

August 2023

Notice: SMARTBAND[™] Packaging Amendment Notification

Dear Valued Customer,

Please be informed that we are implementing a permanent packaging change to SMARTBAND[™] Multi-Band Ligation Kit (SLK6 and SLK6LF).

The device will remain in the original packaging format but will no longer contain printing on the foil pouch. Product details and regulatory information will be combined into one label and applied to the pouch. In addition, the flushing tube has been permanently removed from the product to reduce packaging and material wastage. Production changes will be implemented starting August 11th with Lot 6574758 (SLK6) and Lot 6574766 (SLK6LF).

The device's functionality and capability will not be impacted. All support materials and IFU for the SMARTBAND devices are otherwise identical. There will be no change to the SMARTBAND[™] Multi-Band Ligation Packs (SLP6, SLP6LF).

Please see below images for reference:



We thank you for your continued business. If you have any questions, please reach out to your local STERIS Account Manager.

Sincerely,

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Michael McGrath Vice President, Canada

STERIS provides the language translations in accordance with Article10(11) of the Medical Device Regulation

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