INFORMATION PAPER

Tension Pneumothorax

Material Safety Considerations

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Material quality may impact treatment of the second leading cause of preventable death in the battlefield.

ISSUE:

The quality of medical devices utilized to treat critical battlefield injuries should be a serious consideration when selecting equipment. Some medical equipment contains sub-quality stainless steel. Using materials other than the traditional medical grade surgical stainless steel grade 304 may result in safety or efficacy concerns as noted in the U.S. Food and Drug Administration (FDA) Import Alert #76-01 (which is intended by the FDA to prevent the importation of inferior grade materials). When purchasing medical equipment that is manufactured offshore, exposure to inferior grade materials is a risk that must be considered.

Fig. 1) 10 or 14 ga Needle Decompression kits from NAR are made with American surgical stainless steel grade 304.

BACKGROUND:

The quality of medical devices, such as the needles used to treat a tension pneumothorax (the second leading cause of preventable death on the battlefield), is regulated by the FDA, requiring compliance with Federal Law through supplier evaluation and post manufacturing device functionality testing. Federal Law recognizes that the quality of the materials making up the equipment utilized for life saving procedures is a factor in achieving the best outcome for the patient or casualty.

Buying American made products means you're getting the highest quality products and more – you are also investing in the American economy – in our people, our communities and our future. The Buy American Act (BAA), which requires that "substantially all" materials, manufacturing and labor be U.S. content (not to exceed 50% foreign content), is committed to American made quality. This not only keeps American's working, but also helps to save lives around the world through safer medical equipment.

ARS® Needle Decompression Kits from North American Rescue (NAR) are 100% "Made in America" by U.S. firms registered with the FDA. These devices are manufactured and sterilized according to rigorous national and international standards.* The metals used in the manufacture of the needle is U.S. surgical stainless steel grade 304, the material of choice for civilian medical devices due to its history of safe and effective applications. Each lot is subjected to Limulus Amebocyte Lysate (LAL) testing in order to maximize the device safety and ensure the device application does not introduce any bacterial contamination to the compromised casualty. LAL testing is specifically designed to identify the presence of Endotoxins, which if untreated could introduce fever inducing pyrogens. This issue is known to the civilian medical device market, and precipitated the FDA issuing guidelines for LAL testing and acceptable limits.

"Many agencies, including the FDA, are aware of inferior grade foreign stainless steels, which have resulted in the implementation of import alerts."

RECOMMENDATIONS:

The quality of medical device materials has a direct impact on the safety of the equipment used to treat an already compromised patient. Utilizing Made In America equipment ensures the greatest level of safety, confidence and efficacy.

Many agencies, including the FDA, are aware of inferior grade stainless steels, which have resulted in the implementation of import alerts (i.e. FDA Import Alert, # 76-01). Import alerts are intended by the FDA to prevent the importation of inferior grade materials which may have safety or efficacy concerns. Buying American materials such as the ARS® ensures properly sterilized materials and reduces health risks to our soldiers.

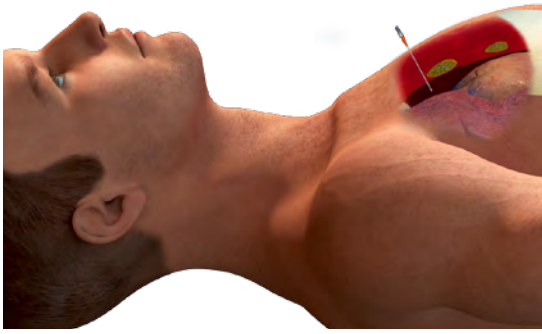

Fig. 2) Needle thoracostamy should be performed with quality surgical steel to avoid health risks.

* 21 CFR 820, Quality System Regulation, ISO 13485:2003- Medical Devices--Quality management systems, and ISO 11137-1:2006, Sterilization of healthcare products –Radiation—Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

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