CORRESPONDENCE

The Diagnosis and Treatment of Pacemaker-Associated Infection

by Dr. med. Michael Döring, PD Dr. med. Sergio Richter, and Prof. Dr. med. Gerhard Hindricks in issue 26/2018

Monitoring Sterile Pacemaker Implants

Recommendations for performing cardiac electronic implantation emphasize strict compliance with comprehensive hygiene regulations (1). The theoretical probability of an unsterile product must not be greater than 1:1 000 000. However, how the high standards of quality and sterility of the applied products can be ensured up to the point of use remains an open question.

The components of sterile packaging have to be gas permeable in order to allow sterilants, such as superheated steam or ethylene oxide, access to the sterile products. Filter performance must compensate for airborne microbial challenge caused by air pressure and temperature variations during transport and storage. Analogous to the sterilization procedure, process evaluation for sterile product storage is necessary to provide data support for ensuring the required high level of quality.

An increase in air pressure of 15 hPa, for example, causes an air inflow of 15 mL in a 1 L packaging volume. Assuming a filtration performance of 99% and an airborne microbial load of 500 microbes per cubic meter, about 75 of 1 000 000 sterile products will be contaminated, which exceeds the sterility assurance level by 75-fold. An increase in the likelihood of non-sterility, for instance to 1:1000 in clinical epidemiological studies, would not be expected to yield significant results. However, it violates international standards and is incompatible with aseptic procedures. According to manufacturers' instructions and some studies, filtration performance of various sterile product packagings with respect to airborne micro-organisms differs considerably (2, 3). In a study funded by seven producers, the filtration performance of the sixteen tested products was mostly between 90% and 99%, with the maximum difference factor at 50 000 (3).

With an annual 105 000 primary implantations in Germany, a postoperative infection rate of 1%, and a hospital mortality of 5% to 15%, data-based monitoring for maintaining sterility should be a priority (1).

DOI: 10.3238/arztebl.2018.0712a

References

1. Döring M, Richter S, Hindricks G: The diagnosis and treatment of pacemaker-associated infection. Dtsch Arztebl Int 2018; 115: 445–52.
2. Dunkelberg H: Sterile supply of medical devices and pharmaceutical products—quality standards and applied risk management. Pharm Ind 2016; 78: 1644–8.
3. Sinclair CS, Tallentire A: Definition of a correlation between microbiological and physical particulate barrier performance for porous medical packaging materials. PDA J Pharm Sci and Tech 2002; 56: 11–9.

Prof. Dr. med. Hartmut Dunkelberg
Bad Sooden-Allendorf, Germany
hdunkel1@gwdg.de

Conflict of interest statement
The author declares that he has a United States patent that is relevant to the topic. He has received consultant honoraria from DuPont and Kimberley & Clark as well as speaking honoraria from Kimberly & Clark.

In Reply:

Several factors can affect the sterility of cardiac implants during transport and storage. As fluctuations in temperature and air pressure lead to an inflow of airborne bacteria into the packaging, they should be minimized to the greatest extent possible. The microbe content of the ambient air, which is a variable that can be measured and controlled, also determines the degree of contamination. On the part of the manufacturers, important indicators are the air volume and filtration performance of the packaging against bacterial spores, which are measured by exposure of the packaging to bacterial spores in an aerosol. For this, the test conditions with regard to flow-through rate, microbe content, and duration of test must be standardized (1). The manufacturer's statements regarding these parameters are very incomplete, and the incomplete data situation prevents the microbe load from being calculated.

Cardiac implants are shipped in double-barrier sterile packaging and sterilized with ethylene oxide gas prior to shipping. Provided that they are properly stored in compliance with the specified temperature, air pressure and humidity limits, they are guaranteed by the manufacturer for 12 to 18 months for implantable units, and 24 to 36 months for electrodes.

If the example given is applied to the sterile packaging of a commercially available cardiac pacemaker, the following applies: with a total volume of 60 mL, an air volume of 40 mL, and all other parameters held constant, three out of 1 000 000 sterile products can be expected to be contaminated.

However, if this calculation takes into account the routinely-used second layer of sterile packaging, one can assume that no significant contamination of the cardiac implants will occur. Once again, the requirement for proper storage according to the manufacturer's specifications must be emphasized.

In summary, it is clear that minimization of clinical risk factors stands in the foreground in preventing infections (2).

DOI: 10.3238/arztebl.2018.0712b

References

1. DIN EN ISO 17664:2018–04, Aufbereitung von Produkten für die Gesundheitsfürsorge – Vom Medizinprodukt-Hersteller bereitzustellende Informationen für die Aufbereitung von Medizinprodukten (ISO 17664:2017); Deutsche Fassung EN ISO 17664:2017.
2. Döring M, Richter S, Hindricks G: The diagnosis and treatment of pacemaker-associated infection. Dtsch Arztebl Int 2018; 115: 445–52.

On behalf of the authors:
Dr. med. Michael Döring
Abteilung für Rhythmologie, Klinik für Cardiology
Herzzentrum Leipzig, Germany
michael.doering@medizin.uni-leipzig.de

Conflict of interest statement
Dr. Döring was reimbursed for congress participation fees as well as travel and accommodation costs by Biotronik and Cook Medical. He has received third-party funding from Biotronik, Boston Scientific, and Abbott.