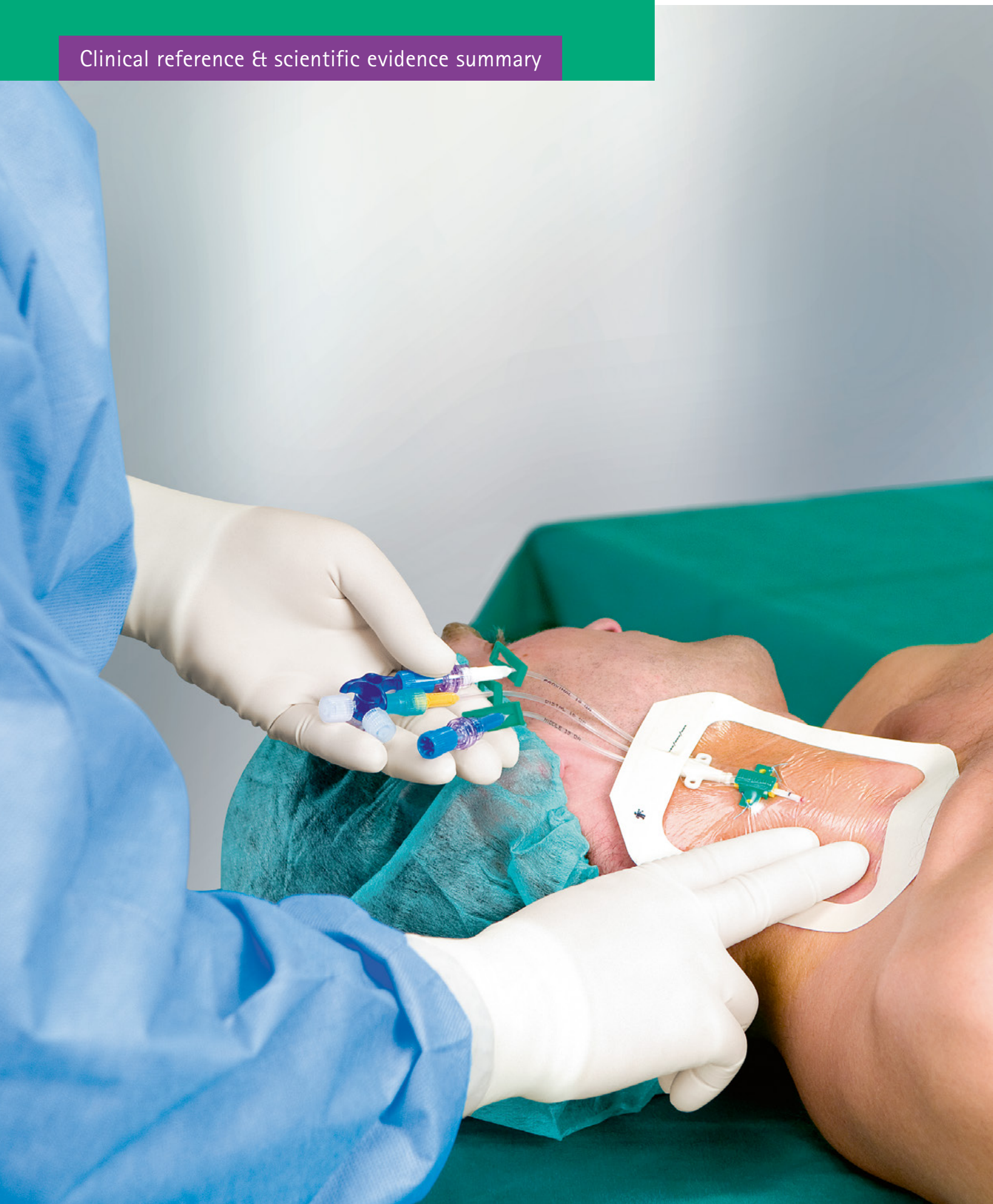
Certofix® protect

Fighting catheter related/central line associated blood stream infection

Clinical reference & scientific evidence summary

B BRAUN
SHARING EXPERTISE



Content overview

Awareness and insights

Introduction

Resuscitation and intensive care of critically ill and injured patients are not possible without the use of intravascular catheters, endotracheal tubes, and numerous other invasive or minimally invasive medical devices. Although lifesaving, implanted artificial materials inevitably bear the risk of bacterial contamination, infection, and harm.[1]

Microbial contamination leads to formation of bacterial and fungal biofilms (an aggregate of microorganisms in a matrix of extracellular polymeric substances) on the surface of implanted medical devices.

