



Product Technical Information

Effective: May 14, 2012

Re: Resterilization policy for pre-sterilized Agee WristJack® System
Item No. CFD-147

IMPORTANT:

Item CFD-147 is delivered as a complete, sterile system. These resterilization instructions are intended for use on an open, but unused Agee WristJack.

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

ORIGINAL STERILIZATION:

The WristJack System labeled as CFD-147 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 for resterilization. The bone pins, WristJack fixator, drill guides, pin placement guide and hex driver can be resterilized. The packaging, printed paper items, pin caps and WristJacket garment are not needed in the sterile field and can not be resterilized.

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} . In the following table, "Wrapped" means double wrapping all the components together in non-woven CSR wrap and "Flash" means unwrapped components.

Cycle	Type of Sterilizer	Temp	Cycle Time
Flash	Gravity Displacement	270 - 272 ° F	10 minutes
Wrapped	Steam Sterilizer		
Flash	Pre-Vacuum	270 - 272 ° F	4 minutes
Wrapped	Steam Sterilizer		

OTHER STERILIZATION METHODS:

Ethylene oxide (EO), liquid chemicals (i.e. glutaraldehyde), chemical sterililant 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 WristJack System.