

MEDICAL DEVICE RECALL: SAM CHEST SEAL COMBO

Supplemental Instructions for Distributors, Sub-distributors
and Direct Customers/End Users

Distributor Recall Response Instructions

1. Indicate with a Yes or No response that you have received the SAM Chest Seal Combo Recall Notification (by signature required UPS delivery, email, fax or by phone) and understand the instructions from the Recall Notification.
2. Indicate with a Yes or No response if there have been any complaints or adverse events reported to you regarding the recalled product. If there was a report that a SAM Chest Seal Combo was not able to be used on a patient, please report the details on the Recall Response Form.
3. Affected Product Information
 - Information on the quantity of recalled devices shipped to your facility and the date the devices were shipped from SAM Medical is included on the Recall Response Form.
 - Quantity in Inventory – Number of recalled SAM Chest Seal Combo products currently in your possession.
 - Quantity to Return – This could be the same as the Quantity in Inventory but could include devices already returned from the sub-distributor or end user.
 - Quantity Used or Destroyed – This is the number of recalled devices that have been used on patients, used in product demonstrations or in training events.
 - Quantity Further Distributed – This is the number of recalled devices that you have sold to Sub-distributors and Direct Customers.
4. Distributor Information

Place a mark in the check box next to each of the statements that are applicable to you as a Distributor.
5. Complete the form by applying your Signature and the date the form was signed, print your name, company affiliation, phone number and email address. Return this Recall Response form to SAM Medical by Fax (503-639-5425) or scan and send by email to chestsealrecall@sammedical.com.
6. Send a copy of the Chest Seal Combo Recall Notification Letter and Sub-distributor / Direct Customer Acknowledgement and Response Form to each Sub-distributor/Direct Customer that you have shipped product. Input the number of recalled Chest Seal Combo products that were shipped to Sub-distributors/Direct Customers and the date of shipment on the response form.
7. When received, send the SAM Chest Seal Combo Recall Response forms from your Sub-Distributors and Direct Customers to SAM Medical by Fax (503-639-5425) or scan and send by email to chestsealrecall@sammedical.com.
8. Collect returned product from your Sub-distributors/Direct Customers and place in quarantine. Contact SAM Medical Customer Service by phone (503-783-6921), by email (chestsealrecall@sammedical.com) to obtain a Return Materials Authorization and to arrange for shipment of the recalled product back to SAM Medical.

Thank you for your assistance in performing the Recall, we apologize for the inconvenience.

Sub-Distributor Recall Response Instructions

1. Indicate with a Yes or No response that you have received the SAM Chest Seal Combo Recall Notification (by signature required UPS delivery, email, fax or by phone) and understand the instructions from the Recall Notification.
2. Indicate with a Yes or No response if there have been any complaints or adverse events reported to you regarding the recalled product. If there was a report that a SAM Chest Seal Combo was not able to be used on a patient, please report the details on the Recall Response Form.
3. Affected Product Information
 - Information on the quantity of recalled devices shipped to your facility and the date the devices were shipped from the Distributor is included on the Recall Response Form.
 - Quantity in Inventory – Number of recalled SAM Chest Seal Combo products currently in your possession.
 - Quantity to Return – This could be the same as the Quantity in Inventory but could include devices already returned from the sub-distributor or end user.
 - Quantity Used or Destroyed – This is the number of recalled devices that have been used on patients, used in product demonstrations or in training events.
 - Quantity Further Distributed – This is the number of recalled devices that you have sold to other Sub-distributors and Direct Customers.
4. Sub-Distributor / Direct Customer Information

Place a mark the in the check box next to each of the statements that are applicable to you as a Sub-distributor.
5. Complete the form by applying your Signature and the date the form was signed, print your name, company affiliation, phone number and email address. Return this Recall Response form to SAM Medical by Fax (503-639-5425) or scan and send by email to chestsealrecall@sammedical.com.
6. Send a copy of the Chest Seal Combo Recall Notification Letter and Sub-distributor/Direct Customer Acknowledgement and Response Form to each Sub-distributor/Direct Customer that you have shipped product. Input the number of recalled Chest Seal Combo products that were shipped to the Sub-distributors/Direct Customers and the date of shipment on the Response form.
7. When received, send the SAM Chest Seal Combo Recall Response forms from your Sub-Distributors and Direct Customers to SAM Medical by Fax (503-639-5425) or scan and send by email to chestsealrecall@sammedical.com.
8. Collect returned product from your Sub-distributors/Customers and place in quarantine. Contact SAM Medical Customer Service by phone (503-783-6921), by email (chestsealrecall@sammedical.com) to obtain a Return Materials Authorization and to arrange for shipment of the recalled product back to SAM Medical.

Thank you for your assistance in performing the Recall, we apologize for the inconvenience.

Direct Customer/End User Response Instructions

1. Indicate with a Yes or No response that you have received the SAM Chest Seal Combo Recall Notification (by signature required UPS delivery, email, fax or by phone) and understand the instructions from the Recall Notification.
2. Indicate with a Yes or No response if you have any complaints that a SAM Chest Seal Combo was not able to be used on a patient, please report the details on the Recall Response Form.
3. Affected Product Information
 - Information on the quantity of recalled devices shipped to you and the date the devices were shipped is included on the Recall Response Form.
 - Quantity in Inventory – The number recalled SAM Chest Seal Combo products currently in your possession.
 - Quantity to Return – This should be the same as the Quantity in Inventory.
 - Quantity Used or Destroyed – This is the number of recalled devices that have been used on patients, used in product demonstrations or in training events.
 - Quantity Further Distributed – This is the number of recalled devices that you may have sent to another end user.
4. Direct Customer/End User Information

Place a mark the in the check box next to each of the statements that are applicable to you as a Direct Customer/End User.
5. Complete the form by applying your Signature and the date the form was signed, print your name, phone number and email address. Return this Recall Response form to SAM Medical by Fax (503-639-5425) or scan and send by email to chestsealrecall@sammedical.com.
6. Contact SAM Medical Customer Service by phone (503-783-6921), by email (chestsealrecall@sammedical.com) to obtain a Return Materials Authorization and to arrange for shipment of the recalled product back to SAM Medical.

Thank you for your assistance in performing the Recall, we apologize for the inconvenience.