



December 14, 2007

The Journal of Bone and Joint Surgery
20 Pickering Street
Needham, MA 02492

To the editor:

I read with interest the article, *The Economic Impact of Reprocessing External Fixation Components* (Oct 2007; 89:2132-36). As Executive Director of the Association of Medical Device Reprocessors (AMDR), the trade association that represents third-party reprocessors of medical devices, I was pleased to see the article confirm what our industry has demonstrated for many years: that reprocessed external fixation devices are safe and effective. However, AMDR discovered errors and false assumptions about the third-party reprocessing industry. A summary of those issues is below, and a detailed response to the article is available at: www.amdr.org.

First, the authors highlight another example of an original equipment manufacturer (OEM) reprocessing its own "single use" devices, confirming once again that "single use" doesn't always mean just that. Indeed, the reprocessing of devices labeled for "single use" has been standard practice in U.S. hospitals for years. Reprocessing emerged when hospitals saw OEMs had begun to change the labels on devices from "reusable" to "single use," without making significant design, performance, or material changes to the devices. It became clear that this label was often motivated by economic objectives rather than patient safety concerns.

Second, third-party reprocessing of "single use" devices (SUDs) is fully regulated by the Food and Drug Administration (FDA). Reprocessed devices marketed in the U.S. are as safe and as effective as original equipment. AMDR's members serve all of the top ten [heart](#) hospitals and all of the top ten [orthopedic](#) hospitals in the nation, as ranked by *U.S. News & World Report*. Overall, we serve 17 of the nation's 18 ["Honor Roll"](#) hospitals.

Third, the nation's third-party reprocessors have accomplished all this while maintaining a stellar safety record. Unlike OEMs who may test or inspect a sampling of the devices they produce, AMDR's members test or inspect 100 percent of the devices they reprocess. AMDR's members are also committed to complete device traceability. Each reprocessed device is marked or otherwise designated so that users know it is reprocessed, and our tracing mechanisms track how many times each device has been reprocessed.

The reprocessing industry has safely reprocessed over 50 million devices and prevented over 10,000 tons of medical waste from entering our landfills. No other segment of the medical device industry is helping hospitals reduce waste and costs like the third-party reprocessors.

Sincerely,

A handwritten signature in black ink, appearing to read "D. Vukelich". The signature is written in a cursive, flowing style.

Daniel J. Vukelich, Esq.
Executive Director