## The Benefits of Ethylene Oxide Sterilization

Since its discovery as an effective sterilant, ethylene oxide (EO) has played a critical role in antimicrobial sterilization that protects public health, and is essential to a functioning and effective U.S. healthcare system. Decades later, it is now used to sterilize more than 20 billion medical devices each year in the U.S. alone. This represents more than 50 percent of all medical devices sterilized annually. EO sterilization is critical in the safe delivery of sterile devices and medical care. The use of EO sterilization provides unparalleled benefits to society by its use throughout the medical community.

Numerous medical, hospital, and laboratory processes rely on EO to sterilize devices and equipment to protect millions of patients from the real risks of infectious diseases caused by bacteria, viruses, and fungi. For the majority of these healthcare products, EO sterilization is the most effective and efficient sterilization technology. The relatively low temperatures at which the EO sterilization occurs provides the medical community significant advantages when sterilizing devices and products. Many critical healthcare products, such as duodenoscopes, are complex and sophisticated devices that are heat and/or moisture-sensitive. The gentle yet thorough nature of EO allows for the sterilization of many critical healthcare products and devices that would otherwise be destroyed and rendered unusable by radiation, moist heat, dry heat, other chemicals, and other alternative sterilization methods. In fact, many of these devices can only be sterilized by EO -- with no practical alternatives currently available.

The use of less effective processing methods can have significant adverse public health consequences. A change in sterilization technology could introduce the real risks of increased morbidity and mortality. In many cases, any change to the sterilization method would require a complete redesign of the product to be sterilized. Even a redesign may not allow the product to be sterilized adequately without the use of EO. Furthermore, it is not feasible for medical device manufacturers to change to alternative sterilization methods within a realistic timeframe. Changes to sterilization technology may cause delays, inadequate sterilization, increased risks to public health, the inability to perform certain medical procedures, and increased healthcare costs. Such modifications have the potential to exchange one risk for another.

The EO sterilization industry is committed to worker safety and closely monitors this issue. Workplace efficacy and safety practices continuously improve as EO sterilization equipment and processes advance with the introduction of advanced technology. In addition, sterilization processes are designed to provide a safe working environment. Many of these modern practices, designed for worker safety, have been approved by the U.S. Food and Drug Administration (FDA) for use in the health care industry. The Association for the Advancement of Medical Instrumentation (AAMI) and the American National Standards Institute (ANSI) have developed consensus-based standards, which are recognized by FDA. By following these standards, hospitals and other facilities are well equipped to ensure the safe and effective use of EO sterilization in healthcare facilities and to minimize any EO exposure to both workers and patients.