

附件一 QIP 執行之項目

分類	執行內容(中文)	執行內容(英文)
清潔 (Cleaning)	使用的清潔劑(酵素清潔劑)應與醫療器械相容，且能有效地去除生物膜	Cleaning agent (enzymatic cleaner) should be compatible with the medical device to be cleaner and effective for biofilm removal.
	再處理醫療器械的水質（沖洗/清洗/最後一道的漂洗與蒸氣)遵守 ANSI/AAMI ST108:2023的標準	The water quality for reprocessing medical devices (Flushing/Washing/Rinsing & Final Rinse/Steam) was compiled with ANSI/AAMI ST108:2023
	每天驗證和查驗超音波清洗機的性能	Validation & verification of the performance of ultrasound washer daily.
	使用後的手術器械或一般器械，在使用地點應以酵素性預處理產品來保持潮濕	Keep used instruments moist by using an enzymatic pretreatment product at the point of use.
	評估軟式內視鏡使用的清潔劑是和其材質相容、低泡、中性pH值、含有酵素，且有去除合成性油脂的能力	Evaluate whether the cleaning solution and detergents are compatible with flexible endoscope, are low-foaming, have a neutral pH, are enzymatic, and have the ability to remove synthetic lipids.
蒸氣滅菌監測 (Steam sterilization Monitoring):	使用包內第五類化學指示劑放置在每個包裝內滅菌劑最難到達的位置（請參閱硬式器械盒製造商關於 CI 放置的說明）	Internal Chemical Indicator Type 5 are placed inside every package in the most challenging location for sterilant to reach (refer to Rigid Container Manufacturers' instructions for CI placement)

	植入物鍋次/租賃器械：使用包含第 5 類化學指示器的 2 號 PCD 包 進行監測。應該隔離直到知道 BI 結果	Implant loads/loaner instruments: Monitor with a BI PCD containing a Type 5 Integrating Indicator. Should be quarantined until BI results were known.
	非植入物鍋次：使用 PCD 進行監測，如：1 號 PCD 包 或 2 號 PCD 包、或 3 號 PCD 包	Non-implant loads: Monitoring with a PCD containing either: a BI, a BI and Type 5, a Type 5 integrating indicator.
	每天(或滅菌鍋使用的當日)使用含 BI 的 PCD 包 進行常規滅菌鍋效能監測：大於 60 升的滅菌鍋應將 BI PCD 包放在要滅菌的第一鍋，滅菌鍋推車的底部架上	Routine sterilizer efficacy testing with a BI PCD is done daily (or when used): Sterilizers larger than 60 liter should place BI PCD in first load of items to be sterilized, on bottom shelf of sterilizer cart over drain.
	應每鍋次使用 BI，並按照 BI 製造商的 IFU 打包成 PCD	BI should be used every load and follow BI's manufacture's IFU to pack as PCD
低溫滅菌監測 (例如：環氧乙烷或過氧化氫) Low temperature sterilization monitoring (e.g. EO, VH2O2)	應每鍋次使用 BI，並按照 BI 製造商的 IFU 打包成 PCD	BI should be used every load and follow BI's manufacture's IFU to pack as PCD.
	每包外具有包外化學指示劑，以及每個包的包內化學指示劑至少應使用符合 ISO 標準的第四類化學指示劑	External Chemical indicators for every pack, and Internal chemical indicators should use at least ISO Type 4 for every pack.
租賃器械和植入物安全 (Loaner instrument and implant safety)	採蒸氣滅菌或低溫滅菌時，含手術器械及租賃器械、植入物的每鍋次應使用包含生物指示劑的PCD包進行監測，應該隔離直到知道BI結果。	Implant loads/loaner instruments: Monitor with a BI PCD. Should be quarantined until BI results were

	<ul style="list-style-type: none"> · 蒸氣滅菌:使用2號PCD包 · 低溫滅菌：使用含生物指示劑及符合ISO標準的第四類化學指示劑的PCD包 	<p>known when using steam sterilization or low temperature sterilization.</p> <p>Steam: Use the BI PCD with type 5 CI</p> <p>Low Temperature: Use the BI PCD with ISO certified type 4 CI.</p>
	<p>租賃器械和植入物安全相關的再處理流程中，出現任何問題或風險時的品質改善計劃</p>	<p>Any issue or risk that happened during the reprocessing of the loaner instruments or implants that should improve.</p>