

Avis de sécurité urgent

Produit affecté	CERTAINS CODES UNIQUEMENT - Remarque : voir l'Addendum « A » pour connaître tous les détails. Sondes d'alimentation, cathéters Nelaton, sondes de Levin, sondes rectales, sondes de Ryles, cathéters à succion, sondes gastriques, kits médicaux.
Type de mesure	Rappel volontaire / Mise au rebut du produit
Réf. Pennine Healthcare :	PHFSN0219
Code(s) du/des produit(s)	Divers - Voir Addendum « A »
Numéro de lot	Divers - Voir Addendum « A » Un exemple de numéro de LOT dans cette gamme est : "06D15"

8 May 2019

Cher client,

Description du problème :

Cette communication vise à vous informer que Pennine Healthcare a volontairement entamé un rappel concernant plusieurs LOTs des produits indiqués dans le présent avis de sécurité (FSN). Au cours des activités de post-production, nous avons identifié qu'il existait une faible probabilité que les produits indiqués dans le présent FSN présentent des yeux (trous) incorrects dans le tube. Ce défaut de fabrication devrait être détectable par un utilisateur formé ; toutefois, si ce n'est pas le cas, ce défaut affectera les performances attendues du produit. Il existe un risque potentiel de blessures graves si un dispositif alternatif non défectueux n'est pas disponible.

Mesures que doit prendre le distributeur ou l'utilisateur :

1. Identifiez et mettez immédiatement en quarantaine la totalité du stock du lot ou des numéros de LOT concernés.
2. Si vous êtes un distributeur, vous devez confirmer à Pennine que vous avez transmis le présent FSN à tous vos clients et que vous avez contrôlé les stocks renvoyés.
3. Complétez le formulaire de réponse (Addendum B) ci-joint pour confirmer que vous avez lu et compris le contenu du présent Avis de sécurité.
4. Sur réception du formulaire de réponse complété, Pennine Healthcare organisera le renvoi des dispositifs ou détaillera les méthodes de destruction du produit affecté. (Une preuve de destruction et les enregistrements du type et des quantités concernés seront requis).
5. Pour obtenir de plus amples informations sur le remplacement ou le remboursement des stocks affectés ou en quarantaine, veuillez contacter votre distributeur local. Pour les stocks fournis directement par Pennine, contactez notre service clientèle via :

- Royaume-Uni : customer.services@penninehealthcare.co.uk Tél. : +44 (0)1332 794 880
- International : exports@penninehealthcare.co.uk Tél. : +44 (0)1332 794 880

6. Conservez le présent avis de sécurité jusqu'à la destruction de la totalité des stocks du LOT concerné ou à leur retour à Pennine Healthcare.

Identification des produits affectés :

Identifiez les dispositifs affectés à l'aide des codes produit et des numéros de LOT indiqués dans l'Addendum A.

Diffusion du présent avis de sécurité :

Le présent avis de sécurité doit être transmis à toutes les personnes qui doivent être informées au sein de votre entreprise et à toutes les entreprises disposant de dispositifs potentiellement affectés.

Veillez conserver le présent avis jusqu'à ce que toutes les mesures requises aient été prises au sein de votre entreprise.

Nous confirmons que cette mesure corrective de sécurité sur le terrain a été communiquée à tous les distributeurs et autorités compétentes.

Pennine s'engage à fournir des produits de qualité à ses clients et nous vous présentons toutes nos excuses pour les inconvénients causés par cet avis.

Pour et au nom de Pennine Healthcare :



Simon Motlib
Responsable de l'assurance qualité

Addendum A - Dispositifs médicaux affectés - (NB : seuls ces codes produit sont concernés)

Code produit	Numéros de lot
Kit médical FRP-04400	02C16,09C16,10M15,15D16,17B16,
Kit médical FRP-04700	05K18,06L18,12B18,19M18,29K18,
Kit médical FRP-04701	04B19,14C19,17D19,23A19,
Sondes d'alimentation (FT ou Feeding Tubes)	
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,
Sondes de Levin (LT ou Levins Tubes)	
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	01B17,01E15,01M17,03E17,03K17,04B16,05F15,06D18,09F14,12M14,15A15,15A18,16B15,16F15,16M16,17B16,17K14,18L14,18M18,19H15,19M16,22A16,22D16,22E15,22F17,22H16,23D18,23E16,25E18,26K15,27G18,29B16,30D18,31C17,18J14,
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,
Cathéters Nelaton (NC ou Nelaton Catheters)	
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,
Sondes rectales (RC ou Rectal catheters)	
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,
Sondes de Ryles (RT ou Ryles Tubes)	
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/BULK	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/BULK	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/BULK	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/BULK	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	01E14,01E15,01J16,01L18,02F14,03E17,03G14,03H15,03H17,03J18,03K17,03L15,03M14,04G17,05B19,05C15,05M16,06C17,06C18,06C19,06D17,06D18,07H14,07L16,08A15,08A19,08F15,08M15,09G15,09M14,10B16,10C15,11D16,11D18,11G18,11H16,11J17,12A18,12E14,13M18,14B18,16F17,16J15,16K17,16M16,17E18,17F15,18C19,18H14,18H16,18K18,18L14,19H15,19J17,20C18,20D15,20K14,20L18,20M17,21L17,22E15,22G14,22M14,23E17,23G18,24J15,24L16,24L17,25C15,25F14,25H15,25J18,26A17,27F18,27G17,27G18,28B17,28C17,28K14,29F16,30A15,30A18,30K17,31E16,03J14,
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	03H15,03M15,04J15,05J17,06C15,06D17,06D18,06E14,06K15,06L14,06M17,07F16,07H14,07L18,08A15,09B15,09E16,09E17,09F14,09F17,10L16,11A17,11D16,11G18,11J14,11K17,11L15,12E15,13A16,13G16,13J18,13M18,14K15,15A18,15C17,15K18,16F14,16G15,16J16,16L16,16M15,17A17,18G18,18H14,19F18,19G17,19H15,20B17,20C18,20K16,20M17,21A19,21L17,22A16,22B18,22C19,22D16,22F17,22H16,22L18,22M14,23D18,24A18,24H18,24J15,24J18,25E18,26J16,27C17,27E14,27E15,27H15,28A19,28B17,28L14,29B16,29F15,29G14,29H17,30D15,30D18,31K17,
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,
RT-2308/EF	08A19,

RT-2310	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-2310/EF	28C19,
RT-2312	01B17,03F14,04H15,05J17,07L18,09F17,10G18,11D18,11H16,11K17,13F16,13F18,15A18,15J17,15K18,16L16,18D19,18G18,20M17,22B18,22D16,22F17,22H14,22K18,22L18,23E16,24A18,24H18,25E18,25F14,26C19,27C17,28A19,29H17,
RT-2314	01C17,02B18,04D19,04H16,04J14,05A16,05H15,05M16,07F18,08F15,09E16,09L17,09L18,10B16,11G18,14K16,14M17,15B17,15C17,16F17,16G15,16L16,16M16,17A17,17H18,18H16,19G18,19J17,20C18,20D15,20F18,20K14,20K15,21A15,21A19,21F16,22H14,23B15,23D18,24A18,25G17,26L15,27L14,28C18,28G16,29C16,29F17,29H17,30E17,31C15,31C17,
RT-2314/EF	20F18,27G18,28C18,
RT-2316	01B17,01J16,03H15,03J14,03J18,03K17,04G17,05A16,08A15,09L18,10B15,11D16,11G18,11H16,11J17,13M18,14H18,17B16,17E16,17E18,18K18,19C15,22B18,22E17,22G16,24L16,27C17,27G17,28A19,28B17,30D18,
RT-2316/EF	02D19,06D18,12K17,23G18,
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,
RT-2320	19J17,22B17,29H17,29K18,
Cathéters à succion (SC ou Suction catheters)	
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,
Sondes gastriques (ST ou Stomach Tubes)	
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	03H17,03M15,04G18,06K15,07F18,09A19,09B15,09F14,10B15,13M18,14C18,18K18,20D15,21A15,21A19,22F17,22H16,22M16,26C19,26J17,27B18,27E14,27G18,29F16,30K17,31C17,
ST-2420	02M16,03A19,03D17,03G18,05C15,05K15,06C18,09K17,10L14,11B15,14D15,14F16,18M15,23F17,25A18,31C15,
Sondes de Levin radio-opaque (XLT ou X-ray Levins Tubes)	

