Infection Prevention with Certofix® protect

Technical brochure of a non-leaching central venous catheter
Reanimation and intensive care of critically ill and injured patients are not possible without the use of intravascular catheters. Although essential for such lifesaving interventions, implanted artificial materials inevitably bear the risk of bacterial contamination, infection and harm. Microbial contamination can lead to the formation of bacterial and fungal biofilms on the surface of implanted medical devices. In the hospital setting, the majority of catheter-related infections are derived from the patient’s own skin microflora. The various microorganisms typically found on human skin are shown in the diagram below:

The risk of infection is enhanced if a central venous catheter is inexpertly inserted or maintained. Catheter-related bloodstream infections (CRBSI) are associated with increases in mortality, morbidity and hospitalization costs for pediatric and adult patients. These infections create additional costs per episode ranging from 4,200 € to 13,030 €. According to knowledge of microbial biofilm formation on catheter surfaces and its role in causing persistent infections and/or sepsis, the pathogenesis of catheter-related sepsis presumably follows these steps:

1. **Catheter insertion**
   - Initial attachment of microorganisms after insertion of an intravascular catheter.

2. **Microbial colonization**
   - Irreversible attachment of microorganisms.
   - The maturation of the microorganisms begins.
   - A release of offspring can lead to an infection development.

3. **Biofilm formation**
   - The risks and limitations
   - Preventive strategies include measures such as antimicrobial line coatings, aseptic insertion technique, improved catheter maintenance, education of clinicians and reduced dwell time through early removal of catheters.

4. **Infection/Sepsis**
   - These infections create additional costs per episode ranging from 4,200 € to 13,030 €.
   - For longer insertion times, there are no data on antibiotic coating, and there is evidence of lack of effect for chlorhexidine-silver sulfadiazine coating.
   - For silver-impregnated collagen cuffs, there is evidence of lack of effect for both short- and long-term insertion.

   **Adverse reactions**
   - Antimicrobial impregnated central venous catheters can be divided into teaching and non-teaching catheter systems. Chlorhexidine or antibiotics may leach from catheter systems impregnated with such agents.
   - Leached chlorhexidine and sulfadiazide silver may sensitize patients, leading to life-threatening anaphylaxis on subsequent exposure.
   - Antibiotic resistance after repeated exposure to minocycline and/or rifampicin-impregnated catheters can develop after bacteria have been exposed to subinhibitory concentration of antibiotics that have failed to eradicate these organisms. Some authors have reported in vitro resistance to leachable rifampicin or a combination of minocycline and rifampicin after repeated use of catheters.

**Microorganisms and catheter-related bloodstream infections**

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**CRBSIs CREATE ADDITIONAL COSTS PER EPISODE RANGED FROM 4,200 € TO 13,030 €.**


### Anti-pathogenic Certofix® protect catheters

The protect coating creates a catheter surface with very good anti-pathogenic characteristics. The adhesion of bacteria, which is normally the starting point of a catheter-related bloodstream infection, is effectively prevented in this non-leaching catheter.

#### The functional principle of Certofix® protect

The polarization of the Certofix® protect catheter surface destroys the cell membrane structure of microorganisms in the event of surface contact. Ongoing chemical interaction between the catheter material (PUR) and the protect coating ensures long-term protection without leaching effect. Certofix® protect prevents catheter-related infections during the entire application period.24

### USER BENEFITS

- A non-leaching antimicrobial central venous catheter
- No active agents are released, long time efficiency up to 30 days24
- The same flexibility as other Certofix® catheters
- Total catheter surface coverage – from tip to hub: On the complete inner surface and outside up to the channel junction

### Efficacy of Certofix® protect in long-term use

The anti-pathogenic characteristics (30 days) of non-leaching antimicrobial central venous catheters on 7 typical CVC-associated infection bacteria was tested with the "Roll-Out" method, (Staphylococcus epidermidis, Staphylococcus aureus MRSA and E. coli, Enterococcus faecalis, Pseudomonas aeruginosa, Klebsiella pneumoniae and Candida albicans).

"Roll-Out" test shows the following results:

- The in-vitro trial demonstrates that Certofix® protect exhibits antimicrobial efficacy and prevents biofilm formation from gram-positive, gram-negative bacteria and fungi for up to 30 days.24
- The study was performed in direct comparison with a non-antimicrobial control catheter, on which all 7 test strains were able to grow to an established surface biofilm.24

### Summary

This is the first in-vitro study to demonstrate antibacterial surface activity and prevention of biofilm formation with antimicrobial, non-leaching CVCs by using the "Roll-Out" method over a period of 30 days. These results demonstrate that non-leaching antimicrobial CVCs can prevent microbial colonization and infection.

### Table: Efficacy of Certofix® protect (30 days)

<table>
<thead>
<tr>
<th>Sample</th>
<th>0 DAYS</th>
<th>7 DAYS</th>
<th>14 DAYS</th>
<th>30 DAYS</th>
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<tr>
<td><strong>Gram-positive bacteria:</strong> Staphylococcus aureus (MRSA)</td>
<td><img src="image" alt="Control sample" /></td>
<td><img src="image" alt="Certofix® protect" /></td>
<td><img src="image" alt="Certofix® protect" /></td>
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<tr>
<td><strong>Gram-negative bacteria:</strong> Pseudomonas aeruginosa</td>
<td><img src="image" alt="Control sample" /></td>
<td><img src="image" alt="Certofix® protect" /></td>
<td><img src="image" alt="Certofix® protect" /></td>
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</tbody>
</table>

### Control sample

- Gram-positive bacteria: Staphylococcus aureus (MRSA)
- Gram-negative bacteria: Pseudomonas aeruginosa

### Certofix® protect sample

- Gram-positive bacteria: Staphylococcus aureus (MRSA)
- Gram-negative bacteria: Pseudomonas aeruginosa
- The抗菌activity was tested using the "Roll-Out" method.

### The same test results were obtained for:

- Escherichia coli, Enterococcus faecalis
- Klebsiella pneumoniae
- Candida albicans

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**Note:** Image links are placeholders as the actual images are not provided in the text. The images are likely visual representations of the test results.
Product Specifications

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Mini Scalpel</th>
<th>Valve/Plug</th>
<th>Cath. Lumen a G</th>
<th>Flow rate (mL/min)*</th>
<th>Length (cm)</th>
<th>Guide wire length (cm)</th>
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* D (distal); M1 (middle1); M2 (middle2); M3 (middle3); P (proximal)

- The sales unit of Certofix® protect Sets is 10 pieces
- All catheters are made of PUR

The base material of the central venous catheter Certofix® protect is polyurethane (PUR). All lumens, including the hub and the outer surface of the catheter, are embedded with a long-chain polymer based on methacrylate. The catheter material also includes hydrophilic side groups such as polyethylene glycol and anisicpic polymeric biguanide.

Literature


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