

URGENT MEDICAL DEVICE RECALL

COOLIEF* TRANSDISCAL* Cooled Radiofrequency Kit in Malaysia

14 August 2024

Re: To Global Healthcare Logistics (M) Sdn Bhd

Dear Customer,

This Field Safety Notice is being issued as it was identified that a specific lot of COOLIEF* TRANSDISCAL* Cooled Radiofrequency Kit was incorrectly released from facility, during the quality check, with a report considering it as pyrogenic, based on the Endotoxin Assay test report.

This advisory notice applies to the following lot number and product code summarized in Table 1- Impacted Products.

Table 1 – Impacted Products

Product Code	Lot Number	Quantity	Product Name
TDK2-17-150-6	30290512	44	COOLIEF* TRANSDISCAL* Cooled Radiofrequency Kit

When does this malfunction occur and what are the potential risks?

Due to an error in the documentation, a single lot (30290512) of COOLIEF* TRANSDISCAL* Cooled Radiofrequency Kits was released for distribution with failed sterility testing. Specifically, the set of samples tested were found to have an endotoxin concentration above the acceptable test limit.

The presence of a higher than acceptable endotoxin concentration may increase the risk of patients developing a severe inflammatory response after being exposed to affected devices. While Avanos has not received any reports of adverse events associated with this issue, due to the increase in risk to patients the decision has been made to recall this device from the distributor.

What steps can the user take to avoid the potential risk of this issue?

Our ship history records show that your facility has received the affected lot. Consequently, Avanos requires that you immediately take the following actions:

1. **CHECK** all storage to determine if any impacted product remains within your possession.
2. **UNUSED INVENTORY**
 - a. **SEGREGATE** and **QUARANTINE** the devices according to your facility's procedures.
 - b. **RETURN** the completed Annex 1 to narissa.isa@avanos.com within five (5) business days of receipt of this letter.
 - c. Once all affected devices have been quarantined and reported to Avanos, **DESTROY** all affected devices per your facility procedure.

AVANOS

We appreciate your understanding and cooperation with this Field Safety Notice and ask you to immediately instruct your personnel accordingly.

We apologize for any disruptions this issue may cause your facility.

Sincerely yours,



Tamara Cardona
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Contact person of this notification

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Annex 1

Acknowledgment of receipt

REQUIRED: I have **read and understood** the recall information and **will follow the instructions** provided in the attached letter.

We have checked our inventory for the affected products listed in Table 1 of the URGENT – Field Safety Notice COOLIEF* TRANSDISCAL* Cooled Radiofrequency Kit in Malaysia and confirm that: (**Please select one option below**)

our facility has **no inventory** of the affected products listed in Table 1, and no further action is required.

the below quantities of affected product have been located in our facility, quarantined, and **will be destroyed and discarded** per business processes.

Product Code	Lot Number	Quantity in Inventory	Product Name
TDK2-17-150-6	30290512		COOLIEF* TRANSDISCAL* Cooled Radiofrequency Kit

Please provide contact information:

Account number:	Facility Name:
Contact Name:	Phone Number:
Signature:	Email: