JSC “MedSil”

FSN Ref: 01/19

FSCA Ref: 00001/2019

Date: 20:AUG:2019

Urgent Field Safety Notice

A set of silicone devices for gastric restriction (MedSil Intragastric Balloon)

For Attention of: All device users

Contact details of local representative
[redacted]

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Urgent Field Safety Notice (FSN)
MedSil Intragastric Balloon
Risk addressed by FSN:

Risk of fluid aspiration during device removal procedure

1. Information on Affected Devices	
1	**1. Device Type**
	A set of silicone devices for gastric restriction (invasive long-term use device), supplied non-sterile, GMDN code 17202 
1	**2. Commercial name**
	MedSil Intragastric Balloon
1	**3. Primary clinical purpose of device**
	The device is intended for assisting weight loss by partially filling of the stomach and inducing satiety. Intragastric balloon is inserted endoscopically into the stomach and inflated with 400-700 cc of saline solution.
1	**4. Device Model/Catalogue/part number(s)**
	GB-01
1	5. Affected serial or lot number range
	All

2 Reason for Field Safety Corrective Action (FSCA)	
2.	**1. Description of the product problem**
	The device is made of silicone with a limited shelf life. High acidity of the stomach may change the properties of silicone. It can result in balloon leakage or balloon burst at the moment aspiration needle contacts the balloon wall during removal procedure.
2.	**2. Hazard giving rise to the FSCA**
	Possible risk linked to balloon burst is saline solution coloured with methylene blue going into the stomach lumen causing diarrhoea and vomiting. Vomiting is a potential cause of aspiration of the stomach contents into the lungs, which could result in aspiration pneumonia. The greatest hazard linked to aspiration pneumonia is patient’s death if a complication occurs due to stomach content. The residual risk if the FSN advice is followed is remote
2.	3. Probability of problem arising
	The manufacturer has analyzed recent studies and IFUs of several manufacturers. The risk of aspiration pneumonia is mentioned and real cases are listed. One of the manufacturers evaluates the possibility of aspiration pneumonia as 1:500 when using their intragastric balloon. For MedSil Intragastric balloon, 2 incidents were reported (balloon burst during removal procedure which DID NOT RESULT IN ASPIRATION PNEUMONIA) for 41181 devices sold worldwide during the last 3,5 years.
2.	4. Predicted risk to patient/users
	The anticipated risk with MedSil Intragastric balloon is acceptable and further reduced by following the FSN advice.

2.	**5. Background on Issue**
	A user reported the risk of vomiting or microaspiration of the content of JSC Medsil Intragastric Balloons due to uncontrollable emptying of the balloon during the removal procedure: 'the balloon, which is filled with NaCl and toluidine blue, is punctured using a special needle to directly aspirate the fluid. In the process, the balloon tears and empties a large amount of the fluid into the stomach of the patient. This fluid is then vomited perorally and there is always the danger of aspiration of massive fluid accumulation.' It was concluded that the adverse event reported is not related to the quality of the product, but to the level of the hydrochloric acid in the stomach. Silicone rubber undergoes a modification, loses its properties and degrades under the influence of hydrochloric acid in the stomach of the patient. That's why all the manufacturers declare a maximum period for the balloon to stay in the stomach. For MedSil intragastric balloon this period is 6 months even if the product can endure the impact of the hydrochloric acid for much longer period (we've come across the numerous cases of keeping our balloons in the stomach for 12, 18 and even 24 months without any deterioration of the device performance.) To keep the normal level of the hydrochloric acid in the stomach, all the patients with gastric balloons are prescribed PPI. It is nevertheless difficult for a doctor to control the accuracy of the patient's behavior and adhesion to treatment to set up the PPI dose. Consequently, in very rare cases, the silicone material of the device loses its properties earlier than declared by the manufacturer. Taking the above into consideration, Medsil came to a conclusion that the balloon rupture during the removal procedure is a risk to the patient, but the risk can be easily prevented by following use recommendations.
2.	6. Other information relevant to FSCA
	The user recommends intubation of the patient to provide aspiration protection upon extraction of the balloon to prevent the complication

	3. Type of Action to mitigate the risk	
3.	**1. Action To Be Taken by the User** ☒ Follow patient management recommendations ☒ Take note of amendment/reinforcement of Instructions For Use (IFU) Recommendations to be followed to prevent balloon rupture with potential aspiration of the fluid mass to the lungs are : prescription of Proton Pump Inhibitors to the patient during the entire period of treatment to lower the acid rate in the stomach and preserve the silicone in good condition, balloon removal in due time (not later than within 6 months after placement), precautions to be taken during placement and removal procedure .	
3.	2. By when should the action be completed?	Actions should be taken immediately for the patients who already have the balloon placed in the stomach.

3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? Yes Regular monitoring of patients as to PPI treatment adhesion	
3.	4. **Is customer Reply Required**? (If yes, form attached specifying deadline for return)	No
3.	**5. Action Being Taken by the Manufacturer** ☒ IFU or labelling change IFU will be updated to include information about the risk of aspiration pneumonia and measures to prevent this risk	
3	6. By when should the action be completed?	September 30th 2019
3.	7. Is the FSN required to be communicated to the patient /lay user?	No

	4. General Information	
4.	1. FSN Type	New
4.	2. Further advice or information already expected in follow-up FSN?	Not planned yet
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	
	b. Address	Novomytishchinski prospect 41A, MYTISHCHI, Moscow Region, Russia, phone number: +79104734665
	c. Website address	medsil.zao@gmail.com
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers: Federal Institute for Drugs and Medical Devices (BfArM)	
4.	5. Name/Signature	[redacted]

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.