MEDICAL DEVICE STERILITY ASSURANCE PROGRAM

Shared responsibilities

is assuring safe & effective sterilization

Functionality

ISO 17664 / TIR 12

STEP 1 : The Medical Device Manufacturer produces a reliable instrument

The MDM determines the functional compatibility and the methods of sterilization that can be approved for use in a STERRAD® System.

Sterility

ISO 14937

STEP 2 : The Sterility Supplier (ASP) provides a reliable sterilization method

ASP evaluates the device for sterile efficacy on the approved materials and lumen clams for a specific STERRAD® system.

SSG

Processing

MDM IFU / AAMI ST 81 / ISO 14937

STEP 3 : The Health Care Professional performs the sterilization process efficiently

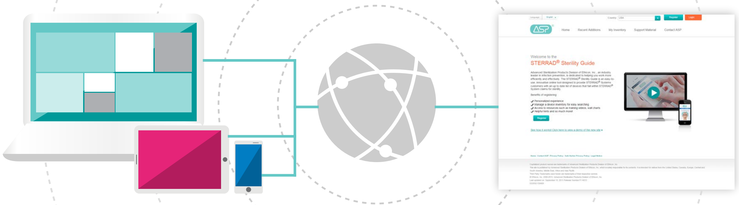
The HCP should follow the MDM's recommended Instruction For Use (IFU) for sterilization.

Sterility Assurance

The centrepiece of the ASP Medical Device Assurance Program is the STERRAD® Sterility Guide (SSG), an intuitive, online database featuring medical devices validated for STERRAD®.

The STERRAD® Sterility Guide is an

intuitive online database for medical devices validated in STERRAD® Systems



The SSG provides hospitals with a list of critical medical devices validated for STERRAD® systems.

"What can I sterilize in my STERRAD®"?

Given the tremendous benefits of minimally invasive procedures, the challenge is to reprocess and sterilize reusable medical devices such as flexible scopes, rigid scopes, batteries, etc.

Medical Device Testing

a) Demonstrate SAL 10^{-6}.
b) Material compatibility.
c) Lumen length.
d) Functionality.
e) Validated packaging options.

More than **19,000** device listing in the SSG

The ASP Medical Device Assurance program is at the heart of ASP innovation and provides customers with sterility assurance and peace of mind and therefore increases patient safety.

Why is it important?

Medical devices vary in size, materials and adhesives and react to chemicals.

Medical device manufacturers are responsible for sterility testing and including reprocessing instructions in the Instruction for Use (IFU).

Sterility testing must comply to regulations.

ASP's Medical Device Manufacturer (MDM) Program provides compliant validation testing services.

ASP partners with Medical Device Manufacturers (MDMs) and provides validations services for medical devices to be validated in STERRAD® systems.