



ZOLL Circulation – San Jose
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Sep 24, 2021

RE: URGENT FIELD SAFETY NOTICE (FSN)

Affected Products: INTRAVASCULAR HEAT EXCHANGE CATHETERS (COOL LINE CATHETERS: MODEL CL-2295AE and CL-2295CO, ICY CATHETERS: MODEL IC-3893A and IC-3893CO, QUATTRO CATHETERS: MODEL IC-4593AE and IC-4593CO, AND SOLEX CATHETERS: MODEL SL-2593AE and SL-2593CO)

Dear Valued Customer,

The purpose of this letter is to advise you that ZOLL Circulation is conducting a field safety corrective action (FSCA) on the product labeling for all Intravascular Heat Exchange Catheters that you have purchased from us.

Review of adverse events reported to the FDA between January 1, 2019, and August 8, 2021, identified over 200 medical device reports (MDRs) that reported catheter balloon leaks associated with all ZOLL Intravascular Heat Exchange Catheters, including 7 deaths and 8 injury MDRs. Within the MDRs, there were reports of unintentional infusion of saline into patients, insufficient or aborted treatment, swelling/edema, blood loss, hemothorax, hematoma, death, balloon fragmentation and possible foreign emboli. These devices are used to treat critically ill patients and the role of the device in the deaths and injuries reported in the MDRs is not clear, and causality cannot be determined based on MDR information alone.

Catheter balloon leaks were identified by users by the “air trap” alarm, observation of decreased saline level, and/or observation of a red tinge in the saline bag or tubing. We also noticed some users replaced the saline bag up to 4 times before performing an investigation on whether a leak was present in either the catheter or the Start-up Kit (SUK) tubing. In some of the reported events, users were unclear on what action to take when a depleted saline bag is noticed during therapeutic use.

Systemic overload of saline fluid can potentially lead to dependent edema and subsequent skin breakdown, internal organ fluid overload, with subsequent overloading of the brain, lungs, or heart. In some cases, this fluid overload may lead to life threatening events. Based on the reported MDRs, ZOLL has volunteered to conduct a customer communication campaign and modify the catheter Instructions For Use (IFU) to provide clarity on the safety and effective use of the ZOLL Intravascular Heat Exchange Catheters.

The revised IFU now includes the following (see page 3 for the detailed leak investigation instructions, warnings, cautions, and adverse reactions associated with leaks from either the catheter or the SUK):

- Detailed step-by-step instructions on how to investigate/confirm potential leaks from either the catheter or the SUK.
- Multiple warning/caution/adverse reaction statements instructing users to avoid replacing depleted saline bags prior to identifying the location of the leak and taking the appropriate mitigation steps.

Actions Required (By the Customer/User):

1. If you have any questions, please contact Doug Lam (Director of Quality and Compliance) or

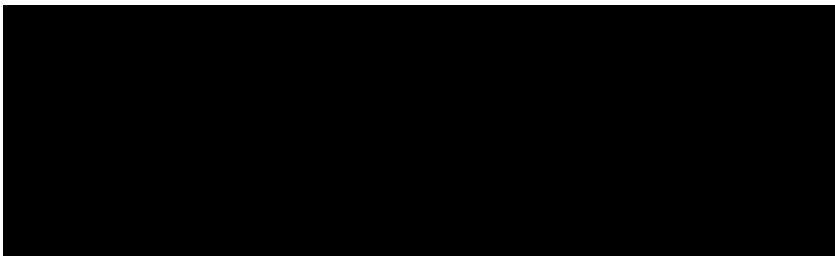
Sam Nanavati (VP of Quality and Regulatory Affairs) at IVTM_Recall@zoll.com.

- Provide this notice (letter) to all those who need to be aware within your organization or to any organization where the affected devices have been transferred.
 - Maintain a copy of the FSCA notification and attachment with the IFU for reference. ZOLL will provide a method to obtain the updated IFU once it is released.
 - If you experience any serious incidents with the use of our products (catheters), please report them to ZOLL and the Competent Authority.
 - Sign and email the attached Form (Customer Acknowledgement Form) to IVTM_Recall@zoll.com acknowledging that you have read and understood the content and requirements on this FSN (letter) within 5 working days from receipt of this notice.
2. If you do not believe that you are the right person to implement the above-mentioned actions, please forward this letter to the right person in your organization.

