

URGENT FIELD SAFETY NOTICE

RECALL OF A SPECIFIC GYRUS ACMI SMART STAPES PISTON LOT NUMBER FROM THE FIELD

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

Description	Model Name	Article Number	LOT number
Gyrus ACMI Smart Prosthesis	Smart Piston 0,4mm x 5,25mm	70142168 (article number on the packaging) EG70142168 (ordering article number)	PR898678

Dear Health Care Practitioner:

Olympus has become aware of an issue that requires your attention. This Field Safety Notice pertains to the Smart Prosthesis (“Stapes Piston”) referenced above. The Stapes Piston are intended to replace a portion of the ossicular chain that has been lost due to disease, trauma or congenital defect.

Due to an anomaly in packaging, a quantity of Stapes Piston were packaged with the outer carton label stating the contents were the 70143662 (EG70143662) Stapes Piston but the inside package contents was the 70142158 (EG70142158) Stapes Piston.(see picture 1) Olympus has received a non-injury complaint of a user receiving the mispackaged Stapes Piston. The insertion of an incorrect length Smart Piston may cause vertigo and loss in the inner ear function.



Picture 1: Carton label (left) and inner packaging label (right)

Actions to be taken by the user:



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

1. Immediately inspect your inventory for the affected Stapes Piston and identify the specified lot number.
2. Return your inventory of the above mentioned lot number 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,



REPLY FORM – QIL 153-004

OLYMPUS URGENT FIELD SAFETY NOTICE RECALL OF A SPECIFIC GYRUS ACMI SMART STAPES PISTON LOT NUMBER 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 (If no Smart Pistons will be returned please insert 0)
Smart Piston 0,4mm x 5,25mm (70142168/EG70142168)	PR898678	

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 Smart Pistons 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