

Q & A for the Recall of A & A Medical, Inc. Devices

1) What are the exact products, lot numbers and/or dates of distribution under recall?

This recall affects *all lots* of medical devices labeled as "Sterile" or "Ethylene Oxide Processed", manufactured and distributed over the past 3 years by a firm identified by any of three names: A & A Medical, Inc., Rocket USA, Inc. or LifeQuest Medical. It is also possible that some devices may have been distributed by an "own label distributor" and thus may have another firm's label. Unfortunately, we do not have a reliable list of the firm's "own label distributors". Devices include, but are not limited to: laminaria, rigid curved or straight curettes, aspiration kit w/sound, mucus samplers, OS dilator sets, mini embryo IUI (hard), insufflation tubing, Simms uterine curettes, Biere ovum forceps, Sopher ovum forceps, Hawkin-Ambler dilators, Kahn Uterine Trigger cannulas, and Pratt dilators. We are making every effort to contact ALL distributors and customers who have received devices from A&A over the past 3 years and provide them with appropriate recall information.

2) Will I be reimbursed? Many hospitals, distributors and healthcare providers have experienced a problem trying to get this answer from the firm.

Unfortunately, FDA does not have an answer to this question. The firm may no longer be in operation and has not assumed responsibility for the devices. The firm's legal representative is Mr. Orrin Walker, 2291 Austell Road, Suite 107, Marietta, Georgia 30008, 770-801-8600.

3) Will FDA reimburse me for recalled product?

No. It is the responsibility of A & A to provide refunds for the recalled product. FDA is conducting this recall notification in the interest of public health.

4) What should distributors, hospitals and healthcare providers do with their recalled stock?

FDA encourages that recalled devices be voluntarily destroyed. However, before destroying the recalled devices, please complete the enclosed self-certification form and fax it to FDA's Atlanta District Office (ATL-DO) at 404-253-1201. ATL-DO is asking for detailed information about the recalled devices and the place, date, and time when the devices will be destroyed, in the event FDA chooses to witness the destruction.

5) How should the stock be destroyed?

We recommend that recalled devices be burned or pulverized. Please complete and mail the enclosed self-certification sheet before doing so.

6) Can we re-sterilize the product?

It cannot be determined which of these devices have already been sterilized. FDA is not aware of any data that would establish conditions for the safe and effective cleaning and subsequent re-sterilization of these devices. Therefore, FDA cannot recommend sterilization or re-sterilization.

7) If I am a distributor, should I sub-recall the product from accounts?

Yes. If you have distributed any of these devices, as labeled above or under your own label or any other label, immediately contact all your accounts and provide them a copy of the enclosed FDA recall letter. Please request that they immediately cease use and distribution of recalled devices and have them promptly return the devices to you. Alternatively, they may destroy the products themselves provided they fill-out the enclosed self-certification form and fax it to FDA's ATL-DO.

8) If I have used this device on a patient, what should I do? If one of my patients has developed a problem possibly related to recall, what should I do?

The health care provider should make decisions about the most appropriate medical care for individual patients. If you would like to speak to an FDA Medical Officer (physician) regarding this issue, you may contact FDA's Center for Devices and Radiological Health (CDRH), Division of Small Manufacturers and International Consumer Assistance (DSMICA) at 1-800-638-2041. Provide your name and telephone number and an FDA Medical Officer will return your call.

If you are aware of an adverse event involving these devices, or should you become aware of one, please contact FDA at the numbers below. Healthcare providers employed by health care facilities that are subject to FDA's user facility reporting requirements should follow the reporting procedures established by their facility. All other providers may submit their reports to MedWatch, FDA's voluntary reporting program. The reports can be submitted by phone at 1-800-FDA-1088; by fax at 1-800-FDA-0178; via the MedWatch website at www.fda.gov/medwatch; or by mail to MedWatch, FDA, HF-2, 5600 Fishers Lane, Rockville, Maryland 20852-9787.