

Identify the Failure Mode

- Visually inspect failure(s).
- Identify any commonality in size, shape, location. Look for seal creep locations if there was a channel in the seal.
- Use a high magnification microscope to identify failure type (i.e. flex crack, abrasion, puncture, channel in the seal, rip/tear).
- Identify if failure occurred from the inside out or outside in.
- If a seal breach occurred, identify whether the failure is on the MDM's seal or the supplier seal.

Review Manufacturing Process

- Interview the operators who packaged and handled the product.
- Identify any potential red flags (i.e. cleanliness, sharp objects/debris around the sealing/final packaging area).
- For seal breach, visually inspect sealer, including gasket wear and tear, and potential for unintended items/particles to enter seal area during sealing.
- Look for use of staples in the boxing process.
- Were boxes sent directly to aging/distribution testing or did they sit in storage somewhere for a period of time? Tour that area to identify any potential red flags.
- Did packages pass visual inspection at any or multiple points throughout the process? This will help determine if there was a point where there were zero defects, visually.
- If additional packaging is available (not used for testing), visually inspect for defects.

Device Analysis

- Inspect devices inside each package. Were there any loose parts or broken pieces?
- Look for burs or flash on device as a potential cause for failure.

Review Sterilization Process

- Review paperwork from sterilization process. Were there any outliers in the validated process?

Review Distribution Testing

- Verify testing was done per protocol. Were there any deviations that occurred?
- Review how samples were handled (internally and externally) before, during and after testing (i.e. any extra handling, accidental drops, etc.).
- If packaging was aged, verify temperature profiles were within range per protocol.

Review Supplier Manufacturing Process

- Confirm lot/lane traceability.
- If all else fails, ask supplier to visually inspect any product from existing lots.

Packaging Design

- Ensure the orientation of the carton inside the protective packaging is optimally designed.
- Is the corrugated shipper absorbing enough shock of the packaging system?
- Are there any loose parts of the device inside the package or parts unintentionally broken off the device?
- Is there any folding or creasing of the packaging at the point of failure?