

Date: 25th May 2019

Subject: Urgent Field Safety Notice for Pennine Healthcare Product reference: PHFSN0219

Dear Customer,

I will like to inform you that Pennine Healthcare has voluntarily initiated a recall to remove multiple LOTs of the products detailed within the attached Field Safety Notice (FSN) reference PHFSN0219. The affected products are Feeding Tubes, Nelaton Catheters, Levins Tubes, Rectal Catheter, Ryles Tubes, Suction Catheters, Stomach Tubes, Medical Packs. Kindly refer to the attached FSN for the affected products and its batches. You are also advised to perform the required actions stated within the FSN.

Please do not hesitated to contact Optimal Medical Products Pte Ltd at 62535247, should you require further clarification on this matter. Thank you for your kind attention.

Yours Sincerely,



Alex Lim Optimal Medical Products Pte Ltd General Manager

Cc: Chairman Medical Board and relevant Head of Departments



Urgent Field Safety Notice

Affected Product	ONLY CERTAIN CODES - Note: see Addendum "A" for full details.	
	Feeding Tubes, Nelaton Catheters, Levins Tubes, Rectal Catheter, Ryles Tubes, Suction Catheters, Stomach Tubes, Medical Packs.	
Type of action	Voluntary Recall / Product Disposal	
Pennine Healthcare Ref:	PHFSN0219	
Product Code(s)	Various – As per Addendum "A"	
Lot Number	Various – As per Addendum "A"	
	An example in this range of LOT numbers is: "06D15"	

8th May 2019

Dear Customer,

Description of the problem:

This communication is to inform you that Pennine Healthcare has voluntarily initiated a recall to remove multiple LOTs of the products detailed within this Field Safety Notice (FSN).

Through post production activities we have identified that there is a small possibility that the products detailed in this FSN may not have been manufactured with the correct eyes (holes) punched into the tube. The defect in the products should be visible to a trained user, however, if the user missed the defect, it would mean the products would not perform to the required expectations. There is a potential for serious harm should an alternative non-defective device not be available at the time.

Actions to be taken by the distributor / user:

- 1. Identify and quarantine all stock of the affected batch / LOT numbers immediately.
- 2. If you are a distributor you are required to confirm to Pennine that you have provided this FSN to all your customers and contained any returned stock.
- 3. Complete the attached Reply Form (Addendum B) to confirm that you have read and understood the contents of this Field Safety Notice.
- 4. Upon receipt of the completed reply form, Pennine Healthcare will arrange for the return or confirm how destruction of the affected product should be organised. (Proof of destruction and records of type and quantities involved will be needed).
- 5. For further clarification of quarantined or affected stock replacements or credits, please contact your local distributor or if supplied directly from Pennine our customer services using:







- UK markets <u>customer.services@penninehealthcare.co.uk</u> tel. +44 (0)1332 794 880
- International Markets <u>exports@penninehealthcare.co.uk</u> tel. +44 (0)1332 794 880
- 6. Maintain awareness of this Field Safety Notice until all stock of the affected LOT batch has been destroyed or returned to Pennine Healthcare.

Identification of affected products:

Use the Product Codes and LOT numbers as detailed in Addendum A to identify the affected devices.

Transmission of this Field Safety Notice:

This notice should be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please maintain awareness on this notice until all required actions have been performed within your organisation.

We confirm that this field safety corrective action has been communicated to the relevant competent authorities and distributors.

Pennine is committed to providing quality products to our customers and we sincerely apologise for any inconvenience this notice may cause.

For and on behalf of Pennine Healthcare:



Simon Motlib Quality Assurance Manager





Addendum A - Affected Medical Devices - (NB - Only these product codes are affected)

Product Code	Batch Numbers
Medical Pack FRP- 04400	02C16,09C16,10M15,15D16,17B16,
Medical Pack FRP- 04700	05K18,06L18,12B18,19M18,29K18,
Medical Pack FRP- 04701	04B19,14C19,17D19,23A19,
Feeding T	ubes (FT)
FT- 1608/105	01C17,01M17,06C18,07L16,09E18,09L17,11K18,12J17,18J14,
FT- 1610/105	09F14,11H17,15J15,17G15,17L14,28A19,30K17,
FT- 1908/105	03J14,04H16,04J15,06H15,08A19,09B15,09F14,09G15,10G17,11B19,11G14,11L15,13E15, 15D16,16K17,16L18,17D18,18C19,18K18,21L17,22M14,25G17,27E14,27L18,29H17,30G14 ,
FT- 1908/60	01C16,02G15,04A18,04D19,04M18,06K14,12C18,13L18,20F17,20J18,25K18,26D16,
FT- 1910/105	03G14,18J14,
FT- 1910/60	04M18,10A19,20J18,25K18,
Levins Tul	bes (LT)
LT-2208	01C17,01E15,01M17,02B18,04G18,05F15,07H14,07L16,09F17,10G17,11H17,13F16,16B15 ,17F15,21A15,22H16,22K18,25E18,28C18,28K14,30A15,30D18,31C15,
LT-2210	01B17,01E15,02M16,04G17,05F15,09F17,11H17,12K16,13F18,14D15,15A15,17D18,17F15 ,17H18,18B16,19C15,23E16,24L17,26E15,26F14,27B18,27C17,28A19,29A16,29G14,30D18 ,
LT-2212	01B17,01E15,01M17,03E17,03K17,04B16,05F15,06D18,09F14,12M14,15A15,15A18,16B15 ,16F15,16M16,17B16,17K14,18L14,18M18,19H15,19M16,22A16,22D16,22E15,22F17,22H1 6,23D18,23E16,25E18,26K15,27G18,29B16,30D18,31C17,18J14,
LT-2214	01B17,01C17,02D19,02M16,03G14,03K16,04B16,04E18,06H15,06L14,06M17,07F18,08F15 ,09E14,10D17,10L16,11B16,12E15,12M14,13A16,13K17,19E14,19F18,20K14,20K15,21A15 ,21D16,22H14,22M16,24A18,25F14,25J18,26E15,26J17,26K15,27K16,27L14,29F17,29K18, 31E16,
LT-2216	01J16,01L18,02D19,02E14,03E17,03G17,03H17,03K17,04J15,05A16,05B19,05M16,06C17, 06C19,06D18,06K15,06M17,07L16,11B16,11D18,11G14,11J14,11K18,12A18,12E14,13F16, 14A19,14C18,14D15,15A15,15D16,16F17,16L16,16L18,17B16,17E16,17E18,17L14,19C15, 19E14,19J14,19J16,19J17,22C19,22F15,22G14,22G16,22M14,23G15,24B16,26E15,27E14, 27F18,27G17,27G18,28B17,28C17,28K15,29B16,30A18,30D18,30K17,
LT-2218	01K18,01M17,02E16,02M16,03K17,04E18,05A16,06C17,06D17,09G15,10B16,10C15, 10D19,10G17,11D16,12E14,13F18,13K15,14C18,15A15,15B17,15J17,16F15,16G18,16L18, 17E16,17L16,18H14,18L15,19J14,20D15,21A19,22F17,22G14,22M14,22M16,24A18,26E15, 26H16,27L14,28H15,28K15,29F16,29K18,30G18,





