Select Sterile Barrier System (SBS) on SOA or PL003-1 & in accordance with AS/NZS 4187:2012 & ISO 11607 suited to size and weight of Reusable Medical Device (RMD) or Instrument tray

Complete and submit product complaint form

Complete and submit HSPL SOA Supplier Performance Report

Find a SBS Defect Flowchart


Inspection SBS for defects (Cuts, tears, holes, damage to seals)

Inspect SBS for defects (Cuts, tears, holes, damage to seals, wet packs)

Inspect SBS prior to use for defects (Cuts, tears, holes, damage to seals)

Release for use by CSD & Store as recommended by AS/NZS 4187 and manufacturer

Wrap/Pack & Sterilize

Defect Found

No Defect Found

No Defect Found

No Defect Found

Defect Found

Include the following information in PRIME patient incident management system:
- Tray type
- SBS used
- Surgery/procedure type
- When the defect was detected (e.g. during surgical set up)
- Was the procedure delayed/cancelled
- Other relevant patient outcomes – discharge, adverse event

Undertake incident analysis to determine cause

Implement and monitor recommendations from incident analysis

SBS can be Preform Sterile Barrier System (PSBS), Wraps, or Rigid reusable containers

Person finding the defect to report via PRIME patient incident management system as a NEAR MISS

Person finding the defect to report via PRIME patient incident management system as an ACTUAL INCIDENT

Direct Patient Impact

No Patient Impact

If all requirements of table 8.1 in AS/NZS 4187:2012 are met the RMD/Instrument set can be used

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