



High Level Disinfection (HLD) Concerns? Things to Consider

What is HLD?

High-level disinfection (HLD) is not sterilization. Our process uses nothing more dangerous than high temperature water. No chemicals or carcinogens are used as in sterilization methods. We utilize a pasteurization method that reaches temperatures high enough to kill all viruses, bacteria, and a majority of spores. No harmful air emissions are released into the environment and no chemical residue is left on the device. The CDC, APIC, and other healthcare organizations support this method of HLD.

What is the Food and Drug Administration (FDA) opinion or view of reprocessed single use medical devices?

The Food and Drug Administration (FDA) has issued enforcement priorities governing reprocessing, and the safe reuse of devices labeled "single-use only". The FDA considers reprocessed devices "substantially equivalent" to (original) manufactured devices and subjects third party reprocessors to the same applicable regulatory guidelines as the original device manufacturer (OEM). The FDA has stated that certain specific single-use medical devices may be reprocessed and are "substantially equivalent" to the OEM device. The General Accounting Office (GAO) and Centers for Disease Control (CDC) have stated there is no evidence reprocessed devices have harmed ANY patients. Further, there has never been an adverse claim on a non-critical or semi critical reprocessed device.

Should I utilize two separate vendors (reprocessors) for a reprocessing program to be successful?

According to the CDC, APIC, AORN, High-Level Disinfection is the appropriate and recommended method for reprocessing non-critical and semi-critical (non-invasive) devices. Further, utilizing the appropriate method for these devices provides a safe non-toxic method to save twice as much as sterilizers.

Are there companies that sterilize single use medical devices and do pasteurization (High-Level Disinfection)?

No. Unless the company has FDA 5-10K authorizations to provide both High Level Disinfection and sterilization. Sterilization is not pasteurization or HLD. ReNu Medical is an FDA approved and compliant High-Level Disinfection medical device reprocessor.

Does ReNu Medical provide reprocessing services nationally?

Yes. ReNu Medical currently services hospitals nationwide.

Is ReNu Medical registered with the FDA? What classification?

Yes. ReNu Medical is classified as a third party medical device reprocessor, FDA registration number 3034520. ReNu's latest FDA inspection was completed in August 2010 with no 483 report issued. ReNu Medical meets or exceeds all FDA regulations and is 100% compliant with the FDA.