LT-2220	01J16,02G14,03E18,06A17,08F18,09K17,13G16,17A17,17G17,19B15,27F15,29E15,31C17,
LT-2408	04B16,04H16,04J15,05D16,08A19,11G14,11H16,12J17,18H16,18J14,18L14,22G15,25F14, 25J14,26J17,30J16,
LT-2410	03G14,06C18,08A19,08D16,09F14,15K18,16J16,17G15,17L14,18J14,23G15,29A16,30K17,
LT-2412	01M17,03G14,04J15,06C18,06E14,08D16,11H16,14D15,15K18,16G15,16M16,17L14, 18G18,19J14,20C18,24J15,26J16,27C17,29B16,30D18,31C17,
LT-2414	02E14,03D17,03G14,03M15,04B16,04H16,05D16,05K15,08J16,09F17,11H16,14C18,14D15 ,14M17,15C17,15D16,15J15,15K18,16F14,16G15,17H17,17L14,19G18,19J14,22M16, 25G17,25J14,27K16,30A15,30E17,
LT-2416	02E14,03G14,04H16,05D16,06C18,06D17,06K15,07L16,08M15,10B15,11A17,11H16,11K18 ,14A19,14D15,15D16,16F14,16F17,16J15,17H17,18L14,19J14,19J16,20M17,22E17,22G15, 22M14,23G18,24B16,26J16,27C17,27G17,29F16,30D18,30K17,
LT-2418	03A18,03H17,03M15,04B16,05F14,08A19,09B15,10C15,10G17,11D16,11H17,12A18, 14D15,15D16,15G14,15K18,16J15,17D18,17L14,19H15,19J14,20K16,22G15,22M16,25G17 ,26C18,28G16,29B16,30E17,30J16,31C17,
LT-2420	02G14,02L17,03B15,10L14,16J16,18J14,
Nelaton Ca	theters (NC)
NC- 1220/SW	02J16,03F16,03G14,03K14,04A19,04D17,04G18,06B17,07C18,07D15,07L17,08E18,08F18, 08L16,09A15,09L15,10D18,10G15,11K17,16D15,16G18,16L15,17E17,18B19,18K18,20J17, 20L14,21J16,22H16,22H18,22J14,24B15,24G14,25E16,26D18,28J18,29E15,30K15,
NC- 1220/SW/ 1	04A17,06B17,07D15,10C17,11J18,20L14,24B16,25J15,26K15,
Rectal Catl	neters (RC)
RC-1820	02C16,02J16,03F16,04A17,04A19,04D17,05F14,06B17,07C18,07D15,08F18,10D18,10M18, 12D16,13M17,15D19,16G18,16M14,17E17,18B19,19K17,20G17,22H18,23B17,24B15, 24F14,25H15,26K15,26K16,28J18,29F15,
RC- 1820/1	01H14,06E15,07C18,07K15,09A15,09H17,10D18,11A18,11J18,12D16,16L15,17E17,18B19, 20G17,22H16,22H18,23B17,26K16,28H14,28J18,29F15,29F16,30L17,
Ryles Tube	es (RT)
RT-2008	01M17,02B18,03M14,04B16,04H16,04J15,05C15,05E15,08A15,08B17,08J16,09E18,09L17, 11B19,11H17,12E14,13E15,14A19,15B17,16B15,16L18,17H18,18C19,18G18,18H16,19G17,20D15,21L17,22B18,22K18,23E16,26H16,26J17,27E14,28K14,28K15,31C15,31E16,
RT- 2008/BUL K	06L15,16C17,21C16,
RT- 2008/L	04G18,09F14,11K18,17K14,22H16,22K18,28C18,
RT-2010	01E15,02B18,02M16,03J14,04G17,04J15,05A16,05F15,06C18,06K15,06L14,07B17,07L16, 08A15,09C15,09E16,09F14,09F17,10D17,11A17,11H17,13B18,13F18,13M18,14D15,14E15 ,14J15,15K18,16J16,16L16,16L18,17D18,17G15,17H18,18C16,18C19,18L15,19E14,19G17, 20M17,21F16,23B15,24J18,24L17,25C15,25E18,25G17,26H16,27C17,27K16,27L14,27L18, 28A19,28K14,29G14,30A15,30G18,31E16,
RT- 2010/BUL K	10A17,15C16,25J17,27C19,14M15,





