

# The Value of Monitoring the Cleaning Process

By Nancy Chobin, RN, CSPDM

## Background

One of the most important parts of the disinfection/sterilization process is effective cleaning of the device. At present, the best method we have is visual inspection, which is very subjective. We might be able to identify that visible soils have been removed but what about invisible soils (e.g., microbes)? However, dependency on visual inspection is risky at best because even with a lighted magnifying lamp, one cannot see inside joints (e.g., box locks of instruments) or lumens. The processing department needs a reliable methodology that will monitor the effectiveness of the cleaning process and identify areas of process improvement, similar to the products in use to monitor the effectiveness of the various sterilization processes (e.g., chemical indicators, integrators, and biological monitors).

With that in mind and with the introduction of some new products designed to monitor the cleaning process, an evaluation of the TOSI cleaning effectiveness tool was evaluated in the Saint Barnabas Health Care System (SBHCS), the largest healthcare delivery system in New Jersey with seven primary-care facilities. With the variety in facilities processing areas and equipment, it gave us an opportunity to evaluate this product line under a wide variety of practice settings and with various types of cleaning equipment.

The facilities selected for this project were: Saint Barnabas Medical Center in Livingston, N.J.; Union Hospital in Union, N.J.; Clara Maass Medical Center in Belleville, N.J.; and Community Medical Center in Toms River, N.J. Each of these facilities represents different processing equipment manufacturers, equipment type, and processing protocols.

## Methodology

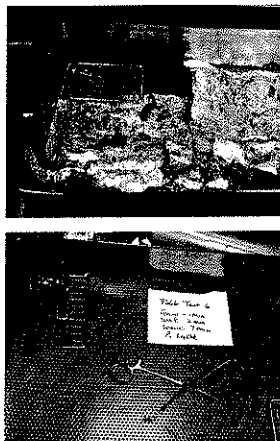
Each facility was contacted regarding participation in the evaluation. The facility's "local" process (process used by their staff) would be challenged vs. other methods (as described). To create a suitable challenge for this project, surgical instruments (Kelly clamps, Kochers, Criles, and Poole abdominal suctions) were exposed to human blood obtained from the Saint Barnabas Medical Center Blood Bank. It was known that the TOSI was designed for use with high-alkaline detergents which are commonly used in the European market but not as widely used in the United States. Only one of the SBHCS facilities uses a high-alkaline detergent with a citrus acid neutralization wash.

In the sterile processing department (SPD) decontamination area and while wearing full personnel protective equipment (PPE), the instruments were opened, disassembled (e.g., Poole suction), and then soaked in the blood for approximately 30 minutes, ensuring that the instruments were thoroughly coated with blood. This represents a challenge, as surgical instruments are routinely wiped off in the surgical field and should

never present to the SPD in this condition. The instruments were then allowed to air-dry for 16 hours (again creating a worst-case scenario for cleaning). These instruments were then used as controls in the TOSI evaluations.

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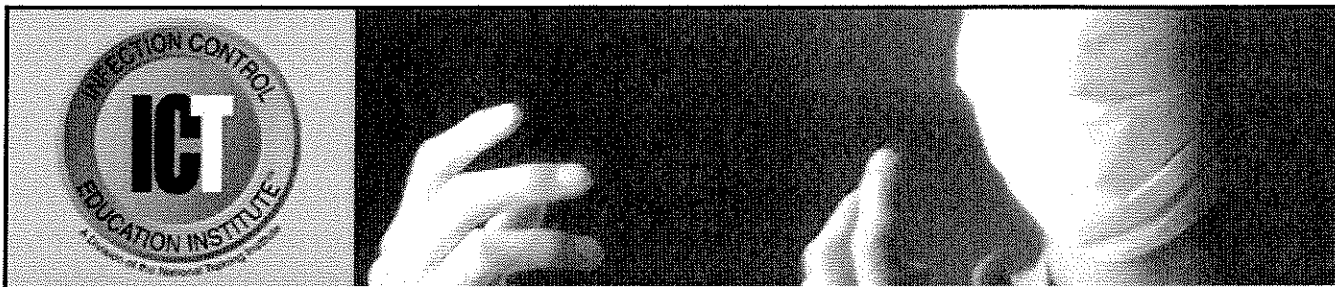
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## **ICRE14-0208: The Value of Monitoring the Cleaning Process**

**Authors:** By Nancy Chobin, RN, CSPDM  
1.2 contact hours

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### **OBJECTIVES**

1. Describe a reliable means of monitoring the cleaning process' efficacy.
  2. Define the function of the TOSI cleaning effectiveness tool.
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### **Background**

One of the most important parts of the disinfection/sterilization process is effective cleaning of the device. At present, the best method we have is visual inspection, which is very subjective. We might be able to identify that visible soils have been removed, but what about invisible soils (e.g., microbes)? However, dependence on visual inspection is risky at best because even with a lighted magnifying lamp, one cannot see inside joints (e.g., box locks of instruments) or lumens. The processing department needs a reliable methodology that will monitor the effectiveness of the cleaning process and identify areas of process improvement, similar to the products in use to monitor the effectiveness of the various sterilization processes (e.g., chemical indicators, integrators, and biological monitors).

