Replacement intervals of infusion systems

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A recommendation of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI)

B. Braun Melsungen AG refers to the recommendations of KRINKO at the RKI (1) for inquiries about recommended replacement intervals of infusion systems.

The term infusion system refers to all components that lie between the infusion container and the catheter lift.
Three-way taps and valves are part of the infusion system and should usually be replaced with it (2).

According to the provisions of the Medical Devices Act, infusion devices are disposable products intended for single use on patients. The duration of use of single-use products may be limited for hygienic reasons or due to the nature of the material. Thus, KRINKO recommends the use of medical devices that are guaranteed stable against alcohol-based disinfection (proven clinical practice). In addition to the recommendations of the Commission for Hospital Hygiene and Infection Prevention, the CDC (Centers for Disease Control and Prevention) (3) or the Royal College of Nursing (4) also provide information on the handling of single-use products.

References

(1) Federal Health Gazette 2017 · 60:171 -206, DOI 10.1007/s00103-016-2487-4, Prävention von Infektionen, die von Gefäßkathetern ausgehen (Prevention of infections caused by vascular catheters), Published online: 16 January 2017

(2) Federal Health Gazette 2017 · 60:171 -206, DOI 10.1007/s00103-016-2487-4, Prävention von Infektionen, die von Gefäßkathetern ausgehen (Prevention of infections caused by vascular catheters), Part 1 – Nichtgetunnelte zentralvenöse Katheter (Non-tunneled central venous catheters), p. 193, section 3.11.3. Wechselintervall von Infusionssystemen (Aspekt der Infektionsprävention) (Replacement intervals of infusion systems (Aspect of infection prevention)), published online: 16 January 2017

(3) Naomi P. O'Grady, M.D. et al., Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011, Centers for Disease Control and Prevention, p. 19, Replacement of Administration Sets, published online: 15 February 2017

(4) Royal College of Nursing (2016), Standards for Infusion Therapy, ISBN: 978-1-910672-70-9, p. 26, published online: December 2016

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Replacement intervals of infusion systems

The Hygiene Commission of the Robert Koch Institute Berlin recommends the **replacement of an infusion system not more often than every 96 hours** (Cat. IA) – excepted are blood, blood products and lipid solutions:

6 h for blood and blood products (5)

Max. 24 h for lipid solutions

(Cat. IB and/or technical information of the manufacturer)

In the case of continuous administration of lipid-containing medicinal products, the information on the maximum infusion time in the SPC for the finished medicinal products is decisive (Cat. IV). If vascular catheter-associated infection is suspected, the entire system should be changed in accordance with good clinical practice.

The requirements for the specified product life, which are also listed in the KRINKO hygiene recommendations, are hygienically correct handling of infusion systems, solutions or containers (6).

From a technical point of view, we can confirm that material fatigue in terms of physical and mechanical influences can be almost completely ruled out for infusion devices of the type "Intrafix® Primeline / Intrafix® SafeSet" when used as intended.

However, since the hygienic conditions of the use of infusion devices and the number of manipulations (disconnection, injection of medication) are not known in individual cases, the replacement intervals of single-use medical devices must remain the responsibility of the user. Within the framework of the quality management of a clinic / practice, hygiene rules/standards and regulations created are legally binding for the staff.

Use of bacterial and endotoxin filters

In accordance with the Commission's recommendation, 0.2 µm filters (bacterial filters) are not recommended in the infusion system for the prevention of vascular catheter-associated infections (Cat. III). In the case of patients under intensive medical care, particulate filters should be used in the infusion system (air separation, lower systemic inflammatory response-reaction) (Cat. II) (7).

Categories in the Hospital Hygiene and Infection Prevention Directive (2010)	
Category IA	This recommendation is based on well-conceived systematic reviews or individual high-quality randomized controlled trials.
Category IB	This recommendation is based on clinical or high-quality epidemiological studies and rigorous, plausible and comprehensible theoretical deductions.
Category II	This recommendation is based on indicative studies/investigations and rigorous, plausible and comprehensible theoretical deductions.
Category III	Measures for whose efficacy insufficient or contradictory indications exist, therefore a recommendation is not possible.
Category IV	Requirements, measures and procedures to be complied with by generally applicable legislation.

References

(5) German Medical Association (2014), Querschnitts-Leitlinien (BÄK) zur Therapie mit Blutkomponenten und Plasmaderivaten (Cross-Sectional Guidelines (BÄK) on Therapy with Blood Components and Plasma Derivatives), 4th updated and revised edition, p. 15, published online: 2014

(6) See Vonberg RP, Gastmeier P (2007) Hospital acquired infections related to contaminated substances. J Hosp Infect 65(1): 15–23

(7) Federal Health Gazette 2017 · 60:171 -206, DOI 10.1007/s00103-016-2487-4, Prävention von Infektionen, die von Gefäßkathetern ausgehen (Prevention of infections caused by vascular catheters), Part 1 – Nichtgetunnelte zentralvenöse Katheter (Non-tunneled central venous catheters), p. 193, section 3.11.5. Bakterien- und Endotoxinfilter (Bacteria and endotoxin filters), published online: 16 January 2017

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