



NATIONAL HEMOPHILIA FOUNDATION
for all bleeding and clotting disorders

MASAC Document # 207

MASAC RECOMMENDATIONS REGARDING NON-STERILE ALCOHOL PREP PADS

The following recommendations were approved by the Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation on November 12, 2011, and adopted by the NHF Board of Directors on November 12, 2011.

In January, 2011, NHF issued a Medical Advisory (#412) about a recall of non-sterile alcohol prep pads produced by one company, Triad, due to reports of serious infections with their use.(1) In March, 2011, the CDC reported on 2 children who had developed life-threatening sepsis due to infection with *Bacillus cereus* from contaminated alcohol prep pads manufactured by Triad.(2) *B. cereus* is a bacterium that is resistant to alcohol and can cause serious, life-threatening infections if it gets into the blood stream. In April, 2011, the FDA required Triad to cease operations.(3)

Now, additional infections with *B. cereus* have occurred in patients using non-sterile alcohol prep pads manufactured by another company, Professional Disposables International (PDI).(4) This company has also been required by the FDA to recall their products.(5)

PDI states that 70% of manufactured alcohol prep pads are sterile and 30% are not. However, the prep pads are not always clearly labeled to indicate whether they are sterile or not. Both Triad and PDI package their products under their own label and under other companies' labels as well. Their prep pads are often included in packaging of medications to be injected in the home.

Based on occurrence of these serious infections, MASAC makes the following recommendations:

1. All individuals who have alcohol prep pads/swabs in their home should examine the individual packages to see if they contain the word "Sterile." This includes prep pads that are packaged with clotting factor concentrates or other IV preparation kits for care of central venous access devices (catheters and ports). If the word "sterile" does not appear on the package, there is no way to determine if they are in fact sterile or not. Therefore, individuals should discontinue use of any prep pads that do not state "sterile" and should request replacement with sterile prep pads from their clotting factor distributor.
2. Nurses should also check their supply of alcohol prep pads to ensure that they are using only sterile prep pads. This is particularly important for patients with indwelling venous access devices (catheters or ports) and for patients with compromised immune systems, but should be standard of care for all patients.
3. Distributors of clotting factor and infusion supplies for use in the home should carry and distribute only sterile alcohol prep pads. This includes home infusion companies and 340B programs.

4. Manufacturers of clotting factor who include alcohol prep pads in their factor packaging should ensure that those prep pads are sterile. If not, either the packages should be recalled or consumers should be provided with additional sterile prep pads. In the future, all such packaging should include only sterile alcohol prep pads. FDA should require that all alcohol prep pads produced and distributed in this country be sterile. Furthermore, FDA should conduct regular inspections of alcohol prep pad manufacturing plants to ensure that the manufacturers are following current Good Manufacturing Practices (cGMP) to ensure that their products are not contaminated with any bacteria or other harmful substances.
5. Healthcare providers, patients who infuse or inject medications at home, and homecare companies should maintain increased vigilance for the occurrence of infections possibly associated with parenteral drug administration and should report suspicious cases of infection to the FDA by filling out the *MedWatch Online Voluntary Reporting Form (3500)*, which can be accessed at <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm> or by calling 1-800-332-1088.

References

1. National Hemophilia Foundation. Recall of alcohol prep pads, alcohol swabs and alcohol swabsticks due to potential bacterial contamination. Medical Advisory #412, January 10, 2011.
2. Contamination of Alcohol Prep Pads with *Bacillus cereus* Group and *Bacillus* Species – Colorado, 2010. MMWR March 25, 2011; 60(11): 347.
3. Wipe-maker shuts doors after U.S. marshals arrive on site. Adverse Event Reporting News, April 19, 2011, pp 17-18.
4. Voluntary product recall of PDI non-sterile alcohol prep pads. PDI Press Release September 20, 2011.
5. Recalls and Field Corrections: Non-Sterile Alcohol Prep Pads/Swabs. FDA Enforcement Report, October 5, 2011.