Approved
“12” May 2021

SETS OF SILICONE DEVICES FOR GASTRIC RESTRICTION

«BARIGLOBE»

Part A

TCF-IBB-01

Content

1. Information on the manufacturer

1.1. The name and address of the company-manufacturer

Limited Liability Company “Epiks Implant Industries” (“Epiks Implant Industries”, LLC).
Address: Room 57, office 1, building 11, 34 Kuryanovskaya 1-st Street, Moscow, Russia, postal code 109235
Tel/fax: +7-977-873-58-23
E-mail: bariglobe@gmail.com
Web site: www.bariglobe-tech.com

1.2. Authorized representative on the territory of European Economic Community (EU REP)

CEpartner4U B.V., ESDOORNLAAN 13,
3951 DB MAARN, THE NETHERLANDS.
Contact person: Mr. Ton Pennings, e-mail: office@cepartner4u.com
Phone +31 343 442 524 / Fax +31 343 442 162

Contract with authorized representative is attached (Annex 1)

2. The name and address of the Notified Body

3EC International a.s.

Notified Body Number: 2265,

Adress:

3EC International a.s.

Hraničná 18

821 05 Bratislava

Slovak Republic
Phone: +421 (0)2 5831 8343
Fax: +421 (0)2 5831 8345
info@3ec.sk

http://www.3ec.sk/

«Epiks Implant Industries», LLC herewith declares that no application has been lodged with any other Notified Body for the same product type and conformity assessment route (Declaration is attached, Annex 2).

3. Definition of the medical device and its intended purpose

Product name: SETS OF SILICONE DEVICES FOR GASTRIC RESTRICTION «BARIGLOBE».
Type/model/number: Intragastric balloon for weight loss/BARIGLOBE, BARIGLOBE EXTENDED
Risk Class/ Rule: Class IIb / Rule 5

GMDN	DEFINITION
17202	A device that is inserted into the stomach in order to inflate within the stomach and thereby reduce the desire for food. The device fools the stomach into feeling that it is almost full. The device is in the form of a balloon, inserted by catheter and remains until such time as the desired effect is accomplished. The device is usually made of a polymer material. Certain kinds of products under this generic device group will degrade over a period of time.

Intended purpose: The medical device is intended for obesity treatment by assisting weight loss of the patient by partially filling the stomach and inducing satiety. The balloon placement should be performed in an operating room or specially equipped room for endoscopy. The balloon placement

should be performed by an endoscopist. The decision to use the medical device is made by a physician on the basis of the data obtained as a result of the total examination of a patient suffering from obesity.

4. Indications and patient population

The medical device can be used by patients, whose body mass index (BMI) is 27-40 kg/m2, aged 18 or older. Patients whose BMI is more than 40 kg/m2 can be treated with the medical device for the purpose of preparation for the surgery.

5. Contraindications, side effects and possible complications

Contraindications and limitations include:

- The use of the device is contraindicated for weight loss in patients with a BMI less than 27, unless accompanied by comorbidities associated with obesity that would be expected to improve with weight loss
- Age under 18
- Any inflammatory disease of the gastrointestinal tract including esophagitis, gastric ulceration, duodenal ulceration, Crohn's disease
- Gastrointestinal tract cancer
- Esophageal or gastric varices, telang iectasis
- Congenital anomalies of the gastrointestinal tract such as atresias or stenoses
- A stricture or diverticulum of the esophagus or pharynx
- Prior gastric or intestinal surgery
- A large hiatal hernia
- Psychological disorder, alcoholism or drug addiction
- Pregnancy or breast-feeding (if pregnancy is confirmed at any time during the course of device treatment, the device should be removed)
- Patients receiving aspirin, anti-inflammatory agents, anticoagulants or other gastric irritants
- Allergic reaction to silicone
- Any other medical condition which would not permit endoscopy
- It is not recommended to use the device for patients with low discipline unwilling to participate in an established diet and behavior modification program, with medical follow-up at least once every two weeks.

