INFORMATIONAL ALERT:

Potential Consequences of Use of Powdered Gloves

March 16, 2012

Executive Summary:

Eye bankers and corneal surgeons should be aware of the potential adverse health effects associated with the use of powdered medical gloves, especially surgical gloves and patient examination gloves. Glove powders are foreign bodies that elicit inflammatory responses, leading to granuloma formation, adhesions, delayed healing, increased scar formation, increased risk of infection, hand irritation, respiratory complications, the transport of allergens or potentially infectious microorganisms, and erroneous laboratory results. These complications are prevented by the use of powder-free gloves.

Modified cornstarch that meets the specification for Absorbable Dusting Powder (ADP) for the United States Pharmacopeia (USP) is a commonly used lubricant for powdered surgical and examination gloves. Powder from these gloves may be dispersed through direct contact, indirect transfer, torn or punctured gloves, and aerosolization. Glove powder may be deposited directly onto the hands of the wearer or onto exposed tissues within the surgical site. Indirect transfer occurs anytime powder from the glove is deposited onto an object (e.g., surgical instruments or suture) which later contacts the patient. Powder may be aerosolized when gloves are snapped in place or when they are removed. Once in the air, powder may be inhaled by healthcare workers and patients or may fall into wounds, onto medical devices, or into the general environment.

Powdered gloves can be a health concern for the wearer. Powder may serve as an irritant and a vehicle for allergens and microorganisms. Once inhaled, powder may trigger nasal, throat, and respiratory symptoms. Powder may contribute to contact dermatitis or Type IV allergy reactions when glove powder is used on natural rubber latex (NRL) gloves. The powder can serve as a carrier for airborne allergenic NRL proteins, leading to sensitization of glove users. The most serious reaction is Type I allergic reaction to the latex protein that can lead to fatality through anaphylaxis.

Patients may be at risk for powder-associated complications including inflammation, adhesion development, granuloma formation, allergic reactions, and increased risk of infection. Powder causes prolonged inflammation which can delay wound healing and increase scar formation. Starch from powdered gloves can cause an inflammatory reaction, which in combination with surgical trauma may induce the formation of peritoneal adhesions. Glove powder has also been reported to promote the formation of granulomas. Powder-induced granulomas are difficult to differentiate from neoplasm, and may not resolve without surgery. Powder can interfere with local immunological defense mechanisms, allowing microorganisms to multiply and increasing the risk of infection.

In 1997, FDA issued the Medical Glove Powder Report discussing the potential adverse health effects of medical glove powder. These adverse events included (1) aerosolized powder on natural rubber latex (NRL) gloves carrying
allergenic proteins as a cause of respiratory allergic reactions, (2) rhinitis, conjunctivitis, and dyspnea, (3) respiratory problems, (4) granuloma formation, and (5) peritoneal adhesions.

Clinical and laboratory studies published after 1997 indicate that cornstarch powder affects wound healing, inflammation, adhesion formation, granulomatous peritonitis, respiratory function, as well as allergic responses. Reports of glove powder complications after eye surgery include severe inflammation, toxic lens syndrome, chronic granulomas, fibrosis and adhesion formation, and sterile endophthalmitis.

Because of the concerns related to the potential adverse health effects from use of medical gloves that use powder and to ensure compliance with section 502 of the Federal Food, Drug, and Cosmetic Act and 21 CFR 801.5, the FDA recommends that medical gloves that use powder include the following statement:

**Warning**: Powdered gloves may lead to foreign body reactions and the formation of granulomas in patients. In addition, the powder used on gloves may contribute to the development of irritant dermatitis and Type IV allergy, and on latex gloves may serve as a carrier for airborne natural latex leading to the sensitization of glove users.

It is essential for eye banking professionals to understand the consequences associated with glove powder, which can affect the health of patients, healthcare providers, and laboratory personnel. Therefore it is important to select powder-free latex or synthetic gloves whenever possible.

**References**

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm113316.htm

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm228557.htm


Inhibition of povidone-iodine’s bactericidal activity by common organic substances: an experimental study. 


