FDA, NIOSH & OSHA JOINT SAFETY COMMUNICATION:
Blunt-Tip Surgical Suture Needles Reduce Needlestick Injuries and the Risk of Subsequent Bloodborne Pathogen Transmission to Surgical Personnel

DATE ISSUED
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AUDIENCE
Surgeons, Operating Room Supervisors, Perioperative Nurses, Hospital Administrators, Hospital Risk Managers, Occupational Health & Safety Managers, Infection Preventionists, Surgeon Educators, Surgical Residents, Medical School Administrators/Faculty, and other Personnel

MEDICAL SPECIALTIES
General Surgery, Urology, Obstetrics/Gynecology, Orthopedics, Anesthesiology, Surgical Technology, and any specialty that includes surgery of the muscle or fascia

PURPOSE
The Food and Drug Administration (FDA), the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH), and the Occupational Safety and Health Administration (OSHA) strongly encourage health care professionals to use blunt-tip suture needles as an alternative to standard suture needles when suturing fascia and muscle to decrease the risk of needlestick injury.

BLUNT-TIP SUTURE NEEDLES
Blunt-tip suture needles (Figure 1), which are not as sharp as standard (sharp-tip) suture needles, are designed to penetrate muscle and fascia and reduce the risk of needlesticks. Blunt-tip suture needles are regulated by the FDA and have been marketed in the U.S. for more than 25 years.

Figure 1: **Blunt-tip Suture Needle**

SUMMARY OF PROBLEM AND SCOPE

Needlestick injuries continue to occur in surgical settings when suturing muscle and fascia, despite the availability of safety-engineered devices, such as blunt-tip suture needles, and the endorsement of their use by professional organizations.

Needlestick injuries have the potential to expose health care personnel to bloodborne viruses, such as Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Human Immunodeficiency Virus (HIV). Of the estimated 384,000 needlestick injuries occurring in hospitals each year, 23 percent occur in surgical settings.[1] Published literature indicates that while needlestick injury rates have been decreasing among non-surgical health care providers, this has not been the case among those who work in surgical settings. According to a 2010 article published in the Association of periOperative Registered Nurses Journal, more than half of needlestick injuries involving suture needles occur during the suturing of fascia or muscle. [2]

BENEFITS OF USING BLUNT-TIP SUTURE NEEDLES

Published studies show that using blunt-tip suture needles reduces the risk of needlestick injuries from suture needles by 69 percent.[3] Although blunt-tip suture needles currently cost some 70 cents more than their standard suture needle counterparts, the benefits of reducing the risk of serious and potentially fatal bloodborne infections for health care personnel support their use when clinically appropriate.

A 2007 report suggests that the slight difference in costs of blunt- and sharp-tip suture needles is balanced by the economic savings associated with needlestick injury prevention. This report, which assessed the costs of managing occupational exposures to blood and body fluids, concluded that the cost of managing a needlestick injury can range from $376 to $2,456 per reported incident.[4] In addition, personnel who receive needlestick injuries may experience anxiety and a loss of productivity as they await the results of blood tests.

GOVERNMENT AGENCIES AND PROFESSIONAL ORGANIZATIONS ENDORSE THE USE OF BLUNT-TIP SUTURE NEEDLES

The OSHA Bloodborne Pathogen standard, revised on Jan.18, 2001 in response to the Needlestick Safety and Prevention Act of 2000,

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1 Jagger J, Berguer R, Phillips EK, Parker G, Gomaa AE. Increase in sharps injuries in surgical settings versus nonsurgical settings after passage of national needlestick legislation. Journal of the American College of Surgeons. 2010;210:496-502.

2 Jagger J, Bentley M, and Tereskerz P. A study of patterns and prevention of blood exposures in OR personnel. Association of periOperative Registered Nurses Journal. 1998;67(5):979-96.

3 Parantainen A, Verbeek JH, Lavoie MC, Pahwa M. Blunt versus sharp suture needles for preventing percutaneous exposure incidents in surgical staff. Cochrane Database of Systematic Reviews 2011;Issue 11. Art. No.: CD009170. DOI: 10.1002/14651858.CD009170.pub2.