Side effects:

- Gastric discomfort
- A feeling of nausea

- Vomiting
- Hypersalivation
- Gastroesophageal reflux

Possible complications:

- Ulcer formation, bleeding or perforation as a result of increased acid production by the stomach.
- The balloon and the probe with the sheath are made of biologically inert silicone, resistant to aggressive environment of the stomach. Nevertheless, the erosion of the balloon's wall could occur in case of ill-time balloon removal (if the balloon is left in the stomach longer than intended period).
- The erosion of the wall of the balloon as a result of strain (pressure or blow) in the anterior abdomen.
- An insufficiently inflated balloon or a leaking balloon may be able to pass from the stomach into the small bowel. It may pass all the way through into the colon and be passed with stool. However, if there is a narrow area in the bowel, as might occur after prior surgery on the bowel or neoformation, the balloon may not pass and then may cause a bowel obstruction. If this occurs, surgery or endoscopic removal could be required.
- Over-eating could be dangerous. If acute gastric dilatation appears as the result of over-eating, the balloon could move to pylorus, and make the situation worse by causing obstruction, which could lead to stomach necrosis.

-Gastric balloon placement and removal is an endoscopic procedure. The procedure usually is very safe. Still, the endoscopy-related complications may occur: reaction or sensitivity to medication used for sedation, perforation (puncture) of the lining of the gullet, stomach, or duodenum, infection in the neck, chest or abdominal cavity following a perforation, bleeding if blood vessels are injected, lung infections due to vomiting and aspiration during the procedure, heart attacks, cardiac arrest, and breathing problems (very rare).

-In case of balloon’s wall breaking, rapid liquid release into the intestine can cause digestive tract disfunction (diarrhea), infection, fever, cramps, vomiting and the risk lung infection (aspiration pneumonia) for some patients.

-Acute pancreatitis as a result of injury to the pancreas by the balloon. Patients experiencing any symptoms of acute pancreatitis should be counseled to seek immediate care. Symptoms may include nausea, vomiting, abdominal or back pain, either steady or cyclic. If abdominal pain is steady, pancreatitis may have developed.

-Spontaneous over inflation of an indwelling balloon with symptoms including intense abdominal pain, swelling of the abdomen (abdominal distension) with or without discomfort, difficulty breathing, and/or vomiting. Patients experiencing any of these symptoms should be counseled to seek immediate care.

- Injury to the lining of the digestive tract as a result of direct contact with the balloon, grasping forceps.

6. External appearance and dimensions

External appearance - see Title page of chapter A of the technical file

Dimensional outline – see Annex 4.

7. Medical device classification

Classification of medical device according to definitions and rules of Annex IX of the Council Directive:

1. Application of definitions:

The device is specified as invasive medical device, because it penetrates inside the human body in whole through a body orifice. The device is of a long-term use because it is intended for continuous use for more than 30 days.

2. The order of classification according to the rules of Annex IX of the Council Directive 93/42/EEC as amended is attached (Annex 5)

Conclusion:

The device is a long-term invasive device and belongs to the class IIb according to the Classification Rule 5.

8. Conformity evaluation procedure

The device is the subject of procedure described in Annex II (except clause 4) of the Council Directive 93/42/EEC as amended (full system of quality assurance).

Check-list of conformity to the essential requirements of the Council Directive 93/42/EEC as amended is attached (Annex 6).

The draft of the declaration of conformity to the requirements of the Council Directive 93/42/EEC as amended (Annex 3)

9. History of the device invention

“Epiks Implant Industries”, LLC (founded March, 2018) is a Russian developer and manufacturer of medical devices made of silicone rubber and other polymeric materials.

Since the use of intragastric balloon had become more popular in bariatric surgery and endoscopy, “Epiks Implant Industries”, LLC had developed the device, which consists of intragastric balloon (s) and accessories for its placement.