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/BULK	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,

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,
Sondes gastriques radio-opaques (XST ou X-Ray Stomach Tubes)	
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/BULK	01B18,10G17,16H18,19K15,20M16,21G15,25H17,26K18,29G16,29H18,
XST-2420	05C15,

Addendum B

Accusé de réception de l'avis de sécurité

Nom	
Poste	
Entreprise/Institut	
Adresse	

Nous ne possédons aucun stock du produit affecté. (✓ cochez si c'est votre cas)	
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Code et quantités du produit affecté en stock		
Code produit	Numéro(s) de LOT	Qté

NB : veuillez contacter le représentant de votre distributeur local ou Pennine pour confirmer la quantité et le type de stock en quarantaine avant de procéder à son retour ou destruction. **Des preuves seront requises avant et après la destruction.**

Je confirme par la présente que j'ai lu et compris le contenu de la présente actualisation d'avis de sécurité.	
Signature	
Date	

Veuillez retourner le formulaire complété à : recalls@penninehealthcare.co.uk

Actualisation - Avis de sécurité urgent

Produit affecté	<p>CERTAINS CODES UNIQUEMENT - Remarque : voir l'Addendum « A » pour connaître tous les détails.</p> <p>Sondes d'alimentation, cathéters Nelaton, sondes de Levin, sondes rectales, sondes de Ryles, cathéters à succion, sondes gastriques, kits médicaux.</p>
Type de mesure	Rappel volontaire / Mise au rebut du produit
Réf. Pennine Healthcare :	PHFSN0219
Code(s) du/des produit(s)	Divers - Voir Addendum « A »
Numéro de lot	<p>Divers - Voir Addendum « A »</p> <p>Un exemple de numéro de LOT dans cette gamme est : "06D15"</p>

4 juin 2019

Cher client,

Description du problème :

L'objet de cette actualisation est de vous informer que des mesures alternatives peuvent être prises, lorsqu'une pénurie des dispositifs affectés par ce rappel peut avoir un impact sur la sécurité des patients. Les mesures alternatives sont décrites ci-après.

Remarque : lorsque la sécurité des patients n'est pas compromise par la pénurie de ces dispositifs, les mesures détaillées dans le FSN d'origine daté du 8 mai 2019 doivent être appliquées (elles sont rappelées ci-dessous).

Les risques engendrés par ce problème sont similaires à ceux détaillés dans le FSN d'origine.

Mesures à prendre par l'utilisateur si des dispositifs doivent être utilisés pour pallier une augmentation du risque pour la sécurité des patients, lorsque les dispositifs alternatifs non défectueux sont indisponibles :

1. Tous les dispositifs affectés doivent être inspectés immédiatement avant leur retrait de l'emballage primaire.
2. En utilisant les illustrations ci-dessous comme référence, manipulez l'extrémité distale du dispositif afin de voir clairement l'embout à travers le film de l'emballage.
3. Détectez la présence d'yeux latéraux.
4. En présence d'yeux latéraux, utilisez le dispositif de manière habituelle.
5. Il est recommandé de procéder à une deuxième vérification visuelle immédiatement avant d'insérer la sonde.

6. En l'absence d'yeux latéraux, n'utilisez pas le dispositif. Sélectionnez un autre exemplaire et procédez aux vérifications indiquées ci-dessus (pour les exemplaires rejetés, suivez les étapes indiquées dans le FSN d'origine (rappelées ci-dessous)).



