



## American Fluoroseal Corporation General Product Warranty

AFC certifies that AFC bags are made with pure USP Class VI FluoroEthylene Propylene (FEP) fluoroplastic, and that AFC bags are not coated or made with laminates of any nature. AFC bags have no leachable materials.

Afc bags have been tested for extractables with hexane extraction for 24 hours at 50 degrees Celsius and found to have no detectible turbidity, no detectable non-volatile residue, or UV absorption in the extract and no detectible residue upon ignition. AFC bags have no detectible extractables. Hexane is used to evaluate lipophilic extractables in polymers. Products that are low in hexane soluble extractables are preferred for use in devices contacting blood and tissues.

AFC bags have been tested for extractables with isopropyl alcohol extraction for 24 hours at 70 degrees Celsius and found to have no detectible extractables. Products that are low in isopropyl alcohol soluble extractables are preferred for use in devices contacting blood and tissues. AFC bags have no detectible extractables.

AFC bags have been tested for extractables with water extraction for 24 hours at 70 degrees Celsius and found to have no detectible extractables. Products that are low in water soluble extractables are preferred for use in devices contacting blood and tissues. AFC bags have no detectible extractables.

AFC certifies that AFC standard bags will not bind, adhere or adsorb any known chemical or biologic.

AFC certifies that the interior of AFC Adherent Cell (AC) bags (not standard bags) have been exposed to electronic corona discharge and those interior surfaces will reversibly bind those entities that can attach to weakly hydroscopic surfaces.

AFC certifies that AFC bags do not react with DMSO or with any other chemical, solvent, or biologic at temperatures below 100 degrees Celsius.

AFC certifies that AFC bags have not been exposed to Ethylene Oxide (ETO) or any other fumigant at any time during or after manufacture. AFC sterilizes AFC bags by wet steam autoclave sterilization to achieve a Sterility Assurance Level of  $1e10^{-6}$ .

AFC certifies that AFC bags remain flexible and will not crack at low temperatures, including immersion in liquid nitrogen.

AFC certifies that AFC maintains Device Master Files with the Food and Drug Administration for its KryoSure bags for cryopreservation.

AFC certifies that AFC maintains Device Master Files with the Food and Drug Administration for its VueLife bags for the culture and storage of leukocytes.

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