cochrane review consisted of only one trial. However, according to the 'Cochrane Handbook for Systematic Reviews of Interventions Version' ... at least two trials are required for meta-analysis

## Analysis 2.9. Comparison 2 Single-use (sterile) catheter versus multiple-use (clean) catheter, Outcome 9 Mean ease of handling.

Review: Intermittent catheterisation for long-term bladder management

Comparison: 2 Single-use (sterile) catheter versus multiple-use (clean) catheter

Outcome: 9 Mean ease of handling



[Go to old article view](#)

PDF



Info

**Cochrane Database of Systematic Reviews** **Withdrawn from publication**[Version History](#)**Intermittent catheterisation for long-term bladder management**[Withdrawn](#)[Review](#)[Intervention](#)

Jacqui Prieto, Catherine L Murphy, Katherine N Moore, Mandy Fader

First published: 8 August 2017

Editorial Group: [Cochrane Incontinence Group](#)DOI: 10.1002/14651858.CD006008.pub4 [View/save citation](#)Cited by (CrossRef): 0 articles [Check for updates](#)

score { 1 }

**Reason for withdrawal from publication**

This review has been withdrawn following Feedback from Andrei V. Krassioukov, Kathleen Christison, Matthias Walter, Jean-Jacques J.M. Wyndaele, Thomas M. Kessler and Michael Kennelly who have identified possible errors in the analysis of data in the review. These concern handling of cross-over and multi-arm trials as well as corrections and clarifications of data used. This review has been withdrawn whilst these issues are addressed. Changes are also required to reflect current methodological standards. The review will be re-published following updating, revision and [peer review](#).

[UBC eLink](#)[» Continue reading full article](#)[» Version History](#)



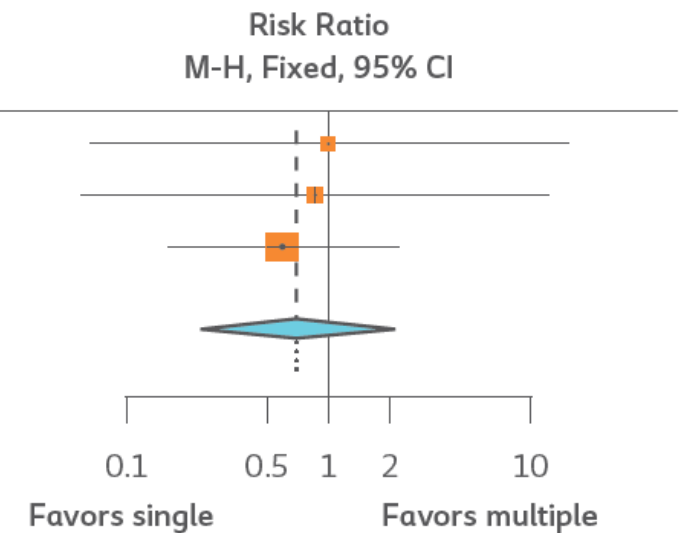


# Intermittent Catheterization: The Devil is in the Details

## Analysis of single versus multiple use of catheters

Trial	Single use		Multiple use		Weight	Risk Ratio M-H, Fixed, 95% CI
	Events	Total	Events	Total		
Pachler 1999	1	32	1	32	14.2%	1.00 [0.07; 15.30]
Sutherland 1996	1	16	1	14	15.1%	0.88 [0.06; 12.73]
King 1992	3	23	5	23	70.8%	0.60 [0.16; 2.22]
Total (95% CI)		71		69	100.0%	0.70 [0.24; 2.05]

Total events                    5    7  
 Heterogeneity:  $I^2 = 0\%$ ,  $r^2 = 0$ ,  $H = 1.00$ ,  $Q = 0.15$ ,  $df = 2$ ,  $p = 0.930$   
 Test for overall effect:  $Z = -0.66$ ,  $p = 0.512$



## Applying the IDSA\* UTI definition

\* Christison K, Walter M et al. Intermittent catheterization: The devil is in the details. Journal of Neurotrauma. DOI: 10.1089/neu.2017.5413.

# Intermittent Catheterization: The Devil is in the Details

## Conclusion:

*The experts stated that until evidence can conclusively demonstrate that multiple use is as safe as single use catheters, healthcare providers should advocate a **single use of catheters** in individuals with SCI.\**

\* Christison K, Walter M et al. Intermittent catheterization: The devil is in the details. Journal of Neurotrauma. DOI: 10.1089/neu.2017.5413.



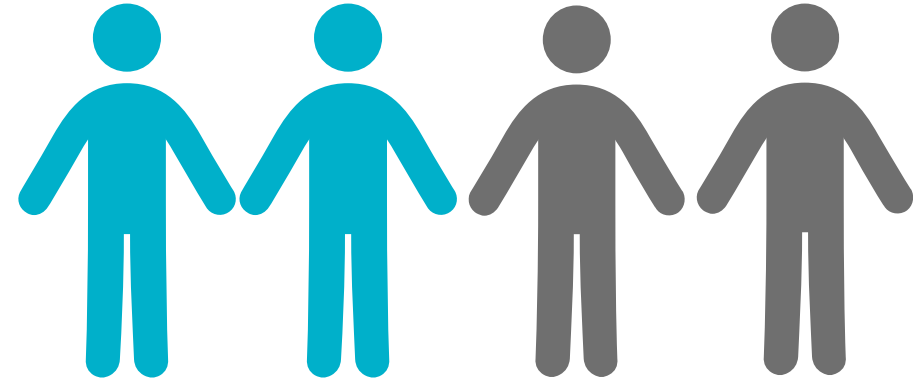
# Invisible insertion difficulties

# In America, the older population is growing...

Between 2000 and 2010, Americans **65** years and older grew at a faster rate than the total population.

