

Field Safety Notice

Single use endoscope cleaning brush

Recall

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For Attention of: Healthcare professional, Vigilance correspondent

The purpose of this letter is to inform you that LTA MEDICAL is conducting a recall of its brushes.

Intended use:

The brushes are single use and are intended for cleaning flexible endoscopes.

Problem Description:

This recall follows reports of the brush detaching from its stem.

Risks for the patients:

The use of these brushes may lead to:

- The brush getting stuck inside the endoscope.
- The risk of the brush becoming lodged in the patient's body during the use of the endoscope, potentially leading to infections.

Affected Products:

Below is the list of relevant references.

Reference	Lot number	GTIN	
100-1824/50	24300356	3760274483875	
100-1824/50S	24490097	3760274488245	
200-1824/5	24370036	3760274487286	
	24250255		
	24260007		
200-1824/50	24270186	3760274483967	
	24370015		
200-1824/50	24430055	3760274483967	
	24470184		
BSC-1824	24480378	3760274485220	
	24490044		
BRONC-STERIL	24500091	3760274487583	
D1111825ND/25	24390035	3701571301493	
	24380158		
D111825ND/25	24420142	3760274484865	
	24430143		
D11-2632/25	24440144	3760274484377	
D11-3748/25	24420037	3760274484391	
	24270165		
D-1824/25	24370019	3760274484346	
	24380294		
D-2632/25	24420160	3760274484360	
D-3748/25	24450027	3760274484384	
DI-3748/25	24420049	3760274484483	
	24420038	3760274484780	
EB100-18/25	24430045		
	24470223		
	24290027		
EB-1824/25	24340172	3760274484117	
	24420183		
	24370021		
	24450193		
EBI-1824/25	24470183	3760274484148	
	24480008		
	24510048		
NGEE-1824	24400066	3760274485299	
	24410166		
D 4004/65	24340170	3760274484179	
R-1824/25	24350099		
	24290032		
RI-1824/25	24400219	3760274484209	
	24490283		
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SD11-3748/25	24440165	3760274484575	
	24250254		
SD-1824/25	24420170	3760274484520	
	24360100		
SD-3748/25	24450030	3760274484568	
SEB100-18/25	24340137	3760274484827	
	24290034	3760274484230	
SEB-1824/25	24350102		
	24420185		
CEDI40040/05	24310104	3760274484834	
SEBI10018/25	24360018		
CEDI40040/05	24430134	0700074404004	
SEBI10018/25	24480027	3760274484834	
	24310118		
SR-1824/25	24380300	3760274484292	
	24420186		

Please verify whether you have any of the products mentioned.

Instructions for the Customer:

Identification and Quarantine: As soon as possible, identify the products in your inventory and quarantine the affected ones.

Return of Products: Return the affected products to LTA MEDICAL by sharing the information to our QARA team through mail address $\underline{regulatory.lta@getinge.com}$. Our back office will organize the replacement of the products.

Acknowledgment: Please complete and return the attached acknowledgment form, even if you do not have any affected products in your inventory.

LTA MEDICAL has notified the Competent Authorities of this action.

We sincerely apologize for any inconvenience this may cause. Patient safety remains our top priority, and we thank you in advance for your prompt action. For any questions related to this communication, please contact: regulatory.lta@getinge.com

Sincerely,

Jerome POLENNE

Managing Director / PRRC

Attachments:

Acknowledgment form



regulatory.lta@getinge.com

LTA MEDICAL 27 Rue Albert Einstein, 93000 Bobigny 01.48.58.33.55

Acknowledgment of receipt

I, the undersigned, hereby acknowledge receipt of the urgent safety notification and confirm that I have fully understood the actions required. Furthermore, I certify that this safety notification has been duly distributed to the relevant personnel.

Reference	Lot number	Quantity
Country:	Facility :	
Date :		Name (function) :
		Signature :
Document to be returned to:		