RT- 2010/L	03L15,04G17,04H15,05F15,06K15,08D16,08K18,09B15,09E16,09F17,13B18,13E15,13F16, 13F18,13M18,15D15,15J17,16K14,16L16,17L14,18H16,19G17,19H15,20B17,22F15,22K18, 24A18,25E18,26C18,26H16,29A16,31G14,
RT-2012	01L18,01M17,03E17,03F14,04B16,04H15,05C15,06C17,06C18,06D17,06E14,06K15,06L14, 07C16,07H14,08A15,08J16,08M15,09E16,09E17,09F14,09F17,10D17,10L16,11D18,11G18, 11K17,11K18,11L15,12K16,13E15,13F16,13F18,13G16,13J18,14A19,14K15,15A18,15J17, 16G15,16K14,16L16,16M16,17A17,17H17,18D19,18G18,18H16,18L14,18M18,19G17, 19H15,20B17,20C18,20D15,20M17,21L17,22B18,22C19,22D16,22F17,22H14,22J14,22K18, 22L18,23D18,23K17,24A18,24H18,24J18,24L16,24L17,25E18,26C19,26J16,26K15,27C17, 27E15,27G17,27H15,27L14,28A19,29C16,29F15,29G14,30G18,31C15,02K14,
RT- 2012/BUL K	02C17,06L15,12A18,21C16,
RT- 2012/L	05J17,07C16,08A15,08K18,09E16,09F14,11D16,11G18,11H16,13E15,13F16,13F18,13J18, 14A19,15D15,15J17,16F15,16G15,16L16,18B16,18D19,18M18,19H15,20B17,21F16,21L17, 22L18,23E16,24H18,24J15,24J18,27E14,27G17,30D18,
RT-2014	01D15,01J16,01K18,02B18,02E14,02F14,03A18,03H17,03J18,03K16,04D19,04E18,04G18, 04J14,05H15,05M16,06C15,06M17,07F18,07H14,07K15,08A15,08A19,08F15,09G15,09L18 ,11B19,11D17,12E14,12E17,12F17,12L15,12M14,13B18,13E15,13K17,13L17,14C18,14F16 ,14K16,14M17,15A15,15B17,15C17,15J15,15J17,15M15,16F14,16K17,16L16,16L18,16M16 ,17A17,17E18,17H17,18C16,18H14,19G18,19H15,19J14,20D15,20F18,20K14,20K15,21A19 ,21D16,22K18,23K17,24A18,25F14,25G17,25J18,26H16,26J17,26L15,27B18,27K16,27L18, 28K15,29A16,29B16,29F15,29F17,29G14,29K18,29L18,30A15,31C17,31K17,
RT- 2014/BUL K	03J15,08F17,10D17,11C16,14J17,15F15,17H16,23D15,24B16,27E16,
RT- 2014/L	01K18,02D19,02F14,03G14,03H17,03K16,05A16,05D16,05K15,07L18,09C15,09E18,11H16 ,11J17,13L17,14M17,15A15,15B17,15J17,16M16,17A17,17H18,17L14,19J14,20D15,22K18, 25H15,26K15,27B18,27K16,27L14,29A16,29B16,29F17,29L18,
RT-2016	01E14,01E15,01J16,01L18,02F14,03E17,03G14,03H15,03H17,03J18,03K17,03L15,03M14, 04G17,05B19,05C15,05M16,06C17,06C18,06C19,06D17,06D18,07H14,07L16,08A15,08A1 9,08F15,08M15,09G15,09M14,10B16,10C15,11D16,11D18,11G18,11H16,11J17,12A18, 12E14,13M18,14B18,16F17,16J15,16K17,16M16,17E18,17F15,18C19,18H14,18H16,18K18 ,18L14,19H15,19J17,20C18,20D15,20K14,20L18,20M17,21L17,22E15,22G14,22M14,23E17 ,23G18,24J15,24L16,24L17,25C15,25F14,25H15,25J18,26A17,27F18,27G17,27G18,28B17, 28C17,28K14,29F16,30A15,30A18,30K17,31E16,03J14,
RT- 2016/L	01E15,02D19,02J14,03J18,04G17,04H16,08A19,09E16,10B15,11G18,11K18,11L15,12A18, 12K16,13A16,13F16,13M18,14A19,14B18,14H14,15A15,16K17,17E18,17K14,17L14,19H15, 19J17,20K15,21L17,22F17,23G15,24L16,25J18,26A17,27F18,28B17,29C16,15M18,
RT-2018	01C17,01D15,01E15,01F18,01M17,02B18,02M16,03H17,03J18,03L15,03M14,04B16,07B17,07C16,08A19,08E14,08F15,09L17,10B16,10G17,10L16,11B19,11D17,11H17,12A18,12E17,12F14,13F16,13F18,13G18,13K17,13M18,14C18,15M15,16L18,17C16,17D18,17E16,17H18,17L16,18H14,18K18,18L15,21A15,21A19,21D16,21G15,22E15,22H16,22M14,24A18,25C15,25F14,25G17,26C19,26H16,27B18,27H15,27L14,28C18,28K14,29K18,30G18,31C17,02K14,11J14,