In addition to mechanical hindrance, device associated biofilms are a primary cause of hospital-acquired (nosocomial) infections that are difficult to eradicate due to the high tolerance of biofilms towards antimicrobial and host defences.[2,3]

Awareness and insights

Definition of CRBSI / CLABSI

Awareness and insights

Pathogenesis of CRBSI / CLABSI

Catheter related blood stream infection, CRBSI:

CRBSI is a clinical definition, used when diagnosing and treating patients, that requires specific laboratory testing that more thoroughly identifies the catheter as the source of the Blood Stream Infection (BSI). It is not typically used for surveillance purposes. It is often problematic to precisely establish if a BSI is a CRBSI due to the clinical needs of the patient (the catheter is not always pulled), limited availability of microbiologic methods (many labs do not use quantitative blood cultures or differential time to positivity), and procedural compliance by direct care personnel (labelling must be accurate).

Simpler definitions are often used for surveillance purposes. For example, CLABSI is a term used by CDC's National Healthcare Safety Network (NHSN) in the USA.

Central line-associated bloodstream infection, CLABSI:

CLABSI is a serious infection that occurs when germs (usually bacteria or viruses) enter the bloodstream through the central line.

CLABSI is a primary BSI in a patient that had a central line within the 48-hour period before the development of the BSI and is not bloodstream related to an infection at another site. However, since some BSIs are secondary to other sources other than the central line (e.g., pancreatitis, mucositis) that may not be easily recognized, the CLABSI surveillance definition may overestimate the true incidence of CRBSI. [4]

Pathogenesis of CRBSI / CLABSI

During the initial stages of intravascular catheter colonisation, a biofilm is formed that is made up of host proteins and microbes. Bacteria and fungi survive and proliferate within the biofilm, despite host immune defences and therapeutic doses of antimicrobial agents. CRBSIs most commonly emanate from microorganisms colonising the catheter.

CRBSIs are systemic blood infections (bacteraemia) directly attributable to a Central Venous Catheter (CVC).

CRBSI is associated with increased morbidity, mortality and duration of hospital stay. From the patient's perspective, there may be soft tissue pain, systemic symptoms such as pyrexia (prompting investigations including blood tests and X-rays), a need to replace an infected CVC, antibiotic treatment, prolonged hospitalization and (infrequently) death. [5, 6, 7, 8, 9, 10, 11]