With that in mind, and with the introduction of some new products designed to monitor the cleaning process, an evaluation of the test object surgical instrument (TOSI) cleaning effectiveness tool was evaluated in the Saint Barnabas Healthcare System (SBHCS), the largest healthcare delivery system in New Jersey, with seven primary-care facilities. With the variety in facilities' processing areas and equipment, it gave us an opportunity to evaluate this product line under a wide variety of practice settings and with various types of cleaning equipment.

The facilities selected for this project were: Saint Barnabas Medical Center in Livingston, N.J.; Union Hospital in Union, N.J., Clara Maass Medical Center in Belleville, N.J., and Community Medical Center in Toms River, N.J. Each of these facilities represents different processing equipment manufacturers, equipment type and processing protocols.

### **Methodology**

Each facility was contacted regarding participation in the evaluation. The facility's "local" process (process used by their staff) would be challenged vs. other methods (as described). To create a suitable challenge for this project, surgical instruments (kelly clamps, kochers, criles and Poole abdominal suctions) were exposed to human blood obtained from the Saint Barnabas Medical Center Blood Bank. It was known that the TOSI was designed for use with high alkaline detergents which are commonly used in the European market but not as widely used in the United States. Only one of the SBHCS facilities uses a high alkaline detergent with a citrus acid neutralization wash.

In the sterile processing department (SPD) decontamination area and while wearing full personnel protective equipment (PPE), the instruments were opened, disassembled (e.g., Poole suction), and then soaked in the blood for approximately 30 minutes, ensuring that the instruments were thoroughly coated with blood. This represents a challenge, as surgical instruments are routinely wiped off in the surgical field and should never present to the SPD in this condition. The instruments were then allowed to air-dry for 16 hours (again creating a worst-case scenario for cleaning). These instruments were then used as controls in the TOSI evaluations.

All of the tests were performed by Nancy Chobin, RN, CSPDM, SPD/CS educator for the Saint Barnabas Healthcare System. The department managers who facilitated this project were Sharon Gilbert, RN, of Saint Barnabas Medical Center; Hattie McCleese, RN, of Union Hospital; Mike Figueroa, of Clara Maass Medical Center, and Terri Matthews, RN, of Community Medical Center.

Each facility represented different cleaning and processing equipment:

- Manual cleaning
- Washer/decontaminator (Getinge, Belimed)
- Ultrasonic cleaners (Getinge, Medisafe, Skytron)\
- Enzymatic pre-soak
- Combinations of the aforementioned entities

At the facilities, the processes were modified slightly to determine the outcome on the product. (NOTE: The modifications were to represent various cleaning protocols. The modification was needed to effect the proper reaction in the TOSI and represented a change in existing practice). The processes modified were the times of exposure to the enzymatic detergent and the steps in the cleaning process.

### **TOSI Products Used/Tested**

At each facility, the mechanical washers would be challenged by the TOSI Cleaning Effectiveness Test and, if needed, alternate cycles were tested to determine if an improved result could be obtained. The TOSI was attached to the TOSI Mini Baskets (TI-102) before placing in the respective washers. TOSI was distributed in the wire mesh baskets in either two opposite corners or in all four corners. The TOSI was further placed in the basket in opposite directions (one half of the TOSI indicators placed in the horizontal position and the other half placed vertically in the pan.

Ultrasonic cleaners were tested using aluminum foil (regular weight) and Sonocheck Ultrasonic Cavitation Indicator (PL227). Lumens were tested at a number of facilities using the TOSI Cleaning Effectiveness Indicator for Rigid Lumen (LUMCHEK #T40375) placed inside a TOSI Lumen Wand (#T40375L). The placement of the TOSI lumen

indicator inside the lumen wand complied with the written instructions that accompanied the lumen wand. The majority of the lumen tests were performed in an ultrasonic lumen cleaner at Community Medical Center.

### **TOSI Test Indicators**

All of the TOSI, sonocheck and lumencheck tools were saved in sealed plastic bags. The surgical instrument controls were visually inspected after each cycle and the results noted. Digital photos were taken at each facility to document the process and results.

