

Product Technical Information

Effective: April 20, 2015

Re: Resterilization policy for pre-sterilized Agee Digit Widget[®] External Fixation System Item No. DWD-232

IMPORTANT:

Item DWD-232 is delivered as a sterile system. These resterilization instructions are intended for use on an open, but unused Agee Digit Widget.

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

ORIGINAL STERILIZATION:

The Digit Widget labeled as DWD-232 is delivered sterile. The sterilization process is gamma radiation and has been validated to a sterility assurance level (SAL) of 10^{-6} . If sterile PACK A is opened and the System not used for the case, resterilization is possible as follows.

RESTERILIZATION:

The pre-drills (remove shipping caps), bone pins (remove shipping caps), drill guide, pin block and hex wrench contained in PACK A can be resterilized. The packaging and printed paper items of PACK A cannot be resterilized. The contents of PACK B are shipped non-sterile and under no circumstances require sterilization.

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 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 Digit Widget System.