Pathogens of CRBSI / CLABSI

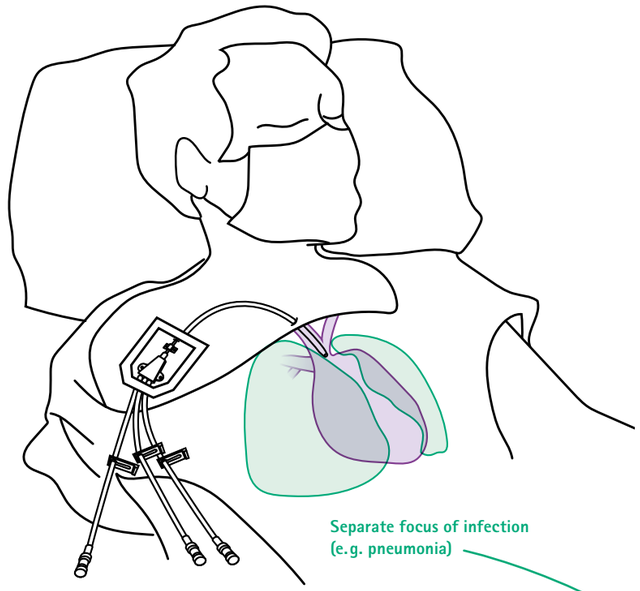
The most frequent pathogens are

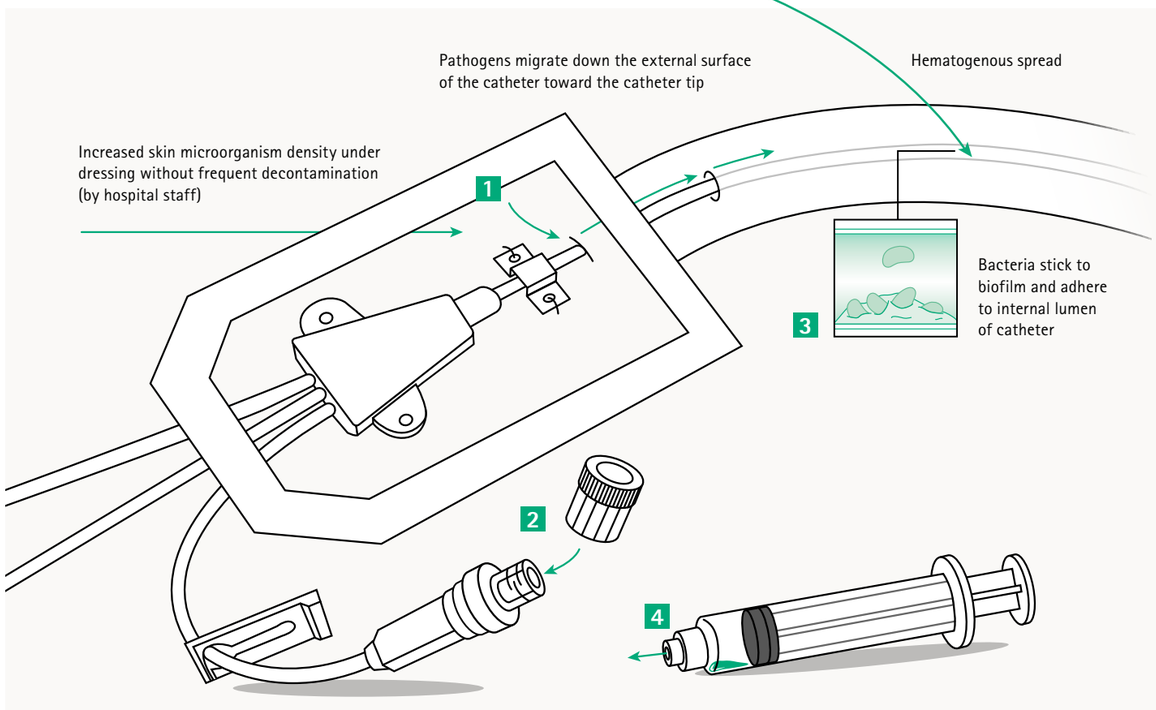
- Staphylococcus epidermidis
- Staphylococcus aureus
- Escherichia coli
- Klebsiella pneumoniae / Klebsiella oxytoca
- Enterococcus faecalis
- Candida species
- Gram-negative bacilli
- Multidrug-resistant germs

The most frequent pathogens of CRBSIs in patients undergoing long term central venous access are coagulase-negative staphylococci, such as St. epidermidis and St. aureus. [12, 13, 14] Also, newer pathogens of CRBSI are coming into the clinically focus as a result of worldwide globalisation, for example Candida auris, multidrug-resistant Acinetobacter baumannii, Leclercia adecarboxylata or pichia species. [15, 16, 17, 18, 19]

Awareness and insights

Routes for catheter contamination





Routes for catheter contamination

1 Catheter contaminated at insertion site (by hospital staff)
– **Extraluminal spread**

2 Catheter hub manipulation (by hospital staff)
– **Intraluminal spread**

3 Catheter contaminated by secondary infection
– **Intraluminal spread**

4 Contaminated infusate
– **Intraluminal spread**

Figure 1 | Routes for catheter contamination.[20]

Routes for catheter contamination

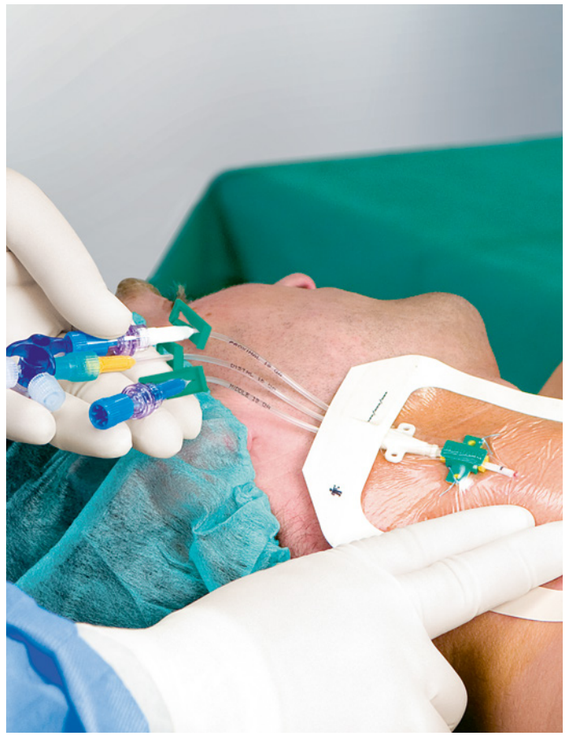
There are four recognized routes for catheter contamination; these are catheter contamination at insertion site, catheter hub manipulation, contamination by secondary infection and via contaminated infusates. (Fig. 1)

First, skin pathogens at the insertion site can enter the cutaneous catheter tract and migrate along the external surface of the catheter with colonization of the catheter tip. This most commonly happens within the first 7 days after catheter placement and is thought to occur at the time of insertion. Insertion-site contamination can also happen when the skin microorganism density increases underneath the catheter dressing over time if the area is not decontaminated frequently.

