MEDICAL IMPLANTS
helioscopie

Product Recall
HELIOSPHERE NEWTECH

M+C
[redacted]

Vienne,
February 28th, 2013

Dear All,

As we said in previous mail dated February 18th 2013, HELIOSCOPIE recently recorded premature deflation of its intra gastric balloons HELIOSPHERE NEWTECH at a higher frequency than usually found on lots listed in attachment. 7 cases have been found including a deflation leading to a migration without any consequence for the patient.

The analysis of the deflated products involves a detachment of the barrier coating placed on the outer surface of the balloon, causing air leaking on the reported cases.

With regard to the result on investigation we made, we have decided for safety reason to recall Heliosphere NEWTECH balloons. Batches concerned by this recall are joined to this mail.

Although the risk of deflation is perfectly documented for all practitioners, HELIOSCOPIE wishes to remind them that they need to perform the next follow-up visit on time (monthly monitoring) and to ensure the level of balloon inflation.

In addition, we remind you to follow the recommendations contained in the instructions for use of the device:

"The patient must be informed how to recognize signs that the balloon has deflated (loss of the feeling of fullness) and that such symptoms warrant investigation by the doctor. Verification of the balloon's correct placement and filling can be made by a plain abdominal x-ray and/or diagnostic ultrasound, or gastroscopy in case of doubt. A deflated balloon must be removed from the stomach. If the balloon migrates into the small intestine it may advance spontaneously into the colon and be excreted in the faeces. Such migration must nevertheless be monitored until the balloon has been excreted (repeated clinical examination, possibly abdominal ultrasound or plain abdominal x-ray) as surgery is required if an obstruction is detected. Of course, any unusual symptom, abdominal pain, interruption of intestinal transit, unusual bloating or repeated vomiting that appears after the balloon is placed must be reported immediately"

Our traceability system indicates that you received some product concerned with the recall, we kindly ask you to proceed as follow:
- make an inventory of stock and fill the formal sheet attached to this mail before you send it to :

Quality department – HELIOSCOPIE – FAX : + 33 4 74 16 18 10

Upon reception of your inventory our commercial department will contact you and organize way of return.

For implanted product we recommend to :
- Limit the duration of balloon implantation at 4 months
- Extract the product if a deflation is observed
- Report any case of prematurely deflation to Helioscopie and keep the explanted product so it can be analyzed.

We are proceeding to the necessary corrections on the product; meanwhile we apologize for any inconvenience this procedure may cause.

We remain at your disposal for any further assistance.

Yours Sincerely,

BATCH CONCERNED BY THE RECALL

COMMERICAL REFERENCE	DESIGNATION	BATCH NUMBER
HELIOSPHERE NEWTECH	Intra-gastric balloon	12-IN 436-2
		12-IN 436-3
		12-IN 436-4
		12-IN 436-5
		12-IN 435-1
		12-IN 435-3
		12-IN 435-4
		12-IN 435-5

HELIOSCOPIE
Rue des Frères Lumière
BP385
38217 VIENNE Cedex

Customer: _____

Adress : _____

Please fill the chart below and send it to Helioscopie by fax (+33 4 74 16 18 10) or by e-mail (lcmartin@helioscopie.fr).

Please let us know the products you have in stock:

REFERENCE	BATCH NUMBER	NUMBER OF IMPLANTED PRODUCTS	QUANTITY TO BE RETURNED
HELIOSPHERE NEWTECH			

NAME : _____

FUNCTION : _____

DATE : _____

SIGNATURE :