URGENT Medical Device Recall
AMALGATOME® SD, SDSYSTEM024
Item number: X101004, Amalgatome Pneumatic Hose

MODEL NUMBER(S) IMPACTED:
X101004: COAXIAL PNEUMATIC HOSE, SCHRADER

Which is a component of: SDSYSTEM024: EXSURCO AMALGATOME SD (2" & 4"), SDSYSTEM024-EVAL: EVALUATION SDSYSTEM024, SDSYSTEM024-LOANER: LOANER SDSYSTEM024, SDSYSTEM024-R&D: RESEARCH SDSYSTEM024.

Information on impacted hoses:
This recall affects Item number X101004, Amalgatome Pneumatic Hose and the range of serial number(s) impacted are:

SDH201607220029	SDH201607220065	SDH201607220047
SDH201607220030	SDH201607220067	SDH201607220001
SDH201607220031	SDH201607220068	SDH201607220002
SDH201607220032	SDH201607220069	SDH201607220003
SDH201607220033	SDH201607220070	SDH201607220004
SDH201607220034	SDH201607220071	SDH201607220005
SDH201607220035	SDH201607220072	SDH201607220006
SDH201607220036	SDH201607220073	SDH201607220007
SDH201607220037	SDH201607220075	SDH201607220008
SDH201607220038	SDH201607220076	SDH201607220009
SDH201607220039	SDH201607220077	SDH201607220010
SDH201607220040	SDH201607220078	SDH201607220011
SDH201607220041	SDH201607220079	SDH201607220012
SDH201607220043	SDH201607220080	SDH201607220013
SDH201607220044	SDH201607220081	SDH201607220014
SDH201607220046	SDH201607220082	SDH201607220015
SDH201607220048	SDH201607220083	SDH201607220016
SDH201607220049	SDH201607220084	SDH201607220017
SDH201607220050	SDH201607220085	SDH201607220018
SDH201607220051	SDH201607220086	SDH201607220019
SDH201607220052	SDH201607220087	SDH201607220020
SDH201607220053	SDH201607220088	SDH201607220021
SDH201607220054	SDH201607220089	SDH201607220022
SDH201607220055	SDH201607220090	SDH201607220023
SDH201607220056	SDH201607220091	SDH201607220024
SDH201607220057	SDH201607220092	SDH201607220025
SDH201607220058	SDH201607220093	SDH201607220026
SDH201607220059	SDH201607220094	SDH201607220027
SDH201607220060	SDH201607220095	SDH201607220028
SDH201607220061	SDH201607220096	SDH201607220042
SDH201607220062	SDH201607220097	SDH201607220045
SDH201607220063	SDH201607220098	SDH201607220066
SDH201607220064	SDH201607220099	SDH201607220074
SDH201804100101	SDH201804100102	SDH201804100103

SDH201804100104	SDH201804100113	SDH201804100122
SDH201804100105	SDH201804100114	SDH201804100123
SDH201804100106	SDH201804100115	SDH201804100124
SDH201804100107	SDH201804100116	SDH201804100125
SDH201804100108	SDH201804100117	SDH201804100126
SDH201804100109	SDH201804100118	SDH201804100127
SDH201804100110	SDH201804100119	SDH201804100128
SDH201804100111	SDH201804100120	SDH201804100129
SDH201804100112	SDH201804100121	SDH201804100130

The impacted pneumatic hoses have been distributed to hospitals since **September 1, 2017**.

What is the issue:

This recall has been initiated due to improper installation of the hand piece (bending hose at the proximal end and applying excessive force at the hose end fitting) by the user which results in a weakening of the internal hose connection to its end fitting. When improper installation occurs repeatedly, the hose connection may fail. The failure mode can result in the hose separation from the end fitting causing loss of pressure to the device or a hose burst or bulge.

This recall affects Item number X101004, Amalgatome Pneumatic Hose and the range of serial number(s) impacted are: **SDH201607220001- SDH201607220099 & SDH201804100101- SDH201804100130.**
The impacted pneumatic hoses have been distributed to hospitals since **September 1, 2017**.

To date Exsurco has received five (5) field complaints regarding the above listed matter.
To date Exsurco has filed one (1) MDR report. The reported minor injury was due to a secondary hazard and not by the device itself.

Risk to Health:

If the hose bursts under pneumatic pressure, the hose and device will most likely shutdown or stop working. However, there is a possibility that the hose may be subjected to unintended movement or uncontrolled movement or a secondary hazard can occur due to a loud popping noise, from the ruptured hose being under pressure. The immediate health consequences to the user or patient can be abrasions, bruises, broken bones, and sprains.

How do you recognize that the device may fail?

The failure mode can result in the hose separation from the end fitting causing loss of pressure to the device or a hose burst or bulge.

Actions required by the customer

1. Please immediately check your stock and quarantine impacted stock of hoses on hand to prevent further use. Replacement of newly designed hoses have been provided with this communication.

2. Review and complete the attached X101004_Pneumatic Hose Customer Response Card, by confirming the information that is listed; serial number(s) of the hose(s), and, check the box that you have received and understood the communication.

3. Upon verifying the information and completing the X101004_Pneumatic Hose Customer Response Card provide this to your Burn Account Manager. Please complete and return the enclosed response card as soon as possible.

4. Render the identified Item Number: X101004 Pneumatic Hose(s) unusable as pictured below. Replace inventory with newly designed hose(s) provided.

5. Document that the hose has been destroyed with a picture of the serial number and swivel assembly as pictured below. Provide this documentation to your Burn Account Manager.

Proper method to destroy the impacted hose: