The Hygienic Benefits of a No-Touch Intermittent Catheter with a Protective Tip and/or Sleeve
Introduction

Intermittent catheterization (IC) refers to the insertion and removal of a catheter into the urinary bladder approximately 4–6 times a day to provide complete bladder emptying. Three methods of IC are noted in the literature: clean, sterile, and aseptic intermittent catheterization. Lapides introduced the clean IC (CIC) technique in 1972. Clean technique is performed by the patient and involves the use of sterile, disposable, or washed reusable catheters, soap and water hand washing, and perineal cleansing, only if there has been contamination by stool or other wastes. Over the years CIC has been accepted in the medical community as standard practice by patients in the community, for management of urine retention and/or neurogenic bladder. Catheter associated urinary tract infections may be a serious problem for people who perform intermittent self-catheterization.

Recent initiatives have focused on the potential role of reused catheters and the increased incidence of urinary tract infections. As a result, the Centers for Medicare and Medicaid Services (CMS) have revised their policies for coverage to support single use catheters for individuals who perform clean intermittent catheterization.

Guttman and Frankel first introduced the sterile IC method and showed it significantly reduced the risk of urinary tract infections (UTI) and/or bacteriuria, compared to any method previously reported. Sterile technique implies the use of sterile gloves and catheters, and other equipment, as well as genital disinfection prior to insertion. Sterile and aseptic technique have been used interchangeably.

Aseptic technique using a “closed system” was introduced as an alternative to strict sterile technique that reduces the UTI risks associated with CIC, but is easier and more economical for use in the community than sterile IC. The European Association of Urology has recently published guidelines for IC, stating aseptic technique should be considered the method of choice for intermittent catheterization. This group defines aseptic technique as, ‘the catheters remain sterile, the genitals are disinfected, and disinfecting lubricant is used’. Since the catheter is a closed system, virtually “touchless”, it means the catheter is not likely to be inadvertently contaminated by the environment or by handling the catheter system. The touch-free closed catheter system offers a protective introducer tip and sleeve, which helps ensure aseptic insertion of a single use sterile catheter. The protective introducer tip allows the catheter to bypass the initial 15 mm of the urethra which harbors perineal bacteria, helping reduce the risk of pushing harmful bacteria into the bladder, thus causing a urinary tract infection. Gloves may be required, but a sterile external environment with gown and mask is not required.

The following summary of clinical and laboratory evidence has shown that a no-touch catheter with a protective tip and sleeve, has been shown to reduce the introduction of bacteria to the urinary tract. Reducing the introduction of bacteria to the urinary tract may help reduce the risk of catheter associated UTIs (CAUTIs). The Advance Plus intermittent catheter from Hollister is hygienic by design because of the protective introducer tip and protective sleeve which facilitates no touch aseptic IC.

This summary of Clinical and Laboratory Evidence is based on a selection of literature, and did not include a full review of all literature. Note: Introducer tip is also referred to as Protective tip by some authors, so these terms are used interchangeably in this document.

7. Local Coverage Determination for Urological Supplies, L27219, CMS 4-01-08.
Objectives
The aim of this study was to determine whether catheters with an introducer tip reduced urinary tract infections in spinal cord injured patients who performed self-intermittent catheterization.

Methods
11 tetraplegic and 16 paraplegic males participated in this study. The MMG/O’Neil catheter system was used, which consists of a plastic catheter enclosed in a pre-lubricated plastic sleeve, and introducer tip which protects the catheter from the first 15 mm of distal urethra bacteria. All catheterizing patients were asked to use one of two systems: The MMG/O’Neil with the introducer tip or the MMG/O’Neil with the introducer tip removed. Urodynamics, urine cultures, and urinalyses were performed and tracked.

