St Jean de la Neuville, January 15, 2025

FIELD SAFETY NOTICE

To :
The Pharmacist in charge of medical devices,
The Vigilance Correspondent,
The biomedical engineer.

SUBJECT: Field safety notice relating to the risk of solute leakage or air ingress induced by stress cracking of the luer lock during prolonged contact with chlorhexidine solution 2% in 70° isopropyl alcohol of Infineed infusions, transfusion and infusion accessories.

REFERENCE DIDACTIC : FSN2025-01
DESCRIPTION AND REFERENCE OF THE PRODUCTS CONCERNED: INFINEED INFUSION SETS, TRANSFUSION SETS AND ASSOCIATED ACCESSORIES WITH LUER LOCK. (full list attached to this letter)

Dear Customer,

The purpose of this letter is to inform you that Didactic has decided, following several reports of medical device vigilance, to publish this safety information due to a risk of solute leakage or air ingress induced by a cracking of the connectors of INFINEED brand infusion devices (extenders and infusion accessories) during prolonged contact with a solution of chlorhexidine solution 2% in 70° isopropyl alcohol.

DIDACTIC recommends not to use chlorhexidine 2% solutions in 70° iso propyl alcohol (the product characteristics summary of this specialty in its paragraph 4.4, specifies that this solution should not be used for the disinfection of medical-surgical devices. This product characteristics summary is attached to this letter)

The weakening of the connections induced by these cracks ("cracking of plastic materials") has exposed, in a certain number of cases, to serious clinical consequences, such as leakage of drug solutions, risks of infection and even risks of air embolism.

The tests carried out following these cases confirm that the possible associated risk is amplified, especially the greater the quantity of solution and the longer the contact is prolonged.

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The SF2H recommendations (page 35 of the guide on the prevention of infections related to vascular and subcutaneous peripheral catheters dated May 2019) recommend 70° ethyl alcohol for the disinfection of infusion connections, which has the same antiseptic power but presents much less risk of cracking. An extract from this page is attached.

Finally, it is important to allow a time for any alcoholic derivatives to evaporate before proceeding with the connection itself; Indeed, cracking phenomena are described as resulting from a double constraint, both chemical and mechanical.

Please forward this information to your organization as soon as possible, to ensure that Infineed devices are not brought into contact with chlorhexidine solution 2% in 70° isopropyl alcohol.

The ANSM is informed of this safety data sheet and its distribution.

We are at your disposal for any questions or any necessary support, through your usual sales contact, or at the following email address: qualite@didactic.fr

Kind regards

Romain LELIEVRE

Pharmacist, PRRC
Director of Quality and Regulatory Affairs
DIDACTIC

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