IRISH MEDICINES BOARD

MEDICAL DEVICE
SAFETY NOTICE

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MANUFACTURER/SUPPLIER

A & A Medical of Aipharetta
Or
A& A Medical / Rocket USA
Or
Lifequest

TARGET GROUPS

Hospital Administrators
Risk Managers
Director, Central Supply
Director, Department of Obstetrics and Gynaecology
Director, Department of Surgery
Ambulatory Surgical Centres

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.

BACKGROUND

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

ACTION OR RECOMMENDATIONS

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.

ENQUIRIES

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:	(01) 6764971
Fax:	(01) 6767836
e-mail:	medicaldevices@imb.ie
Website:	www.imb.ie

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