ESTABLISHMENT OF PENETRATION TIME ON MEDICAL DEVICE PRODUCT FAMILIES BASED ON ISO 17665-3 DURING PERFORMANCE QUALIFICATION OF STEAM STERILIZATION CYCLES

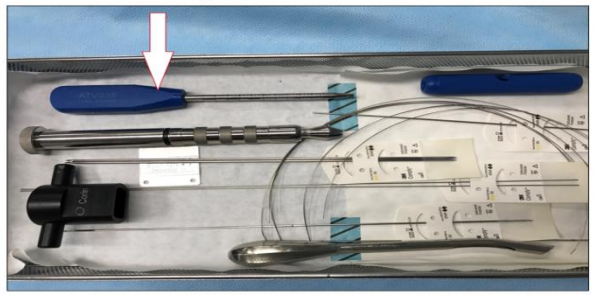
INTRODUCTION: Reusable medical devices (RMDs) significantly differ in material construction and geometric configuration; ISO 17665-3 provides information in grouping medical devices into product families in order to cater to the demand of every unique device during steam sterilization process. This underpins the need to establish penetration time at equilibrium throughout the medical device surfaces during performance qualification in situ based on delegated product families. This data is necessary to ensure sufficient exposure to steam sterilization process is delivered throughout the RMD, thereby process lethality is established and confirms operational requirements of compliance to standards. This study aims to provide an on site investigation on the credibility of ISO 17665-3 requirements. Is it really necessary to comply with standards to meet lethality of steam sterilization process?

METHOD: All medical device item/s is grouped according to designation of product family based on ISO 17665-3. Specific attributes are tabled presenting medical devices that can be grouped together as a product family identified for a particular steam sterilization process. The most difficult to sterilize item/s in each product is chosen as a master product. This master product is used as part of the reference load of the performance requalification of the steam sterilizer. The most challenging item of identified resistance (based on ISO 17665-3) in the master product is chosen for the study of penetration time. A thermometric measuring device attached to a software reader will be strategically located on the chosen medical device surface. This method provides live information of penetration time until equilibrium establishing the time lapse to attain plateau of identified lethal temperature

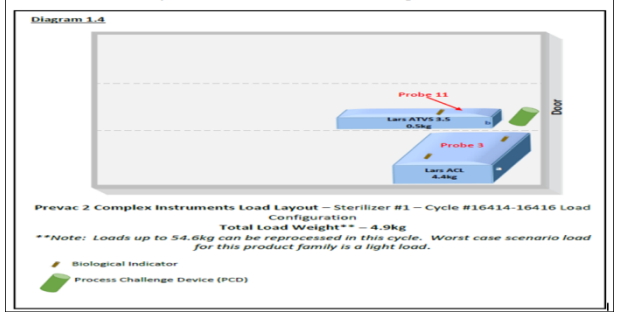
RESULTS: Based on data gathered, the material construction and complexity of medical device surfaces is directly related to resistance of heat transfer. This means the more complex in configuration and/or mixed material construction provided a longer time required to reach the innermost parts and render the device surface at a lethal temperature plateau. This confirms the ISO 17665-3 approach grouping medical devices into families of similar penetration resistance in order to attain lethality of process.

CONCLUSION: It is beneficial to establish penetration time of medical devices during annual performance qualification. This will address the reprocessing requirements to ensure sterilization lethality is achieved

MUH Ultra Complex Instrument Test: LARS ACL Screw Driver



MUH Ultra Complex Instrument Test Results Load Configuration: Reference Load



MUH Ultra Complex Instrument Test Results on 3 Consecutive Cycles: Penetration table

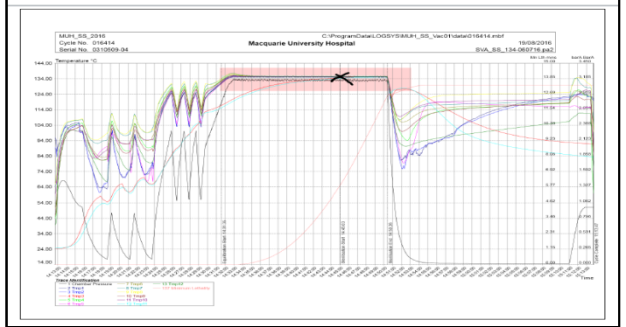
5.5 Ultra Complex Instrument Load Test Results

Program Parameters		Sterilizer Cycle	Test Cycle Sequence	Test Result
Program Name: 'Prevac 2'		#16414	1/3	PASS
Sterilization:	134°C for 18m	#16415	2/3	PASS
Drying:	20m dry	#16416	3/3	PASS

Load Description and Instrument Penetration times. (Also refer to diagram over page).

Pack#	Description	T/Couple ID#	Penetration Time during sterilize phase			Location of Pack in Chamber	Wrap	Weight (Kg)
			Cycle #16414	Cycle #16415	Cycle #16416			
a	Lars ACL Tray	3*	10m 48s	8m 59s	9m 10s	Lower Shelf, Front	Smartfold®	4.4
b	Lars ATVS 3.5 *(instrument provided by SVA for testing)*	11*	12m 43s	10m 43s	11m 7s	Centre Shelf, Front	Orestige® Standard	0.5
							Total Weight:	4.9kg

Macquarie University Hospital – CSSD Sterilizer #1, Cycle #16414, Ultra Complex Load Test, Full Cycle Chart, 1/3



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