**Males** experienced more rapid growth than females in older ages.

Approximately **50%** of all men  
over **60** will have an  
**enlarged prostate**



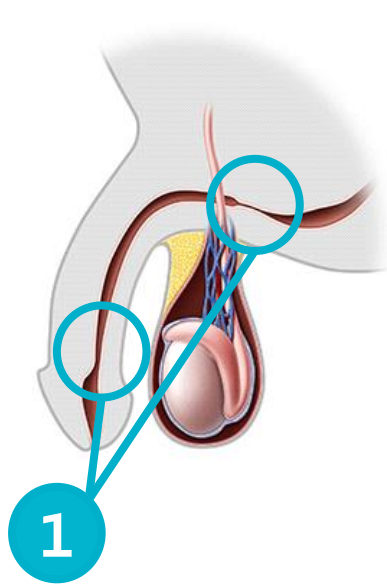
- Prostate grows to a normal size in teenage years
- Begins to grow again around the age of 50
- Hormones, diet, and genetics

# Coudé catheter evolution

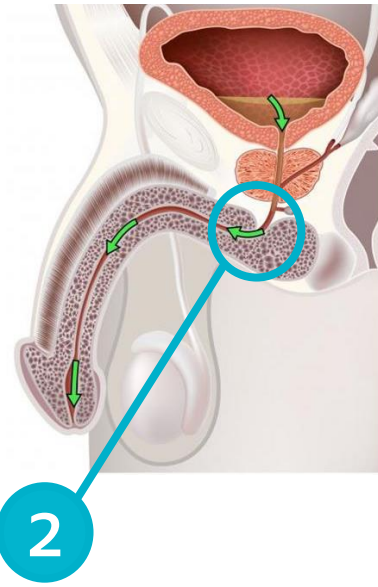


1. Mattelaer, JJ., Billiet, I., Catheters and sounds: the history of bladder catheterization. (1995), Paraplegia, 33, 429-433.

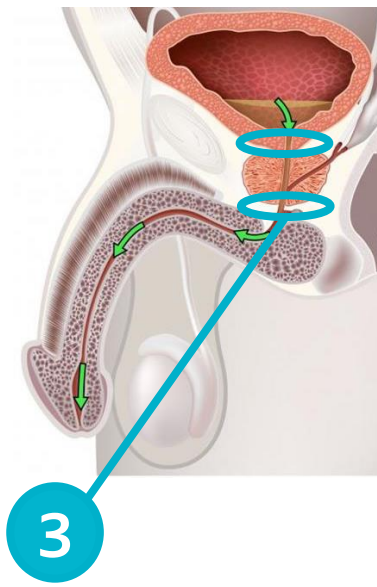
# Common anatomical challenges that can cause catheter insertion difficulties?



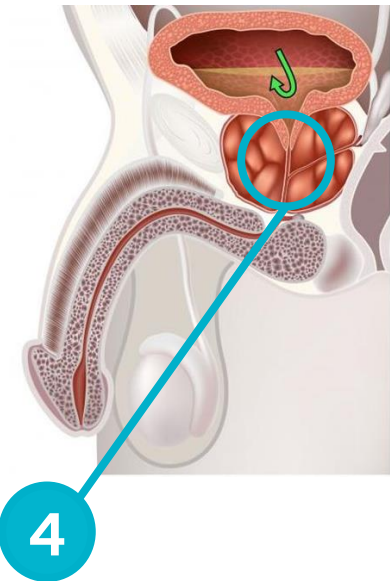
Strictures in urethra



Sharp, natural  
'L' bend (pars bulbosa)



