



## Original Article

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# Improving Foley Catheter Insertion Procedure by Developing Foley Introducer: A 100-Year Overdue Innovation

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**Purpose:** Foley catheter (FC) insertion is very basic yet one of the most widely performed procedures all across the fields of medicine. Since FC was first introduced in 1920's, no significant improvement has been made in view of methodology, despite the inconvenience associated with cumbersome preparation, procedure, and the patients' discomfort with having to have their genitalia exposed. We developed a new, easy-to-use FC insertion device, Quick Foley, that provides an innovative approach to introducing FC while simplifying and minimizing time spent without compromising the sterility.

**Methods:** We developed an all-in-one disposable FC introducer contains all the necessary components in a single-device-kit. Minimal plastic components are necessary to keep accuracy and consistency, but the rest are made of the paper to minimize plastic waste. The preparation is done by connecting to the drainage bag, spurring the lubricant gel through gel insert, separating the tract, and connecting with the ballooning syringe. For the insertion, after sterilizing the urethral orifice, rotate the control knob to feed FC to the end of the urethra. After ballooning, dissembling of the device is done only by opening and removing the module, then only the FC remains.

**Results:** As the device is all-in-one, there is no need to prearrange the FC tray, simplifies the FC preparation and catheterization procedure. This device not only makes it convenient for the practitioner, but ultimately, it will reduce the psychological discomfort experienced by patient by truncating perineal exposure time.

**Conclusions:** We have successfully developed a novel device that reduces the cost and burden of using FC for practitioners while maintaining an aseptic technique. Furthermore, this all-in-one device allows the entire procedure to be completed much more quickly compared to the current method, so this minimizes perineal exposure time. Both practitioners and patients can benefit by this new device.

**Keywords:** Urinary catheter; Cystostomy; Equipment and supplies; Urinary tract infection

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## INTRODUCTION

Catheterization through the urethra has been used by mankind to the extent that there are records of urethral catheterization

even in Egypt, almost 3,500 years ago [1]. The most commonly used device for urethral catheterization is the Foley catheter which is a flexible tube with inflatable balloon designed in 1929 by Frederic Foley, a surgeon, as a way to help expel urine out of

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the body through the urethra [2]. It is still widely performed today: the Foley catheter is inserted into one out of 4 hospitalized patients. In detail, it is known that approximately 8%–20% of internal medicine inpatients undergo catheterization, and about 80% of surgical patients undergo catheterization [3-5]. In addition, 13% of patients admitted to nursing institutions are receiving long-term urinary catheterization with regular change [4]. Therefore, Foley catheter insertion is certainly inevitable, irreplaceable, and worldwide. The Foley catheter insertion is a very basic skill performed throughout all fields of medical care for a long time, but it is fundamentally rooted in the urological technique.

Although it has been almost 100 years since it was invented, it is not an exaggeration to say that there has been almost no change made and no innovation of any new insertion method, other than material aspects such as rubber, silicone, latex, and silver coating [6]. While it is a relatively simple and conventional procedure without much difficulty, the insertion method still requires a significant amount of effort from the healthcare providers, including preparation of insertion sets, associated costs such as cleaning and sterilization, as well as the insertion procedure

(Fig. 1B). For insertion, a presterilized package in a set, perforated drape, bowels, and clamp should be prepared and delivered to the wards. Before the procedure, a syringe containing distilled water, lubricating gel, povidone cotton, and proper size Foley catheter should be added carefully not to violate sterility. To outline the insertion procedure, the package should be opened to set between patients naked legs. Then, the area around the urethra and perineum has to be widely sterilized and covered by sterile perforated drape for exposing urethra orifice. After applying gel on the catheter, it is gently inserted all the way into the urethra, then, finally the balloon is inflated with distilled water syringe and connected with the urine bag [7,8]. This procedure is not difficult but quite cumbersome and time-consuming.

Most of all, this procedure also causes considerable psychological distress to the patient who is already in pain. From the time the practitioner prepares for insertion at the bedside until the insertion procedure is completed, the patient must lower their clothing, spread their legs, and expose their genitals and perineums. Since these postures and processes cause considerable psychological discomfort to the patients, simplifying the



**Fig. 1.** Comparison of Foley catheter insertion set. (A) A new Foley catheter introducer, Quick Foley (UFU Health Co., Seoul, Korea). (B) Conventional insertion set (image from Korean Urology Association home page, [https://www.urology.or.kr/file/file\\_180426.pdf](https://www.urology.or.kr/file/file_180426.pdf)). (C) Disposable prearranged insertion set. (<https://wts.pressbooks.pub/nursingskills/chapter/21-10-checklist-for-foley-catheter-insertion-male/>).

process and reducing the procedure time can play a major role in alleviating patients' discomfort.