Subjects were enrolled into 4 groups based on their ability to reflex void:

- **Group 1**: Intermittent catheterization with introducer tip catheter; not spontaneously voiding or wearing external urinary catheter
- **Group 2**: Intermittent catheterization with non-introducer tip catheter; not spontaneously voiding or wearing external urinary catheter
- **Group 3**: Intermittent catheterization with introducer tip catheter; voiding by reflex and wearing external urinary catheter
- **Group 4**: Intermittent catheterization with non-introducer tip catheter, voiding by reflex and wearing external urinary catheter

Results
In comparable non-voiding groups, the difference between the introducer and non-introducer tips was clearly significant \( p < 0.0093 \), as was the overall difference between all introducer tip catheter groups compared to all non-introducer tip catheter groups \( p < 0.01 \).
According to this study, the MMG/O’Neil catheter with introducer tip significantly decreased urinary tract infections in hospitalized, spinal cord injured men who performed intermittent catheterization.

Conclusion

According to this study, the MMG/O’Neil catheter with introducer tip significantly decreased urinary tract infections in hospitalized, spinal cord injured men who performed intermittent catheterization.
Objectives
The goal of this study was to determine if a new method of catheterizing female patients using a new catheter with a sealed introducer tip (O'Neil) would reduce the transfer of organisms from the distal urethra to the bladder at the time of catheterization.

Methods
132 female patients from 2 centers were enrolled in the study. Urine specimens were taken before and after intermittent catheterization. 2 groups were formed:

- **Control Group:** Used a 14 Nelaton catheter
- **Experimental Group:** Used the new catheter with introducer tip

The O'Neil tip catheter and introducer tip consists of a plastic catheter enclosed in an introducer tip, with a rubber flange, which prevents the tip from being introduced beyond the first 15 mm (previous study showed potential pathogens in the distal urethra in 90% of females¹). This tip protects the catheter from the first 15 mm of distal urethra bacteria, and therefore the catheter enters the bladder without being in contact with the distal urethra.

Results
25% of patients (17/67) who were catheterized in the Control Group developed bacteriuria as a result of the catheterization. For those in the Experimental Group, using the O'Neil catheter with introducer tip, only 4% of patients (2/52) developed bacteriuria. This was a statistically significant result ($p < 0.005$).

Due to pre-existing bacteriuria, 13 of the 132 patients were excluded from the study.

<table>
<thead>
<tr>
<th></th>
<th>Total No.</th>
<th>Pre-existing Bacteriuria &gt;10⁵</th>
<th>Infection Rate Control Group</th>
<th>Infection Rate New Catheter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glasgow</td>
<td>57</td>
<td>5</td>
<td>6/25</td>
<td>1/27</td>
</tr>
<tr>
<td>Perth</td>
<td>75</td>
<td>8</td>
<td>11/42</td>
<td>1/25</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>132</strong></td>
<td><strong>13</strong></td>
<td><strong>17/67</strong></td>
<td><strong>2/52</strong></td>
</tr>
</tbody>
</table>

Conclusion
According to this study, the O'Neil catheter introducer tip reduced the transfer of organisms from the first 15 mm of the distal urethra to the bladder, which may help reduce catheter acquired urinary tract infections (CAUTIs) in females.
The ‘No-Touch’ Method of Intermittent Urinary Catheter Insertion: Can it Reduce the Risk of Bacteria Entering the Bladder?

Hudson E, and Murahata R.
Spinal Cord. 43; 611-614.
This study was authored by Hollister employees and funded by Hollister Incorporated.

Objectives
This *in vitro* model was conducted to determine whether the no-touch protective sleeve affects the degree of contamination to the catheter while being prepared and inserted.

Methods
- 6 different types of intermittent catheters were tested in triplicate
- Gloved hands were contaminated with known amounts of *S. aureus* or *E. coli* and intermittent catheter preparation for insertions mimicked manufacturer’s instructions
- Bacteria transferred to the catheter was quantified and validated using a validated technique. Negative controls were non-handled samples

  Catheters A, B, C: Standard hydrophilic catheters  
  Catheter D: Hydrophilic catheter handled through the wrapper  
  Catheters E, F: Gel catheters with no-touch sleeve

Results
The bacteria count on catheter E and F was significantly lower than that recovered from the traditional hydrophilic catheters (p < 0.05).

