

CUSTOMER NOTIFICATION

MedStream Refill Kits, Codman 3000 Refill Kits Product Codes: 91-4289, 91-4290, AP-07014 (specific lots)

September 24, 2019

Dear Operating Room Supervisors, Materials Management Personnel, and Chief of Surgery:

At Codman & Shurtleff, Inc., our first priority is to our customers and their patients, ensuring the safe and effective use of our products.

We have initiated a medical device Customer Notification with regard to 10 lots of MedStream Refill Kits, MedStream Refill Kits (6-pack), and Codman 3000 Refill Kits distributed in Germany, Switzerland, Spain, Portugal, Russia, and Israel containing an alternate adhesive bandage.

Due to the unavailability of the previously provided adhesive bandages that were included in the Refill Kits, alternate adhesive bandages have been included in the refill kits outlined in the table below. This change in adhesive bandages is pending regulatory approval. We are working with the regulatory body to complete the approval process.

<u>Customer Action</u>: There is no customer action required. The refill kits meet specification and are safe to use.

The scope of this Customer Notification includes the product codes and lots listed in the table below:

Table 1 – Product Subject to this Customer Notification

Part Number	Description	Lot Number
91-4289	Medstream Refill Kit	18L091CT 19A041CT 19A501CT 19A506CT 19A507CT
91-4290	Medstream Refill Kit (6-Pack)	18L092CT 19A042CT 19B022CT 19B024CT
AP-07014	Codman 3000 Series Re-fill Kit	19B212CT

CUSTOMER NOTIFICATION

MedStream Refill Kits, Codman 3000 Refill Kits Product Codes: 91-2489, 91-2490, AP-07014 (specific lots)

If you have additional questions regarding this Customer Notification or to report any customer complaints, please contact [INSERT AFFILIATE INFORMATION].

Sincerely,

Yolanda Bolanos Director of Quality