Allergan + LifeCell
Plastic and Regenerative Medicine

Urgent Field Safety Notice (FSN)

Commercial Name: Revolve™ Advanced Adipose System (Revolve™ System)

Type of Action: Return of Medical Device
FSCA Identifier: EVAL-2017-007-A

Date: 19 September 2017

Dear Customer,

You are receiving this communication as our records indicate that you have received LifeCell product that is the subject of this Field Safety Notice (FSN). Information describing the issue and any actions to be taken are provided below.

Details of Affected Devices:

Product Type:	Tissue Canister
Product Name:	Revolve™ Advanced Adipose System (Revolve™ System)
Product Description:	The Revolve™ System is a sterile, single-use disposable tissue canister used for harvesting, filtering, separating, concentrating, and transferring autologous tissue components for reintroduction to the same patient during a single-surgical procedure for repair, reconstruction, or replacement of integumentary or musculoskeletal tissues.

Description of the problem:
The Revolve™ System is labelled as "Non-Pyrogenic", however there were no prior release criteria for finished product endotoxin testing and as such LifeCell is unable to substantiate the label claim. In addition, LifeCell has conducted testing on a sampling of lots and found that several lots tested have endotoxin levels above the limits defined in US Pharmacopeia (USP<161>).

Affected Product Catalogue Numbers:
RV0001WW, RV0002WW, and RV0004WW

Risk Assessment:
A detailed analysis of product complaints and adverse events received on the Revolve™ System since 2012 found no complaints or adverse events confirmed to be related to elevated endotoxin levels.

LifeCell have tested the levels of endotoxin in samples of finished product lots and determined that the likelihood of a harmful physiological reaction to endotoxin that could be potentially introduced via the

device is clinically improbable. A review of published literature determined that endotoxin exposure at the levels observed in the Revolve™ samples, did not lead to harmful physiological reactions. This resulted in the determination that the overall risk of harm to patients is negligible.

There is no known failure of the device to perform in accordance with its intended purpose, when used in accordance with the manufacturer's instructions for use.

Processing controls have been implemented to correct this issue.

Action to be taken by customer:

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 Field Safety Notice.
2. Carry out a physical count of the affected product in your possession and record the count on the enclosed Field Safety Notice Response Form (FSNRF).
3. Email or fax the completed FSNRF immediately. To assure that we can account for all recalled product, it is imperative that you return the FSNRF.
4. If you have product in your inventory contact LifeCell via Email: LifeCellRevolve@allergan.com for further instructions on return of recalled product.
5. This recall should be carried out to the consumer/user level.

Transmission of this Field Safety Notice:
This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

LifeCell has informed all relevant regulatory agencies of this FSN.

If you have any questions regarding this FSN, please contact your in-country LifeCell/Allergan representative using the details provided in the following table.

Contact reference person:

Country	Contact	Phone	Email
Austria	Nina Labhart Meuli	+41442042312	Labhartmeuli_Nina@Allergan.com
Belgium	Hendrik Staels	+32477996702	Staels_Hendrik@Allergan.com
Denmark	Lovisa Sondefors	+46763143418	Lovisa.Sondefors@Allergan.com
Finland	Lovisa Sondefors	+46763143418	Lovisa.Sondefors@Allergan.com
France	Marie Chiffoleau	+33149078300	Materio_vigilance@Allergan.com
Germany	Claudia Rohrer	+4969920381358	Rohrer_Claudia@Allergan.com
Ireland	Sarah Graham	+35316445271	Graham_Sarah@Allergan.com
Italy	Mariarosaria Toteda	+390650956247	Toteda_Mariarosaria@Allergan.com
Netherlands	Hendrik Staels	+32477996702	Staels_Hendrik@Allergan.com
Portugal	Javier Mariano	+34918076208	Mariano_Javier@Allergan.com
Spain	Javier Mariano	+34918076208	Mariano_Javier@Allergan.com
Sweden	Lovisa Sondefors	+46763143418	Lovisa.Sondefors@Allergan.com
Switzerland	Nina Labhart Meuli	+41442042312	Labhartmeuli_Nina@Allergan.com
United Kingdom	Madhavi Sabharwal	+44162849427	Madhavi.Sabharwal@Allergan.com

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

Attachment 1 - Impacted Lot Information

Lot Number	Catalog Code	Expiration Date
10698	RV0001WW	11/30/2017
10699	RV0001WW	10/31/2017
10701	RV0001WW	12/31/2017
10703	RV0001WW	1/31/2018
10703	RV0002WW	1/31/2018
10707	RV0001WW	3/31/2018
10707	RV0002WW	3/31/2018
10709	RV0002WW	6/30/2018
10736	RV0001WW	9/30/2017
10782	RV0002WW	6/30/2018
10783	RV0002WW	7/31/2018
10799	RV0001WW	1/31/2018
10841	RV0001WW	6/30/2018
11218	RV0001WW	9/30/2018
11219	RV0001WW	9/30/2018
11262	RV0001WW	9/30/2018