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EXCELLENCE IN SURGICAL PRODUCTS WINNER

The Clean Challenge

The TOSI™, a diagnostic challenge device and the winner of the 2010 Excellence in Surgical Products Awards, allows surgical facilities to ensure automated instrument cleaning equipment is working effectively, helping to improve efficiency, infection control, and patient and staff safety.

Interview by Amanda Hankel

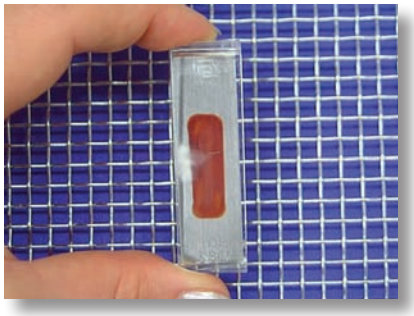
How do you know that your automated instrument cleaning equipment is effectively cleaning surgical instruments and preparing them for sterilization? Until recently, not many surgical facilities could confidently confirm their washers were working properly. Enter the TOSI™, Healthmark Industries Company, Inc.'s Test Object Surgical Instrument (TOSI), a challenge device that works to test automated instrument washers and diagnose potential problems. Here, Ralph J. Basile, Vice President of Marketing at Healthmark discusses the device that has proven to make such an impact on surgical facilities that it is the winner of the 2010 ESP Award.

Surgical Products: **How was the idea for the TOSI developed? What needs were you looking to meet with this product?**

Basile: We introduced the TOSI in 2001. What we recognized in talking to our customers was that while a great deal of effort, and rightly so, was going into monitoring sterilizer performance and sterilization, that kind of effort, or nothing close to it, was going into making sure that instrumentation was getting properly cleaned. Before you can effectively sterilize, you need to effectively clean.

The TOSI is a surrogate device for surgical instruments soiled with blood to test automated instrument cleaning equipment.

Our approach was to look at the primary object of cleaning in a sterile processing department, and that's typically a stainless steel instrument soiled with blood. Depending on how long it takes for the instrument to get to sterile processing, usually it's dry blood. Dry blood is a major challenge to cleaning because as soon as blood dries, it denatures, becoming highly water insoluble and a challenge to clean. We recognized there was a need to be able to monitor or verify the cleaning process, so we worked to come up with a surrogate device – something that would be similar to what the department is trying to clean – and that is typically dried blood on a stainless steel instrument.



The type of soil left on the TOSI after being run through a washer indicates potential problems with the equipment.

What we developed is a challenge device. It's the same test every time. It's comprised of dry blood soil on stainless steel inside of a plastic holder. It's plastic so you can see through it. You can see the stainless steel surface and the blood soil, but it provides a physical challenge to the cleaning process, which is similar to the areas of instruments that are blocked from direct spray action. The idea is you run the TOSI just like you would a surgical instrument, so you place it inside an automated instrument washer, run it through a

normal instrument cycle and the test should come clean. If it doesn't, the test is diagnostic, so depending on what kind of soil is left, it suggests the possible problem with the washer.

Surgical Products: **What are some potential problems that can occur with automated instrument cleaning equipment?**

Basile: 1. The water is at the wrong temperature at the wrong time. For instance, the initial rinse in a washer is cold. It's very important that indeed it be cold water and not heated water, because heat denatures proteins. If it's heated water – 110° F or hotter – it will almost instantly denature the proteins, which renders them water insoluble and very difficult to clean. In the detergent stage, the detergent being used must be at the optimal temperature as indicated by the manufacturer. In the thermal disinfection stage, the water must be hot to kill most of the microbes and render the instruments safe for handling.

2. The detergent is at the wrong concentration. One of the biggest issues we see is that the right amount of detergent is not being delivered to the chamber or the washer. This can happen, for example, if the tube is kinked, there is air in the line, or the pump is not working properly.

3. Problems with mechanical efficiency or functioning of the washer, such as blocked spray nozzles or a bushing on a washer rack is broken.

4. The human element, or how the machine is loaded. The machine can be working absolutely perfectly to the manufacturer's specifications, but if the machine is overloaded — if instruments are stacked up on one another, or the trays are loaded with instruments with the cover on top — it's not being used properly.

