

Wednesday, July 08, 2020

Victor Nunes
QMed Innovations
1005 Aquidneck Ave, Unit 1N
Middletown, RI 02842

Re: Sterilization Revalidation

Dear Victor,

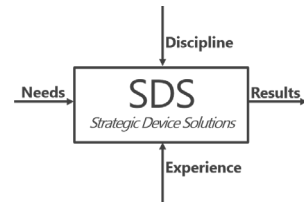
Strategic Device Solutions has completed an analysis of sterilization trays for Orthopedic Instruments to determine if the Quest Device impacts the original sterilization validation of the instrument tray.

Orthopedic Instrument Trays come in many sizes, configurations, and steam hole patterns. Strategic Device Solutions was able to procure several instrument trays that were representative of the sterilization trays used in Trauma, Total Joint Reconstruction and Sports Medicine across several OEM's. A review of these sterilization trays was completed by Strategic Device Solutions to calculate the ratio of steam holes to overall surface area. Table 1 in the attachment shows the different sizes and configuration of sterilization trays. Based on this review of cases, the ratio of steam holes to total surface area ranged from 7% to 26% with most sterilization trays being around 26%.

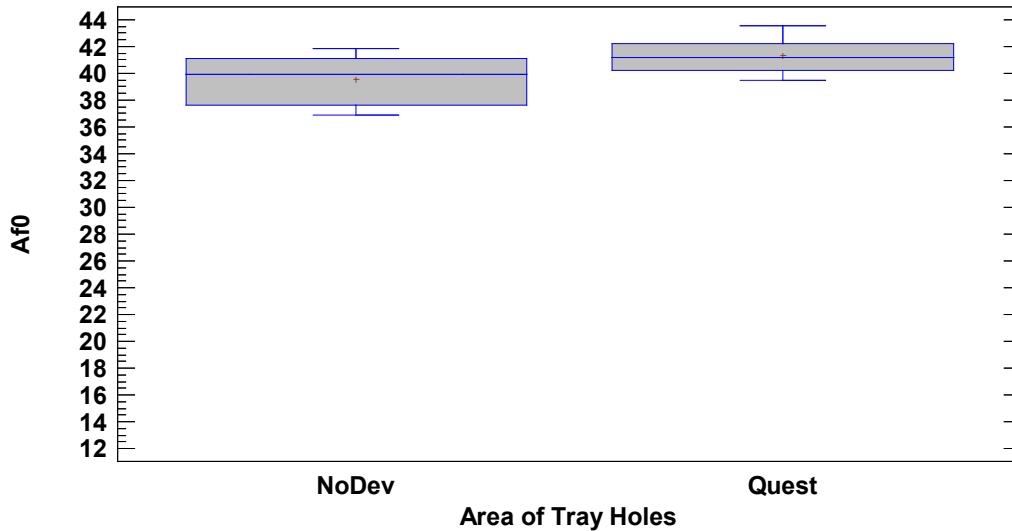
Quest is a 4.0"x1.9" Tracking Device attached to the end panel of a sterilization tray. The reduction in open steam hole area when Quest is attached to a sterilization tray ranges from 0-0.52%. A test was conducted to determine if the small percent reduction in open steam holes had an impact on the sterilization validation of the instrument tray.

To ensure the worst-case sterilization tray was being testing, a tray was selected that started with an open steam hole area of 10.3%. Multiple sterilization cycles were performed with temperature probes at three locations to measure the internal AF_0 on this tray with and without Quest attached.

Any AF_0 greater than 12 insures sterility of the product. The AF_0 with Quest was 41.31 showing that the product inside the tray is sterile with Quest. Additionally, the AF_0 with and without Quest was analyzed to determine if they were significantly different. Since the p-value of .1179 is greater than .05, the accumulated lethality of the AF_0 is thermally equivalent for steam penetration with and without Quest attached.



Af0 Plot between Tray Without Quest Device and Tray With Quest Device



ANOVA Table for Af0 by Area

Source	Sum of Squares	Df	Mean Square	F-Ratio	P-Value
Between groups	9.38	1	9.38	2.93	0.1179
Within groups	32.0	10	3.2		
Total (Corr.)	41.4	11			

The results demonstrate that there was no significant difference in accumulated lethality with the Quest device attached and that attaching Quest to a sterilization tray has no impact on the original Sterilization Validation.

Sincerely,

Douglas Kornbluth
Principal
Strategic Device Solutions

Attachments

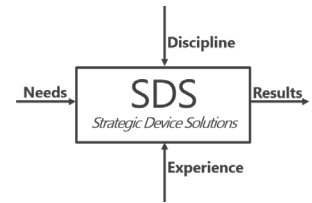


Table 1: Instrument Case Steam Hole Analysis with and without Quest

Tray Manufacturer	Total Surface Area of Tray (in ²)	Total Surface Area of Steam Holes (in ²)	% area of Stream Holes	Total Surface Area of Steam Holes with Quest (in ²)	% area of Stream Holes with Quest	Reduction in Steam Hole Area with Quest
Tray1	764	174	22.8%	170	22.3%	0.52%
Tray 2	725	75	10.3%	72	9.9%	0.41%
Tray 3	657	46	7.0%	46	7.0%	0.00%
Tray 4	830	78	9.4%	77	9.3%	0.12%
Tray 5	679	180	26.4%	176	26.0	0.47%