4 O'Malley EM, Scott RD 2nd, Gayle J, et al. Costs of management of occupational exposures to blood and body fluids. Infection Control Hospital Epidemiology. 2007; 28(7):774-82.

requires the use of safer devices, such as blunt-tip suture needles, when clinically appropriate, to reduce the risk of needlestick injury and subsequent pathogen transmission to personnel. The revised standard requires employers, with input from non-managerial direct patient care employees, to consider and implement available appropriate and effective safer medical devices designed to eliminate or minimize occupational exposure.

In 2007, OSHA and NIOSH issued a joint Safety and Health Information Bulletin emphasizing OSHA's requirement and NIOSH's recommendation to use blunt-tip suture needles, when clinically appropriate, to decrease needlestick injuries to surgical personnel.

The American College of Surgeons (ACS) recommends the universal adoption of blunt-tip suture needles as the first choice for the closure of fascia and muscle. This statement is endorsed by the Association of periOperative Registered Nurses, American Association of Nurse Anesthetists, American Association of Surgical Physician Assistants, American Society of Anesthesiologists, American Society of PeriAnesthesia Nurses, and Association of Surgical Technologists.

In addition, the 2011 Viral Hepatitis Action Plan issued by the U.S. Department of Health and Human Services recommends the use of blunt-tip suture needles, when clinically appropriate, to help reduce device-related needlestick exposures among health care personnel.

RECOMMENDATION

The FDA, NIOSH, and OSHA strongly encourage health care professionals in surgical settings to use blunt-tip suture needles to suture muscle and fascia, when clinically appropriate, to reduce the risk of needlestick injury and subsequent pathogen transmission to surgical personnel.

REPORTING OCCUPATIONAL NEEDLESTICK INJURIES

When an employee reports a sharps injury to their employer, the OSHA Bloodborne Pathogens standard requires the employer to record the injury, make immediately available to the employee a confidential medical evaluation and provide follow-up immediately available to the employee, and investigate and document the circumstances and type of device involved. The employer can use this information to assist in preventing similar injuries in the future. Needlestick injuries must be documented as required in OSHA's Recordkeeping standard (29 CFR 1904.8).

In addition, OSHA's Bloodborne Pathogens standard (29 CFR 1910.1030(h)(5)) states that any employer required to keep occupational injuries and illnesses records under 29 CFR 1904 must maintain a sharps injury log to record needlestick injuries. The sharps injury log should contain, at a minimum, the following information:

- Type and brand of device involved in the incident;

- Department or work area where the exposure incident occurred; and
- Explanation of how the incident occurred.

Furthermore, prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect a problem with suture needles (sharp and blunt), we encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program. Health care personnel employed by facilities that are subject to FDA's user facility reporting requirements should follow the reporting procedures established by their facilities. Additional information about types of needlestick adverse events to report to the FDA is available at Needlesticks – Medical Device Reporting Guidance for User Facilities, Manufacturers and Importers.

To help the FDA learn as much as possible about the adverse events associated with suture needles, please include the following information in your reports, if available:

- Manufacturer's name
- Device name (needle brand name)
- Type of needle (blunt or sharp)
- Type of suture
- Date device was manufactured
- Distributor's name
- Details of adverse event and medical and/or surgical interventions (if required)
    - Date the event occurred
    - Location of the event
    - Nature of the injury and associated health outcome
    - Status of the device
    - Can the FDA contact the reporter for further follow-up

CONTACT INFORMATION

If you have questions about OSHA's Bloodborne Pathogens standard and its requirement to use safer devices to prevent needlestick injuries, contact OSHA's Directorate of Technical Support and Emergency Management at 1-800-321-6742 or 202-693-2300.

If you have questions about this communication, please contact FDA's Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@FDA.HHS.GOV, 1-800-638-2041, or 301-796-7100.

ADDITIONAL LINKS

1. Bloodborne Pathogens and Needlestick Prevention Safety and Health Topics Page
2. Frequently Asked Questions about the Needlestick Safety and Prevention Act
3. Use of Blunt-Tip Suture Needles to Decrease Percutaneous Injuries to Surgical Personnel Safety and Health Information Bulletin
4. Needlesticks — Medical Device Reporting Guidance for User Facilities, Manufacturers and Importers