Currently, to improve these shortcomings, disposable pre-arranged insertion sets has been used in developed countries (Fig. 1C) [9,10]. This set is a product that packed the necessary materials such as syringe, gel, and povidone which are laid in a reverse order of usage, and the Foley catheter is inserted by taking out the contents in order of the arrangement. However, the overall laborious process remains the same, and thus there is no significant change for the inconvenience of the practitioners and the discomfort of the patients during the procedure.

To solve these problems, we developed a new device, Quick Foley (UFU Health Co., Seoul, Korea) that can conveniently, rapidly, and accurately, introduce the Foley catheter while maintaining the principle of the sterilization.

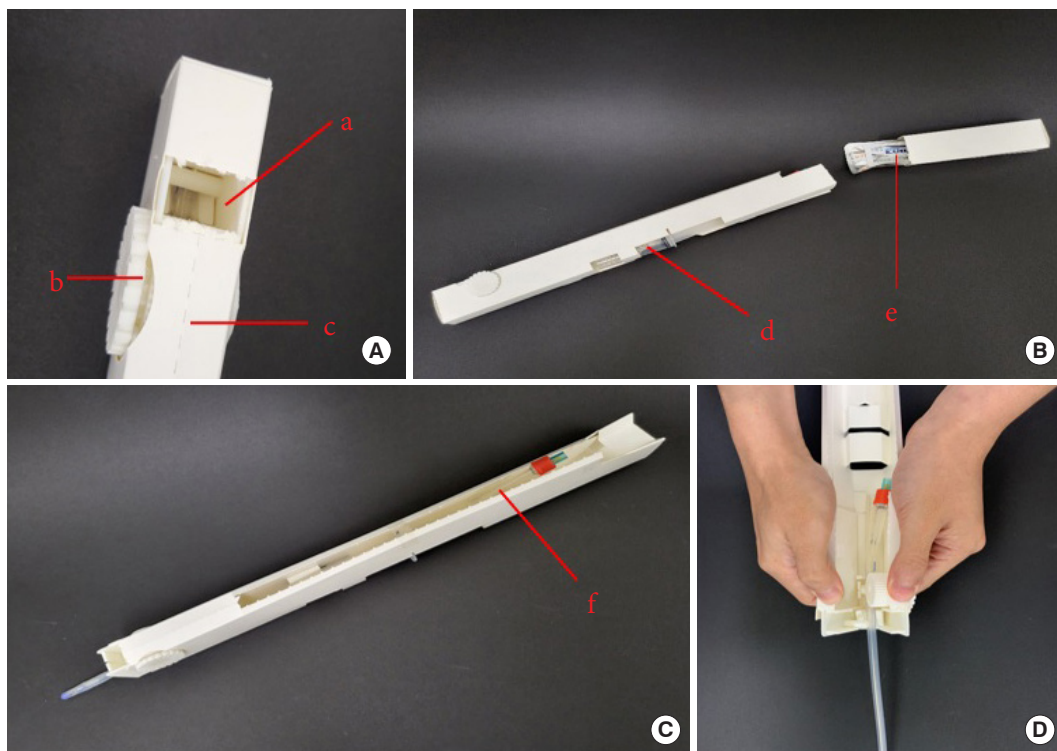
## MATERIALS AND METHODS

Quick Foley is a disposable all-in-one Foley catheter introducer which can be used rapidly and easily without compromising

aseptic principle (Fig. 1A). It consists of 2 main parts: a modular Foley catheter insertion drive and a cassette that covers the Foley catheter from contamination and attaches the accessories (Fig. 2A). Insertion driving unit is made of plastic for functional accuracy and consistency, and advancing roller is inserted, which divides manual drive and catheter drive to allow the catheter to be inserted and to maintain sterility. This module contains a space, gel insert, which allows the lubricating gel to be applied automatically as the catheter advances (Fig. 2B). The cassette contains the Foley catheter, and the rest is made of paper which makes it easier to assemble and dispose. The assembled device has a tract through which Foley catheter and ballooning syringe move (Fig. 2C) and is equipped with 2 separated spaces: one for lubricating gel and povidone cotton and the other for distilled water prefilled syringe.