Second, intraluminal spread can happen when the catheter hub is contaminated by contact with hands or contaminated fluids or devices. Pathogens gain access to the intraluminal surface of the device, where they adhere and become incorporated into biofilm, which allows for sustained infection and hematogenous dissemination. This contamination typically occurs more than 7 days after catheter insertion and is related to the care and maintenance of the catheter, as well as the number of times the catheter is manipulated or accessed.

Third, and less commonly, catheters become contaminated by hematogenous spread from a secondary bloodstream infection that develops from another focus of infection (e.g., pneumonia or a urinary tract infection). Bacteria stick to the biofilm that is formed and adhere to the internal lumen of the catheter.

Finally, in rare cases, contaminated infusate taints the catheter (i.e., in outbreaks with contaminated injectable flushes). Knowledge of the pathogenesis of CRBSI has informed the development of strategies for prevention.[20]



Awareness and insights

Risk factors & clinical and economic consequences

CLABSI/CRBSI risk factors

Patient factors	Provider factors	Device factors
▪ Immunocompromise	▪ Emergency catheter insertion	▪ Catheter material
▪ Neutropenia	▪ Incomplete adherence to aseptic technique	▪ Catheter insertion site
▪ Burns	▪ Multiple manipulations of the catheter	▪ Indication of use (e.g., for haemodialysis)
▪ Malnutrition	▪ Low nurse-to-patient ratio	▪ Multilumen catheter
▪ BMI > 40	▪ Failure to remove unnecessary catheter	
▪ Prolonged hospitalization before catheter insertion	▪ Total parenteral nutrition (TPN)	
▪ Prematurity in infants	▪ Chemotherapy treatment	
▪ Limited venous access	▪ Number of days of catheterization	

Table 1 | CLABSI/CRBSI Risk factors.[20,21]

Clinical and economic consequences

CRBSI are associated with increases in mortality, morbidity, and hospitalization costs.[22] One recent cohort study in Europe (Table 2) revealed that hospital costs directly attributed to the onset of CLABSI were 8,810 € per case. CLABSI had a significant impact on the overall healthcare costs. Knowledge about risk factors and infection control measures for CLABSI prevention is crucial for best clinical practice. Furthermore, significant differences in the single cost items between CLABSI cases and non-CLABSI controls were found for pharmaceuticals (2,117 € vs. 1,541 €; p = 0.001), nurses (7,083 € vs. 6,061 €; p = 0.003) and medical products (3,451 € vs. 2,838 €; p = 0.02).[23,24]

	Case patients with CLABSI (n= 79)	Control patients without CLABSI (n = 158)	p-value
Median costs	54,454 (25,634 – 112,697)	48,965 (17,538–78,706)	0.025
Median reimbursements	74,662 (18,331–82,801)	74,662 (17,478–79,745)	0.290
Median loss/profit	-8,888 (-29,993 – 2,522)	1,000 (-11,198 – 9,581)	<0.001
Median costs attributable to CLABSI	8,810 (-2,237 – 3,487)		<0.001
Median loss attributable to CLABSI	-8,171 (-29,090 – 2,396)		<0.001

Table 2 | Costs and reimbursements (in Euro) for case patients with CLABSI and control patients without CLABSI in the matched case-control study – study carried out with hematologic and oncologic patients.[23]

Awareness and insights

Prevention strategy of CLABSI (SHEA/IDSA/APIC practice recommendation (2022 update))[25]

 Quality of evidence: **high**

 Quality of evidence: **moderate**

 Quality of evidence: **low**

 Quality of evidence: **high in adult patients, moderate in pediatric patients**

Essential practices

1. Before insertion

 1 | Provide easy access to an evidence-based list of indications for CICC use to minimize unnecessary CICC placement

 2 | Require education and competency assessment of HCP involved in insertion, care, and maintenance of CICCs about CLABSI prevention

 3 | Bathe ICU patients aged >2 months with a chlorhexidine preparation on a daily basis

2. At insertion

 1 | In ICU and non-ICU settings, a facility should have a process in place, such as a checklist, to ensure adherence to infection prevention practices at the time of CICC insertion

 2 | Perform hand hygiene prior to catheter insertion or manipulation

 3 | The subclavian site is preferred to reduce infectious complications when the catheter is placed in the ICU setting

 4 | Use an all-inclusive catheter cart or kit

 5 | Use ultrasound guidance for catheter insertion

 6 | Use maximum sterile barrier precautions during CICC insertion

 7 | Use an alcoholic chlorhexidine antiseptic for skin preparation

3. After insertion

 1 | Ensure appropriate nurse-to-patient ratio and limit use of float nurses in ICUs

