Allergan + LifeCell
Plastic and Regenerative Medicine

September 21, 2017

FIELD SAFETY NOTICE

Dear Valued Customer,

This is to inform you of a product recall involving:

Revolve™ Advanced Adipose System (Revolve™ System)

Lot No.	Catalogue Code	Expiration Date
10838	**RV0001**	**04/30/2018**

Reason for Recall

This recall has been initiated due to the presence of bacterial endotoxins levels above the acceptable limits as defined in the standard, USP <161> ("*Medical Devices - Bacterial Endotoxin and Pyrogen Tests*"). You are being notified because you have been identified as having received this product.

Risk to Health

All Revolve, non-expired lots distributed to date are impacted, as all Revolve is labeled as "Sterile" and "Non-pyrogenic". No direct reports of injury have been received to date, however, use of this product may cause a pyrogenic response to endotoxin, such as fever, increased heart rate, low blood pressure, and decreased white blood cell count.

LifeCell's Actions

Through the course of this evaluation, investigation, and resulting testing, all Revolve product inventory was placed on hold while samples of units from previously released and unreleased finished product lots of the Revolve™ System were taken and tested for endotoxin.

Actions to be taken

1. Immediately examine your inventory and quarantine all product subject to this recall. In addition, if you have further distributed this product, please identify your customers and notify them at once of this product recall, and that all product should be quarantined. Your notification to your customers may be enhanced by including a copy of this recall notification letter.
2. Carry out a physical count of the affected product in your possession and record the count on the enclosed Field Safety Notice (FSN)Response Form.
3. Email or fax the completed FSN Response Form immediately. To assure that we can account for all recalled product, it is imperative that you return the FSN Response Form.
4. If you have product, a representative of LifeCell will contact you to arrange pick-up of the device.
5. This recall should be carried out to the consumer/user level.

Revolve™ System Indications for Use

REVOLVE Advanced Adipose System is intended for use in the following surgical specialties when the aspiration of soft tissue is desired: plastic and reconstructive surgery, neurosurgery, gastrointestinal and affiliated organ surgery, urological surgery, general surgery, orthopedic surgery, gynecological surgery, thoracic surgery, and laparoscopic surgery.

Contact Information

For Questions regarding the Recall: Contact LifeCell via Email: garry.ang1@allergan.com

For Adverse Events/Product Complaints: Contact LifeCell via Email: complaintfeedbackregistration@lifecell.com

For Credit or Reimbursement Questions: Contact LifeCell at 1-800-367-5737, during the hours of 9 AM - 5 PM EST or via Email: CustomerSolutionsManagers@lifecell.com

This recall is being made with the knowledge of the Health Sciences Authority.

LifeCell regrets any inconvenience that may result from this field correction and appreciates your patience as we take steps to resolve this issue and return the product to the market. Please be assured that maintaining patient safety and quality is LifeCell's utmost priority.

Sincerely,

LifeCell

CC: Chairman Medical Board and relevant Head of Departments