The idea of the placement of a balloon into the stomach for the purpose of weight loss belongs to 2 doctors from Denmark — Ole Nieben and Henrik Harboe. First intragastric balloon approved by FDA and placed endoscopically was manufactured by Garren-Edwards in 1985. Intragastric balloon Garren-Edwards was made of polyurethane and filled by air, its capacity was only 220 ml, and it has cylindrical shape and sharp edges. But, because of complications like stomach erosions and ulcers, damage of stomach walls by edge of the cylinder, balloon volume loss and bowel obstruction as the result of its migration, and in total, low efficiency in use of the balloon, the production of the balloon was stopped by the company-manufacturer in 9 months since being started. In 1987 a conference of approximately 75 experts in the field of bariatrics gathered in Florida. And as a result of this meeting they worked out the requirements for the ideal gastric balloon:

- The balloon should be filled in stomach by liquid, not by air. Liquid-filled balloon intensifies the feeling of satiety.
- The opportunity to regulate the volume of liquid to fill the balloon in the stomach
- Smooth surface.
- The availability of radiopaque marker so that the doctor could control the position of the balloon in the digestive tract
- The intragastric balloon should be made of durable materials and exclude leakages.

The most appropriate technical solution to meet these requirements was BIB, Bioenterics Intragastric Balloon by Inamed Health, USA (now “Orbera” intragastric balloon produced by “Apollo Endosurgery”, USA), but this device also had important disadvantages. First of all, patients often couldn’t bear the material of the balloon, up to complete intolerance; consequently the silicone compound used for the balloon production wasn’t biocompatible enough. Also, damages of the wall and the valve of BIB balloon occur, which results in volume loss and necessity of the balloon removal.
The use of intragastric balloon for obesity treatment had become very popular in Russia, because of its simplicity and availability. The first studies dedicated to balloon treatment were published in 2003.

The quality of **“BARIGLOBE”** intragastric balloons is similar to that of “Orbera” set produced by “Apollo Endosurgery”, but the balloon of the device by “Epiks Implant Industries”, LLC is better in biocompatibility of the silicone compound used, thus it causes less negative feelings to the patient.

Moreover, **“BARIGLOBE”** is much cheaper than its American analogue. The mentioned advantages will help the device to take a large share of the global market of medical devices for obesity treatment.

Main “milestones” of the device development are:

March 2018 – the company foundation

May 2018 -Biocompatible materials development/ valve design

June 2018 – The project of the device is complete

January 2018 – technical tests are completed

February 2020 – Technical Specification №32.50.13-001-27600691-2018 are approved; the the registration of the device in the Russian Federation started

May 2021 – the start of sales in the countries of Latin America in the Middle East planned

10. General description of the medical device

10.1. Introduction

The medical device - SETS OF SILICONE DEVICES FOR GASTRIC RESTRICTION «BARIGLOBE» – is offered in 2 modifications:

1) **“BARIGLOBE”**

2) **“BARIGLOBE EXTENDED”**

The modifications differ in the duration of use (see p. 10.3).

10.2. Safety and interaction with the environment

The device is a long-term invasive device and belongs to the class IIb according to the Classification Rule 5 (see Annex 5)

10.3. Storage and exploitation conditions

The device is portable. The balloon placement should be performed in an operating room or specially equipped room for endoscopy. The balloon placement should be performed by an endoscopist.

Conditions of storage: Store in closed room at the temperature range from +5°C to +40°C, relative humidity – no more than 50% at +25°C. Prevention measures should be held against cuts and punctures.

The balloon should be placed in the stomach within 24 months after the date of manufacture of the device. Maximal time of exploitation after placement of the device for modification **“BARIGLOBE”** is 6 months (thus maximal length of product life is 2 years and a half – 24 months from the date of manufacture till balloon’s placement + 6 months from placement till removal).

Maximal time of exploitation after placement of the device for modification **“BARIGLOBE EXTENDED”** is 12 months (thus maximal length of product life is 3 years– 24 months from the date of manufacture till balloon’s placement + 12 months from placement till removal). If the device is stored longer than 24 months, the adhesion of balloon’s walls is possible and problems with inflation of the balloon could occur.

The devices should be stored in closed rooms on the shelves in primary package and protected from the direct UV radiation. The devices should not be stored close to bactericyde lamps, open bowels with caustics, acids, oils, gasoline and other organic dissolvent.

10.4. Transportation rules

The device should be transported by all types of closed transport according to the rules of transportation for the exact type of transport, at the temperature range from -10°C to +50°C and relative humidity up to 50% at temperature +25°C.

10.5. Environmentally harmful factors and utilization

After the date of expiry the device could be recycled into not-medical products.

Utilize with other disposables after use.