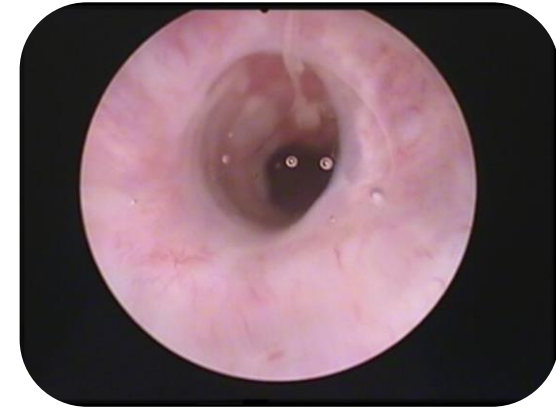
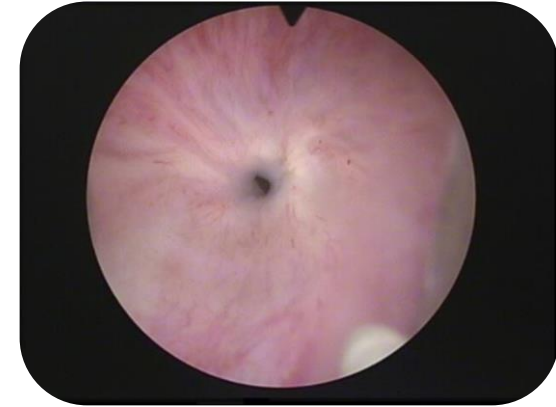
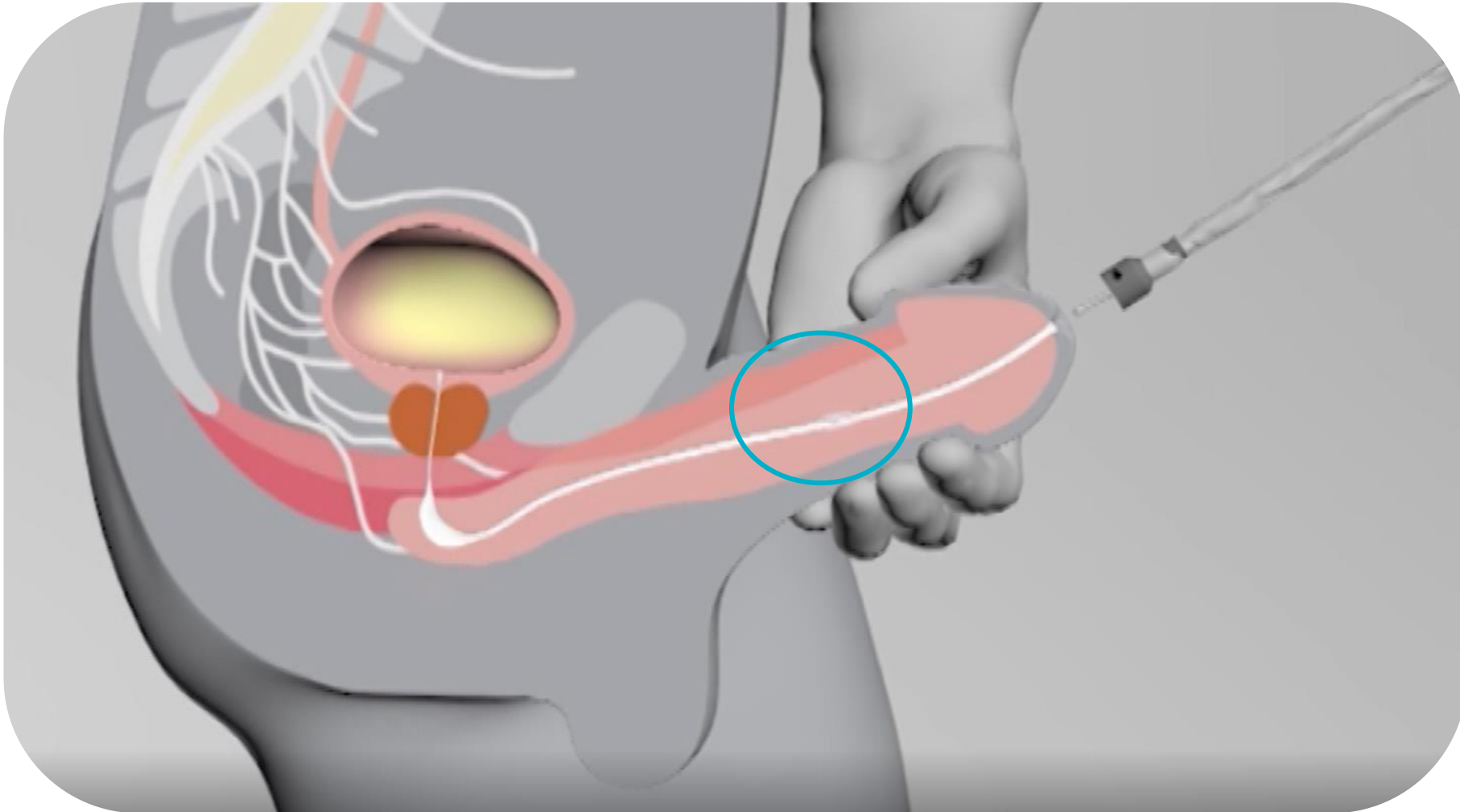
Tight internal and  
external sphincters



