



FERRIS MFG. CORP.

5133 Northeast Parkway • Fort Worth, TX 76106-1822 • U.S.A.
Direct 817-900-1301 **1-800-POLYMEM** Fax 817-625-4277 info@polymem.com

MODIFICATIONS TO INSTRUCTIONS FOR USE

A note from our CEO:

PolyMem dressings have been used for more than 35 years to assist in healing wounds. PolyMem dressings are available in many sizes and configurations, including non-adhesive and various adhesive options. I like to say, “If you’ve got a wound, we’ve got a dressing.”

Some of our newer products featuring silicone adhesive borders are sterilized by ethylene oxide gas (EtO). All other PolyMem dressings are sterilized by gamma radiation. Silicone adhesives lose their function when sterilized by gamma radiation, so it’s necessary to use EtO to sterilize them. A byproduct of this process is ethylene chlorohydrin (ECH), and ECH levels are measured to ensure safety.

Historically, international standards for ECH levels for limited exposure were the same for all patients: adults, pediatrics, and neonates. The most recent ISO standards decreased the limits for residuals in dressings for use on neonates by a factor of more than 20 (from less than 9 mg per device to less than 0.448 mg per device).

Because the residual levels in our silicone border dressings sometimes exceed the newer, stricter limits for neonates, we are removing any reference to using silicone border dressings on neonates. PolyMem silicone border dressings remain safe and effective for adults, and all other configurations of PolyMem dressings remain safe and effective for any age group.

PolyMem silicone border dressings remain well below the standard of 9 mg per device for residuals and remain safe and effective for adults.

We continue to monitor all our products and will update you if there are other changes to our Instructions for Use or changes/recommendations for use of our products.

Roger Sessions, DO
CEO/Chairman, Ferris Mfg. Corp.