RT- 2018/L	01E14,03H15,03M14,07B17,08K18,09L17,13E15,17H18,17L16,19H15,20K15,20K16,24A18, 26C19,26J17,26K15,29B16,
RT-2020	02B17,03B15,03C16,03F14,05K15,06M18,07C19,09K17,10D18,10J18,12B16,13G18,13K14 ,14D15,15A16,16A17,16K17,17H15,19J17,20F14,26K16,26L15,27F15,30A18,30D15,30H16, 31C15,
RT-2108	01M17,02B18,02D19,02E16,03H15,04G18,04J15,06E14,07C16,08A19,09B15,09C15,09E18 ,09G15,09L17,10L16,11A17,11B19,11K18,11L15,12F17,12J17,13F16,14A19,15D16,17D18, 18G18,18L14,19E14,19G17,20K15,21A15,25E18,25G17,26A17,26J17,27K16,27L18,28C18, 29F16,30D18,31E16,
RT- 2108/EF	02D19,
RT-2110	02B18,04G17,05A16,05F15,06C18,06L14,07C16,08A15,09B15,09E17,09F14,09F17,09L17, 11A17,12A18,12E15,13B18,13F18,13G18,15D15,15D16,15J17,15M15,16F14,16L18,17D18, 17F15,18B16,18C19,19E14,19G17,19H15,20K15,20K16,20M17,21L17,22G15,22M14,24L17 ,25J14,26C15,26C18,26E15,26J17,26L15,27C17,27G17,27K16,27L14,27L18,28A19,28B17, 30D18,31E16,
RT- 2110/EF	28C19,
RT-2112	03H15,03M15,04J15,05J17,06C15,06D17,06D18,06E14,06K15,06L14,06M17,07F16,07H14, 07L18,08A15,09B15,09E16,09E17,09F14,09F17,10L16,11A17,11D16,11G18,11J14,11K17, 11L15,12E15,13A16,13G16,13J18,13M18,14K15,15A18,15C17,15K18,16F14,16G15,16J16, 16L16,16M15,17A17,18G18,18H14,19F18,19G17,19H15,20B17,20C18,20K16,20M17,21A1 9,21L17,22A16,22B18,22C19,22D16,22F17,22H16,22L18,22M14,23D18,24A18,24H18,24J1 5,24J18,25E18,26J16,27C17,27E14,27E15,27H15,28A19,28B17,28L14,29B16,29F15,29G1 4,29H17,30D15,30D18,31K17,
RT-2114	01B17,02B18,02C17,02E16,03A18,03D17,03J14,03J18,03K17,03M14,03M15,04D19,04E18, 04H16,04J15,05B19,05H15,05J17,05K15,06E14,06M17,07C16,07F18,07L16,08F15,09C15, 09F17,09L17,09M15,10B16,11D17,11G18,11J17,11L15,12E15,12E17,12M14,13A16,13B18, 13F16,13K17,14A19,14D15,14J15,14K16,14M17,15C17,15M14,16F15,16F17,16G15,16J16, 16K14,16L18,17E18,17K14,18C16,18C19,18H14,19G18,19J17,20F18,20K15,21F16,22F15, 22K18,22M14,23D18,23K17,24A18,24L16,25F14,25G17,25H15,25J14,25J18,26C15,26J17, 27B18,27E14,27G18,27L18,28C18,28L14,29F15,29F16,29F17,29G14,29H17,29L18,30A15, 31K17,
RT-2116	01C16,01F18,02C17,02F14,02K14,03E17,03J18,03K17,03L15,03M14,04G17,05A16,05B19, 06C17,06C19,06D17,06D18,07F16,07H14,07M17,09C15,09M14,10B15,10G15,10L16, 11A17,11G18,11J17,11K18,12M14,14A16,14A19,14B18,14J15,15B17,15D15,16F17,16K17, 16L18,17D18,17E18,17F15,18H16,19J17,20C14,20C18,20K16,20L18,21F16,21L17,22C19, 22F15,22H16,23E17,24A18,25H15,25J18,26C15,26K15,27F18,27G18,27H15,28B17,28L14, 29H17,29L18,30A18,30D18,
RT-2118	01B17,01C17,01E14,01K18,01M17,02B18,02E16,03A18,03F14,03G14,03J18,03M15,05F15 ,05H15,07F16,08K18,09L17,11B19,11K17,12A18,12M14,13A16,13E14,13K15,13M18, 14A19,14C18,14J15,15G14,15J17,16B15,16G18,16K14,16L18,17C16,17K14,19G17,21A15, 21A19,22B18,22F17,22H16,23K17,24A18,26C15,27K16,27L18,28B17,28C18,28C19,28L14, 29F16,
RT-2308	01D15,02E16,06K15,08J16,09G15,09L17,11K18,18H16,18L15,19G17,23E16,26H16,29B16, 29H17,30A18,31E16,





