



Urgent Field Safety Notice

RES-Q-VAC® Suction Unit with Soft Yankauer and FSP (Full Stop Protection) Filter

January 27, 2012

Type of Action: Advice given by Manufacturer regarding the use of the device

Attention: All customers using RES-Q-VAC® Suction Unit with Soft Yankauer and FSP Filter

Details on affected devices:

Part numbers of affected devices are P1 F1B110NLED, P1 F1B1AFNLED, P1 F1B1AFSLED, P1 F1H110N, P1 F1S000N, P1 F1S000NE, P1 F1S000NGE, P1 F1S110N, P1 F1S110NE, P1 F1S114S, P1 F1S1C1S, P2 F1B1AFN, P2 F1B1AFS, PC F8S181NLED, R1 F1B1AFS, R1 F1S000N, R1 F1S110N, R1 F1S1C1S, RC F81S81N.

See the below website for a part number explanation:

http://www.rmsmedicalproducts.com/downloads/resources/rqv/literature/ROV_FL_part_number_matrix_03-3024vA.pdf

This issue only applies to the use of *Soft Yankauer*; the *Rigid Yankauer* is NOT affected.

Description of the problem:

Large food particles entered the Soft Yankauer suction tube and became stuck in the passage between the tubing and the canister.

This issue is a potential risk for patients who use the Soft Yankauer with the FSP filter only.

Advise on action to be taken by the user:

As stated in the revised user manual, the manufacturer “recommended to always have a spare canister on hand when using FSP”.

If a blockage should occur, the Manufacturer recommends the user to:

1. Immediately switch to another canister or, if not available,
2. Remove the FSP cap from the canister and tap on a hard surface to dislodge the particle. A pen, or similar item, may also be used to remove the particle.

Transmission of this Field Safety Notice:

Please transfer this notice to other organizations and users on which this action has an impact.

Contact reference person:

Customer Service at RMS Medical Products, see footer for contact details.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Signature

 1.27.12



RMS Medical Products
Claire Becker
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Chester
NY 10918

ACKNOWLEDGMENT FORM

I _____
(please print name and organization) hereby confirm receipt of
the RMS Medical Products **Field Service Notice** dated January
2012. I understand that this edition supersedes the FSN that was
distributed earlier and is dated August 2011.

Yours sincerely
(Please sign below)

Date _____

Please send the completed form to the above address or fax number.
Alternatively, please email a signed copy to cbecker@rmsmedicalproducts.com