### Insertion Procedure

After removing the packaging, we can cut off the back of the introducer to expose the posterior part of the Foley catheter, then connect it with the urine bag. The other side of the cutoff



**Fig. 2.** Detail parts of Quick Foley (UFU Health, Seoul Korea). (A) Drive module and gel insert. (B) Gel & povidone cotton space and syringe attach. (C) Ballooning tract. (D) Opening the module to disassemble the device, leaving the Foley catheter only. a, gel insert; b, advancing roller; c, tearing dot-line for disassembly; d, syringe slot & prefilled syringe; e, gel & povidone cotton; f, tract for ballooning pump.

part contains disposable lubricating gel and disposable povidone cotton. The distilled water prefilled syringe is detached from the cassette and connected with the Foley catheter balloon pump. We may spur the lubricating gel into the gel insert and tear off the tract part along the perforation line to make a tract to move the syringe, then we sterilize the area around urethra and turn the advancing roller with the thumb for the Foley catheter to move it forward to the bladder. Then, we may introduce distilled water into the balloon as conventionally done and disconnect the syringe. To disassemble the device, all we have to do is tear off the paper portion of the cassette along the pre-made dotted lines and open the module, which leaves the Foley catheter by itself (Fig. 2D).

## RESULTS

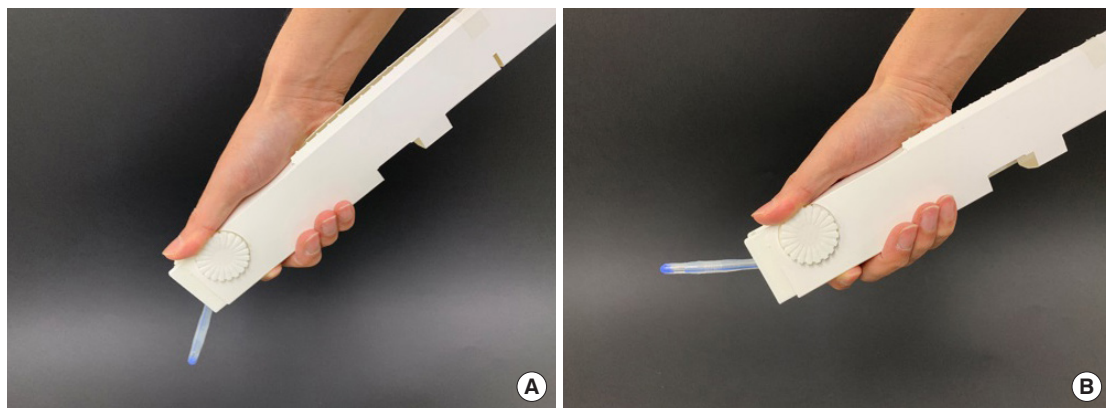
We were able to invent a Foley catheter introducer that integrates all of the contents. The internal compartment of the device is completely isolated to provide sterile environment in which the catheter and all other moving parts are not in contact with outside. Advancing the catheter is also achieved by the internally situated cog mechanism that translates the motion of the control knob to the driving roller preventing any parts exposed to the outside from coming in contact with the sterile contents (Fig. 2). In addition, the small orifice of the device ensure accuracy and sterility, reducing the need for the region be sterilized as it is precisely introduced through the urethra.

All necessary accessories for Foley catheter insertion, such as lubricating gel, povidone cotton, and distilled water prefilled syringe, are included in the device and are well mounted in the

cassette, making it an all-in-one device that is convenient to carry and operate. The cassette is made of paper, and the units are easily assembled. Also, its disposal is environment friendly as only the drive module for consistent operation is made of an inexpensive synthetic resin.

It has a selective antiretraction mechanism, so the catheter retraction can be prevented after insertion is initiated. Also, retraction can be reset by pushing and reversely turning the advancing roller if an unexpected situation arises during the procedure. In addition, it can be used in case of suprapubic cystostomy change, too.

Lastly, this device has a unique feature that it is differentially designed for men and women to accommodate unique anatomical structures of the urethra for each sex. For men, we design the head of the catheter exit angled 45 degrees lower, so the catheter is coming out in 45 degrees downward, and as the user adds another 45 degrees naturally due to human hand and wrist's position, the catheter is introduced vertically. So overall this makes it more convenient for the users to insert the catheter to the male genital (Fig. 3A). For suprapubic cystostomy catheter change, this new device for males can be used since the catheter needs to be introduced vertically. Using the same concept, for females, the head of the catheter exit is angled 45 degrees up, so as the user lowers 45 degrees naturally, once again because of how the human hand and wrist moves naturally in that direction, this positions the catheter to be introduced horizontally (Fig. 3B). So overall, this would allow the users to more easily maneuver the device in a natural way.



**Fig. 3.** Difference between Men's and Women's. (A) Device for Men's (Including for suprapubic cystostomy catheter change): Foley catheter is advanced vertically by rolling the roller with natural grip. (B) Device for Women's: Foley catheter is advanced horizontally by rolling the roller with natural grip.



## DISCUSSION

The features of Quick Foley are as follows.