Enlarged prostate

# Strictures in the urethra

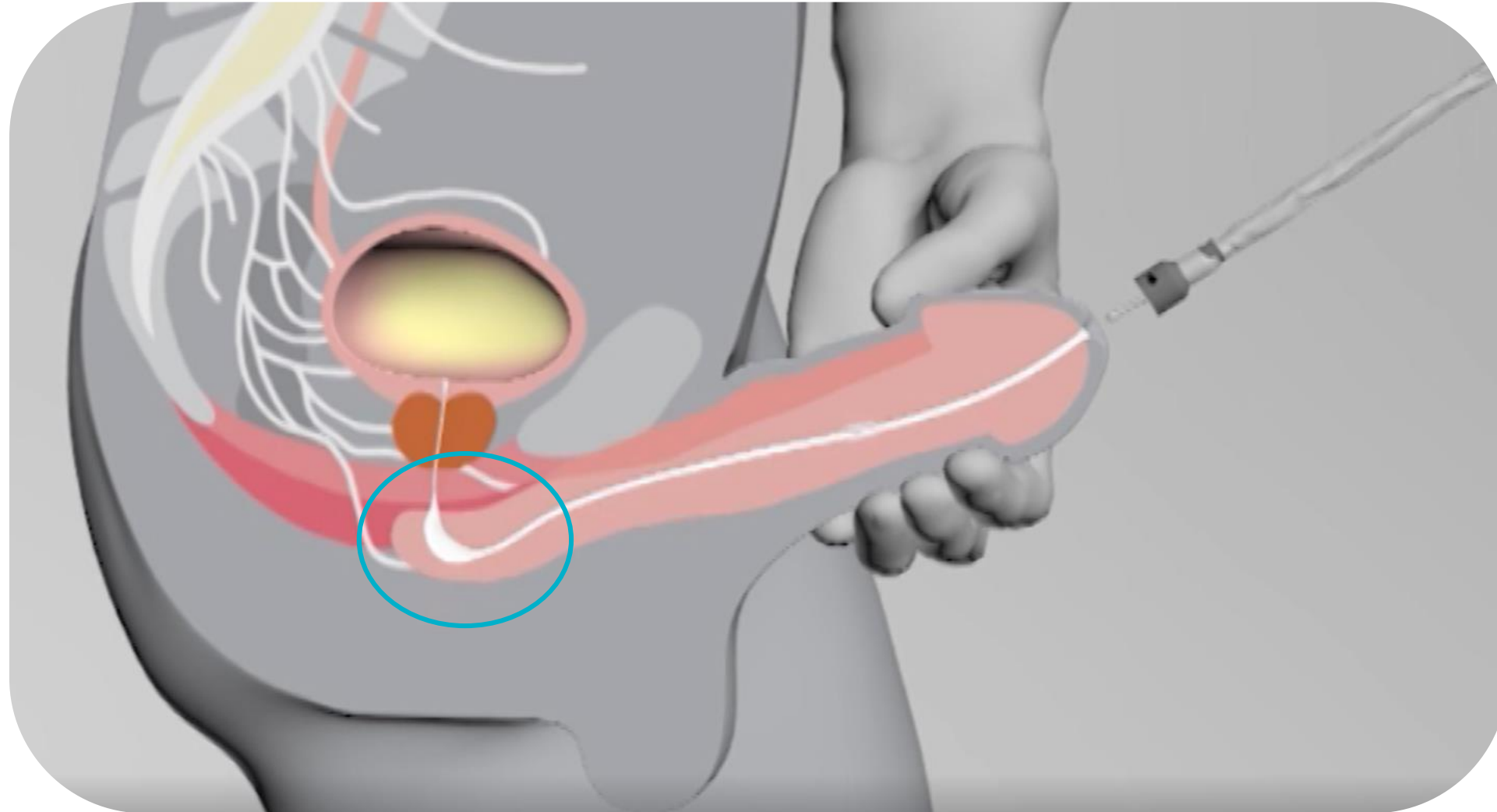
1





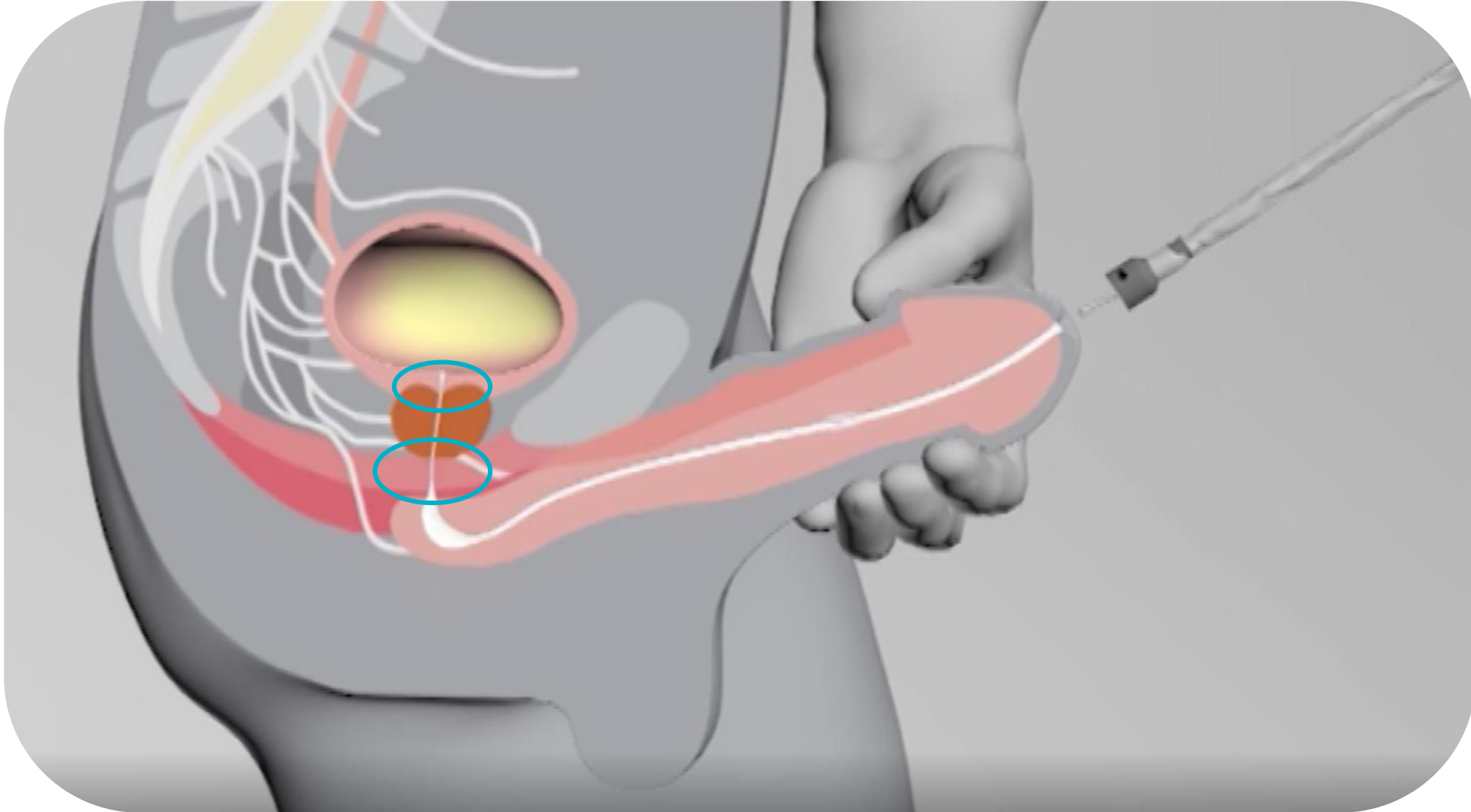
