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FIELD SAFETY NOTICE

DATE: 16th July 2014

Dear Theatre Manager / Procurement Manager,

Single Use Surgical Ltd is issuing a Field Safety Corrective Action of two lots of S353 Pulse Lavage System due to a labelling error.

What is the reason for the Corrective Action?

The product was not labelled to our Specification. The Specification requires that all items be packed inside a labelled sterile barrier peel pouch. On these batches, the main product was packed inside a labelled sterile barrier peel pouch and the coaxial canal tip (an accessory to the device) was packed in a separate sterile barrier peel pouch, but was not labelled.
The product, including the coaxial tip accessory, was packed in a unit pack (box), but this is not a sterile barrier pack.

Which lots are affected by the Action?

Lot number 1404-09
Lot number 1404-15

What is the safety risk?

There is no safety risk. The unit box contains full lot traceability information, as does the main product. If the coaxial canal tip accessory was to become separated from the original box, it would not be possible to identify it and therefore should not be used.

What action do we need to take as a facility?

Our Area Sales Manager will contact you to arrange to visit, review stock held and label the coaxial tip accessory pack. No further action other than to support this activity will be necessary.
Should you have any questions relating to this, please contact Single Use Surgical Ltd on +44(0)1226 732333. The MHRA has been informed of this Field Safety Corrective Action.

Steve Whittall
General Manager,
Single Use Surgical Ltd.