Since the most significant complication of Foley catheter insertion is urinary tract infection, it is very important to maintain sterile principles during the insertion [3,11-13]. Since the catheter is enclosed in the sterilized inner space of the module and the cassette, this device avoids nonsterile contacts from the users and make it possible to introduce the catheter to the urethra without contamination. This process allows practitioners to avoid exposing perineum and sterilizing of the whole genitals, and this is a major advantage of the new device. Theoretically, the user does not need to wear the sterile gloves as the mechanism of the device ensures sterility.

The disposable prefilled ballooning syringe with distilled water, lubricating gel, and povidone cotton which are all necessary components for the Foley catheter insertion, are all conveniently assembled as a set, so it can be easily and rapidly utilized just after unpacking for insertion. When lubricating gel is poured into the gel insert and the advancing roller is turned, the Foley catheter is automatically coated with gel and moves forward, and this minimizes the mess and prevents the gel from splattering all over the place. After the balloon syringe is installed with Foley catheter, the advancing roller outside the cassette is driven, the roller inside the cassette advances the Foley catheter, and the ballooning pump advances along the tract of the cassette with the syringe attached. After detaching the ballooning syringe, the drive unit and the cassette can be disassembled by opening the module and tearing the cassette along the predotted line.

In the case of this device, only the operating part is made of plastic for consistency of operation and moist gel application, otherwise the outer part of the cassette is made of paper. The use of paper in medical devices is rare because lack of its durability during the operation, its fragility which makes it difficult to maintain its structure, and as well as it being easily dampened by moisture. However, for our device, the paper can be used since the cassette is only used to cover the Foley catheter and no compelling force needs to be applied. Furthermore, as sustaining environmental protection is emphasized nowadays, reducing cost and providing environmental-friendly products become vital. Lastly, the device is compartmentalized, the Foley catheter pump tract, syringe attachment, gel, and cotton insertion space, etc. could be easily provided.

Here is a summary of the benefits of using Quick Foley:

All the essential principles of conventional Foley catheter insertion are followed, but as the sterilized catheter cassette and insertion driver operate independently, this prevents extended usage of sterilization technique.

An important factor to consider in Foley catheter insertion is the psychological discomfort of the patient. During the procedure, the patient's legs are opened to expose the genitals and perineum. Foley catheter insertion requires sterile method during the procedure, so inevitably patient needs to expose the private area from the time when the catheter parts are prepared until the end of the procedure. Therefore, in order to minimize such psychological discomfort, it is necessary to simplify the procedure preparation steps and shorten the procedure time as much as possible. When using this device, the Foley catheter can be isolated from the outside throughout the insertion process, so you do not have to expose the private area until the Foley catheter is actually inserted. Duration of discomfort of the patients is certainly minimized by this new device.

In terms of hospital management, this new device can yield cost reduction by curtailing the number of sterilized set usage and simplifying internal logistics. Naturally, this will lead to reduction of works by the nursing staff. In addition, reduced preparation time and simplified insertion procedures curtail workload of the hospital staff, but more importantly, this new device can be indispensable in the setting of the emergency rooms, critical care, and military field hospitals.

Medicine is a study that deals with the human body, and innovation is imperative not only in the cutting-edge medical front but also in the basic yet essential procedures. As much as the Foley catheter is widely used to facilitate patient care, this newly developed device can be vastly helpful to clinicians who perform this procedure day in and day out. Broadly speaking, this new innovation can be deemed as advancement of medicine as well as an opportunity to open up a new market for medical devices. Commercialization of this new all-in-one Foley catheter device will have a positive impact on the economy as this product will bring a competition in the existing Foley catheter market in addition to create new field of mechanically inserting the Foley catheter, and overall, this can lead to incremental increases in the Foley catheter market share.

In conclusion, though the Foley catheter has been used for a long period of time, there has not been significant changes about how we insert the device into patients, and current usage has its own limitations such as time-consuming and cumbersome preparations along with unnecessarily long exposure of

the perineum that the patient has to go through. Our novel device can definitely change the status quo for the practitioners and the patients, as the device can simplify the whole procedure with maintaining aseptic principle and reduce the exposure time of the patients as this new all-in-one device is preprepared and minimize perineal sterilization. Medical innovation is not only for the forefront medicines but even more so for basic yet essential ones. Improvement of simple yet widely practiced medical procedures (e.g., Foley catheter insertion) can have a wider and deeper impact.

### AUTHOR CONTRIBUTION STATEMENT

- Conceptualization: *KJC*
- Project administration: *KHK*
- Visualization: *KJC*
- Writing - original draft: *KJC*
- Writing - review & editing: *KHK*

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