

ANGIOKARD Medizintechnik GmbH · Industriestraße 15 · D-26446 Friedeburg

Industriestraße 15
D-26446 Friedeburg
Fon: +49 4465 9484-0
Fax: +49 4465 9484-74
customer-service @angiokard.de
www.angiokard.deAuftragsannahme :
customer service:
Fon: +49 4465 9484-82
Fax: +49 4465 9484-748. August 2019
Tel.: 04465-9484-93
Email: s.janssen@angiokard.de**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!

.....
.....Sitz der Gesellschaft:
D-26446 Friedeburg
Industriestraße 15
Geschäftsführerin: Ulrike MarczakHandelsregister: HRB 108030
Amtsgericht Hamburg
Ust-IdNr.: DE267647320
St.-Nr.: 7120011031Bre'fner Landesbank Oldenburg
BLZ: 290 500 00 Kto.: 3030915008
SWIFT-BIC: BRLADE22XXX
IBAN: DE32 2905 0000 3030 9150 08Oldenburgische Landesbank AG Oldenburg
BLZ: 280 200 50 Kto.: 8402462900
SWIFT-BIC: OLB0DEH2XXX
IBAN: DE30 2802 0050 8402 4629 00

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.

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

D Yes, there are still some batches in our inventory

Article number	Description	Batch	Delivery year				Inventory (please specify)
			2016	2017	2018	2019	
013.0001 .1	Wondreinigingsset	176945-000		50			
		187585-000			50		
		192836-000				50	
960129.13	Angiokit Radiologie	167279-000	90	85			
		167303-000		180			
		169726-000		150			
		170464-000		150			
		172428-000		200			
		173638-000		100			
		174483-000		105			
		175590-000		120			
		176750-000		90	30		
		177518-000				120	
		178543-000				100	
		179419-000				120	
		180601-000				75	45
960131.4	Punktie Set Radiologie	166877-000	270				
		168038-000	30	135			
		168535-000		270			
		170861-000		270			
		171882-000		240			
		172635-000		205			

