Materials with antimicrobial properties

RAUMEDIC Infect-Protect
Especially antimicrobial designed medical devices can provide a substantial contribution to the prevention of infections.

Biofilms are complex aggregations of microbes, embedded into a mucous matrix, attached to surfaces. In the biofilm microorganisms significantly change their properties and are very much better protected against attacks by antibiotics. Upon detachment of biofilms the microbes can fully unfold their pathogenic effect inside the body and thus lead to serious infections.

The aim is therefore to generally prevent the attachment of microbes on surfaces and thus to prevent the formation of biofilms. The problem of biofilm formation affects medical diagnostic and analytical equipment, but mainly products used inside the body, from drainage tubing and catheters to pacemakers.

An obvious measure is therefore the development of medical devices with antimicrobial properties; either by adding antibiotics to the material or by application of antimicrobial coatings.

The growing resistance against antibiotics and the increased occurrence of multi-resistant microbes has led to silver compounds receiving increased medical attention. The antimicrobial function of silver has been known for many centuries. In the middle ages, for example, drinking water was preserved by adding silver coins. Silver is known for its wide-ranging efficiency and it is active against a wide number of bacteria and yeast organisms. No resistance formation has been observed to date.
Silver's antimicrobial function is based on the interaction of free silver ions with specific bacterial cell structures. The silver ions block the enzymatic respiration chain, cause destruction of the cell membrane (lysis), or prevent mitosis of these organisms. The different attack points can therefore eliminate bacterial resistance. RAUMEDIC has more than 40 years of experience in the formulation and processing of polymers for medical devices. On the basis of this expertise we developed special material formulations with silver compounds to achieve the desired antimicrobial effect.

In the course of this research we developed significant know-how:

- in the selection of suitable agents
- in the addition to and tailoring of additives to the selected polymers
- in the processing of the diverse formulations,

To ensure the desired silver ion release over the period of use. As the result of our in-vitro studies we now have selected formulations in polyurethane, polyamide and silicone available that demonstrated very good antimicrobial properties.

The activities of the new material formulations were investigated with standardised tests. As an additional indicator for the efficacy the quantity of ions released were monitored against time.

The in-vitro tests were carried out in line with the usual test norms JIS Z2801 and ASTM E2180 in accredited test laboratories. This included extensive tests against Methicillin-resistant staphylococcus aureus (MRSA, gram positive), Escherichia coli (gram negative), Pseudomonas aeruginosa (aerobic), Enterococcus faecium (anaerobic), Candida albicans (fungus) and Staphylococcus epidermidis (gram positive).
Active Properties

In summary, our tests showed the following relevant results:

Summary of test results

- Identification of several effective formulation variations based on PUR, PA and SIK
- Very good efficiency against all tested organisms
- Very fast commencement of antimicrobial effect (close to 100% destruction of microbes after 6h)

Proof of efficiency up to 24 hours

The efficiency is demonstrated in the following diagram which shows Inhibition of microbial growth (equivalent of 99.9% microbe destruction) for antimicrobial PU.

<table>
<thead>
<tr>
<th>Microbe destruction after 24 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microbe destruction</td>
</tr>
<tr>
<td>PU</td>
</tr>
<tr>
<td>----</td>
</tr>
<tr>
<td>Reference 6 h</td>
</tr>
<tr>
<td>MRSA 6 h</td>
</tr>
<tr>
<td>14 h</td>
</tr>
<tr>
<td>24 h</td>
</tr>
<tr>
<td>Escherichia coli 24 h</td>
</tr>
<tr>
<td>Staphylococcus epidermidis 24 h</td>
</tr>
<tr>
<td>Candida albicans 24 h</td>
</tr>
<tr>
<td>Enterococcus faecium 24 h</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa 24 h</td>
</tr>
</tbody>
</table>
The selected antimicrobial materials PU, PA and SiK showed a consistently but slowly decreasing release of silver ions in aqueous media. These findings correlate with the observed in-vitro tests with regards to the ability of the formulations to inhibit bacterial growth. As an example, we have listed the cumulative silver ion release for PU over a period of eight days.

The magnitude and duration of the antimicrobial effect can be altered by the silver loading of the material formulation. The silver reservoir of the material formulation as such ensures the continuous long lasting antimicrobial effect.

The observed silver ion concentrations are not toxic to humans. The released silver ions show only a local effect and are not systemic available. Thereby the colonoziation of surfaces by microbes and biofilm formation is prevented.

A series of tests were conducted with inverse voltametry, which measured the ion release over a period of several days. This showed that the release significantly depended on the material-additive combination.
RAUMEDIC „Infect-Protect“ material grades in silicone, polyurethane and polyamide offer a development platform for the creation of medical devices that exhibit antibacterial properties.

This provides the user with support in the reduction of nosocomial infections and helps to realise not just improved patient care but also significant cost reductions.

The efficiency of these formulations was demonstrated in in-vitro tests. As a component supplier to OEMs RAUMEDIC provides all prerequisites with certified clean-room production and material expertise to support your development of antimicrobial medical devices.

---

1) Mielke M.: Das Problem der nosokomialen Infektionen und Antibiotikaresistenz aus mitteleuropäischer Sicht
Robert Koch-Institut www.rki.de (August 2007): S. 1


RAUMEDIC AG
Hermann-Staudinger-Straße 2
95233 Helmbrechts
Germany

Telephone + 49 (0) 92 52 359-0

www.RAUMEDIC.com

Qualified sales staff in your area offer direct communication channels and service tailored to your requirement.

Your technical contact partners:
Dr. Ralf Ziembinski ralf.ziembinski@raumedic.com
Jörg Grzeskowiak joerg.grzeskowiak@raumedic.com