10.6. Components

The set for modification “BARIGLOBE” consists of:

	1 - a folded silicone balloon volume 400-700 ml (the period of the balloon stay in the stomach is maximum 6 months) with a silicone probe for the balloon placement and a silicone sheath and a metal guide wire to increase the probe hardness 2 - a PVC tube with plastic connectors for liquid transfusion 3 – instruction of use 4 - patient’s information card

The dimensions of the main components:

Balloon volume: 400-700 ml.

Probe diameter 6±0,2 mm.

Device weight: net weight: no more than 70 g

gross weight: no more than 200 g

The set for modification “BARIGLOBE EXTENDED” consists of:

	1 - a folded silicone balloon volume 400-700 ml (the period of the balloon stay in the stomach is maximum 12 months) with a silicone probe for the balloon placement and a silicone sheath and a metal guide wire to increase the probe hardness 2 - a PVC tube with plastic connectors for liquid transfusion 3 - – instruction of use 4 - patient’s information card

The dimensions of the main components:

Balloon volume: 400-700 ml.

Probe diameter 6±0,2 mm.

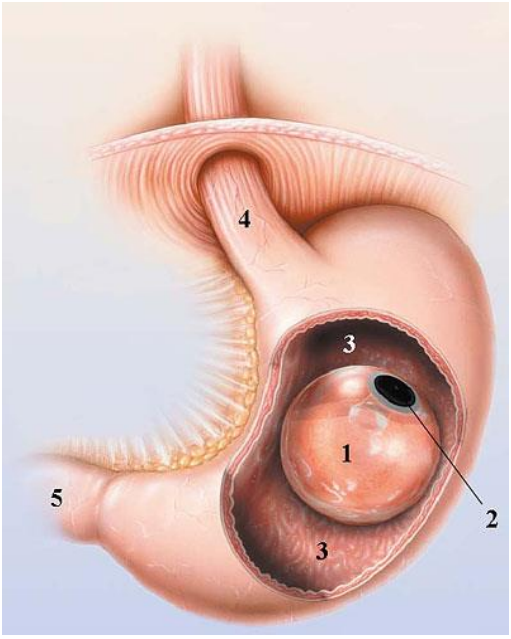
Device weight: net weight: no more than 70 g

gross weight: no more than 200 g

10.7. Technical data

The device should comply with the essential requirements and provisions of the Council Directive 93/42/EEC as amended (Ann II). The outer surface of the probe and the guide wire should be even and smooth. The basic balloon filled with 400-700 ml of liquid should be leak proof after the probe withdrawal. The connection between the probe and the balloon should be leak proof. The guide wire should move free within the probe and be corrosion-resistant. The device should be resistant to aggressive biological liquids at temperature from +32°C to +42°C.

10.8. The principle of action



Pict. 1. Disposition of installed balloon in patient’s stomach.

1.Inflated balloon in the stomach.2. Balloon’s valve 3.Stomach lumen. 4. Esophagus 5. Duodenum.

The balloon is a spherical membrane of high-tension silicone. There’s a valve incorporated into the wall of the balloon. Silicone probe and PVC tube are included in the set to fill the balloon with saline solution. The collapsed balloon is installed with gastroscope under intravenous anesthesia. After filling the balloon up with saline infusion it forms a ball. Depending on the capacity of the stomach, the volume of filled up basic balloon could vary from 400 up to 700 ml (picture 1). Inside the stomach, the balloon fills its excessive volume, thus less quantity of food needed to provoke the reaction of the receptors, which signalize about stomach filling. Therefore the patient gets the feeling of satiety earlier than usual. In course of time patient forms the habit to eat less. Later patient adjusts to the new habit of taking nourishment, and this habit keeps for a long time after the balloon removal. Within the first several days after the balloon placement, patient feels nausea, overfilling of the stomach and unpleasant sensations in epigastria. The level of these feelings is individual and depends on the patient. The presence of extraneous body in the stomach rises the production of gastric acid and irritation of mucous membrane, thus for the prevention of this effects special medicines are prescribed. In general, after 7-14 days after the balloon placement, patient doesn’t feel the presence of the balloon and could live in a usual lifestyle. The intragastric balloon is installed temporarily. Maximum period of the balloons stay in patient’s stomach is 6 months for modification **“BARIGLOBE”** and 12 months for modification **“BARIGLOBE EXTENDED”,** and the balloon should be removed afterwards.

