How can we make sure, it works properly?

**Multiple Activities**
- Vacuum Test
- Bowie Dick Test
- Helix Test
- Indicatror per Set
- Validation
- Process Testing
- Sterile Barrier
- Integrity Inspection

AIM: Find a proper Risk Management Strategy!

**RESULTS FROM 150 CONSULTANTIES + LITERATURE**
- Parameters not met (Machine Error, slow heating): rarely
  - Indicator Errors (1)
  - Low influence of geometry (2)
- Steam Penetration Tests helpful (3)
- Wet Sets (more than 80% of hospitals)
  - from 1 to 48h/month, up to 1% of sets
  - detected, but cancellation of cases
- Damaged soft Packs (folding, handling, storage)
  - difficult to detect (4,5)
- Damaged Containers (lack of inspection)
- Soft packs compromised by moisture (6,7)
  - severe results (8)

**Risk Management and Evaluation adapted from ISO14971 and VDI5700**

**Risk Management**

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<th>Probability</th>
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**Methods: Failure Analysis (FMEA)**

**Basic Failures in Steam Sterilization**

1. Sterilization Condition not reached
   - Time – Temperature – Contact
2. Sterile Goods not dry
3. Sterile Barrier Compromised

**Stress States (Impact Strength, Material, Temperature)**

**Root Cause Analysis – Example (Fish Bone Technique)**

**LESS EFFECTIVE**

- Chemical Indicators per Set Tolerances
- Biological Indicators
  - with Challenge Pack
  - w/o Challenge Pack

**Risk Evaluation and Indicators**

- Wet Sets and Compromised Sterile Barrier systems are by far more frequently responsible for Sterility Failures than Process Failures
- Risk of sight parameter deviations is limited (2,9)
- Indicators w/o challenge packs do provide much additional extra information beyond sterilization data (3)
- Little Damages of rigid Containers impose little risks and can be detected visually (10)
- Damaged or compromised soft packs are hard to detect and have lead to severe consequences (4,8), recommended practices frequently not kept

**Efficient Precautionary Measures**

- Process Qualification (Validation / Verification) & Testing under worst case conditions & Defining loads and packaging
- Qualified Personnel & Parametric release & Equipment Inspection
- Robust Sterile Barrier System & Inspection, Proper Handling & Steam penetration tests & depending on load & Process Indicators

**Biological Indicators**

- Chemical Indicators (ISO 11138)
  - e.g. Tolerances: Designed for 134°C, 300s, Class 5 (ISO 11140)
  - minimum 132°C
  - maximum 135°C
  - saturated steam

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**Key Message: Current Quality Measures in Steam Sterilization partly focus in the wrong direction. Effective Strategies are "worst case"-testing, steam penetration monitoring, a robust sterile barrier system and education of personnel."