Surgical Products: **How does the TOSI help diagnose problems?**

Basile: The TOSI is comprised of two types of proteins – water soluble proteins and water insoluble proteins. It's comprised percentage-wise by weight at the same ratio as human blood, which is approximately 95 percent water soluble and 5 percent water insoluble.

On the TOSI, the red soil is the water soluble hemoglobin. If any hemoglobin is left, it's usually an indication of a mechanical problem that is preventing water from getting in there. It's a water-soluble soil, so as long as you get water, the hemoglobin will wash away. That is, with one exception – if the cold water rinse is hot, it will bake the blood on. So, it's indicative of either a mechanical issue or an initial water temperature issue.

The other soil is fibrin, a translucent soil that is the coagulating agent in blood. By nature, it is water insoluble and it requires detergents to break it down. If fibrin is left, it's usually an indication that it's a chemistry problem – exposure time to detergent is too short, the water temperature was wrong for that detergent, or not enough of the detergent went into the chamber.

Surgical Products: **How often should a facility use this product?**

Basile: Association for the Advancement of Medical Instrumentation (AAMI) ST79 guidelines now state that automated instrument cleaning equipment should be tested at least weekly, preferably daily. In the Association of periOperative Registered Nurses' (AORN) recommended practices, it's recommended to test automated cleaning equipment weekly.

Surgical Products: **How can using the TOSI help facilities improve patient safety, infection rates and overall efficiency?**

Basile: A colleague of mine always says, "Quality doesn't cost, quality pays." When you have a tray of instruments, it's really hard to say that one dirty instrument has caused an infection in a patient. Yet, we know that if one dirty instrument is used on a patient, the patient is likely to have a reaction to it.

Particularly when we are talking about introducing blood from one patient to another because the instrument was not properly cleaned, we have a very high chance for surgical site infection. We have heard of patients being operated on and the surgeon is using a lumened instrument. They're flushing, they're sucking and something comes out of an instrument in the middle of a surgery, as in a chunk of dried blood. If those instruments have not been properly cleaned, now, the patient has been compromised and a foreign body has touched them.

Secondly, when the washers are not functioning properly or not being used properly, the staff spends a great deal of time manually cleaning. That is a lot of time and money spent when the role of the washer is to do the cleaning. If your machine is functioning properly, it means less staff-time spent cleaning instruments, so the facility can save money and be efficient.

It's also very costly if an instrument comes through decontamination, gets to the clean side, and somebody says, 'Hey, this instrument is dirty.' The instrument needs to go through the process again, which costs money. Even worse, if a set of instruments is opened in the OR and the surgeon or nurse discovers that an instrument is dirty, that whole set is assumed not sterile. Increasing the incidence of clean instruments literally can save tens of thousands, if not hundreds

To learn more about the TOSI's impact on surgical facilities, go to www.surgicalproductsmag.com to read a Q&A with an end-user who nominated the product for the ESP Awards.

2010 ESP Winner: A User's Perspective

Cheron Rojo, Sterile Processing Department Educator at Children's Hospital Central California, first nominated Healthmark's TOSI™ for the Excellence in Surgical Products Awards. Here, he talks about the impact this product can have on a facility.

Interview by Amanda Hankel

Surgical Products: **How did you learn about the TOSI and how did you decide it was a product you'd like to try out?**

Rojo: I was first introduced to the TOSI test back around 2004 at a vendor exhibit booth. It was not much to look at, but something caught my eye; it was a device to test your washers. At the time there was nothing of its kind, and the concept of "If it is not clean, it is not sterile" made sense.

I put some of the samples in my bag and I took it with me. When I used the product for the first time, it did not turn. It wasn't turning like the pictures said it would, and I thought the product didn't work. I called tech support for the product and found that the product did not turn because the washers at the time had no detergent/enzyme coming through the lines, all the spray arms were plugged, the temperature was too high for the detergent/enzyme and the dilution rate was incorrect. How long had it not been working? Without this product, we would have continued to think our washer was operating at its full potential.

