

OBALON[®]

Inflation System Directions for Use: Obalon EzFill Dispenser[®] & Obalon Inflation Can



**Caution: Federal (USA) law restricts this device to
sale by or on the order of a physician**

Rx Only

OBALON® INFLATION SYSTEM – OPERATIONAL INSTRUCTIONS

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INTRODUCTION

The Obalon Balloon System (the “System”) is designed to assist weight loss by partially filling the stomach. The System consists of up to 3 intragastric balloons placed during a 6-month period. The balloons are swallowable in that they are delivered via capsule. Each balloon is placed individually within the first three months. All three balloons are removed 6 months after the first balloon was placed.

For administration, a Balloon Kit is used, which includes a balloon and catheter assembly. Each balloon is contained within a USP grade capsule, which is attached to a miniature catheter. The balloon capsule delivers the balloon in a similar manner that a medicinal capsule delivers pharmaceuticals. The catheter comes pre-attached to the compacted balloon’s radio-opaque, re-sealing valve.

The administration (placement) procedure requires no sedation. The catheter/capsule is swallowed by the patient. The catheter is then attached to the EzFill Dispenser that contains an Inflation Can (a can containing nitrogen-sulfur hexafluoride gas mixture) to fill the balloon. After the patient swallows a balloon capsule, radiography must be done prior to inflation to ensure the balloon is in the stomach (visualized by the radio-opaque marker). The preferred radiographic method is fluoroscopy or digital x-ray since both provide real-time image of the balloon using low levels of radiation with immediate imaging feedback. The balloons are only intended to remain in the stomach for 6 months from the time of placement of the first balloon. There should be no less than 14 days between Balloon placements. All balloons placed must be removed at the end of 6 months using endoscopy per the specified tool dimensions. All placed devices must be removed by a trained healthcare professional proficient in endoscopy.

OBALON BALLOON-EZFILL INFLATION SYSTEM OVERVIEW

The Obalon Balloons must only be inflated utilizing the EzFill Inflation System. The EzFill Inflation system consists of an Inflation Can and EzFill Dispenser. The Inflation Can provides a gas source for transfer of a fixed volume of inflation gas to the

Obalon Balloon and the EzFill Dispenser transfers and monitors the fixed volume of the inflation gas to the Obalon Balloon.

The EzFill Inflation System should be set up for use no more than 15 minutes prior to balloon administration. The Extension Tube and 3-way stopcock from the Accessory Kit is connected to the dispenser to facilitate connection of the balloon catheter to the dispenser and the Pre-Pulse Verification Step conducted after digital radiography verification that the balloon valve is below the gastroesophageal junction. The EzFill Dispenser contains a digital pressure gauge that provides a continuous read-out of the pressure status of the system and the transfer of the gas from the can to the balloon.

After Balloon administration and confirmation that the balloon valve has passed the gastroesophageal junction and is in the stomach, the EzFill Inflation System is connected to the catheter by way of the Extension tube. All entries and exits within the Dispenser and Catheter connections are sealed and it is imperative that all system connections are fully secured during the procedure such as to maintain a closed gas pathway between the Can and Balloon. The pressure gauge on the Dispenser must be monitored to ensure there are no leaks in the system during the gas transfer process and balloon inflation. All decision points require that prior to moving to the next step that the measured value is stable and does not change more than 0.3 kPa in a 30 second period. Unstable or unexpected values indicate that there is a leak in the closed loop system.

INDICATIONS FOR USE

The Obalon Balloon System (the “System”) is a swallowable intragastric balloon system indicated for temporary use to facilitate weight loss in adults with obesity (BMI of 30 – 40 kg/m²) who have failed to lose weight through diet and exercise. The System is intended to be used as an adjunct to a moderate intensity diet and behavior modification program. All balloons must be removed 6 months after the first balloon is placed.

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OBALON INFLATION SYSTEM COMPONENT DEVICES

The Obalon Inflation System is comprised of two components to support the use of the Obalon Balloon: The Obalon Inflation Can and EzFill Dispenser.

The Inflation Can provides a gas source for transfer of nitrogen-sulfur hexafluoride to the Obalon Balloon. The EzFill Dispenser serves as a method for the passive transfer of the fixed volume of nitrogen-sulfur hexafluoride gas to the Obalon Balloon.

EzFill Dispenser



Inflation Can



Syringe and
Extension Tube



Obalon Balloon

CAUTIONS

This manual only provides information on how to prepare the Obalon Inflation System. You must follow the Obalon Balloon System Instructions for Use for balloon administration/removal. A complete listing of the Indications for Use, Contraindications, Cautions, and Complications are provided in the Obalon Balloon System Instructions For Use.



CAUTION

You must read the Obalon Balloon System Instructions for Use in its entirety for Balloon Administrations, Use and Removals. This manual is not intended to replace the Instructions for Use but is to be used as supplementary information to prepare the Inflation System. This document is not intended for use as a standalone document.

