American Journal of Infection Control publishes TSO3 study on terminal sterilization of duodenoscopes

Québec City, Canada/Myrtle Beach, SC, USA, November 15, 2018 – TSO3 Inc. (“TSO3” or the “Company”) (TSX: TOS), an innovator in sterilization technology for medical devices in healthcare settings, announces today that the results of the Company’s clinical in-use and simulated use testing of the terminal sterilization of duodenoscopes have been published in the American Journal of Infection Control. The paper describes innovative testing methods developed and deployed by the Company in support of its STERIZONE® VP4 Sterilizer, which has received a 510(k) clearance from the U.S. Food and Drug Administration (FDA), for terminal sterilization of multi-channeled, flexible endoscopes that fall within the specified indications for use, including duodenoscopes.

The paper is titled “Elevating the standard of endoscope processing: terminal sterilization of duodenoscopes using a hydrogen peroxide-ozone sterilizer.” The paper is available on line in advance of the print publication:  https://doi.org/10.1016/j.ajic.2018.09.009

“In this study, we were able to conclusively demonstrate, in both simulated use testing as well as real-world clinical testing, the ability of the STERIZONE VP4 Sterilizer to terminally sterilize the most challenging locations of these complex devices, including the elevator recess location in the distal end cap of the duodenoscope,” stated Brad Catalone, TSO3’s Chief Scientific Officer and one of the authors of the paper. “The rigorous testing employed by TSO3 included validating the terminal sterilization effectiveness under worst case conditions, including devices that had been intentionally contaminated with the most resistant form of bacteria mixed in the absence and presence of an organic load without any prior cleaning.”

Duodenoscopes are flexible endoscopes used in a procedure called an Endoscopic Retrograde Cholangiopancreatography or ERCP, which enables a physician to perform diagnostic and therapeutic procedures involving a patient’s gallbladder, common bile duct, pancreas and liver. Approximately 500,000 ERCP procedures are performed each year in the United States. Antibiotic-resistant infections that resulted in life-threatening infections and deaths have recently been linked to the improper reprocessing of duodenoscopes. Carla Warner of North Carolina knows the devastating impact that Carbapenem-resistant Enterobacteriaceae (CRE), an antibiotic resistant infection, had on her husband, who contracted the infection following an ERCP procedure and died. Click here to hear more of Warner’s story. As recently as June 2018, infections believed to be transmitted via a duodenoscope were reported to the FDA through FDA’s Manufacturer and User Facility Device Experience (MAUDE) Database. Failure to consistently and effectively reprocess flexible endoscopes is listed second on the Top 10 Health Technology Hazards for 2018 published by the ECRI Institute, and has been in the top 10 list for several years.

“We are proud to share our continued innovations with the scientific and medical communities and are pleased to have additional peer confirmation of the science behind our transformational sterilization technology that is playing a role in solving a significant and urgent unmet medical need,” stated R.M (Ric) Rumble TSO3’s President and CEO.
About the STERIZONE VP4 Sterilizer

The STERIZONE VP4 Sterilizer is a low-temperature sterilization system that utilizes the dual sterilants of vaporized hydrogen peroxide (H₂O₂) and ozone (O₃) to achieve terminal sterilization of heat and moisture-sensitive medical devices. Its single pre-programmed cycle can sterilize a large number and wide range of compatible devices, creating a cost-effective sterilization process with error-free cycle selection. The device's unique Dynamic Sterilant Delivery System™ automatically adjusts the quantity of injected sterilant based on the load composition, weight and temperature. This capability removes the guesswork and potential for human error, as there is no need to sort instruments and choose the appropriate cycles as with other machines.

The STERIZONE VP4 Sterilizer is the only terminal sterilization method that is FDA cleared to sterilize multi-channeled flexible endoscopes (with a maximum of four channels) of up to 3.5 meters in length, such as video colonoscopes, duodenoscopes and gastroscopes - an industry first for any medical device sterilization process.

The STERIZONE VP4 Sterilizer is also the only cleared low temperature sterilizer that can process a mixed load consisting of general instruments, single channel flexible endoscopes, and single or double channel rigid endoscopes in the same cycle with load weights of up to 75 lb. The ability to run mixed loads significantly reduces labor costs by minimizing the amount of instrument sorting required, while maximizing the device turns (more productivity from increased throughput capacity).

More information about the STERIZONE VP4 Sterilizer is available through TSO₃'s website, under the Products section at www.tso3.com.

About TSO₃

Founded in 1998, TSO₃’s activities encompass the sale, production, maintenance, research, development and licensing of sterilization processes, related consumable supplies and accessories for heat-sensitive medical devices. The Company designs products for sterile processing areas in the hospital environment that offer an advantageous replacement solution to other low temperature sterilization processes currently used in hospitals. TSO₃ also offers services related to the maintenance of sterilization equipment and compatibility testing of medical devices with such processes.

For more information about TSO₃, visit the Company’s website at www.tso3.com.

The statements in this release and oral statements made by representatives of TSO₃ relating to matters that are not historical facts are forward-looking statements that involve certain risks, uncertainties and hypotheses, including, but not limited to, the limited history of sales or distribution of the Company, the ability of the Company to obtain the required regulatory clearances to market its products, general business and economic conditions, the condition of the financial markets, the ability of TSO₃ to obtain financing on favourable terms and other risks and uncertainties. Although TSO₃ believes that the expectations reflected in such forward-looking statements are reasonable, it can give no assurance that such expectations will prove to have been correct. The complete versions of the cautionary note regarding forward-looking statements as well as a description of the relevant assumptions and risk factors likely to affect TSO₃’s actual or projected results are included in the Management’s Discussion and Analysis for the year ended December 31, 2017, which is available on the Company’s website. The forward-looking statements contained in this press release are made as of the date hereof, and TSO₃ does not assume any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise unless expressly required by applicable securities laws.

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Source: TSO3 Inc.

For further information

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