



Re: Field Safety Notice

12th September 2017

Dear Valued Synergy Health Customer:

Synergy Health (UK) Limited is implementing a recall of several sterile theatre products. Our records indicate that you purchased affected products as shown on the attached list.

Description of the problem – Product inspections performed by Synergy Health personnel identified small amounts of debris in finished packaged products. Internal investigation found this debris originated from sources including Synergy packaging equipment and incoming goods. The products are sterilized following packaging and, in our evaluation, this incidental debris is unlikely to present a hazard to patients or users. Nonetheless, Synergy Health is recalling these products as they do not meet our quality standards.

Following discovery of this issue, Synergy Health has taken the necessary steps to ensure this situation does not recur. All products currently being supplied to Customers meet our quality standards.

User action requested:

- Review your on-hand inventory and quarantine all affected product lots in your possession that are listed in this Field Safety Notice.
- Please complete and return the attached Reply Form included with this notice.
- To arrange collection and replacement of affected stock, please contact the Synergy Health [UK] Ltd Customer Services Department at: +44 [0] 1772 299 999.

Communication of this Field Safety Notice within your organisation:

We advise that this notice should be passed on to all those who need to be aware within your organisation, including any organisation where the potentially affected devices have been transferred. Please maintain awareness of this notice until all required actions have been completed in your organisation.

We appreciate your cooperation and apologise for any inconvenience this may cause. We value our relationship with you and trust that with your cooperation this issue shall be resolved. If you have any further questions or concerns, please do not hesitate to contact your customer service representative.

Kind regards,

A handwritten signature in black ink that reads "M. Sutcliffe".

Martyn Sutcliffe
Acting Managing Director and Divisional Finance Director

Attachments

List of Affected Products

REF	Product Description	Lot No
18004	SUTURE INSTRUMENT PACK	180040617, 180041517
18020	Single Use Turn Over End Dissecting Forceps	180201517, 180202217
18037	BASIC PODIATRY PACK SU	180371117, 180371417
18038	SINGLE USE PODIATRY ASSISTANT PACK	180380716
28102	PLAIN GAUZE SWABS 10X10CM 16PLAINY 5 PACK SINGLE WRAPPED	281021817
28103	XRD GAUZE ROLL 182X11CM, DOUBLE WRAPPED	281031917, 281032217
28105	GAUZE TISSUE PAD 45X45CM	281054416, 281054616, 281054916
28107	DETEX 45X45CM 12PLAINY NON TPD Tied 5s	281071617
28110	ANAESTHETIC THROAT PACK 180X10CM 4PLAIN, Double Wrapped	281101717, 281102117, 281105116
28113	NONWOVEN BALLS 5 PACK SIZE F, SINGLE WRAPPED	281130217
28114	PLAIN SWAB 22.5X10CM 16PLAINY 2 PACK, DOUBLE WRAPPED	281140817, 281141217
28116	PLAIN SWAB 10X10CM 12PLAINY 5 PACK, DOUBLE WRAPPED	281161517, 281161917
28117	IV DRESSING PACK INC TEGADERM	281171717
28119	DETEX 30X30CM 12PLAINY NON TPD Tied 5s	281192116
28124	GAUZE/COTTON TISSUE PAD 45X30CM	281241617
28125	STERILE FIELD CREPE WHITE 500X500MM	281250917
28125	STERILE FIELD CREPE WHITE 500X500MM	281252117
28129	DETEX 76X7.5CM 12PLAINY Tied 5s, DOUBLE WRAPPED	281291417
28132	IV DRESSING PACK 5	281321817
28138	STERILE IV DRESSING PACK 8 AMBULANCE SERVICE	281381617, 281382317
28139	IV DRESSING PACK 9 ADULT	281390817
28144	STERILE THEATRE WOUND PAD	281441917
28155	STERILE MATERNITY PAD	281551717
28177	IV DRESSING PACK	281772017
28186	GAUZE/TISSUE PAD 20X27.5CM	281861317, 281862217
28379	CATHETER PACK	283790417
28722	120ML GALLIPOT	287221817
28725	ORAL HYGIENE PACK	287251917
28732	60ML GALLIPOT	287321517, 287321717, 287321817
28751	STERILE DRESSING PACK	287510217, 287514716
28762	HOME DIALYSIS PACK	287620716, 287620717, 287621617
28767	PULP KIDNEY DISH	287672317
28769	POLY BOWL 500ML	287692916, 287694316
28771	BASIC DRESS PACK	287711217

28781	SUTURE REMOVAL PACK	287811917
28783	VELBAND UNDERCAST PADDING 5CM X 2.75MTRS	287830317, 287832317
28784	VELBAND UNDERCAST PADD 7.5CM X 2.75MTRS , Double Wrapped	287841717
28785	VELBAND UNDERCAST PADDING 10CM X 2.75MTRS	287850117, 287850917, 287851117, 287851417, 287852117
28786	VELBAND UNDERCAST PADDING 15CM X 2.75MTRS	287861217, 287862117
28787	DRESSING PACK	287871214, 287871814, 287872814
28884	SOFSORB SWABS 10X10CM 4PLAINY 10 , SINGLE WRAPPED	288842017, 288843316
28897	800ML POLY KIDNEY RECEIVER	288971517