# Sharp, natural 'L' bend (pars bulbosa)

2



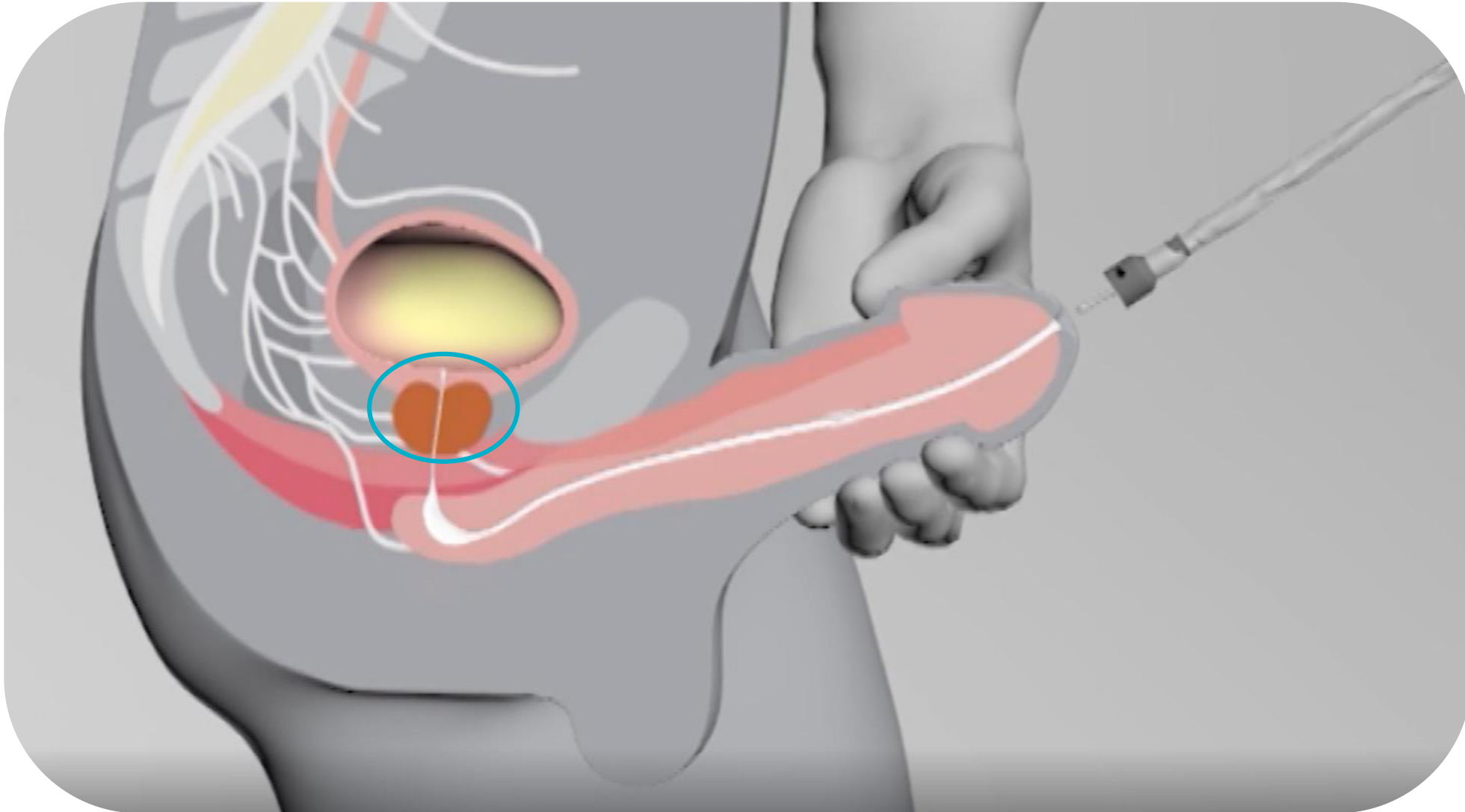
# Tight internal and external sphincters