 2 | Use chlorhexidine-containing dressings for CICCs in patients over 2 months of age

 3 | For non-tunneled CICCs in adults and children, change transparent dressings and perform site care with a chlorhexidine-based antiseptic at least every 7 days or immediately if the dressing is soiled, loose, or damp. Change gauze dressings every 2 days or earlier if the dressing is soiled, loose, or damp

 4 | Disinfect catheter hubs, needleless connectors, and injection ports before accessing the catheter

 **5** | Remove nonessential catheters

 6 | Routine replacement of administration sets not used for blood, blood products, or lipid formulations can be performed at intervals up to 7 days

 7 | Perform surveillance for CLABSI in ICU and non-ICU settings

CLABSI, central line-associated bloodstream infection.
CICC, centrally inserted central catheter.
HCP, healthcare personnel.
ICU, intensive care unit.

Additional approaches

 1 | Use antiseptic- or antimicrobial-impregnated CICCs

 2 | Use antimicrobial lock therapy for long-term CICCs

 3 | Use recombinant tissue plasminogen activating factor (rt-PA) once weekly after hemodialysis in patients undergoing hemodialysis through a CICC

 4 | Utilize infusion or vascular access teams for reducing CLABSI rates

 5 | Use antimicrobial ointments for hemodialysis catheter insertion sites

 6 | Use an antiseptic-containing hub/connector cap/port protector to cover connectors

Approaches that should not be considered a routine part of CLABSI prevention

 1 | Do not use antimicrobial prophylaxis for short-term or tunneled catheter insertion or while catheters are in situ

 2 | Do not routinely replace CICCs or arterial catheters

Unresolved issues

1 | Routine use of needleless connectors as a CLABSI prevention strategy before an assessment of risks, benefits, and education regarding proper use

2 | Surveillance of other types of catheters (e.g., peripheral arterial or peripheral venous catheters)

3 | Standard, non-antimicrobial transparent dressings and CLABSI risk

4 | The impact of using chlorhexidine-based products on bacterial resistance to chlorhexidine

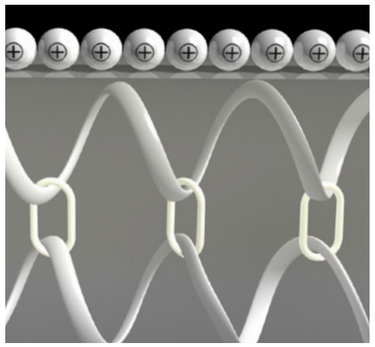
5 | Sutureless securement

6 | Impact of silver zeolite-impregnated umbilical catheters in preterm infants (applicable in countries where it is approved for use in children)

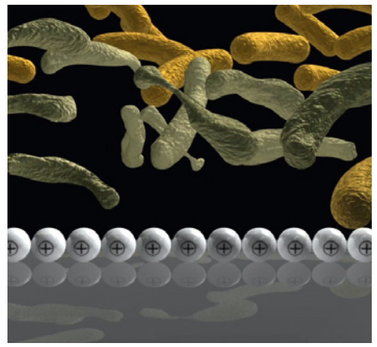
7 | Necessity of mechanical disinfection of a catheter hub, needleless connector, and injection port before accessing the catheter when antiseptic-containing caps are being used

B. Braun solution – non-leaching antimicrobial catheter, Certofix® protect

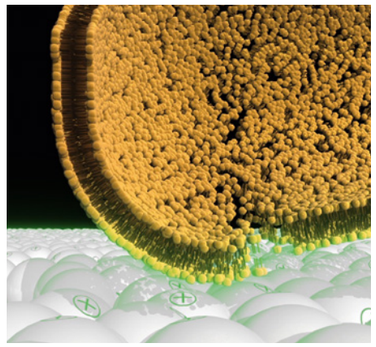
Mechanism and scope of action



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.

Mechanism of action

The base material of the CICC Certofix® protect consists of thermoplastic polyurethane. All lumens, including the hub and the outer surface of the catheter, are coated with a tailored copolymer comprising of hydrophilic polyethylene glycol and antiseptic polymeric biguanide side groups, attached to a methacrylate-based backbone. A comparable polymeric biguanide can be found in some wound irrigation solutions. The copolymer is partially embedded in and bonded to the base material of the catheter with the side groups being freely accessible on the catheter surface.

Mode of action

All catheter lumens and the outer side of the CICC Certofix® protect exhibit a copolymer modified surface, which kills bacteria and fungi as soon as they come into contact with the catheter surface.