WARNINGS

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

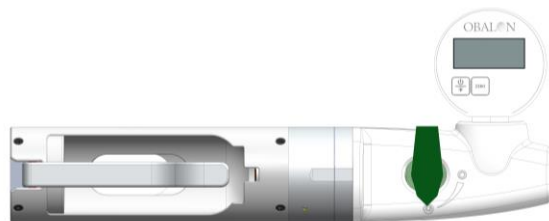
WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Obalon Inflation System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: The Obalon Inflation System has not been tested for MR compatibility and is therefore MR Unsafe. The Obalon Balloon has been tested and is designated as MR Conditional.

HOW SUPPLIED

All components are supplied non-sterile and are compatible with the Obalon Balloon System.

1. Obalon EzFill Dispenser (PN 4200) contains:
 - A re-usable dispenser with digital pressure gauge (pictured below)
 - AAA Batteries (QTY: 2)



Your EzFill Dispenser has been designed to operate at your center's specific elevation. Do not use the device outside of the operating Altitude Range indicated on the EzFill Dispenser label.



CAUTION

No modifications to this equipment are allowed.

Prior to use, verify that you have an EzFill Dispenser labeled with an operating altitude range (elevation) that you intend to use it in.

DO NOT USE the EzFill System at an elevation outside of the prescribed Operating Altitude Range. Doing so could over- or under-inflate a Balloon and can lead to an increased risk of balloon deflation.

2. Obalon Inflation Can (PN 8200, single-use only, disposable)



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ADDITIONAL ITEMS REQUIRED FOR DEVICE USE

Refer to the Obalon Balloon System Instructions For Use for complete information on additional supplies required to administer the device.

The following items are required for use with the Obalon Inflation System and are sold separately by Obalon:

- Obalon Balloon Kit
- Obalon Accessory Kit
- Obalon Placebo Capsule

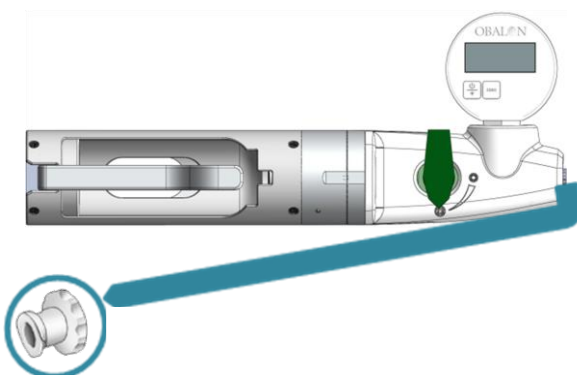
PREPARATION FOR USE

Preparing the EzFill Dispenser

1. Remove the cover from the end of the EzFill Dispenser as seen in **Figure 1**. It is important to save this cover; it should be placed back on the EzFill Dispenser after use to keep the EzFill Dispenser luer lock fitting free of debris. **If this is the first use**, remove the shipping plate from the shuttle.



FIGURE 1. REMOVING COVER FROM EzFILL DISPENSER



2. Open the Accessory Kit that is shipped with the Balloon Kit. Remove the extension tube that is connected to the Stopcock with a 3-way valve from the packaging.
3. Connect the proximal end of the Extension Tube (end furthest from the stopcock) to the EzFill Dispenser as shown in **Figure 2** and make sure the 3-way valve is in the closed position. Ensure the connection is tight but do not over-tighten.

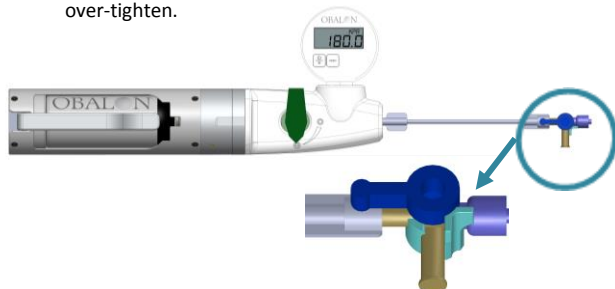


FIGURE 2. EzFILL DISPENSER VALVE CLOSED AND ATTACHED TO EXTENSION TUBE WITH 3-WAY VALVE CLOSED

4. Turn the green valve on the EzFill Dispenser to the open position as seen in **Figure 3**.

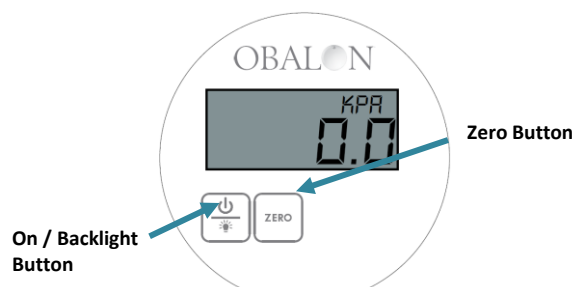
FIGURE 3. GREEN VALVE ON EzFILL DISPENSER IN OPEN POSITION



5. Turn on the EzFill Dispenser by pressing the “ON” button on the digital gauge. Verify that the displayed value is in kPa and reads “0.0.”

