REVOX™ Sterilization Solutions
by Cantel Medical

NEWSLETTER

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OVERCOMING THE CHALLENGES OF DEPYROGENATION

For companies that produce class III devices, the FDA requires not just sterilization of their products but depyrogenation as well. Up until now, that has limited the materials available to product design because of the typical methodologies used to achieve this additional step. But thanks to the REVOX® Sterilization room-temperature, peracetic acid-based sterilization method, medical device, biotech, and pharmaceutical companies now have another, innovative choice when it comes to eliminating the risk of pyrogens.

A pyrogen is a substance or agent that can cause a rise in body temperature or perhaps more serious complications, including death, specifically when introduced into the bloodstream. Pyrogens are endotoxins derived from a purified lipopolysaccharide layer in the cell wall of bacteria that is secreted or released into the surrounding environment during bacterial death, lysis, or multiplication. Because pyrogens are toxins and not bacteria, they can be present in a sterile product. "Sterile" doesn't mean "endotoxin free". Therefore, depyrogenation of injectables and devices posing risk of transfer of endotoxins into the bloodstream requires specific methods.

These methods traditionally involve techniques such as dry heat, base hydrolysis, and oxidation. The most common tactic for depyrogenation involves dry heat. This method involves "baking" the equipment in dry heat ovens at 250°C for 30 minutes or 200°C for 60 minutes, and so it can only be used on objects that are extremely heat tolerant, such as laboratory equipment (glassware), and stainless steel instruments and devices. By comparison, REVOX™ sterilization can achieve depyrogenation at temperatures an order of magnitude lower—from 18°C to 30°C—thanks to the oxidizing and antimicrobial properties of peracetic acid (PA). This means manufacturers have a greater choice when choosing materials for devices or medications

in direct contact with blood or injected into the bloodstream.

Another alternative method of depyrogenation, base hydrolysis (acid or alkaline), changes the biological activity of the lipopolysaccharide layer by deactivating the lipid A, thereby reducing or eliminating the pyrogenicity. A drawback of the acid-base hydrolysis process though, is that the lipopolysaccharide moiety (endotoxin) may not be completely soluble in water and thus it is not considered an effective process. What's more, the efficiency of hydrolysis heavily depends on the cleanliness of the glassware prior to treatment. REVOX™ depyrogenation, on the other hand, is based on the oxidation of fatty acids present in the lipopolysaccharide moiety, which makes it more effective than hydrolysis.

Depyrogenation via liquid chemical oxidation utilizes hydrogen peroxide, which is known to oxidize the fatty acids that will then inactivate the lipid A in the lipopolysaccharide layer, thus inactivating the pyrogenicity of the endotoxins. REVOX sterilization, however, offers a stronger alternative because it pairs peracetic acid with hydrogen peroxide.

Manufacturing medical devices for use within the bloodstream can pose numerous technical challenges. Previously, companies were forced to use several limiting technologies to meet the FDA's depyrogenation requirements. But the REVOX room-temperature, peracetic acid-based method has opened up a range of innovative material choices for the industry in terms of critical class II and class III devices. In short, REVOX Sterilization has changed the depyrogenation equation.

VISIT THE REVOX STERILIZATION BOOTH DURING THE FOLLOWING CONVENTIONS

- AAMI Annual Conference
  Denver, CO
  June 5-8, 2015
  Booth # 642

- MD&M East
  New York, NY
  June 9-11, 2015
  Booth # 1068

- TechConnect World
  Innovation Conference
  Washington, DC
  June 14-17
  Booth # 513

- BIOMEDevice
  San Diego, CA
  September 1-2

- MD&M Minneapolis
  Minneapolis, MN
  November 4-5
  Booth # 1353

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