In addition, the polymer is having hydrophilic moeities contributing to the haemocompatibility of the catheter. The modified catheter's mode of action is based exclusively on the destruction of bacteria that come into contact with the surface, also termed as contact-kill mechanism. There are no active chemical substances being released into the surrounding tissue or the bloodstream. Hence, a systemic effect on organisms in the blood can be excluded.

Despite the antimicrobial surface, the usual hygienic procedures for inserting a CICC must still be conducted.

Scan it to watch more information in Certofix® protect animation

Certofix® protect

Scope of action

The Certofix® protect catheter is effective against the most frequently occurring pathogens which can cause a catheter-associated infection:

- Staphylococcus aureus
- Staphylococcus epidermidis (coagulase-negative Staphylococci)
- Methicillin-resistant Staphylococcus aureus (MRSA)
- Enterococcus faecalis
- Escherichia coli
- Pseudomonas aeruginosa
- Klebsiella pneumoniae
- Candida albicans

B. Braun solution – non-leaching antimicrobial catheter, Certofix® protect

Material performance and safety

Reduction of CRBSI

Significant decrease of CRBSI compared to non-antimicrobial CVCs [26]

Krikava I, Kolar M, Garajova B, Balik T, Sevcikova A, Roschke I, Sevcik P. The efficacy of a non-leaching antibacterial central venous catheter - a prospective, randomized, double-blind study. Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub. 2020 Jun;164(2):154-160.

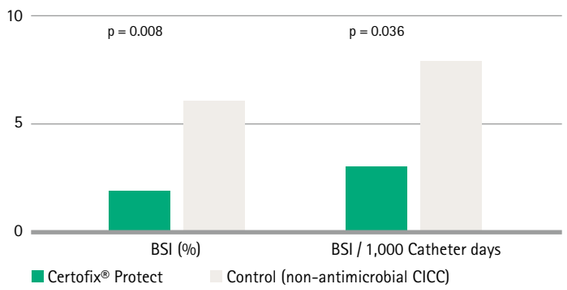
1. Topic

Reduction of CRBSI

2. Design & Method

- The study was conducted in two centers using a prospective, randomized, double-blind and controlled design (680 intensive care patients; a protective CICC (Certofix® protect) or a standard CICC (Certofix®).
- Primary objectives were the rates of catheter colonization and BSI in the two groups.
- Other baseline demographics, APACHE II score, insertion site, location of CICC placement (ICU or theatre), indwelling time and length of ICU stay were comparable for both groups.

3. Results



A clinical study with Certofix® protect has proven (n=616):

- Use of Certofix® protect is associated with significant reduction of blood stream infection (BSI) from 6.5 % to 2 % and from 8.3 to 3.2 / 1,000 Catheter days.
- The group using Certofix® protect underwent less antibiotic therapy. [6]

4. Key Findings

The non-leaching antibacterial coating of the protective catheter was **effective in reducing the incidence of BSI but not the rate of catheter colonization.** However, the **incidence of BSI is a better surrogate marker** for the risk of developing clinical signs of infection suggesting that **use of the non-leaching protective catheter is effective** in this regard.

Reduction of CRBSI

Estimation of usage of central venous catheter with antimicrobial coating for prophylaxis of catheter-associated infections [27]

Ivanova O., Kuga P., Oparina Y., Popova M., Mushchitskaya I., Lazarev A., Bogomolnyj M. Estimation of usage of central venous catheter with antimicrobial coating for prophylaxis of catheter-associated infections. Bone Marrow Transplantation 2011; 46 (SUPPL. 1): S445-S446.

1. Topic

Reduction of CRBSI

2. Design & Method

- Aim of the study: to estimate the efficiency of Certofix® CICCs with antimicrobial coating for patients undergoing chemotherapy or bone marrow transplant (BMT); to calculate the duration of CICC's usage; to define the influence of CICC's lumina on catheter-associated infections (CAI).
- 124 patients (pts) aged 17-48 years with different oncology and hematological diseases were included. 81 pts underwent BMT, 36 pts – chemotherapy, 7 pts – ECP therapy.
- Pts were divided into two groups: group I used CICCs with antimicrobial coating (58 pts) and group II CICCs without antimicrobial coating (66 pts). In all patients the vena subclavia was cannulated with subclavian accession. There were no complications of cannulation procedure.
- Assumption of CAI was made in case of fever without site of infection or / and growth of microgerms in hemoculture of blood. Infections were proved by comparing blood from CICC and peripheral vein or by taking a culture of CICC's distal part after its removal.

