

Product Technical Information

Effective: August 13, 2009

Re: Resterilization policy for pre-sterilized Agee TurnKey FCS[®], Catalog No. FCS-400.

IMPORTANT:

Item FCS-400 is delivered as a complete, sterile system. These resterilization instructions are intended for use on an open, but unused TurnKey FCS system.

DO NOT REUSE TurnKey FCS System components. While resterilization will not damage the sterile field components, multiple patient use may cause the TurnKey FCS to fail.

Steam sterilization weakens elastic bands. Replace steam sterilized bands as soon as possible with non-sterile bands post surgery.

ORIGINAL STERILIZATION:

The TurnKey FCS labeled as FCS-400 is delivered sterile. The sterilization process is gamma radiation and has been validated to a sterility assurance level (SAL) of 10^{-6} . If the sterile packaging is opened and the System not used for the case, resterilization is possible as follows.

RESTERILIZATION:

Separate the components within the sterile pack for resterilization. The device, pre-drill (remove shipping cap), bone pins (remove shipping caps), pin placement guide, pin cap applicator, pin cut off spacer, hex wrench, bands (removed from vial) and pin caps (removed from vial) in the sterile pack can be resterilized. The packaging and printed paper items cannot be resterilized. Do not sterilize items external to the sterile pack.

A STEAM autoclave should be used for sterilization. Follow normal hospital guidelines for processing and sterilizing a mixed pack of metallic and non-metallic components.

The following table includes recommended parameters for use with properly maintained and calibrated sterilization equipment. These settings have been validated to provide a sterility assurance level (SAL) of 10^{-6} .

Cycle	Type of Sterilizer	Temp	Cycle Time
Flash or Pouched	Gravity Displacement or Pre-Vacuum	270 - 272 ° F	10 minutes

OTHER STERILIZATION METHODS:

Ethylene oxide (EO), liquid chemicals (i.e. glutaraldehyde), chemical sterilant gases (i.e. formaldehyde) or dry heat have not been validated as recommended means of sterilization.

Contact Hand Biomechanics Lab, Inc. at (800) 522-5778 if you need further technical information on the TurnKey FCS system.