Actions Underway by ZOLL:

1. ZOLL has submitted a revised IFU to the Notified Body with heavy focus on providing clear instructions to the users on how to investigate/mitigate a potential catheter leak whenever a depleted saline bag is noticed by the users.
2. ZOLL will provide all affected users a method to obtain the revised IFU once it is reviewed and cleared by the Notified Body.
3. ZOLL is retraining all Sales staff to the revised IFU.
4. ZOLL has informed the Notified Body and all appropriate Competent Authorities in EU about this Field Safety Corrective Action.

If we could be of any further assistance in this matter, please contact ZOLL Technical Support Line at 1 (800) 348- 9011 or ZOLL 24/7 Temperature Management clinical support line at + 1 (877) 225-7487.



Key Revised Sections of the Instructions For Use That Must be Read:

WARNING. Intraluminal or balloon leakage. Intraluminal leakage (between the saline lumen and infusion lumens) or balloon leakage is a potential catheter failure mode. In the event of such a failure, sterile saline from the cooling circuit is introduced into the patient. Intraluminal leakage or balloon leakage is typically associated with a fluid loss alarm once the saline bag has been depleted and stops the system. **Always investigate fluid level alarms.** The cooling circuit is a closed loop system – usually fluid loss alarms indicate a breach somewhere in this closed loop. With any fluid loss alarm, check both the integrity of the catheter and the Start-Up Kit (see below).

WARNING. If you notice a depleted saline bag or an air trap alarm, do not replace the saline bag prior to identifying the location of the leak and taking the appropriate mitigation. Check for system leaks according to the instructions in the Check for a Start-Up Kit leak and Check for a catheter leak sections below. (Note that a leak could be external or internal.)

Replacing the saline bag repeatedly without investigating the leak or loss of saline may result in unintended infusion of saline into the patient. Saline infusion may lead to the following adverse effects: local swelling that can cause subsequent local tissue damage; systemic fluid overload that can lead to dependent edema and subsequent skin breakdown; internal organ fluid overload, with subsequent overloading of the brain, lungs, or heart. In some cases, this fluid overload may lead to life threatening events.

Caution. The console emits an alarm when the saline bag is empty. The bag must be completely empty and additional saline must have drained between the saline spike and the air trap for the saline level in the air trap to drop sufficiently to trigger the alarm.

Check for a Start-Up Kit leak

1. Check the air trap for condensation. If the air trap shows signs of condensation, wipe the air trap and reinstall it in the console. In the case of an air trap alarm, verify that the air trap alarm is cleared after this step.
2. Carefully check the saline path from the saline bag to the console for any leaks. Check if there is saline on the floor, console, or the patient's bed.
3. If there is any saline on the floor, console, or the patient's bed, check that the Luers on the catheter and Start-Up Kit are not cracked or damaged and that the connections are tight enough to prevent leaks.
4. If you find a leak in the Start-Up Kit, replace the Start-Up Kit and see if there is also a leak in the catheter.
5. If you do not find a leak in the Start-Up Kit, there is likely a leak in the catheter. Investigate further.

Check for a catheter leak

1. Disconnect the Start-Up Kit from the catheter. Properly cap both the catheter and Start-Up Kit using an aseptic technique.
2. Fill a sterile 10 mL slip tip syringe with sterile saline.
3. Connect the syringe to the IN Luer of the catheter and disconnect the OUT cap. Infuse 10 mL of saline – the saline should flow out the OUT Luer. If the saline does not flow out of the OUT Luer, a catheter leak is indicated.
4. Cap the OUT Luer and pull 5 cc of vacuum. Sustain for at least 10 seconds. Up to 4 mL of saline (not blood) should enter the syringe and you should be able to maintain the vacuum. If traces of blood are seen in the syringe or vacuum cannot be maintained, it indicates a catheter leak.
5. If you find a leak in the catheter, replace the catheter.
6. Replace the saline bag and re-prime the Start-Up Kit.
7. Ensure leak-tight Luer connections to the Start-Up Kit and continue the therapy.

Customer Acknowledgement Form

1. Customer Details	
Healthcare Organization Name	
Organization Address	
Contact Name	
Title or Function	
Telephone Number	
Email	

2. Customer action undertaken on behalf of Healthcare Organization	
<input type="checkbox"/>	I confirm receipt of the Field Safety Notice (FSN) and that I read and understood its content.
<input type="checkbox"/>	The information has been brought to the attention of all relevant users.
Print Name	
Title or Function	
Signature	
Date	

3. Return acknowledgement to sender	
Email	IVTM_Recall@zoll.com
Deadline for returning the customer reply form	01 October 2021

It is important that your organization takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organization's reply is the evidence we need to monitor the progress of the corrective actions.