11. Marking and instruction for use

Annex 8.2 “Labeling” contains marking drafts. See Annex 8.1 for instruction of use.

12. The definition of technical standards which the product is declared to conform with

See Annex 9 for the full list of standards used in conformity evaluation procedure

13. Brief description of the process of the device production

The production of the device is arranged as the process of production of components and the following assembly of the components of the set. The purchased components and raw materials pass through the incoming control to confirm meeting the requirements of technical standards. The list of materials and range of incoming control tests are defined by the constantly updated “List of incoming control”. Such an approach prevents low-quality materials from being used for production purposes.

The production and testing of the manufactured components is specified by Process Chart. The tested components go to the assembly operation. Assembly takes place at the equipped workplaces according to the Process Chart. Permanent quality control of assembly is organized. All the processes take place in especially detached place, with permanent removal of dust and other pollution from the working space.

Assembled devices (or components of the set) after conducting of acceptance tests according to the requirements of technical specificationare accepted by the Quality Control Department. After the acceptance, the components are finally assembled, then packed, and go to the stock of ready-made products.

14. Performance parameters and safety requirements check

Protocols and reports concerning performance parameters and safety requirements can be found in the following ANNEXes:

- Risk Analysis (Annex 7.3);
- Cinical Evaluation (See Annex 10);
- Post-Market Surveillance (Annex 12.1);
- Biocompatibility Study Report (see Annex 13.1: Biocompatibility Study No.3197-MI ddt.27.5.2019; Annex 13.2: Certificate of accreditation No.ROSS RU.0001.21RK75 ddt.15.8.2014 for Laboratory Center CKK ONC, Dmitrovskoe, Krasnogorskiy rayon, Russia; Annex 13.3: Scope accreditation TL QCC OSC);

15. The clinical evaluation of the device

Clinical evaluation is held according to Annex X of the Council Directive 93/42/EEC as amended, MEDDEV 2.7/1 rev.4 **(**See Annex 10 for the report on clinical data evaluation.**)**

This report provides insight into the clinical experience at the intragastric balloon devices intended for obesity treatment obtained by studying various articles in the literature.

It was established clinical data of equivalent intragastric balloons which meet the requirements of Council Directive 93/42/EEC as amended (especially SETS OF SILICONE DEVICES FOR GASTRIC RESTRICTION «BARIGLOBE» and BioEnterics Intragrastric Balloon (BIB) and “MedSil” intragastric balloon) in order to demonstrate that the devices are functioning efficiently and safety.

When these publications were analyzed, the efficacy and safety of equivalent intragastric balloons devices were compared with conventional therapy effect.

The use of the balloons by and under control of competent physicians, according to the Instruction of use can cause only reversible or negligible damage or temporary discomfort and benefits for patient far prevail hazards.

The study of literature and experience and the analysis of experience in the clinical practice related to these devices suggest that available clinical data is sufficient to demonstrate the compliance of intragastric balloon devices with the essential requirements of the clinical efficacy and safety and the requirements of Council Directive 93/42/EEC as amended.

16. Risk analysis

The document (Annex 7.3) is prepared to meet General Requirements of the Council Directive 93/42/EEC as amended.

Risk analysis is performed according to the international standard EN ISO 14971:2012 (RISK MANAGEMENT)

Analysis is divided into the following phases:

- At the first phase, all the sources of possible risks during the process of the device production and use are identified
- At the second phase the level of the risks identified is estimated and the appropriate corrective measures to lower the possibility of harm inflicting are defined
- At the third phase, it is checked whether corrective measures lead to the new risks

The result of the risk analysis for the device, after identification and carrying out measures to lower possible risks, is the conclusion – “Acceptable risk”, Level II. Discovered side effects have been estimated as insignificant, there are much more advantages for the patient, than hazards.

17. Technical file keeping

Technical file is kept for 15 years since the end of device manufacture.

Record of Changes

Chge No.	Sheet (page) number				Document name, ver.no.	Signature	Date of change	Implementation date
	Revised subpart	Re-placed page num-ber	new	annulled				