3



# Enlarged prostate

4



Mercy Medical Plaza

  
Carolinan  
Medical Center  
Mercy

# Retrograde Urethrogram Fluoroscopy Study

Carolinan Surgical Skills Center

Coloplast Group – Ostomy Care / Continence Care / Wound & Skin Care / Urology Care





**SpeediCath® Flex Coudé**  
launched in 2017,  
designed for male  
patients with insertion  
difficulties

***SpeediCath® Flex Coudé***

# Investigators



## **Michael J. Kennelly, MD, FACS, FPMRS**

Professor of Urology and Obstetrics & Gynecology  
Female Pelvic Medicine and Reconstructive Surgery  
Director, Charlotte Continence Center  
Co-Director, Women's Center For Pelvic Health  
Director of Urology, Carolinas Rehabilitation



## **Birte Petersen Jakobsen, MD**

Radiologist  
Global Medical Director, Coloplast

# Method

- Fluoroscopy imaging technique with a cadaver



## Male urethra with x-ray contrast

Contrast media was inserted into the urethra showing the shape and anatomy of the lower urinary tract (the urethra and the bladder.)



## Catheter with and without contrast

The photo shows two catheters – one prepared with contrast media and one without (almost not visible).

Evaluated multiple different types of catheters navigating the urethra.

# Retrograde Urethrogram Fluoroscopy Study

**Objective** Compare clinical functionality between SpeediCath<sup>®</sup> Flex Coudé Catheter and traditional coudé catheter

---

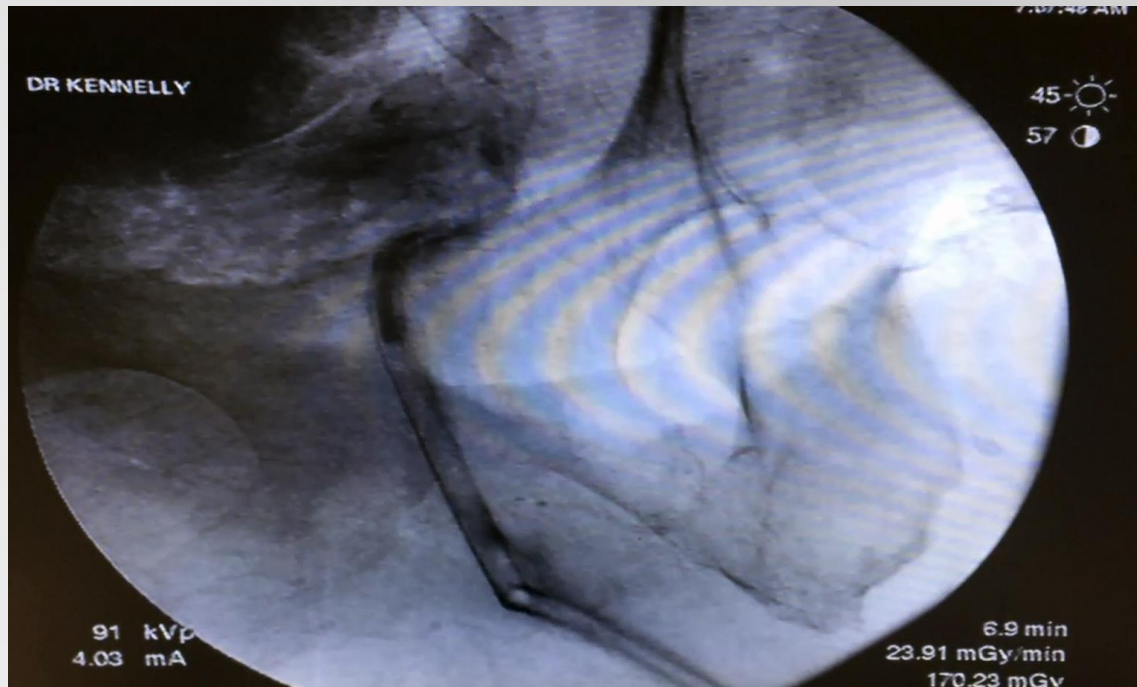
**Method** Fluoroscopy video study on male cadavers:  
Male with 2 strictures (55 years old)