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2310/EF		02E16,03J14,04G17,04H15,06C18,07H14,08A19,08M15,09E18,09L17,09L18,11A17,11H17, 13F16,13F18,15D15,16B15,17D18,17H18,19G17,19J16,22E17,22G16,22H14,23E16,24A18, 27C17,27G17,28C19,30D15,
RT-2312 01B17,03F14,04H15,05J17,07L18,09F17,10G18,11D18,11H16,11K17,13F16,13F18,13F18,15A18, 15J17,15K18,16L16,16D19,18G18,20M17,22B18,22D16,22F17,22H14,22K18,22L18,23E16, 24A18,24H18,25E18,25E14,25E14,25E14,25E14,29H17, RT-2314 01C17,02B18,04D19,04H16,04J14,05A16,05H15,05M16,07F18,08F15,09E16,09L17,09L18, 10B16,11G18,14K16,14M17,15B17,15C17,16F17,16G15,16L16,16M16,17A7,17H18, 18H6,19G18,19L17,20C18,20D15,20F18,20K15,21A15,21A19,21F16,22H14,23B15, 23D18,24A18,25G17,26L15,27L14,28C18,28G16,29C16,29F17,29H17,30E17,31C15,31C17, . RT- 2314/EF 01B17,01J16,03H15,03J14,03J18,03K17,04G17,05A16,08A15,09L18,10B15,11D16,11G18, 11H16,1J17,13M18,14H18,17B16,17E16,17E18,18K18,19C15,22B18,22E17,22G16,24L16 27C17,27G17,28A19,28B17,30D18, RT- 2316/EF 02D19,06D18,12K17,23G18, 2316/EF RT- 2316/EF 03H15,03K17,10G17,11D17,11L15,12E17,12K16,13K17,14H18,15B17,15D16,16G18,16L18 1,77D18,17E16,21A19,22F17,28G16,29H17,30E17,31C17, RT- 2318/EF 03H15,03K17,20G18,27G18, 2318/EF Suction Catheters (SC) Sc-1020 01E14,01H14,02C16,03B17,04G18,05F17,06C15,06E16,07C18,07K15,07L14,08E18,09A17 09L15,10D18,10H17,118K18,19G17,20F16,24B16,24G14,25H15,27B14,25H15,26D18,26F17,27L14 ,28J18,29F15,29L16,30K18,30L15,31G15,31H17,14K14, Stomach Tubes (ST) ST-2408 01E15,02E16,04G18,09M15,10D17,11H17,12F17,16B15,17D18,22K18, 30K17, ST-2410 02B18,02K14,02M16,04F14,04G17,05C15,07H14,08D16,09E18,09F17,11H17,12J17,15M16, 13G14,77C16,17H18,18H86,19G17,20F15,20M17,22E17,25G17,28A19,28C19,30G18, 30K17, ST-24		28C19,
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RT-2318 03H15,03K17,10G17,11D17,11L15,12E17,12K16,13K17,14H18,15B17,15D16,16G18,16L18,17D18,17E16,21A19,22F17,28G16,29H17,30E17,31C17, RT- 2318/EF 04G18,26C18,27G18, Suction Catheters (SC) Sc-1020 01E14,01H14,02C16,03B17,04G18,05F17,06C15,06E16,07C18,07K15,07L14,08E18,09A17,09L15,10D18,10M18,11A18,11H17,11K17,12B15,12D16,12D19,12K16,13D17,14C17,15J16,16L18,17H17,13K18,19G17,20F16,24B16,24G14,25A16,25F14,25H15,26D18,26F17,27L14,28J18,29F15,29L16,30K18,30L15,31G15,31H17,14K14, Stomach Tubes (ST) ST-2408 01E15,02E16,04G18,09M15,10D17,11H17,12E17,16B15,17D18,22K18, ST-2410 02B18,02K14,02M16,04F14,04G17,05C15,07H14,08D16,09E18,09F17,11H17,12J17,15M15,16G15,17C16,17H18,18B16,19G17,20K15,20M17,22E17,25G17,28A19,28C19,30G18,30K17, ST-2412 03H15,06C17,06D17,10C15,12M14,14L14,20B17,22A16,23D18,24A18,24L16,25F14,26K15,28A19,31K17, ST-2414 04J14,05M16,07K15,09E14,10D17,11D16,14C18,15C17,15J15,16M16,19F14,19F18,20D15,21A15,23D18,29A19,31E16,31K17, ST-2418 03H17,03M15,04G18,06K15,07F18,09A19,09B15,09F14,10B15,13M18,14C18,18K18,		02D19,06D18,12K17,23G18,
2318/EF RT-2320 19J17,22B17,29H17,29K18, Suction Catheters (SC) 01E14,01H14,02C16,03B17,04G18,05F17,06C15,06E16,07C18,07K15,07L14,08E18,09A17 SC-1020 01E14,01H14,02C16,03B17,04G18,05F17,06C15,06E16,07C18,07K15,07L14,08E18,09A17 09L15,10D18,10M18,11A18,11H17,11K17,12B15,12D16,12D19,12K16,13D17,14C17,15J16 16L18,17H17,18K18,19G17,20F16,24B16,24G14,25A16,25F14,25H15,26D18,26F17,27L14 ,28J18,29F15,29L16,30K18,30L15,31G15,31H17,14K14, Stomach Tubes (ST) ST-2408 01E15,02E16,04G18,09M15,10D17,11H17,12F17,16B15,17D18,22K18, ST-2410 02B18,02K14,02M16,04F14,04G17,05C15,07H14,08D16,09E18,09F17,11H17,12J17,15M15 ,16G15,17C16,17H18,18B16,19G17,20K15,20M17,22E17,25G17,28A19,28C19,30G18, 30K17, ST-2412 03H15,06C17,06D17,10C15,12M14,14L14,20B17,22A16,23D18,24A18,24L16,25F14,26K15 28A19,31K17, ST-2414 04J14,05M16,07K15,09E14,10D17,11D16,14C18,15C17,15J15,16M16,19F14,19F18,20D15 21A15,23D18,29A19,31E16,31K17, ST-2416 06C18,06D17,10B15,11A17,11D16,11G18,11K18,14A19,14D15,16L16,20K14,22C19,22J14 22M14,26C15,29A19,29F16,30K17, ST-2418 03H17,03M15,04G18,06K15,07F18,09A19,09B15,09F14,10B15,13M18,14C18,18K18,		03H15,03K17,10G17,11D17,11L15,12E17,12K16,13K17,14H18,15B17,15D16,16G18,16L18 ,17D18,17E16,21A19,22F17,28G16,29H17,30E17,31C17,
RT-2320 19J17,22B17,29H17,29K18, Suction Catheters (SC) SC-1020 01E14,01H14,02C16,03B17,04G18,05F17,06C15,06E16,07C18,07K15,07L14,08E18,09A17 09L15,10D18,10M18,11A18,11H17,11K17,12B15,12D16,12D19,12K16,13D17,14C17,15J16 ,16L18,17H17,18K18,19G17,20F16,24B16,24G14,25A16,25F14,25H15,26D18,26F17,27L14 ,28J18,29F15,29L16,30K18,30L15,31G15,31H17,14K14, Stomach Tubes (ST) ST-2408 01E15,02E16,04G18,09M15,10D17,11H17,12F17,16B15,17D18,22K18, ST-2410 02B18,02K14,02M16,04F14,04G17,05C15,07H14,08D16,09E18,09F17,11H17,12J17,15M15 ,16G15,17C16,17H18,18B16,19G17,20K15,20M17,22E17,25G17,28A19,28C19,30G18, 30K17, ST-2412 03H15,06C17,06D17,10C15,12M14,14L14,20B17,22A16,23D18,24A18,24L16,25F14,26K15 28A19,31K17, ST-2414 04J14,05M16,07K15,09E14,10D17,11D16,14C18,15C17,15J15,16M16,19F14,19F18,20D15 21A15,23D18,29A19,31E16,31K17, ST-2416 06C18,06D17,10B15,11A17,11D16,11G18,11K18,14A19,14D15,16L16,20K14,22C19,22J14 22M14,26C15,29A19,29F16,30K17, ST-2418 03H17,03M15,04G18,06K15,07F18,09A19,09B15,09F14,10B15,13M18,14C18,18K18,		04G18,26C18,27G18,
SC-1020 01E14,01H4,02C16,03B17,04G18,05F17,06C15,06E16,07C18,07K15,07L14,08E18,09A17 09L15,10D18,10M18,11A18,11H17,11K17,12B15,12D16,12D19,12K16,13D17,14C17,15J16 09L15,10D18,10M18,11A18,11H17,11K17,12B15,12D16,12D19,12K16,13D17,14C17,15J16 16L18,17H17,18K18,19G17,20F16,24B16,24G14,25A16,25F14,25H15,26D18,26F17,27L14 28J18,29F15,29L16,30K18,30L15,31G15,31H17,14K14, Stomach Tubes (ST) ST-2408 01E15,02E16,04G18,09M15,10D17,11H17,12F17,16B15,17D18,22K18, ST-2410 02B18,02K14,02M16,04F14,04G17,05C15,07H14,08D16,09E18,09F17,11H17,12J17,15M16,16G15,17C16,17H18,18B16,19G17,20K15,20M17,22E17,25G17,28A19,28C19,30G18,30K17, ST-2412 03H15,06C17,06D17,10C15,12M14,14L14,20B17,22A16,23D18,24A18,24L16,25F14,26K15,28A19,31K17, ST-2414 04J14,05M16,07K15,09E14,10D17,11D16,14C18,15C17,15J15,16M16,19F14,19F18,20D15,21A15,23D18,29A19,31E16,31K17, ST-2416 06C18,06D17,10B15,11A17,11D16,11G18,11K18,14A19,14D15,16L16,20K14,22C19,22J14,22M14,26C15,29A19,29F16,30K17, ST-2418 03H17,03M15,04G18,06K15,07F18,09A19,09B15,09F14,10B15,13M18,14C18,18K18,		19J17,22B17,29H17,29K18,
Stomach Tubes (ST) Stomach Tubes (ST) ST-2408 01E15,02E16,04G18,09M15,10D17,11H17,12F17,16B15,17D18,22K18, ST-2408 01E15,02E16,04G18,09M15,10D17,11H17,12F17,16B15,17D18,22K18, ST-2410 02B18,02K14,02M16,04F14,04G17,05C15,07H14,08D16,09E18,09F17,11H17,12J17,15M15,16G15,17C16,17H18,18B16,19G17,20K15,20M17,22E17,25G17,28A19,28C19,30G18,30K17, ST-2412 03H15,06C17,06D17,10C15,12M14,14L14,20B17,22A16,23D18,24A18,24L16,25F14,26K15 28A19,31K17, ST-2414 04J14,05M16,07K15,09E14,10D17,11D16,14C18,15C17,15J15,16M16,19F14,19F18,20D15 21A15,23D18,29A19,31E16,31K17, ST-2416 06C18,06D17,10B15,11A17,11D16,11G18,11K18,14A19,14D15,16L16,20K14,22C19,22J14 22M14,26C15,29A19,29F16,30K17, ST-2418 03H17,03M15,04G18,06K15,07F18,09A19,09B15,09F14,10B15,13M18,14C18,18K18,	Suction Ca	atheters (SC)
