

# Sterilization of single-use helical stone baskets: an experimental study

Esterilização de cestas helicoidais descartáveis extratoras de cálculo: um estudo experimental

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## ABSTRACT

**Objectives:** To experimentally evaluate the efficacy of a standard sterilization protocol employed during reuse of disposable helical stone baskets. **Methods:** Study performed on 20 helical stone baskets: 10 were used in the initial validation process, contaminated with *Escherichia coli* ATCC 25922 and imprinted on Müller-Hinton media; 10 catheters were contaminated with *Geobacillus stearothermophilus* ATCC 7953, processed, inoculated in TSB and incubated in a water bath at a temperature of 55°C. Bacterial growth was evaluated after 1, 3, 5 and 7 days. After sterilization, stone baskets were also opened and closed 40 times to check for functional problems. All plastic and basket parts were carefully checked for damages. **Results:** After the 72-hour incubation period, there was growth of *E. coli* ATCC 25922 in 100% of imprints. After the sterilization process and up to 7 days incubation period on a blood agar plate, there was no growth of *G. stearothermophilus* ATCC 7953 or any other bacteria. There were no functional problems or damage to baskets after the sterilization process. **Conclusion:** The ethylene oxide system is efficacious and safe for sterilization of disposable helical stone baskets. However, further clinical studies are required and should provide more safety information.

**Keywords:** Catheterization; Equipment reuse/standards; Sterilization/methods; Disposable equipment; Ethylene oxide

## RESUMO

**Objetivo:** Avaliar experimentalmente a eficácia de um protocolo padrão de esterilização de cestas helicoidais descartáveis extratoras de cálculo. **Métodos:** Estudo realizado com 20 cestas helicoidais descartáveis extratoras de cálculo: 10 foram utilizadas no processo inicial de validação do método, contaminadas com *Escherichia coli*

ATCC 25922 e semeadas em meio de Müller-Hinton; 10 foram contaminadas com *Geobacillus stearothermophilus* ATCC 7953, processadas, inoculadas em TSB e incubadas em banho maria, a 55 °C. O crescimento bacteriano foi avaliado depois de 1, 3, 5 e 7 dias. Após a esterilização, as cestas helicoidais descartáveis extratoras de cálculo foram abertas e fechadas 40 vezes para avaliar problemas funcionais. Todas as partes plásticas foram avaliadas quanto a danos. **Resultados:** Após as 72 horas de incubação, observou-se crescimento de *E. coli* ATCC 25922 em todos os meios. Após a esterilização e até 7 dias de incubação, não houve crescimento de *G. stearothermophilus* ATCC 7953 ou de qualquer outra bactéria. Não foram observados problemas funcionais ou danos nas cestas após a esterilização. **Conclusão:** O processo de esterilização com óxido de etileno é seguro e eficaz para re-esterilizar cestas helicoidais descartáveis extratoras de cálculo descartáveis. Contudo, são necessários mais estudos clínicos para fornecer mais informações sobre segurança.

**Descritores:** Cateterismo; Reutilização de equipamento/normas; Esterilização/métodos; Equipamentos descartáveis; Óxido de etileno

## INTRODUCTION

The past decades have seen an explosion in the use of single-use medical devices, stemming from the desire to improve product performance and minimize the potential for disease transmission. However, single-use devices are typically more expensive.

Because of the rising costs of health care, the practice of reusing various disposable medical devices has been adopted by many hospitals<sup>(1,2)</sup>. It is very common

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in Brazilian public hospitals to reuse these devices, mainly for urinary calculi surgeries. Sterilization can be performed using ethylene oxide or glutaraldehyde. Heat sterilization is not performed given these devices have plastic parts. Glutaraldehyde has not been recommended because *Mycobacteriae* can be resistant<sup>(3)</sup>.

The major concerns in reusing single-use items regard the several potential risks to patients such as infection, toxicity, contamination and device breakage. Urosepsis from manipulation of the urinary tract during stone surgery can be catastrophic despite antibiotic prophylaxis<sup>(4)</sup>.

Stone baskets are the most often single-use devices used in most of the ureteroscopy procedures. As they cost several hundred dollars, in a subset of hospitals these procedures are only available through sterilization and reuse. Even though this is a common practice, no previous studies have evaluated its safety.

## OBJECTIVE

The aim of the present study was to experimentally evaluate the efficacy of a standard cleaning and sterilization protocol employed during reuse of disposable helical stone baskets.

## METHODS

This study was carried out at the Disciplines of Urology and Microbiology of Faculdade de Ciências Médicas da Santa Casa de São Paulo (FCMSCSP) between 2008/09.

The study was performed on 20 helical stone baskets (Handle Cook®, Helical Stone Extractor, 4 wire basket, length 115 cm) and comprised three phases:

1. validation process, aiming to demonstrate that baskets were contaminated with bacteria after usage;
2. test for sterility, to evaluate ethylene oxide sterilization process efficacy;
3. functional test, to evaluate if the disposable devices could resist reutilization.

Standard suspensions of bacterial strains from the American Type Culture Collection (ATCC) were inoculated: *Escherichia coli* ATCC 25922 (concentration around  $1.5 \times 10^8$  CFU/mL, 0.5 on the McFarland scale) and *Geobacillus stearothermophilus* ATCC 7953.