---

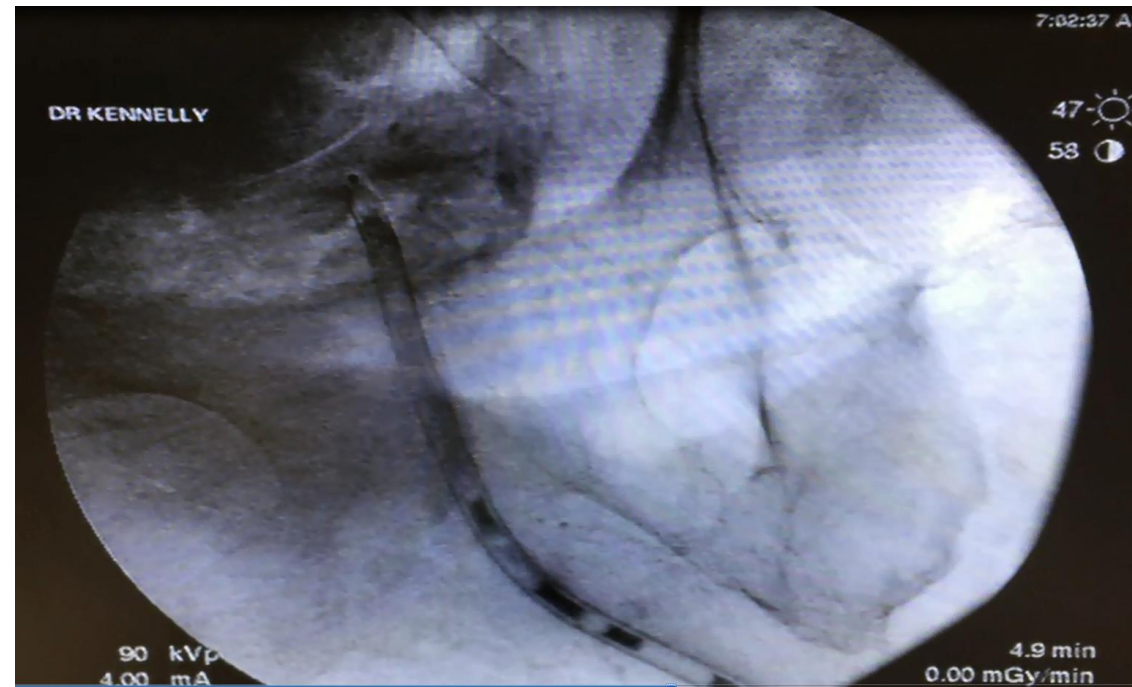
**Result** SpeediCath<sup>®</sup> Flex Coudé works for male patients with complex anatomies, including but not limited to patients with BPH



