



ENGLISH

FIELD SAFETY NOTICE

EndoBarrier[®] Gastrointestinal Liner with Delivery System
December 5, 2014
Field Safety Notice

Attention: EndoBarrier Users

This notification is intended to ensure appropriate communication is made to all customers regarding revised Instructions For Use.

Details of Affected Device:

EndoBarrier[®] Gastrointestinal Liner with Delivery System Model Number: 40-10-00364

Description of Problem:

As a result of a review of the company's historical Clinical Evidence for the EndoBarrier[®] product, the company will clarify its indications for use and possible adverse events to reflect that its obesity indication includes a restriction to patients with a body mass index (BMI) ≥ 30 kg/m². The company's revised indications for use will now read: The GI Dynamics' EndoBarrier[®] Gastrointestinal Liner System is used for the treatment of obese type 2 diabetes with BMI ≥ 30 kg/m², or obese patients with BMI ≥ 30 kg/m² with ≥ 1 co-morbidities, or obese patients with BMI >35 kg/m². Based on these indications for use, and the Clinical Evidence used for the review, the Risk:Benefit profile of EndoBarrier[®] Therapy is considered appropriate.

A copy of the revised Instructions for Use, with applicable changes is attached.

Actions to be taken by GI Dynamics:

GI Dynamics is issuing this Field Safety Notice to notify all EndoBarrier[®] users of the changes made to the Instructions for Use and Indication statement.

Transmission of this Field Safety Notice:

This notice needs to be passed along to all physicians trained in the use of the EndoBarrier[®] Gastrointestinal Liner with Delivery System.

Please maintain awareness of this notice and resulting action to ensure effectiveness of the corrective action. If there are any questions regarding this Field Safety Notice, please contact the GI Dynamics representative using the contact information provided below.

Contact reference person:

Karl-H Blohm, PhD
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The undersigned confirms that this notice has been submitted to the appropriate Competent Authorities.

This document is being provided to all users in duplicate. Please sign and date one copy to confirm your receipt of this notice and your understanding of the change.

[Redacted Signature]

[Redacted Name] President & CEO
25 Hartwell Avenue, Lexington, MA 02421

www.gidynamics.com www.endobarrier.com



Receipt of notice confirmed by:

www.gidynamics.com

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