

**Testimony of Brian Sullivan,
Chief Executive Officer,
SterilMed, Inc.
before the
Joint Public Health Committee
of the
Massachusetts Legislature
on the
Reprocessing of Medical Devices (SB 1338/HB 2233)**

September 26, 2007

Mr. Chairman, members of the Committee:

My name is Brian Sullivan. I am the CEO of SterilMed, Inc., one of the nation's leading commercial reprocessors of medical devices.

I am here today in **opposition to Senate Bill 1338 and House Bill 2233** pertaining to a Patient's Right to Know of the reprocessing of certain medical devices labeled for "single use."

Today, I'd like to explain what exactly reprocessing is, and what it is not, describe the process of how my sales and service personnel implement these programs in health care facilities, and describe how important reprocessing is to Massachusetts hospitals in their mission to provide high quality, safe, cost-effective, and environmentally responsible health care.

What is Reprocessing

The reprocessing of select group of “single-use” devices in accordance with federal law produces medical products that are as safe and as effective as the original devices, but at a fraction of the original cost. Furthermore, it is an environmentally sound operating decision helping avoid unnecessary disposal of medical devices.

In brief, reprocessing is the cleaning, function testing, inspecting, packaging and sterilization of select “single use” labeled devices. Of the tens of thousands of devices less than 2% are determined appropriate for reprocessing. These are not high risk devices. When evaluating whether or not to submit a device for FDA clearance, we look very carefully at the track record of the new devices to assure that they do not have high failure rates as new devices, and are durable enough to withstand our disinfection and cleaning procedures. The FDA then evaluates our engineering and scientific data to confirm that we have met their current regulations and guidelines for safe reprocessing.

We do not reprocess anything implantable such as a pacemaker or defibrillator. In fact, we only reprocess devices categorized by FDA as Class I low risk or class II medium risk devices. We do not reprocess any class III high risk devices. In addition, we also provide a valuable resterilization service to hospitals. Called our “opened-but-unused & date expired”

business segment, we collect, repackage and resterilize devices that have been taken out of their packaging but have never even been used. These devices, many of which cost hundreds of dollars, would otherwise be sent to a landfill.

Hospitals reprocessed these same devices themselves for decades. Initiatives at the federal level in 2000 shifted this activity to commercial reprocessing companies such as ours under a tightly regulated standard.

When a hospital is considering a reprocessing program the evaluation process is very thorough and typically involves a tour of a reprocessing facility to examine the science, engineering and technology of our procedures. These hospital committees usually include representatives of nursing, infection control, medical officers, surgeons, risk managers and material managers. Often they bring with them extensive questionnaires outlining concerns or questions raised within their organization. I do not know of a single incident of a hospital team going through any reprocessors' facility that has not gone on to implement a reprocessing program.

America's & Massachusetts Hospitals Rely on Reprocessed Devices

The reprocessing of these medical devices plays a crucial role in our nation's health care system. Members of the Association of Medical Device

Reprocessors (AMDR) serve a majority of U.S. hospitals, including the best of the best, many of which are located right here in Massachusetts. Nationwide, 17 of the 18 “Honor Roll” hospitals, as listed by *U.S. News & World Report* in 2007, use the reprocessing services from FDA-regulated, third-party vendors. Currently, members of AMDR serve over 70% of the hospitals and surgical centers in Massachusetts. The top teaching hospitals in Massachusetts use reprocessed devices, and have for decades, because it has proven to be safe, cost-effective, and environmental responsible.

At a time when hospitals face extraordinary operational and cost challenges, this proposed legislation would further burden them with unnecessary bureaucracy and create a significant impediment to implementing a safe, effective cost savings strategy. The alternative hospitals would be left with would be to cut staff, eliminate programs or reduce services.

In closing, I would like to emphasize that this legislation is not about safety. My company and its employees produce safe and effective products. Rather, it is about economics. Original equipment manufacturers who support this legislation want to protect their market share, and increase their profit margins.

I strongly urge you to defeat this bill. It does not serve the best interests of the people of Massachusetts or the fine hospitals that serve them. Thank you for allowing me the opportunity to be heard on this matter.