



## Banner Health®

April 26, 2010

Dear Business Partner:

This letter is to confirm to your company that Banner Health supports single-use device (SUD) reprocessing and remanufacturing as a responsible and sustainable healthcare practice.

As a Banner business partner, your assistance is expected with this initiative.

Reprocessing is supported by the FDA. With FDA guidelines and the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), reprocessing is now codified in Federal law and there is arguably more government regulatory oversight to assure the safety and effectiveness of reprocessing devices labeled by the manufacturer as “single-use” than almost any other type of medical device used on patients.

A follow up study by the GAO was conducted from 2005 to 2008. In addition to gathering additional information on the safety and performance data concerning reprocessing, this study also incorporated a review of the FDA’s volume of regulatory requirements for medical device reprocessors that had been instituted since the original report was published in 2000. The 2008 report notes that “FDA’s analysis of reported device-related adverse events does not show that reprocessed SUDs present an elevated health risk.” In fact, this most recent GAO report noted that participants in FDA’s Medical Product Safety Network (MedSun) were aware “that reprocessing establishments are more stringently regulated by FDA than are the manufacturers of the original devices and this provided them a sense of confidence in the reprocessing process.”

Because FDA requires the filing of scientific cleaning, performance and sterilization validation data prior to allowing a reprocessor to reprocess any device, one can be assured that reprocessed single-use devices are clean, sterile, and perform as originally intended and will not put patients in harms way.

In order to meet our goals for the success of this program, our expectations of you and your company are as follows:

1. Do not speak negatively to any surgeon, nurse, or Banner Health employee about SUD reprocessing.
2. Do not distribute any materials about SUD reprocessing to any surgeon, nurse, or Banner Health employee. This includes verbal, written, email, or any other communications.

Any violation of this policy will result in your immediate and permanent expulsion from our company and trigger a re-evaluation of the products purchased from your company.

We appreciate your support of this important initiative.

Sincerely,

A handwritten signature in black ink that reads "Doug Bowen". The signature is written in a cursive style with a large, looping initial "D".

Doug Bowen  
Vice President, Supply Chain