



To Whom It May Concern:

Over the past year Innovative Sterilization Technologies (IST) has had multiple engagements with the Joint Commission (JC), the Joint Commission Resource (JCR) and their legal counsel regarding the use of the ONE TRAY® sterilization container and applicable JC surveying policies.

On December 7th 2016 the JC sent the following to IST and the JC listserv and ensured that all JC and JCR employees would be retrained to this policy:

“On August 31, 2016, an email from The Joint Commission’s Infection Control Specialist on the topic of ONE TRAY® Sealed Sterilization Container was forwarded to this list-serve. Apparently, the email has caused some confusion. Please understand that The Joint Commission advises organizations to follow the manufacturer’s instructions for use, and if the instructions for use are silent or confusing on a particular topic, organizations should contact the manufacturer directly.”

Since this initial interaction with the JC, IST has had additional reported events from our customers related to JC surveyors and JCR consultants related to the ONE TRAY® use. Upon notice, IST immediately worked with both legal counsels (IST and JC) to resolve these issues.

The JC’s legal counsel has repeatably ensured IST that they have addressed these internal issues related to their surveying practices and have retrained all JC surveyors and JCR consultants to follow these JC policies which apply to any medical device being reviewed during a survey.

The JC and JCR have been warned by IST that inaccurate statements, which are outside of the context of what our product is cleared for, and the entity making false and misleading statements about ONE TRAY® must stop immediately, or IST will take further action.

To date, IST has **NEVER** been contacted by a JC or JCR representative related to the use of the ONE TRAY® according the current User Manual.

IST is sorry for the confusion the JC has created for our customers and we will be relentless in getting this matter resolved.

Please contact the below for any further questions regarding this matter.

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