

Strategies to prevent Infections caused by Medical Devices

Biological Studies to show their efficacy

The infection rate in hospitals after a surgery is an increasingly severe issue in many countries of Europe and in the USA. About 1.5 % of implants induce complications due to infections. One strategy to prevent these infections is to coat the surface of the medical devices with an antimicrobial substance.

The choice of antimicrobial coatings depends on the type and usage of the medical device. Bone cement for example, can be mixed with antibiotics. A combination of the oral and local treatment of Gentamycin has shown to be much more effective than only the oral application. Another example are silver coated textiles that help reduce dermal infections of neurodermatitis patients.

When the manufacturer has chosen an antimicrobial coating, he has to prove the antimicrobial efficacy for certification or marketing purposes. A broad array of test designs is available. The suitable test design has to be chosen very thoroughly as it has a great impact on the results of the study. The antimicrobial efficacy can be determined

- by using liquid media and determining the minimum inhibitory concentration of special bacterial test strains
- by placing the material on solid media (agar plates) and measuring the growth inhibition zone
- by examining influence on the bacterial growth in the so called proliferation assay etc.

It must be considered, that antimicrobial substances usually have a cytotoxic effect. Therefore it is important, that all the results of the test for biocompatibility have to be evaluated by an expert.

As a source for infections reusable medical devices, like surgery instruments, have been identified that



have not been reprocessed properly. Due to this problem the hygienic departments for reprocessing of some hospitals in Munich were closed temporarily some time ago. Furthermore, there were infections caused by unproperly cleaned reusables.

The Robert Koch Institut published a guideline for the hygienic reprocessing of medical devices in 2001, which is now in revision, for the users in health care facilities.

Since the publication of DIN EN ISO 17664 (2004) manufacturers of

reusables have to indicate at least one procedure for cleaning, disinfection and sterilization in their instruction for use. Various guidelines and technical standards describe how the steps of reprocessing have to be validated. In principle, the medical device is contaminated by a test soil similar to practice and/or inoculated with test organisms. Afterwards it is cleaned, disinfected and sterilized. At last the protein residuals and/or the microbial count of the survivors are determined and the results evaluated.

A brand new FDA draft has been released recently, increasing the requirements for the validation studies by focusing on worst case test strategies.

So, the issue of reprocessing will still be very important in the future. ■

Author:



Dipl. Biol.
Anja Friedrich

Senior Manager
Marketing &
Sales Microbiology

BSL BIOSERVICE
Scientific Laboratories GmbH

Behringstr. 6 / 8
82152 Planegg/Munich - Germany
Phone +49 (0) 89 899 650 0
Fax +49 (0) 89 899 650 11
www.bioservice.com