Exemple de produit non défectueux avec des yeux latéraux



Exemple de produit défectueux sans yeux latéraux

Mesures d'origine que doit prendre le distributeur ou l'utilisateur :

1. Identifiez et mettez immédiatement en quarantaine la totalité du stock du lot ou des numéros de LOT concernés.
2. Si vous êtes un distributeur, vous devez confirmer à Pennine que vous avez transmis le présent FSN à tous vos clients et que vous avez contrôlé les stocks renvoyés.
3. Complétez le formulaire de réponse (Addendum B) ci-joint pour confirmer que vous avez lu et compris le contenu du présent Avis de sécurité.

4. Sur réception du formulaire de réponse complété, Pennine Healthcare organisera le renvoi des dispositifs ou détaillera les méthodes de destruction du produit affecté. (Une preuve de destruction et les enregistrements du type et des quantités concernés seront requis).
5. Pour obtenir de plus amples informations sur le remplacement ou le remboursement des stocks affectés ou en quarantaine, veuillez contacter votre distributeur local. Pour les stocks fournis directement par Pennine, contactez notre service clientèle via :
 - Royaume-Uni : customer.services@penninehealthcare.co.uk Tél. : +44 (0)1332 794 880
 - International : exports@penninehealthcare.co.uk Tél. : +44 (0)1332 794 880
6. Conservez le présent avis de sécurité jusqu'à la destruction de la totalité des stocks du LOT concerné ou à leur retour à Pennine Healthcare.

Identification des produits affectés :

Identifiez les dispositifs affectés à l'aide des codes produit et des numéros de LOT indiqués dans l'Addendum A.

Diffusion du présent avis de sécurité :

Le présent avis de sécurité doit être transmis à toutes les personnes qui doivent être informées au sein de votre entreprise et à toutes les entreprises disposant de dispositifs potentiellement affectés.

Veuillez conserver le présent avis jusqu'à ce que toutes les mesures requises aient été prises au sein de votre entreprise.

Nous confirmons que cette mesure corrective de sécurité sur le terrain a été communiquée à tous les distributeurs et autorités compétentes.

Pennine s'engage à fournir des produits de qualité à ses clients et nous vous présentons toutes nos excuses pour les inconvénients causés par cet avis.

Pour et au nom de Pennine Healthcare :



Simon Motlib
Responsable de l'assurance qualité

Addendum A - Dispositifs médicaux affectés - (NB : seuls ces codes produit sont concernés)

Code produit	Numéros de lot
Kit médical FRP-04400	02C16,09C16,10M15,15D16,17B16,
Kit médical FRP-04700	05K18,06L18,12B18,19M18,29K18,
Kit médical FRP-04701	04B19,14C19,17D19,23A19,
Sondes d'alimentation (FT ou Feeding Tubes)	
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,
Sondes de Levin (LT ou Levins Tubes)	
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	01B17,01E15,01M17,03E17,03K17,04B16,05F15,06D18,09F14,12M14,15A15,15A18,16B15,16F15,16M16,17B16,17K14,18L14,18M18,19H15,19M16,22A16,22D16,22E15,22F17,22H16,23D18,23E16,25E18,26K15,27G18,29B16,30D18,31C17,18J14,
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,
Cathéters Nelaton (NC ou Nelaton Catheters)	
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,
Sondes rectales (RC ou Rectal catheters)	
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,
Sondes de Ryles (RT ou Ryles Tubes)	
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/BULK	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/BULK	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/BULK	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/BULK	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	01E14,01E15,01J16,01L18,02F14,03E17,03G14,03H15,03H17,03J18,03K17,03L15,03M14,04G17,05B19,05C15,05M16,06C17,06C18,06C19,06D17,06D18,07H14,07L16,08A15,08A19,08F15,08M15,09G15,09M14,10B16,10C15,11D16,11D18,11G18,11H16,11J17,12A18,12E14,13M18,14B18,16F17,16J15,16K17,16M16,17E18,17F15,18C19,18H14,18H16,18K18,18L14,19H15,19J17,20C18,20D15,20K14,20L18,20M17,21L17,22E15,22G14,22M14,23E17,23G18,24J15,24L16,24L17,25C15,25F14,25H15,25J18,26A17,27F18,27G17,27G18,28B17,28C17,28K14,29F16,30A15,30A18,30K17,31E16,03J14,
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	03H15,03M15,04J15,05J17,06C15,06D17,06D18,06E14,06K15,06L14,06M17,07F16,07H14,07L18,08A15,09B15,09E16,09E17,09F14,09F17,10L16,11A17,11D16,11G18,11J14,11K17,11L15,12E15,13A16,13G16,13J18,13M18,14K15,15A18,15C17,15K18,16F14,16G15,16J16,16L16,16M15,17A17,18G18,18H14,19F18,19G17,19H15,20B17,20C18,20K16,20M17,21A19,21L17,22A16,22B18,22C19,22D16,22F17,22H16,22L18,22M14,23D18,24A18,24H18,24J15,24J18,25E18,26J16,27C17,27E14,27E15,27H15,28A19,28B17,28L14,29B16,29F15,29G14,29H17,30D15,30D18,31K17,
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,
RT-2308/EF	08A19,

