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OBALON

URGENT FIELD SAFETY NOTICE

The Obalon Inflation Systems must NOT be used at elevations higher than 660 meters (2,165 feet) above sea level.

DATE: September 18, 2013

AFFECTED PRODUCTS/MODEL NUMBERS:

Obalon Nitrogen Fill System (P/N 8000)

Obalon EzFill Dispenser (P/N 4100)

Dear Obalon Distributor:

We have discovered an issue with the Obalon Inflation System products (referenced above) when used at elevations higher than 660 meters (2,165 ft) above sea level. Inflating balloons at these higher elevations with the affected Inflation System products will result in over-inflation of the balloon to pressures outside of the acceptable range (**8.3-17.2 kPa**). Our current Balloon System Instructions for Use specify that readings outside of the range of 8.3-17.2 kPa indicate the balloon has not been properly inflated and requires endoscopic removal of the Balloon be performed within 24 hours. To date, Obalon is unaware of any actual product failures or patient injury as a result of this product issue. However, Obalon is requiring the **IMMEDIATE ACTION** specified below to ensure the safest use of the Obalon System and its Accessories. Balloons that have been administered with a confirmed pressure of 8.3-17.2 kPa are unaffected by this issue.

Action Required:

Inform all of your accounts and customers who are using either generation of the Obalon Inflation Systems at elevations higher than 660 meters (2,165 feet) above sea level to **IMMEDIATELY STOP** using their Inflation Systems with use of the Obalon Balloon. We have included a letter template that you may use to inform customers of this issue and we are asking that this is done immediately and **no longer than 5 days** from this notification. We ask that you please document the notification of all customers affected and communicate back that this has been done.

Obalon understands the root cause of this issue and is working on a solution to allow for administration of the Obalon Balloon at higher elevations. However in the interim you must not use the device at elevations higher than 660 meters (2,165 feet) above sea level. Additional information will be provided shortly.

Should you have any questions please contact [REDACTED] Obalon European Regional Director (+39 342 541 [REDACTED] or [REDACTED]@obalon.com).

Regards,

[REDACTED]
Vice President of Regulatory Affairs and Quality Assurance
Obalon Therapeutics, Inc.

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(Distributor Signature/Date)

My signature above indicates that I have read and understand the notification requirements related to use of these devices.