### Validation process

Ten helical stone baskets were used in this initial validation process. The helical baskets had their tip

inserted in the *E. coli* ATCC 25922 suspension, and were opened and closed 40 times, guaranteeing that the entire inner part of the catheter was also contaminated. The wire and the plastic handle were also contaminated with a swab.

The baskets were allowed to dry for 24 hours on a clean bench. The catheters were then detached and imprinted on Müller-Hinton media. Individual analysis of media was assessed for the following imprints: (1) plastic handle, (2) basket, (3) proximal internal steel wire, (4) medium internal steel wire, (5) distal internal steel wire and (6) external plastic sheet.

Müller-Hinton media were incubated at  $35 \pm 2$  °C, and bacterial growth was evaluated at days 1, 3, 5 and 7.

### Testing for sterility

Ten catheters were contaminated with *G. stearothermophilus* ATCC 7953 according to the previously described protocol. These bacteria were used in this part of the study, as they are more resistant to high temperatures<sup>(5,6)</sup>. After air-drying, the bacteria-infected catheters were sent to the hospital's Sterile Service Department.

They were separated into their parts and manually cleaned with hot water. The internal parts were cleaned with a syringe. The water was drained, and parts were left in an enzyme solution for 10 minutes. They were then cleaned with water again and put into an 80% alcohol solution for 15 minutes. They were air-dried and the catheter was hermetically sealed in a sterilization pouch, allowing penetration of sterilization gases but providing a barrier against penetration by microorganisms.

Ethylene oxide gas sterilization was done in a two-stage cycle of 24 hours by using the 100% ethylene oxide sterilizer. After the sterilization process, catheters' parts – (1) plastic handle, (2) basket, (3) proximal internal steel wire, (4) medium internal steel wire, (5) distal internal steel wire, (6) external plastic sheet – were inoculated in tubes with Tryptic Soy Broth (TSB) and incubated in a water bath at 55°C. Bacterial growth was evaluated after 1, 3, 5 and 7 days. Acceptable test results were to be indicated by an absence of microbial growth in all sterility tests.

### Functional aspects after sterilization

After sterilization, stone baskets were opened and closed 40 times to check for problems in function. All plastic and basket parts were carefully checked for damages.

## RESULTS

During the experimental basket contamination and validation process and after the 72-hour incubation period, there was growth of *E. coli* ATCC 25922 in 100% of imprints.

After the sterilization process and up to 7 days incubation period in a TSB tube, there was no growth of *G. stearothermophilus* ATCC 7953 or any other bacteria.

There were no functional problems or damage to baskets after the sterilization process.

## DISCUSSION

Disposable devices used in the endourology setting have a higher percentage of plastic in their construction than similar reusable devices<sup>(7-9)</sup>. Moreover, single-use catheters not necessarily have flushable lumens and removable parts to allow cleaning solutions and sterilization to reach all areas of the device.

In this study, lumens were submitted to a gross contamination, after the baskets were immersed, opened and closed several times in bacterial broths. In the first part of the present study, we tested an experimental model of stone basket contamination. *E. coli* ATCC 25922 was chosen as it is easily manipulated and has a low virulence<sup>(5,6)</sup>. In the second part, *G. stearothermophilus* ATCC 7953 was used, as it has a high resistance to sterilizing methods<sup>(5,6,10)</sup>. After sterilization, there were no detectable bacteria in any of the segments of the internal wire (proximal, medium or distal).

The ethylene oxide sterilization process can therefore be considered efficient in eliminating bacteria from disposable helical stone baskets. Since these devices get in contact with urine, major concerns are related to bacterial infection. To reduce the risk of mycobacteria, it was our option to use ethylene oxide sterilization. Another important issue would also be to test destructibility or breakdown in reprocessing procedures. Ethylene oxide can be considered a flexible sterilization process, meaning cycles can be tailored to handle complex devices. It can be used with a wide range of plastics and other materials without affecting the integrity of the device<sup>(10,11)</sup>. According to the US Food and Drug Administration (FDA), urological baskets and catheters are class II semi-critical devices<sup>(2,12)</sup>. This means that they are not products that intend to support or sustain human life, and therefore can be considered for reprocessing<sup>(2,12)</sup>. We did not find any product damage after the sterilization process, suggesting that patients' safety would not be threatened.

We are aware of several limitations of this study; for example, we did not test for viral infection or sterilization. However, previous studies have demonstrated that appropriate cleaning and sterilization of reused disposable devices inactivates blood-borne viruses, and the risk of infection is virtually zero<sup>(13)</sup>. The policy on the reprocessing and reuse of single-use helical stone basket devices is affected by several factors such as health costs, equipment manufacturers' interests, hospitals' interests and third-party reprocessors. However, policy should be based mainly on patient safety concerns. The present study and available data show that single-use stone baskets can be reprocessed with a reasonable assurance of safety and effectiveness, and reused without increasing patients' risk.

## CONCLUSION

This experimental study demonstrated that ethylene oxide system is efficacious and safe for sterilizing disposable helical stone baskets contaminated with bacteria. However, further clinical studies are required and might bring more safety information.

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