RT-2310	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-2310/EF	28C19,
RT-2312	01B17,03F14,04H15,05J17,07L18,09F17,10G18,11D18,11H16,11K17,13F16,13F18,15A18,15J17,15K18,16L16,18D19,18G18,20M17,22B18,22D16,22F17,22H14,22K18,22L18,23E16,24A18,24H18,25E18,25F14,26C19,27C17,28A19,29H17,
RT-2314	01C17,02B18,04D19,04H16,04J14,05A16,05H15,05M16,07F18,08F15,09E16,09L17,09L18,10B16,11G18,14K16,14M17,15B17,15C17,16F17,16G15,16L16,16M16,17A17,17H18,18H16,19G18,19J17,20C18,20D15,20F18,20K14,20K15,21A15,21A19,21F16,22H14,23B15,23D18,24A18,25G17,26L15,27L14,28C18,28G16,29C16,29F17,29H17,30E17,31C15,31C17,
RT-2314/EF	20F18,27G18,28C18,
RT-2316	01B17,01J16,03H15,03J14,03J18,03K17,04G17,05A16,08A15,09L18,10B15,11D16,11G18,11H16,11J17,13M18,14H18,17B16,17E16,17E18,18K18,19C15,22B18,22E17,22G16,24L16,27C17,27G17,28A19,28B17,30D18,
RT-2316/EF	02D19,06D18,12K17,23G18,
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,
RT-2320	19J17,22B17,29H17,29K18,
Cathéters à succion (SC ou Suction catheters)	
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,
Sondes gastriques (ST ou Stomach Tubes)	
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	03H17,03M15,04G18,06K15,07F18,09A19,09B15,09F14,10B15,13M18,14C18,18K18,20D15,21A15,21A19,22F17,22H16,22M16,26C19,26J17,27B18,27E14,27G18,29F16,30K17,31C17,
ST-2420	02M16,03A19,03D17,03G18,05C15,05K15,06C18,09K17,10L14,11B15,14D15,14F16,18M15,23F17,25A18,31C15,
Sondes de Levin radio-opaque (XLT ou X-ray Levins Tubes)	

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/BULK	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,

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,
Sondes gastriques radio-opaques (XST ou X-Ray Stomach Tubes)	
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/BULK	01B18,10G17,16H18,19K15,20M16,21G15,25H17,26K18,29G16,29H18,
XST-2420	05C15,

Addendum B

Accusé de réception de l'actualisation de l'avis de sécurité

Nom	
Poste	
Entreprise/Institut	
Adresse	

Nous ne possédons aucun stock du produit affecté. (✓ cochez si c'est votre cas)	
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Code et quantités du produit affecté en stock		
Code produit	Numéro(s) de LOT	Qté

NB : veuillez contacter le représentant de votre distributeur local ou Pennine pour confirmer la quantité et le type de stock en quarantaine avant de procéder à son retour ou destruction. **Des preuves seront requises avant et après la destruction.**

Je confirme par la présente que j'ai lu et compris le contenu de la présente actualisation d'avis de sécurité.	
Signature	
Date	

Veuillez retourner le formulaire complété à : recalls@penninehealthcare.co.uk