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SHARING EXPERTISE

Patient Access

Infection Prevention with Certofix® protect

Technical brochure of a non-leaching central venous catheter

Microorganisms

and catheter-related bloodstream infections

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.[1]

In the hospital setting, the majority of catheter-related infections are derived from the patient' s own skin microflora.[2] The various microorganisms typically found on human skin are shown in the diagram below.[2]

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.[6-9]

Staphylococcus aureus	15 %
Methicillin-resistant Staphylococcus aureus	<5 %
Candida species	<5 %
Enterococci	2-4 %
Coagulase-negative staphylococci, such as Staphylococcus epidermis	60-70 %

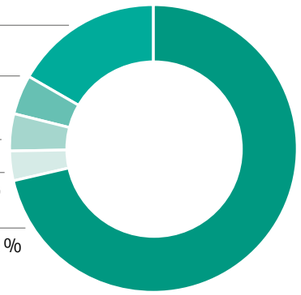


FIGURE 1 | Microorganisms and risk of catheter-related infections[2]

CRBSIs CREATE ADDITIONAL COSTS PER EPISODE RANGED FROM 4,200 € TO 13,030 €.[10]

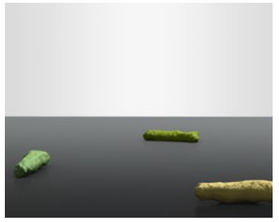
Pathogenesis of CVC infections

Contamination prior to and during catheteter insertion may result in catheter-related infections. The risk of infection is exacerbated 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.[3-7]

These infections create additional costs per episode ranging from 4,200 € to 13,030 €.[10]

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.

3. Biofilm formation

The maturation of the microorganisms begins.

4. Infection/Sepsis

A release of offspring can lead to an infection development.

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.[11,12]

As each patient pathway bears several risks and may have an unexpected twist the choice of the right catheter which is adequate for all therapy is very important.

Dwell time

- Approximately 75 % of patients have a catheter dwell time of less than 7 days.[13] These patients have the lowest risk of catheter-associated bloodstream infections.
- Clinical trials have demonstrated that higher dwell time is associated with significantly higher occurrence of central line associated bloodstream infections.[11,13-15]

Efficacy in short insertion times

Line coatings have been developed to reduce central venous catheter-related infections.

- Antibiotic and chlorhexidine-silver sulfadiazine coatings are anti-infective for short (approximately one week) insertion times. For longer insertion times, there are no data on antibiotic coating, and there is evidence of lack of effect for chlorhexidine-silver sulfadiazine coating.[9]
- For silver-impregnated collagen cuffs, there is evidence of lack of effect for both short- and long-term insertion.[9]

Adverse reactions

Antimicrobial impregnated central venous catheters can be divided into leaching and non-leaching 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.[16-18]
- 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.[19-21]

Certofix® protect

for optimizing catheter care

Anti-pathogenic Certofix® protect catheters

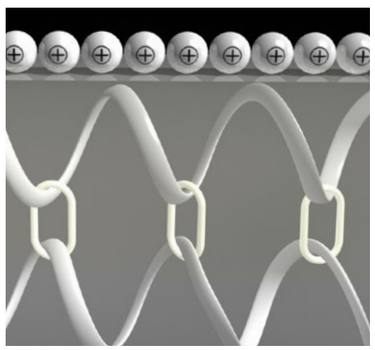
The protect coating creates a catheter surface with very good anti-pathogenic characteristics. The adhesion of bacteria, which is normally the starting point of a catheter-related bloodstream infection, is effectively prevented in this non-leaching catheter.

The functional principle of Certofix® protect

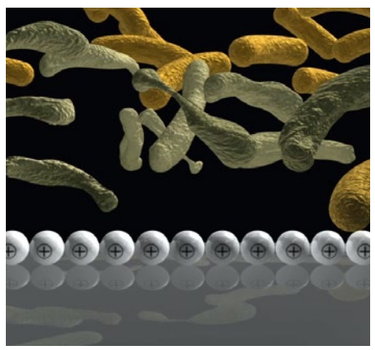
The polarization of the Certofix® protect catheter surface destroys the cell membrane structure of microorganisms in the event of surface contact. Ongoing chemical interaction between the catheter material (PUR) and the protect coating ensures long-term protection without leaching effect. Certofix® protect prevents catheter-related infections during the entire application period.[22]

USER BENEFITS

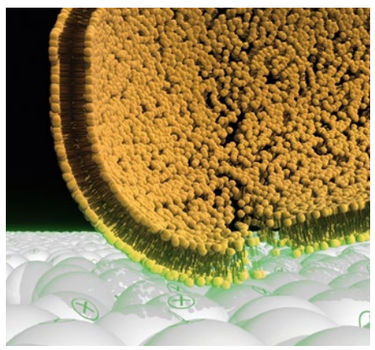
- A non-leaching antimicrobial central venous catheter
- No active agents are released, long time efficiency up to 30 days[22]
- The same flexibility as other Certofix® catheters
- Total catheter surface coverage – from tip to hub: On the complete inner surface and outside up to the channel junction



