

URGENT FIELD SAFETY NOTICE

RECALL OF SPECIFIC GYRUS ACMI ARMSTRONG VENTILATION TUBES LOT NUMBERS FROM THE FIELD

Attention: Otolaryngology Department, Operating Room Manager, Risk Management Department

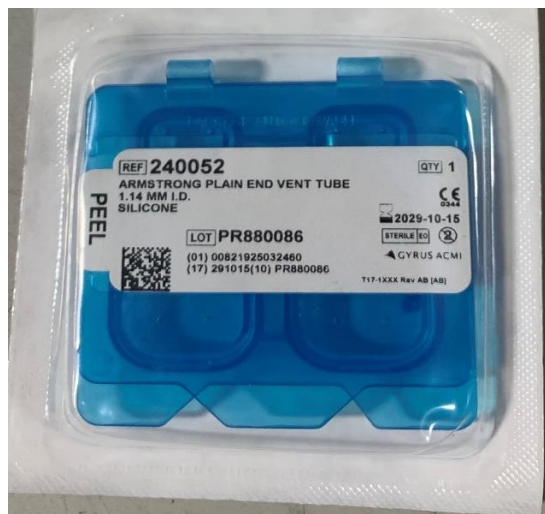
Description	Model Name	Article Number	LOT number
Gyrus ACMI Armstrong Ventilation Tubes	ARMSTRONG SIL DRAIN TUBE, 6x	240052 (article number on the packaging) EG240052 (ordering article number)	PR867938, LZ863139, LZ850409

Dear Health Care Practitioner:

Olympus has become aware of an issue that requires your attention. This Field Safety Notice pertains to the Armstrong ventilation tubes ("Armstrong vent tubes") referenced above. The Armstrong vent tubes are intended to be used to ventilate the middle ear subsequent to otitis media, which is inflammation/infection of the middle ear.

Due to an anomaly in packing, the Silicone Shepard vent tube was mispackaged into the immediate clamshell package and outer box container labeled as Armstrong vent tubes. Olympus has received complaints of users receiving Silicone Shepard vent tubes instead of the Armstrong Vent tube stated on the package label. (see picture 1) of the clamshell package) The wrong vent tube is an inconvenience with little to no potential of injury as the intended use of the various shapes and configurations of vent tubes is the same.

The lot number can be found on the individual vent tube package and the outer package labels.



Picture 1: Clamshell package



Actions to be taken by the user:

Our records indicate that your facility has purchased one or more of the above-referenced Armstrong vent tubes. Therefore, Olympus requires you to take the following actions:

1. Immediately inspect your inventory for the affected Armstrong vent tubes and identify the specified lot numbers.
2. Return your inventory of the above mentioned lot numbers to your local Olympus organization at XXXXXX to get a free of charge replacement/credit note in return. Indicate on the enclosed Reply Form that you have received and understood this Field Safety Notice as well as the quantities per LOT number you are going to return to Olympus. Olympus will provide a free of charge replacement or a credit note to your facility for any returned affected products.
3. Send the completed Reply Form back to your Olympus representative (xxx) latest by XXXX regardless of whether you have any affected inventory at your facility.
4. If you have further distributed this product, identify your customers, forward them this Field Safety Notice including the attachments and appropriately document your notification process.

Olympus regrets any inconvenience caused and fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact Olympus directly at (XXX) XXX-XXXX from Monday till Friday or by e-mail at XXX.Sincerely,

Olympus Contact Name



REPLY FORM – QIL 153-005

OLYMPUS URGENT FIELD SAFETY NOTICE		
RECALL OF SPECIFIC GYRUS ACMI ARMSTRONG VENTILATION TUBES LOT NUMBERS FROM THE FIELD		
[Name & Address of Hospital/Medical Facility]		
[Dept/Attn]		
[Date]		
Model Name	LOT No. to be returned to Olympus	Quantities to be returned to Olympus (please indicate if a complete box (6pcs) or single vent tubes are still available. If no Armstrong vent tubes will be returned please insert 0)
ARMSTRONG SIL DRAIN TUBE, 6x (240052/EG240052)	PR867938	
	LZ863139	
	LZ850409	

I herewith acknowledge the receipt of your Field Safety Notice (FSN).

Further I confirm that I have informed the responsible personnel on the actions required in the FSN for the specific Armstrong vent tubes and transferred the information to all affected departments on which this action may have an impact. I confirm that I have no more affected LOTs on site besides the above mentioned quantities which I will return to Olympus immediately.

Name (Signature) _____

Name (Print) _____

Position _____

Please fax this completed reply form to Olympus at [contact number] latest by XXXX