<table>
<thead>
<tr>
<th>CFU (colony forming unit)</th>
<th>E. coli</th>
<th>S. aureus</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>240</td>
<td>7</td>
</tr>
<tr>
<td>B</td>
<td>410</td>
<td>5</td>
</tr>
<tr>
<td>C</td>
<td>260</td>
<td>32</td>
</tr>
<tr>
<td>D</td>
<td>17</td>
<td>5</td>
</tr>
<tr>
<td>E</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

Catheter A – EasiCath (Coloplast, Humlebaek, Denmark)  
Catheter B – SpeediCath (Coloplast, Humlebaek, Denmark)  
Catheter C – LoFric (Astra Tech, Mölndal, Sweden)  
Catheter D – LoFric H2O (Astra Tech, Mölndal, Sweden)  
Catheter E – Hollister Advance Intermittent Catheter (Hollister, Illinois, USA)  
Catheter F – VIALOG Mobile (Medical Service, Bad Liebenzell, Germany)

Conclusion
The *in vitro* model showed that intermittent catheters with the hygienic feature of a no-touch sleeve helped reduce the potential for external contamination during preparation and insertion of an intermittent catheter. This reduction may help reduce the risk of bacteria entering the bladder.
Benefits of Hygienic Design as Demonstrated by Laboratory Testing

Murahata R, and Nichols T.
Presented at ICS, Toronto, Canada, August 2010.

Objectives
An *in vitro* laboratory test was conducted to compare degree of contamination transmitted to the catheter with a protective tip and one without, when inserted through a laboratory urethral model.

Methods
• Commercially available sterile catheters with* and without** a protective tip were used in the experiment.

• A centrifuge tube containing a 15 mm thick layer of agar, contaminated with either *S. aureus* or *E. coli*, was designed as a model to simulate the urethra contaminated at the distal end.

• The urethra pathway was simulated by leaving a pipette in situ until the agar had set.

• Each catheter type was tested in triplicate for each of the test microorganisms. Negative controls were tested the same way with uninoculated agar.

• Suspensions of *E. coli* and *S. aureus* were prepared as the microbial challenge.

• Using sterile gloves and scissors, the catheters were cut into sterile containers once the catheters were extended through the agar.

• The microorganisms present on all of the catheters and the negative controls were determined via bioburden extraction and validated plate count procedure.

Figure 1 Diagram of model designed to simulate urethra contaminated in the distal end.

1. 50 mL Centrifuge tube
2. Contaminated agar
3. Catheter with protective tip
4. Protective tip
5. Catheter without protective tip

* Advance Intermittent Catheter
** Lo-Fric Insti-Cath
Results
The number of bacteria found on catheter without protective tip, was 4 times that on catheter with protective tip for both *E. coli*, and *S. aureus*, and the difference reached statistical significance for *S. aureus* (*p* = 0.0309).

Figure 2

Conclusion
The results obtained using this *in vitro* model support the premise that catheters with introducer/protective tip can help reduce the level of contamination from distal urethra on insertion of an intermittent catheter.
Frequently Asked Questions

1. Q: What is the importance of a protective tip when selecting a catheter?
   A: Clinical evidence has shown that the protective tip on an intermittent catheter bypasses the first 15 mm of the distal urethra, and in doing so, reduces the bacteria that are pushed up into the bladder. The protective tip has been shown to reduce the potential for catheter contamination which may help reduce the risk for infection.\textsuperscript{1,2,3}

2. Q: What are the advantages of having both the protective tip and sleeve features on an intermittent catheter?
   A: The protective tip and sleeve help guard against contamination both from the environment and the distal urethra. The protective tip and sleeve allow a no-touch technique to be used, which means there is no direct hand contact on the catheter, thus reducing the introduction of bacteria into the urethra\textsuperscript{1,2,3}. These features may help reduce the risk for infection.