ST-2408 01E15,02E16,04G18,09M15,10D17,11H17,12F17,16B15,17D18,22K18, ST-2410 02B18,02K14,02M16,04F14,04G17,05C15,07H14,08D16,09E18,09F17,11H17,12J17,15M15,16G15,17C16,17H18,18B16,19G17,20K15,20M17,22E17,25G17,28A19,28C19,30G18,30K17, ST-2412 03H15,06C17,06D17,10C15,12M14,14L14,20B17,22A16,23D18,24A18,24L16,25F14,26K15 28A19,31K17, ST-2414 04J14,05M16,07K15,09E14,10D17,11D16,14C18,15C17,15J15,16M16,19F14,19F18,20D15 21A15,23D18,29A19,31E16,31K17, ST-2416 06C18,06D17,10B15,11A17,11D16,11G18,11K18,14A19,14D15,16L16,20K14,22C19,22J14 22M14,26C15,29A19,29F16,30K17, ST-2418 03H17,03M15,04G18,06K15,07F18,09A19,09B15,09F14,10B15,13M18,14C18,18K18,	SC-1020	01E14,01H14,02C16,03B17,04G18,05F17,06C15,06E16,07C18,07K15,07L14,08E18,09A17, 09L15,10D18,10M18,11A18,11H17,11K17,12B15,12D16,12D19,12K16,13D17,14C17,15J16 ,16L18,17H17,18K18,19G17,20F16,24B16,24G14,25A16,25F14,25H15,26D18,26F17,27L14 ,28J18,29F15,29L16,30K18,30L15,31G15,31H17,14K14,
ST-2410 02B18,02K14,02M16,04F14,04G17,05C15,07H14,08D16,09E18,09F17,11H17,12J17,15M15,16G15,17C16,17H18,18B16,19G17,20K15,20M17,22E17,25G17,28A19,28C19,30G18,30K17, ST-2412 03H15,06C17,06D17,10C15,12M14,14L14,20B17,22A16,23D18,24A18,24L16,25F14,26K15,28A19,31K17, ST-2414 04J14,05M16,07K15,09E14,10D17,11D16,14C18,15C17,15J15,16M16,19F14,19F18,20D15,21A15,23D18,29A19,31E16,31K17, ST-2416 06C18,06D17,10B15,11A17,11D16,11G18,11K18,14A19,14D15,16L16,20K14,22C19,22J14,22M14,26C15,29A19,29F16,30K17, ST-2418 03H17,03M15,04G18,06K15,07F18,09A19,09B15,09F14,10B15,13M18,14C18,18K18,	Stomach 1	lubes (ST)
,16G15,17C16,17H18,18B16,19G17,20K15,20M17,22E17,25G17,28A19,28C19,30G18, 30K17, ST-2412 03H15,06C17,06D17,10C15,12M14,14L14,20B17,22A16,23D18,24A18,24L16,25F14,26K15 28A19,31K17, ST-2414 04J14,05M16,07K15,09E14,10D17,11D16,14C18,15C17,15J15,16M16,19F14,19F18,20D15 21A15,23D18,29A19,31E16,31K17, ST-2416 06C18,06D17,10B15,11A17,11D16,11G18,11K18,14A19,14D15,16L16,20K14,22C19,22J14 22M14,26C15,29A19,29F16,30K17, ST-2418 03H17,03M15,04G18,06K15,07F18,09A19,09B15,09F14,10B15,13M18,14C18,18K18,	ST-2408	01E15,02E16,04G18,09M15,10D17,11H17,12F17,16B15,17D18,22K18,
ST-2412 03H15,06C17,06D17,10C15,12M14,14L14,20B17,22A16,23D18,24A18,24L16,25F14,26K15 28A19,31K17, ST-2414 04J14,05M16,07K15,09E14,10D17,11D16,14C18,15C17,15J15,16M16,19F14,19F18,20D15 21A15,23D18,29A19,31E16,31K17, ST-2416 06C18,06D17,10B15,11A17,11D16,11G18,11K18,14A19,14D15,16L16,20K14,22C19,22J14 22M14,26C15,29A19,29F16,30K17, ST-2418 03H17,03M15,04G18,06K15,07F18,09A19,09B15,09F14,10B15,13M18,14C18,18K18,	ST-2410	
21A15,23D18,29A19,31E16,31K17, ST-2416 06C18,06D17,10B15,11A17,11D16,11G18,11K18,14A19,14D15,16L16,20K14,22C19,22J14 22M14,26C15,29A19,29F16,30K17, ST-2418 03H17,03M15,04G18,06K15,07F18,09A19,09B15,09F14,10B15,13M18,14C18,18K18,	ST-2412	03H15,06C17,06D17,10C15,12M14,14L14,20B17,22A16,23D18,24A18,24L16,25F14,26K15,
22M14,26C15,29A19,29F16,30K17, ST-2418 03H17,03M15,04G18,06K15,07F18,09A19,09B15,09F14,10B15,13M18,14C18,18K18,	ST-2414	04J14,05M16,07K15,09E14,10D17,11D16,14C18,15C17,15J15,16M16,19F14,19F18,20D15, 21A15,23D18,29A19,31E16,31K17,
	ST-2416	06C18,06D17,10B15,11A17,11D16,11G18,11K18,14A19,14D15,16L16,20K14,22C19,22J14, 22M14,26C15,29A19,29F16,30K17,
31C17,	ST-2418	20D15,21A15,21A19,22F17,22H16,22M16,26C19,26J17,27B18,27E14,27G18,29F16,30K17,





