

Customer
[REDACTED]

8. August 2019
[REDACTED]

Urgent Safety Information
Refers to the product: Sets with cardboard kidney dishes

Dear Customer,

With this letter we would like to inform you about a possible problem with the sterilisability of the cardboard kidney dish which is included as a carrier tray for sterile instruments/utensils for the operating theatre area as a part of your sets.

Intended use

Kidney dishes are intended for the collection of body excreta and/or as a collection container for smaller medical waste for short-term use.

The following has been established

Our supplier (see letter in the appendix) has identified non-sterile carrier dishes during an inspection using a standard method for determining the total bacterial count.

Possible hazards

This problem can lead to a re-contamination of the surgical utensils when using a non-sterile surgical kit in the operating theatre area and thus to a possible infection of patients.

As a preventive safety measure, we have decided to recall all sets containing cardboard kidney dishes.

Please check whether you have any inventory of the products listed on the following page and make sure that any further use is excluded.

Please confirm receipt of the safety information in your reply letter. If there are still any products in your inventory, please enter the quantities of the respective products beside the corresponding batch numbers so that we can arrange for their collection.

Until further notice, your sets will be fabricated without cardboard kidney dishes.

We would like to apologize greatly for any inconvenience caused by this callback and thank you for your understanding!

Yours sincerely,
[REDACTED]
[REDACTED]

Reply

to the following email address

QM-Team@angiokard.de

or

by fax to: 04465/9484-74

Customer:

With our signature we confirm the receipt of the safety information.

No, there are no sets of the sets listed below in our inventory

Yes, there are still some batches in our inventory

Article number	Batch	Description	Delivery year				Inventory (please specify)
			2016	2017	2018	2019	

Contact person for queries: _____

Tel. no. _____

Email
address: _____

Date/ Signature: _____