### **Test Results**

#### **TOSI T-101**

The TOSI tools clearly identified sub-optimal cleaning processes/practices. The results correlated well to the artificial controls used and identified the lack of parts of the process (e.g., enzymatic pre-soak, ultrasonic cleaning).

The tools also clearly identified best practices for cleaning. These results also correlated well to the controls and reflected completeness of the process (enzymatic activity and access, exposure times and solution temperature). The use of the alkaline/acid detergent system consistently cleaned the TOSI and controls.

There was marginal correlation on moderate/average cleaning processed. The artificial controls were not as resistant to the process changes as was the TOSI. The mixed results appear to indicate an aggressive challenge design for TOSI.

All judgments were based upon visual inspection of the devices.

#### **Final Assessment T1-101**

Re-assessments were performed approximately two months after the initial testing. The key cycles that delivered mixed results at one facility were re-visited. The same protocol was followed for preparing the artificial controls. In one trial, T1-101 was used vs. the controls and liquid-gel-hemo-sensitive solution. In addition, the use of an actual dried instrument set (11 hours dried) was used in lieu of the control instruments.

The addition of the actual controls and hemo-sensitive liquid inspection produced excellent correlations. Key cycles used for cleaning produced visually clean actual controls with liquid verification of soiled hinges/serrations. The focus was on three different cycles:

- two-minute enzymatic pre-soak, three-minute ultrasonic cycle, P-1 cycle (heavy soil instruments)
- five-minute enzymatic pre-soak, five-minute ultrasonic cycle and P-2 cycle (light soil instruments)
- two-minute enzymatic pre-soak, seven-minute ultrasonic cycle (in tunnel washer)

### **Conclusions**

The T1-101 correlation to the actual soiled instruments shows value as an objective monitor of the effectiveness of the cleaning process. This study allowed us to identify that various processing equipment and detergents can affect the overall cleaning process. The use of these tools can assist processing managers and staff to identify previously unseen challenge areas and quickly evaluate the efficacy of their cleaning processes. The ability to determine the cleanliness of lumens is a tremendous benefit.

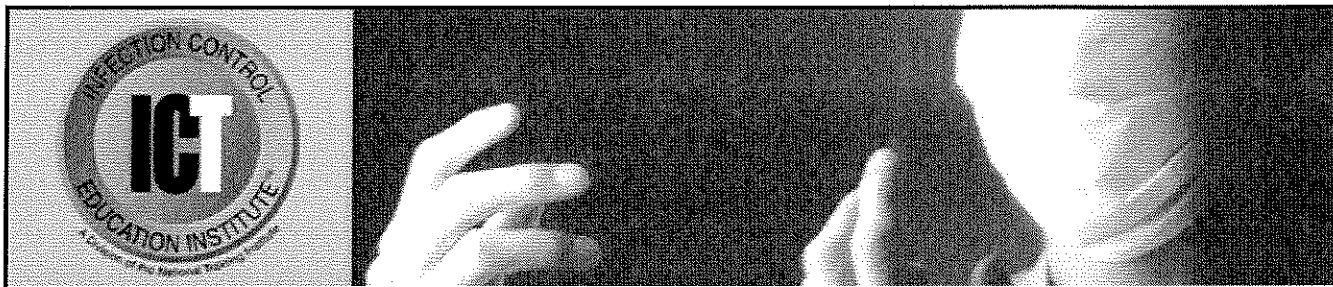
The use of these tools can be cost-justified as a critical first step to promote process improvement activities (when deficiencies are identified by the tools) as well as capital equipment justifications (only manual cleaning is available or when processing equipment needs to be replaced). They can also be used as part of a total process improvement process for sterile processing.

*Nancy Chobin, RN, CSPDM, is the SPD/CS educator for Saint Barnabas Healthcare System in West Orange, N.J.*

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1. The best method of determining if cleaning was effective is via visual inspection.  
 True  
 False
2. The TOSI is designed for use with low alkaline detergents.  
 True  
 False
3. To begin the challenge, instruments are first soaked in blood for five minutes to ensure they are fully coated.  
 True  
 False
4. The next step is allowing the instruments to air-dry for two hours.  
 True  
 False
5. The surgical instrument controls were inspected after each cleaning cycle and the results were noted.  
 True  
 False
6. TOSI did not accurately identify sub-optimal cleaning processes in this case.  
 True  
 False
7. The TOSI results correlated well with the controls.  
 True  
 False
8. Artificial controls were not as resistant to the process changes as the TOSI was.  
 True

False

9. Adding actual controls and hemosensitive liquid inspection produced excellent correlations.

True

False

10. The TOSI tools can be cost-justified as a critical first step to promoting process improvement.

True

False

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