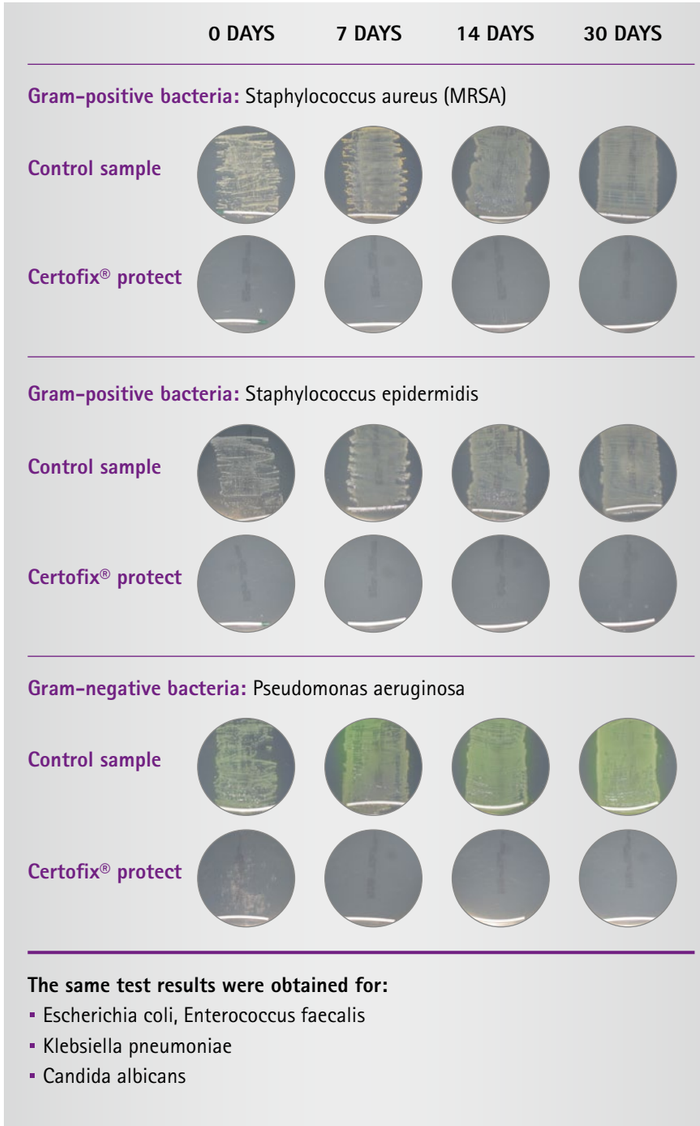
Ongoing chemical interaction between polarized catheter material and antimicrobial agent.



The antimicrobial inner and outer surface makes for a non-leaching catheter.



The cell wall structure of microorganisms is destroyed.



The same test results were obtained for:

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

Efficacy of Certofix® protect[22]

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 aerugionosa, 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.[22]
- 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.[22]

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.

Product Specifications

Product Type	Mini Scalpel	Valve/Plug	Cath. Lumen ø G	Flow rate (ml/min)*	Length (cm)	Guide wire length (cm)	Code No. (REF)
Mono V 320 Protect	–	–	16	D 52	20	50	4160266P
Mono V 420 Protect	–	–	14	D 80	20	50	4160320P
Mono V 330 Protect	–	–	16	D 40	30	70	4160290P
Mono V 430 Protect	–	–	14	D 75	30	70	4160789P
Duo V 715 Protect	•	Safsite® Valve	16/16	D 60; P 50	15	50	4166159P
Duo V 720 Protect	•	Safsite® Valve	16/16	D 55; P 45	20	50	4161211P
Duo V 730 Protect	•	Safsite® Valve	16/16	D 52; P 37	30	70	4161319P
Duo HF V 720 Protect	•	Safsite® Valve	14/18	D 100; P 27	20	50	4168534P
Trio V 715 Protect	•	Safsite® Valve	16/18/18	D 50; M1 28; P 28	15	50	4162153P
Trio V 720 Protect	•	Safsite® Valve	16/18/18	D 46; M1 22; P 22	20	50	4163214P
Trio V 730 Protect	•	Safsite® Valve	16/18/18	D 38; M1 18; P 18	30	70	4163311P
Trio HF V 1220 Protect	•	Safsite® Valve	16/12/12	D 55; M1 165; P 165	20	50	4160622P
Quattro V 815 Protect	•	Safsite® Valve	14/18/18/16	D 50; M1 20; M2 20; P 50	15	50	4167767P
Quattro V 820 Protect	•	Safsite® Valve	14/18/18/16	D 40; M1 15; M2 15; P 40	20	50	4167775P
Quattro V 830 Protect	•	Safsite® Valve	14/18/18/16	D 35; M1 10; M2 10; P 35	30	70	4167783P
Quinto V 1220 Protect	•	Safsite® Valve	16/18/18/18/12	D 55; M1 28; M2 28; M3 28; P 185	20	50	4166868P

***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 antiseptic polymeric biguanide.

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Date of last revision: 11.2022