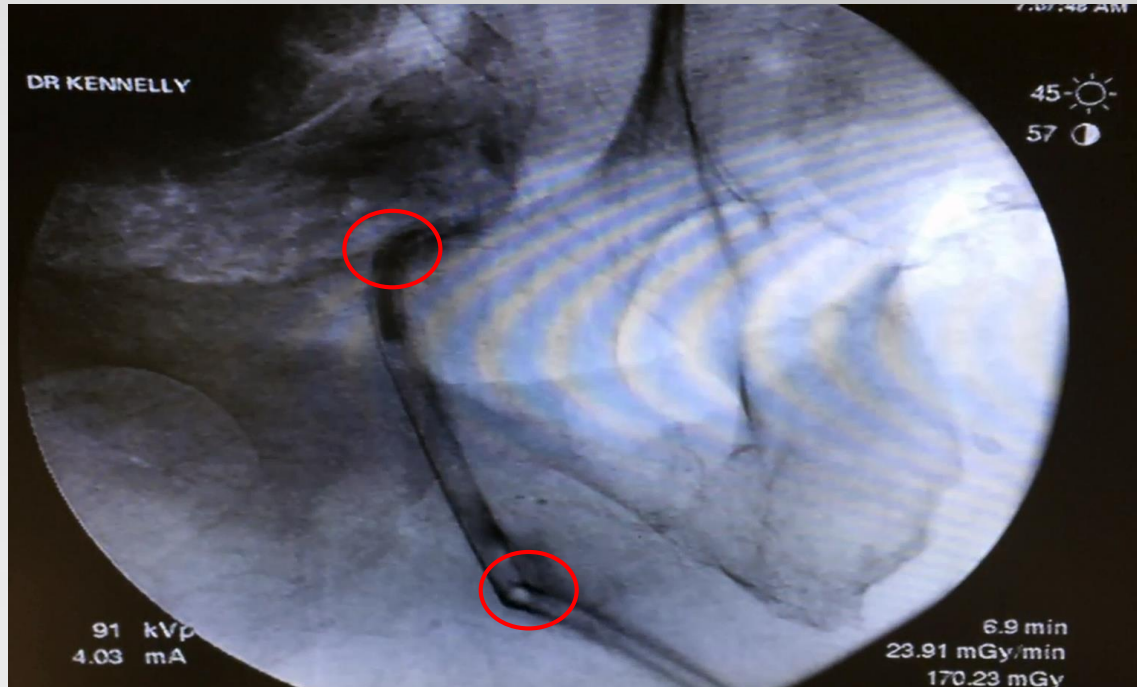
## Video 1 SpeediCath® Standard Coudé



## Video 2 SpeediCath® Flex Coudé



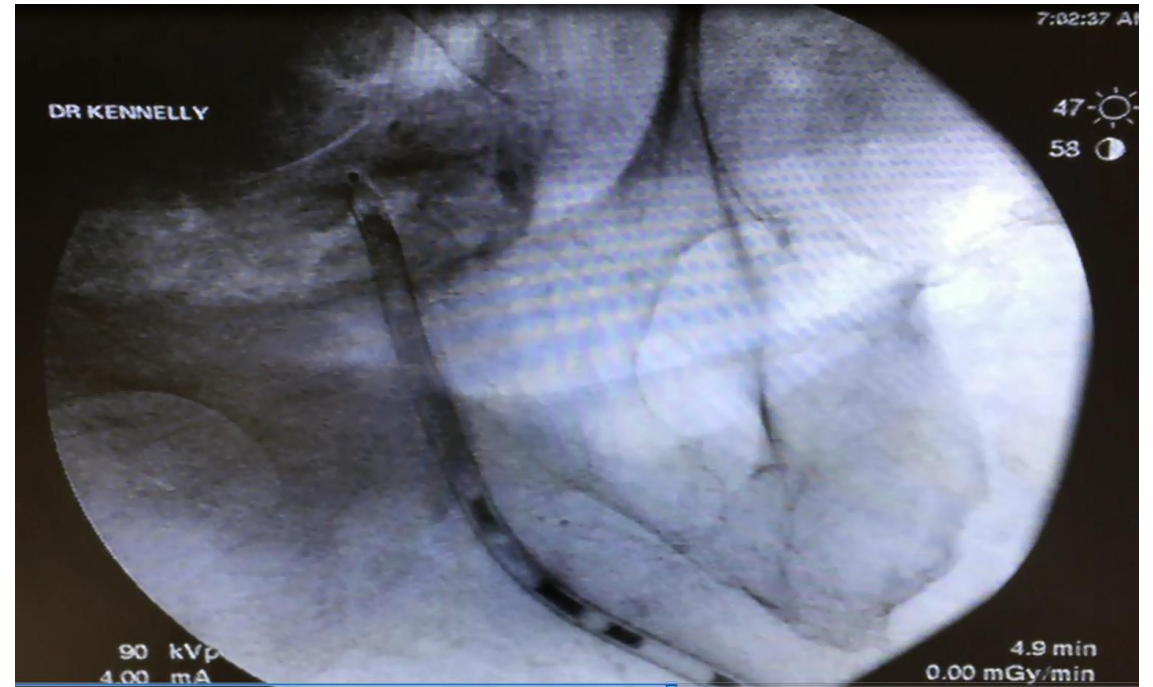
## SpeediCath® Standard Coudé



- The catheter has some difficulty following the passage of urethra curvatures
- With additional force, the catheter eventually reached the bladder

## Summary

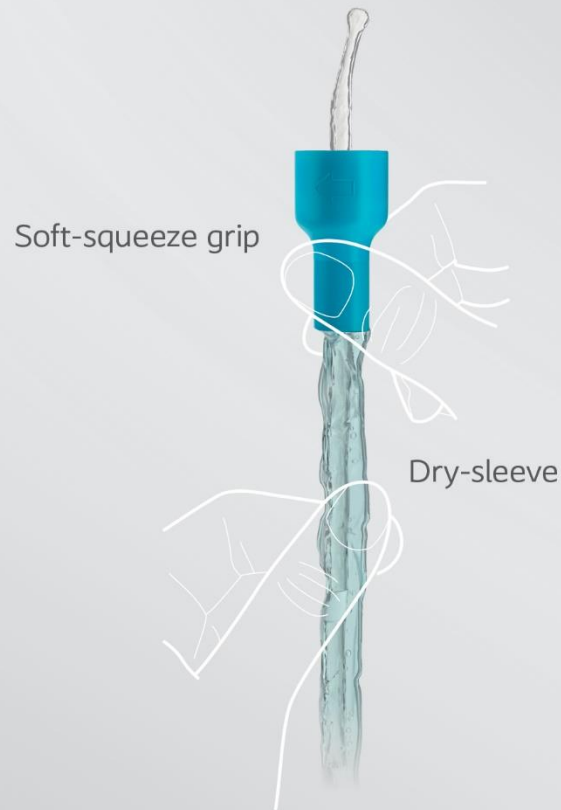
## SpeediCath® Flex Coudé



- The catheter follows the curvatures of urethra, reaching the bladder
- The catheter bypasses all obstructions smoothly, reaching the bladder successfully

**SpeediCath® Flex Coudé**

# SpeediCath® Flex Coudé Pro launched in 2018



# Questions?

## Our mission

Making life easier for people  
with intimate healthcare needs

## Our values

Closeness... to better understand  
Passion... to make a difference  
Respect and responsibility... to guide us

## Our vision

Setting the global standard  
for listening and responding

SpeediCath® catheters are prescribed for use by patients who require bladder drainage due to urine retention or post void residual volume (PVR). Before use, carefully read all of the instructions. Call your doctor if you think you have a UTI or can't pass the catheter into the bladder. For more information regarding risks, potential complications and product support, call Coloplast Corp. at 1-866-226-6362 and/or consult the company website at [www.coloplast.us](http://www.coloplast.us).