12200 SW Tualatin Road, Suite 200
Tualatin, OR USA 97062

MEDICAL DEVICE RECALL

SAM Chest Seal Combo

January 27, 2022

Distributor/Customer Name
Street Address
City, State, Zip Code

Dear SAM Medical Customer or Distributor,

The purpose of this letter is to advise you that SAM Medical Products is voluntarily recalling the SAM Chest Seal Combo (CS203-EN) with Lot Number Y060321-09 that is used as a temporary bandage to treat penetrating chest wounds that could compromise the pleural space and to be used in emergency situations and left in place while a patient is transported to definitive care. Inspection of the devices indicated that a small portion of the Chest Seal Combo products with LN Y060321-09 have a defect that could pose a potential risk if applied to a patient. These devices were distributed from September 2021 through November 2021.

Note: There have been no complaints, injuries and/or deaths reported due to the failure mode associated with the recalled product at this time.

Reason for the Voluntary Recall

The SAM Chest Seal Combo is comprised of two dressings, one with a valve and one without a valve. Inspection of the product at SAM Medical identified a non-conformance in one of the two dressings in the package. Based on testing performed by SAM Medical and the contract manufacturer, it is estimated that the non-valved dressing (occlusive dressing) in the package is non-conforming in 1.4% of the manufactured lot and will not perform its intended use as stated in the instructions for use. The non-conforming chest seal is a partially assembled valved dressing that has a hole in the center where a valve would be placed which will prevent the dressing from performing as an occlusive chest seal.

Risk to Health:

The primary risk from the non-conforming dressing is that it would not be effective in creating an occlusive seal over an open chest wound due to a hole in the center of the dressing. The package also contains a Valved Chest Seal which is not affected by the non-conformance and can be used to treat open chest wounds.

- **Frequency of Failures**

  The defect in the dressing was found in approximately 1.4% of the manufactured lot inspected. An analysis of the probability that both Chest Seal dressings were needed to treat an open chest wound and that one of the recalled dressings is in the Chest Seal package utilized is very low. To date there have been no reports to SAM Medical of any complaints or health consequences due to the recalled product.

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- **Potential severity of using recalled product**

  If a recalled dressing was needed in addition to the primary Valved Chest Seal, and if the hole in the dressing is centered over the chest wound, it would prevent the dressing from forming an occlusive seal. If the non-conforming dressing was needed for a patient that has more than one penetrating chest wound, the compromised pleural space could not be converted to a closed chest wound.

- **How to recognize a recalled device**

  The defect can be easily recognized by a user when the Chest Seal Combo pouch is opened and will be seen as a 1.25 in. (3.2 cm) hole in the center of the dressing without a valve.

Actions to be taken by the Distributor/Customer/User:

SAM Medical will contact each Distributor and direct customer with the Recall Notification to alert them to the recall. The following actions will be taken by SAM Medical Distributors, Direct Customers and End Uses of the SAM Chest Seal Combo recalled device:

1. Customers/End Users should immediately discontinue use of the recalled devices.
2. SAM Medical Distributors should immediately discontinue shipment of the recalled devices and quarantine their inventory of recalled SAM Chest Seal Combo devices. Share this recall notification with others in your organization to ensure they are aware of this recall.
3. SAM Medical Distributors will in turn send a Recall Notification Letter to any sub-distributor or customer to whom a recalled device was provided.
4. SAM Medical Distributors and direct customers need to return the Recall Response Form acknowledging their receipt of the Notification and to provide information on the status of recalled devices in their possession and actions they have taken.
5. SAM Medical Distributors and direct customers who have resold the SAM Chest Seal Combo recalled product to sub-distributors and end users will document on the Recall Response Form that their customers have been notified.
6. If any complaint or adverse event is received by a Distributor or Sub-Distributor, please document this on the Recall Response Form.
7. The Recall Response Form should be returned by the sub-distributors and end users through their distribution channel back to SAM Medical though the methods (provided envelope, fax, email) outlined on the Recall Response Form.
8. SAM Medical will arrange for the return of the recalled product and arrange for replacement devices free of charge or provide a credit.

Product and Distribution Information: The table below contains information on the product that is subject to this recall.

SAM Chest Seal Combo			
Catalog Number	**Lot/Serial Number**	**Labeled Expiration Date**	**Shipment Date(s)**
CS203-EN	Y060321-09	2027-06-01	23 Sep 2021 to 30 Nov 2021

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Failure Investigation Findings:

The root cause was determined to be poor segregation of production assembly steps and process flows that allowed a partially assembled valved dressing to be packaged with a fully assembled valved dressing. The nonconformance was not captured or contained due to a lack of a down-stream inspection prior to sealing the pouch to ensure that only one non-valved chest seal was combined with one valved chest seal.

Type of Action by the Company:

SAM Medical has modified the inspection of the dressings from the Contract Manufacturer to ensure increased confidence that the defect is not present in the final product.

The contract manufacturer has implemented multiple short-term corrections in their assembly line to isolate the assembly of non-valved dressings to reduce the opportunity for a mix up. A separate table contains only fully assembled valved and non-valved dressings are present in the final device packaging station. In addition, prior to sealing the pouch a 100% visual inspection is being performed to ensure the package contains one valved dressing and one non-valved dressing.

SAM Medical and the contract manufacturer are implementing a new subassembly part number thereby preventing a partially assembled device from entering the final production area.

Contact Information

Inquiries related to this recalled product should be addressed to SAM Medical Customer Service at:

- **Phone:** 503-783-6921 Monday through Friday from 8:30 am to 5:00 pm Pacific Time
- **Email:** ChestSealRecall@sammedical.com
- **Website:** www. sammedical.com/ChestSealRecall

Product quality is of utmost importance to SAM Medical, and we take this issue very seriously. We are committed to continuous product improvement and striving for zero product failures. We appreciate your prompt attention and cooperation in this voluntary recall.

Device users should contact SAM Medical if they have experienced any problems that may be related to using this product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Authorized by:

Jeff Lipps

Director of RA/QA

SAM Medical Products

- **Attachment:** Recall Response Form (separate sheets)