3. Results

- The number of CICC's lumina did not influence CAI.
- The average duration of CICC's usage was 49 days in group I (2-101 days) and 39 days in group II (1-78 days).
- CICCs were removed in 4 pts in group I and in 11 pts in group II because of assumption of infection. Bacteriological improvement of the infection was found in 1 case from group I (0,6 %) and in 8 cases from group II (5,2 %).
- Infectious agents in group I was St. Epidermidis, in group II St. Aureus, St. Epidermidis, Kl. Pneumoniae, Acinetobacter, Enterobacter, Pseudomonas aeruginosae, Candida.

4. Key Findings

Usage of **CICC with antimicrobial coating** leads to **decreased rates of CAI** in patients **undergoing BMT and chemotherapy.**

B. Braun solution – non-leaching antimicrobial catheter, Certofix® protect

Material performance and safety

Reduction of biofilm formation

Significant germ reduction compared to non-antimicrobial catheter[28]

Bruenke J, Roschke I, Agarwal S, Riemann T, Greiner A. Quantitative Comparison of the Antimicrobial Efficiency of Leaching versus Nonleaching Polymer Materials. Macromol Biosci. 2016 May;16(5):647-54.

1. Topic

Reduction of biofilm formation

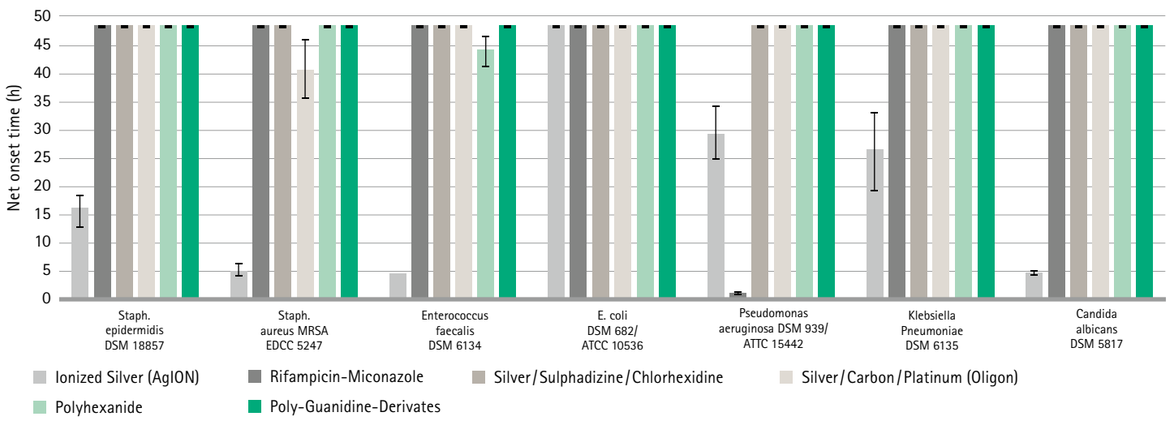
2. Design & Method

- The performance of different antibacterial catheter types was tested in vitro with the proliferation method (Certika test) for their antimicrobial efficacy against typical CRBSI-related gram-positive, gram-negative bacteria, and fungus yeast.
- This test is especially designed to test antimicrobial properties of leachable and non-leachable materials.

4. Key Findings

- This contribution demonstrates that the **non-leaching antimicrobial CICCs are equivalent to conventional leaching CICC** systems in their **antimicrobial performance** against gram-positive and gram-negative bacteria, as well as Candida species.
- The use of new non-leaching antimicrobial polymers as shown here for CICCs represents a **different mode of action** with the aim to prevent infections also with **antibiotic-resistant strains** and **reduced side effects.**

3. Results



- The equal antimicrobial effect of leaching and non-leaching coated antibacterial catheters could be demonstrated. It was also shown that all catheter components of non-leaching antimicrobial catheters possess antimicrobial activity.
- The CICC with ionized silver failed to reduce 3 log scales of Staphylococcus aureus MRSA, Enterococcus faecalis, and Candida albicans, the CICC with rifampicin-miconazole Pseudomonas aeruginosa.
- The CICCs treated with silver/sulphadizine/chlorhexidine, silver/carbon/platinum, polyhexanide, and poly-guanidine derivatives (Certofix® protect) demonstrated antimicrobial performance >99.99% (log 4 reduction) against all tested germs.

Reduction of biofilm formation

30 days antimicrobial efficacy of non-leaching central venous catheters[29]

Brunke J, Riemann T, Roschke I, 30 days antimicrobial efficacy of non-leaching central venous catheters (Poster 063), Critical Care 2016, Volume 20 Suppl 2.