3. Q: Is there any clinical evidence that shows that a protective tip and/or protective sleeve on an intermittent catheter helps reduce the risk of infection for patients who self-catheterize?
   A: Yes. Both the Bennett \textit{et al.} and O’Neil clinical studies indicate that a protective tip on a catheter may help reduce the risk of infection for those catheterizing. The Hudson/Murahata laboratory studies suggested that a gel pre-lubricated intermittent catheter with a true no-touch protective sleeve and protective tip may help reduce the risk of bacteria being transmitted to the catheter.

4. Q: What catheterization technique does the European Association of Urology (EAU) recommend in their Guidelines?
   A: Aseptic technique is recommended by the EAU Guidelines as the method of choice.\textsuperscript{4} IC in general is the gold standard for the management of neurogenic lower urinary tract dysfunction.

5. Q: What are the three methods of intermittent catheterization?

<table>
<thead>
<tr>
<th></th>
<th>Sterile (Hospital Aseptic)</th>
<th>Aseptic* (Outside of Institution)</th>
<th>Clean</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hygienic hand disinfection</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Sterile gloves</td>
<td>Yes</td>
<td>Sometimes</td>
<td>No</td>
</tr>
<tr>
<td>Sterile cover</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Protective gown</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Antisepsis of urethral opening and surrounding area</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Sterile intermittent catheter</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Disinfecting lubricant*</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

* Some authors indicate sterile lubrication is sufficient for Aseptic technique. Aseptic technique is defined differently by the EAU and by Knopf, the difference being the EAU includes use of a disinfecting lubricant.
References

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2. O’Neil AG, Jenkins DT, and Wells JI.


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6. Day R, Moore K, Albers M.
   A Pilot Study Comparing Two Methods of Intermittent Catheterization: Limitations and Challenges. *Urologic Nursing* 2003: 23 (2); 143-147.

7. PVA.


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    The value of intermittent catheterization in the early management of traumatic paraplegia and tetraplegia. *Paraplegia* 1966; 4(2); 63-84.

13. Hudson E, Murahata R.

### The Hygienic Benefits of a No-Touch Intermittent Catheter with a Protective Tip and/or Sleeve

#### Clinical and Laboratory Evidence

<table>
<thead>
<tr>
<th>Clinical and Laboratory Evidence</th>
<th>No-Touch Features</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>The ‘No-Touch’ Method of Intermittent Urinary Catheter Insertion: Can it Reduce the Risk of Bacteria Entering the Bladder?</strong> Hudson E, Murahata R. Spinal Cord: 43; 611-614.</td>
<td><img src="checked" alt="Protective Tip" /></td>
</tr>
</tbody>
</table>


#### Warning:
To help reduce the potential for infection and/or other complications, do not reuse. Dispose of appropriately after procedure.

If discomfort or any sign of trauma occurs, discontinue use immediately and consult your healthcare professional.

#### Caution:
Federal (USA) law restricts intermittent catheters to sale by or on the order of a licensed healthcare professional.

Prior to use of this device, be sure to read (i) the complete information on how to use this device including Warnings, Cautions, and Instructions for Use, and (ii) all other package inserts and labels supplied with the product and accessories.

Please consult a medical professional before using this product if any of the following conditions are present:
- Severed urethra, unexplained urethral bleeding, pronounced stricture, false passage, urethritis – inflammation of the urethra, prostatitis – inflammation of the prostate gland, epididymitis – inflammation of the epididymis (testicle tube).

Self-catheterization should only be carried out after medical advice and only in accordance with the instructions provided. Always follow the care plan and advice given by your healthcare professional. For urethral intermittent self-catheterization (ISC), it is typical to catheterize at least 4 times a day at intervals of 6 to 8 hours. If you are unsure about your catheterization, please contact your regular healthcare professional.

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