

### **WHIRL-PAK® Sterilization & Shelf-Life Information**

Whirl-Pak® bags are sterilized with ethylene oxide gas. Each load goes through a preconditioning, gas injection, and aeration cycle, taking four to five days to complete.

Parametric Release Processing is used to verify sterility of the bags. Parametric release involves the addition of the direct monitoring of ethylene oxide concentration and humidity within the sterilization chamber during processing. All sterilization records are reviewed to verify that the appropriate sterilization process was utilized and that all required parameters for sterilization were achieved. The sterilization facility is certified to ISO 13485:2003.

The shelf life for Whirl-Pak® bags should be at least 5 years if stored in its original or similar carton in ambient conditions. As long as the liner bag is not opened or damaged and stored in a clean, dry environment, sterility should not be compromised. Like any other sterilized laboratory product, care must be taken when storing and handling Whirl-Pak® bags.

Regards,

A handwritten signature in black ink, appearing to read "J. Romenesko", written over a horizontal line.

Jim Romenesko  
Sr. Director of Business Development  
Whirl-Pak®, Filtration Group