1. Topic

Reduction of biofilm formation

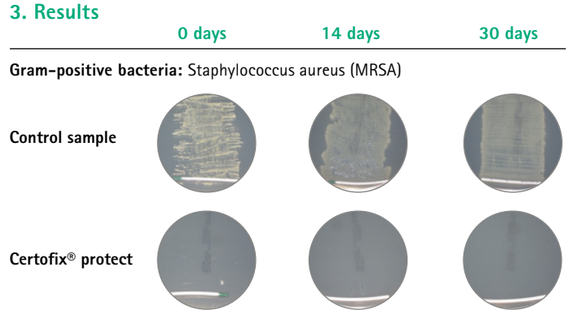
2. Design & Method

- The antimicrobial performance (30 days) of non-leaching antimicrobial CICCs on 7 typical CICC-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).
- After inoculation, washing, incubation at 37 °C, immersion in a minimum medium solution, and a second washing process, the catheter sample was placed on an agar plate and rolled 3 times over the agar plate to transfer surface bound bacteria to the agar medium.
- After overnight incubation (37 °C), bacterial growth was recorded by photography.

3. Results

- The present in-vitro data demonstrate that non-leaching antimicrobial CICCs (e.g. Certofix® protect, B. Braun) exhibit antimicrobial efficacy and prevent biofilm formation from gram-positive, gram-negative bacteria and fungi for up to 30 days.
- 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.

3. Results



The same test results were obtained for:

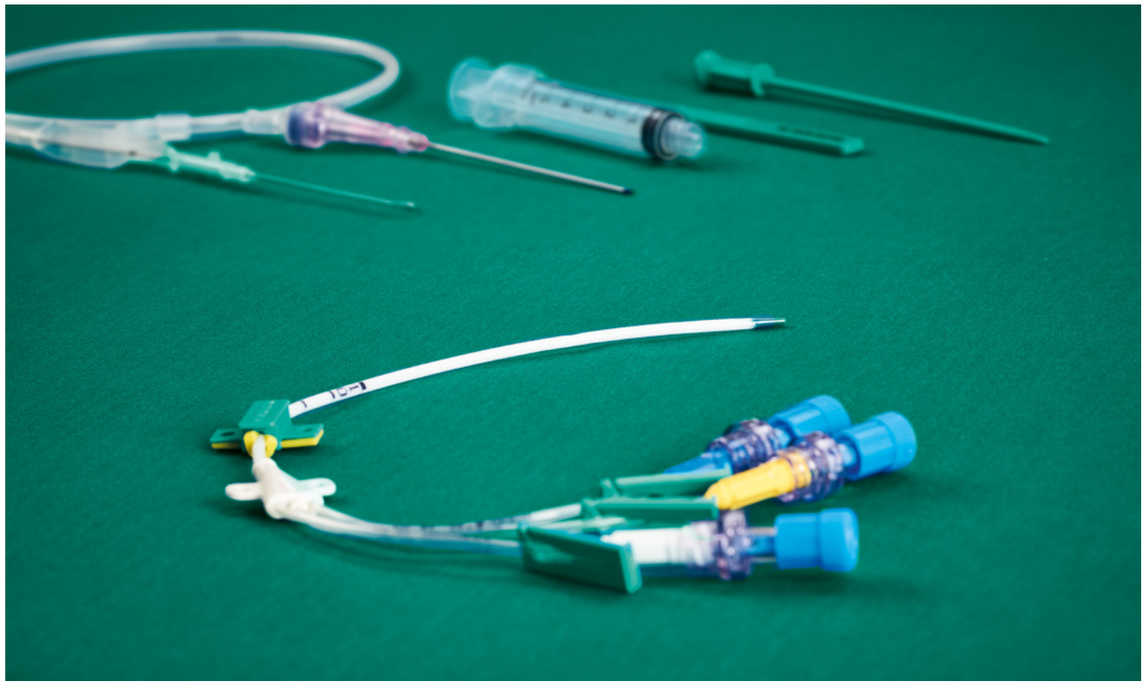
- Staphylococcus epidermidis, Pseudomonas aeruginosa
- Escherichia coli, Enterococus faecalis
- Klebsiella pneumoniae
- Fungi: Candida albicans

4. Key Findings

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

B. Braun solution – non-leaching antimicrobial catheter, Certofix® protect

Material safety



Mechanical stability/patency of Certofix® protect catheter		
Rate of malfunction:	0 %	Krikava et al 2020[26]
Occlusion:	0.6 %	
Thrombotic complications in general: 3–54 %	0 %	
	0.67 %	Clinical Study Report (data on file)

Potential complications	
More than 80 % of the catheters could be placed without any complications.	Krikava et al 2020[26], Spirin et al. 2019[30]
Cannulation rate. Success rate: 99.4 %	Krikava et al 2020[26]
The number of CVC's lumina does not influence CRBSI	Ivanova et al. 2011[27]

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