Surgical Products: **How does using the TOSI benefit your facility, as well as others?**

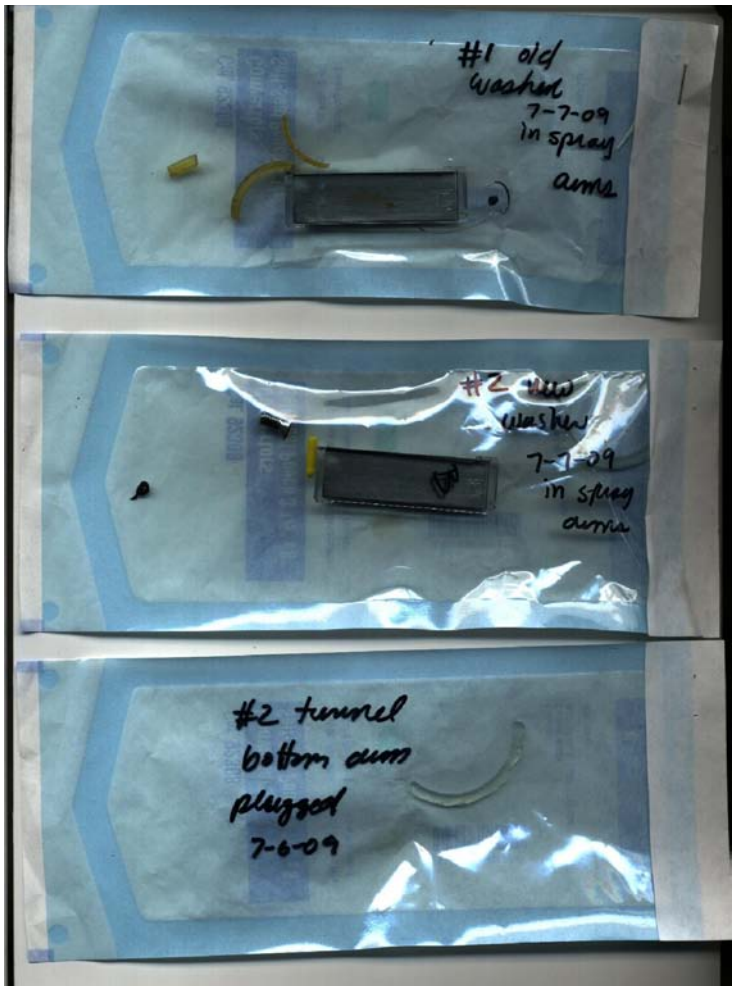
Rojo: Over the years, I have used and currently use the TOSI test as one of my tests when I was auditing facilities in my area. Every time, the results are accurate; telling me what is the issue. On one of my audits, the spray arms were put on incorrectly and were aimed at the walls of the chamber and there was no solution coming through due to huge air pockets in the lines.

The pictures shown were taken from an audit at one facility where the tests did not pass. The items with the test were blocking the arms from rotating, so the instrumentation in the chamber were not getting the impingement of the arms, and note that the peel pack on the top has a suture needle with it, which was also caught. The other items in the pictures plugging the arms were: suture booties, color code tape and seals from the original installation of the washer.

In 2009, the first recommendation by AAMI was issued saying that you had to test your washers weekly, preferably daily. At our facility, we test our washers with the TOSI daily. Since we've started using TOSI, we have more support by our maintenance department. They can't know every piece of equipment that detailed and a lot of times, they are kind of thrown in there to figure out what is wrong with the equipment, but they don't know all the ins and outs of the machine – they know basic stuff. Now, when the test fails, our staff shows them the fail and it helps them figure out what it could be. Are the blades plugged? Is there air in the line when there's no solution coming through?

Surgical Products: **What does this product do for patient and staff safety, and infection prevention?**

Rojo: If it's not clean, it's not sterile. A piece of tissue doesn't become sterile tissue. If it goes into the body, even though it's been sterilized, it's still a foreign body and the body is going to react to that. If the blades are plugged and it's not cleaned correctly and the staff happen to overlook



that kind of stuff, that is a big deal.

And, it's not just about patient care, but it's about co-workers. If the instruments are not being cleaned, so there is no detergent, they come out with a blood smell – well, I'm touching that!

Surgical Products: **What do you think was the biggest draw for your peers to vote for this product?**

Rojo: I think since the AAMI recommendation, people are now very aware and educated to know that washers have to be tested. You have to see if they're working correctly. People are starting to understand that it is very important to test your washers – as important as testing your sterilizers – and that's why they voted the way they did.