

## Notice Information: Medical Devices - Recall 13 June 2002

### Part 1. Product Information

- a) Title: A&A Products
- b) Product Name/Type: A&A Products
- c) Reference: SN2002(03)
- d) Manufacturer/Supplier: A & A Medical of Alpharetta or A&A Medical / Rocket USA or Lifequest *Note:* The A&A Medical/ROCKET USA/LIFEQUEST products that are referred to in this safety notice do not relate to the ROCKET MEDICAL products that are distributed by Fannin Healthcare.

### Part 2. Target Audience

- a) Target Audience: Hospital Administrators; Risk Managers; Director, Central Supply; Director, Department of Obstetrics and Gynaecology; Director, Department of Surgery; Ambulatory Surgical Centres

### Part 3. Problem/Issue

- a) Problem/Issue: FDA is alerting consumers and health care professionals of a nationwide/international recall of all medical devices labelled as sterile or ethylene oxide processed, manufactured by A&A of Alpharetta, Georgia. The firm also does business as A&A Medical/Rocket USA, and Lifequest. Some of the products manufactured by this company have been labelled and shipped as sterile but in fact may not have undergone any sterilization process. This has the potential of causing death or serious injury such as infection, infertility, and miscarriage. As a result, the company is recalling all products labelled as sterile and shipped nationwide and internationally to Canada, Egypt, Italy and Lebanon

### Part 4. Background Information

a) Background Information:

This firm manufactures many types of OB/GYN and surgical devices. These devices are used only in the clinical setting during surgical and gynaecological procedures. The recall includes, but is not limited to curettes (flexible and rigid), uterine dilators (e.g. Laminaria), endometrial sampling sets, fetal blood samplers, fetal bladder drains, laparoscopy accessories, bone marrow needles, aspiration sets, biopsy pipettes, and harvesting pumps used in in-vitro fertilization. List of Known Ob/Gyn and Surgical Devices Recalled by A & A Medical, Inc. (This is a partial list; as known at the time of this alert.) Curette (flexible and rigid, all sizes) Collection set tubing Aspiration sets Laminaria IUD removal instruments Mucus samplers Biopsy pipettes/Endometrial sampling sets Uterine sounds Pratt dilator set Ovum forceps Tenaculum forceps Needle extenders and guide Fetal bladder drain Fetal blood sampler Harvesting Pump and accessories Loop/ball electrodes Laparoscopy accessories

## Part 5. Action to be taken

a) Action to be taken:

Do not use any A & A Medical, Inc., Rocket USA, or Lifequest products. Please ensure that those responsible for the purchase of these devices are made aware of this issue.

## Part 6. Enquiries

a) All enquiries should be made to:

All adverse incidents relating to a medical device should be reported to the: Medical Devices Department Irish Medicines Board Earlsfort Centre Earlsfort Terrace Dublin 2 If you have any enquiries, you may contact the Medical Devices Department at: Telephone: +353-1-6764971 Fax: +353-1-6767836 Email: vigilance@imb.ie Website: www.imb.ie SN2002(03): A&A Products

## Part 7. Keywords

a) Keywords:

A&A Products