ST-2420	02M16,03A19,03D17,03G18,05C15,05K15,06C18,09K17,10L14,11B15,14D15,14F16, 18M15,23F17,25A18,31C15,				
X-ray Levi	X-ray Levins Tubes (XLT)				
XLT-2208	01C17,01E15,02D19,03H15,04G18,05A16,05D16,06L14,07C16,09E18,09M15,10D17, 10G17,10L16,11A17,11B19,11G14,11L15,12E14,12J17,14F16,16B15,16K14,18G18,19E14, 21L17,22B18,23E16,24L16,25E18,25F14,25G17,25H15,26A17,28C18,28K14,29H17,30G14, 31E16,				
XLT-2210	02B18,03G14,04G17,05A16,06C18,06D17,07C16,08D16,08K18,09A19,09B15,09C15,09F14 ,09L18,11A17,12E14,12E17,13B18,13G16,13G18,13M18,14E15,14L14,15K18,16B15,16K14 ,16L16,17F15,18C19,18J14,18L15,19E14,19F18,19G17,20B17,20K15,22D16,22G16,22K18, 23E16,23K17,24A18,24L17,25E18,25H15,26C18,26E15,26H16,26J17,27G17,27K16,27L18, 28B17,28K14,29A16,29G14,29H17,30D14,				
XLT-2212	01B17,03K17,04J15,05F15,05J17,06D18,06E14,06L14,07C16,07H14,07L18,08K18,09B15, 09M15,10D17,11D16,12J18,12M14,13A16,13F18,13G16,14D15,14E15,15A18,16B15, 16G15,16L16,16M15,16M16,17K14,18G18,18J14,18M18,19G17,19H15,20B17,20C18, 20K16,20M17,22B18,22C19,22F17,22H16,22K18,23E16,23K17,24H18,24J18,25E18,26K15, 27E14,27H15,29G14,31C17,31E16,				
XLT- 2212/BUL K	11L14,11M14,19E14,				
XLT-2214	01C17,01F18,02B18,02D19,02E14,02M16,03A18,03H15,03J18,03K16,04E18,05B19,05J17, 06H15,06M17,07F18,07K15,08A15,08A19,09E17,09E18,09F14,10B16,10D17,11G18,11H16 ,12F17,12L15,13A16,13K17,14K16,14M17,15B17,15C17,15D16,15J15,15K18,15M15, 16G15,16L18,17A17,17E16,17L14,18C19,18H14,18L15,18M18,19E14,19F18,19J17,20C18, 20K14,21D16,21F16,22G16,23B15,23K17,24A18,24J15,25G17,25J14,26E15,26H16,26J17, 26K15,26L15,27G18,27L14,27L18,29A16,29B16,29F16,29F17,29G14,29L18,30A15,30D18, 31C15,				
XLT-2216	01B17,01F18,01J16,01L18,02F14,03E17,03G14,03J14,03K17,04G17,04H15,04J15,05B19, 05M16,06C17,06C19,07C16,07F16,07H14,07M17,08A19,08F15,09C15,09G15,10B16, 11D16,11G14,11G18,11H16,11J14,11J17,11K18,11L15,12A18,12K16,12M14,13A16,13G16, 13K15,13M18,14B18,14D15,14E15,14H18,15A15,15M15,16F14,16F17,16J15,16K17,16L16, 16L18,17E16,17E18,18K18,18L14,19E14,19J17,20C18,20D15,20K14,20M17,21F16,22B18, 22C19,22F15,22G14,22M14,23B15,23G18,24L16,24L17,25J18,26A17,27F18,27G17,27L14, 28C17,28K15,29H17,30A15,30A18,30D18,30E17,30K17,31E16,				
XLT-2218	01B17,01K18,01M17,02K14,02M16,03A18,03J18,04E18,05A16,05B19,06H15,06L14,08A15, 08A19,08J16,08K18,09G15,10G17,11D16,11D17,11H16,11L15,12E15,12K16,13B18,13F16, 13F18,13K15,13K17,14C18,15J17,15M15,16F14,16G18,16J15,17E16,17H18,18K18,18L15, 20K14,20K16,21A19,21D16,22A16,22F17,22G14,22L18,22M16,23B15,23E16,23K17,25E18, 25G17,25J18,26C18,26E15,26H16,26J17,26L15,28C17,28G16,28K15,29B16,29H17,29K18, 30J16,31C15,				
XLT-2220	01B17,03B15,03E18,05C15,05K15,06L14,09K17,16L15,19A15,20F14,23B16,23F17,30D15, 31C15,				
XLT-2408	03A18,03J14,04G18,07L16,09B15,11G14,14C18,18L14,26A17,27L18,28K14,28K15,				
XLT-2410	09F17,13G16,16B15,24J18,25H15,29F16,29G14,				
XLT-2412	01L18,08J16,09F17,15D16,18H16,18J14,24J18,26C19,27C17,27H15,03G14,				
XLT-2414	01C17,03D17,04E18,06H15,07L18,08A19,09E17,09M15,11B16,11G18,11H16,15K18,16J16 ,21A19,21D16,23G14,27G18,27L18,29C16,29H17,29K18,30A15,31K17,				
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XLT-2416	01B17,01F18,02D19,02E14,02E16,03E17,06C15,06C19,06D18,08A19,09B15,09M15,10B15 ,10B16,11G14,11L15,12E14,13K15,13M18,14A19,16F17,17E18,18K18,19C15,20C18, 20D15,20L18,21A15,22G14,23E17,23G15,23G18,24B16,24L17,25F14,27F18,27L14,28C17, 28C19,28K14,29C16,30A18,
XLT-2418	01D15,01E14,02C17,03M15,07F16,09A19,09B15,09C15,09E17,10B16,12E17,18K18,19C15 ,19H15,19J14,22F15,22F17,22G14,22G15,22H14,23B16,26C18,26C19,27G18,29C16, 29H17,30K17,07H14,
XLT-2420	03A19,03E16,04G18,07C19,08G15,10L14,12B16,12E17,13K14,17K14,18K18,19H16,19J17, 19L14,23G14,25A18,26L14,26L15,29L17,30A18,31C15,
X-Ray Stor	nach Tubes (XST)
XST-2408	01D15,01E15,06K15,08M15,09B15,12F17,18B16,18H14,19G17,22K18,25J14,
XST-2410	19G17,26L15,29A16,
XST-2412	26L15,27L14,
XST-2414	01C17,07K15,14K16,29F17,
XST-2416	04G17,06D17,13K15,18H16,
XST-2418	02C17,06K15,19G17,22H16,
XST- 2418/BUL K	01B18,10G17,16H18,19K15,20M16,21G15,25H17,26K18,29G16,29H18,
XST-2420	05C15,





Addendum B

Field Safety Notice Acknowledgement Form

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Company/Institute	
Address	

Confirmation of having none of the products referenced in this FSN.

We do not have any	y stock of the affected	product (√	tick if this is y	vour answer)
		produot. (

Product Code and Quantity of Affected Product in Stock			
Product Code	LOT Number(s)	Qty.	

NB: Please contact your local distributor representative or Pennine directly to confirm quantity and type of quarantined stock before completing returns or plans for destruction. **Evidence will be required prior to and after destruction.**

I hereby confirm that I have read and understood the contents of this Field Safety		
Notice.		
Sign		
Date		

Please return the completed reply form to: recalls@penninehealthcare.co.uk

Pennine City Gate, London Road, Derby, DE24 8WY, United Kingdom	T: +44 (0)1332 794880	info@penninehealthcare.co.uk	www.penninehealthcare.co.uk
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