If the EzFill Dispenser Gauge does not read 0.0 then you must reset the digital gauge. This is done by holding the zero button for at least 2 seconds. The screen should clear and reset to 0.0.

FIGURE 4. RESETING THE DIGITAL GAUGE



CAUTION

Do not start a Balloon Administration until the EzFill Dispenser has been properly set up.

Do not proceed with EzFill Dispenser set up until the digital gauge reads “0.0 kPa”.

If the EzFill Dispenser Gauge fails to turn ON or reads “LOW BAT”, replace the AAA batteries located in the back of the device by removing 3 screws with a Philips screwdriver.

Batteries are to be properly disposed of in waste-battery receptacle.

DO NOT mix batteries from different manufacturers. DO NOT mix old batteries with new batteries.

Remove Batteries if equipment is not likely to be used for an extended period of time.

6. Remove and discard the cap from the Inflation Can. The Inflation Can will not fit into the EzFill Dispenser if the cap has not been removed (**Figure 5**).

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FIGURE 5. REMOVING THE CAP ON THE INFLATION CAN FOR PLACEMENT



CAUTION

DO NOT USE the can if the Tamper Evident seal is missing or broken.

7. Open the EzFill Dispenser Lever by lifting up on the lever. Insert the disposable Inflation Can into the EzFill Dispenser horizontally with the area where the cap was facing toward the digital gauge (Figure 6).

FIGURE 6. PLACEMENT OF THE INFLATION CAN INTO EzFILL DISPENSER



Lever in Open Position

8. Press down on the EzFill Dispenser Lever; this secures the Inflation Can into place. There will be an audible release of gas as the system self-adjusts. During this time the Pressure Gauge may alternately display "OFL" (OverFlow) and a pressure measurement. This is normal until the pressure drops below 350kPa.
9. Verify that the Digital Gauge measures between the corresponding pressure ranges provided on the EzFill Dispenser body.
10. The digital gauge measurement may fluctuate with movement and/or temperature changes. After movement/temperature changes have resided, assess the EzFill Dispenser for potential leaks by monitoring the gauge for pressure stability. The dispenser pressure is stable if it does not steadily decrease by more than 0.3 kPa within a 30 second period.



CAUTION

DO NOT PROCEED with use of the EzFill Dispenser until you have verified that the gauge pressure is within the appropriate range and that the gauge pressure is stable.

11. Close the green valve on the EzFill Dispenser by rotating the valve clockwise (to the right). Leaving the green valve open will compromise the Balloon Administration procedure.

FIGURE 7. EzFILL DISPENSER WITH INFLATION CAN - GREEN VALVE TURNED TO CLOSED POSITION



12. Re-verify that the Digital Gauge pressure remains stable. The dispenser pressure is stable if it does not decrease by more than 0.3 kPa within a 30 second period.



CAUTION

If the EzFill Dispenser does not stabilize or if it does not read the corresponding pressure range expected with your EzFill Dispenser, then there may be an error in the system. DO NOT PROCEED to use with the Obalon Balloon System. Re-verify that you have a Dispenser with the correct altitude labeled for the altitude you reside in or retry the Preparation for Use section with a new Inflation Can.

Prior to patient administration, the green valve on the EzFill Dispenser must remain in the closed position. Leaving the green valve open will compromise the Balloon Administration Procedure. Do not proceed with the Balloon Administration Procedure if the green valve is opened.

13. Proceed to the Obalon Balloon System Instructions for Use for balloon administration, use and removal instructions. Waiting more than 15 minutes to administer a balloon after EzFill Inflation System preparation increases the chance that the starting pressure may be out of range when starting balloon administration. **Do not proceed with balloon administration if the starting pressure is out of range.**

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14. After completion of a Balloon Administration, lift the lever on the EzFill Dispenser and **dispose of the Inflation Can.**



15. To complete another balloon administration, repeat steps 1-14.

SERVICING & REPLACEMENT REQUIREMENTS

The EzFill Dispenser Gauge requires service every two years. The EzFill Dispenser cannot be used with more than 5,000 Cans (useful life). A Cycle Counting Card (LIT-4200-0004) has been provided with your EzFill Dispenser to document the number of uses of your system. If you have not exceeded the 5,000 uses of your system, but the date is beyond 2 years from labeled calibration date located on the gauge, please contact customer service immediately for service of your Dispenser. If during Preparation for Use the pressure on the gauge does not match the required pressure range or a leak is detected during use, please contact Obalon Customer Service for repair and/or servicing.

STORAGE AND MAINTENANCE

EzFill Dispenser

- Always replace the cover on the EzFill Dispenser when the Dispenser is not being used. (Figure 1)
- Keep the EzFill Dispenser clean and protected when not in use
- The EzFill Dispenser should be stored according to the Product Specifications table.
- The digital gauge on the EzFill Dispenser must be serviced every 2 years from initial calibration. The date of last calibration is located on the back of the digital gauge. Contact Obalon Customer Service for Servicing at 1.844.3OBALON (1.844.362.2566) or customerservice@obalon.com
- The maximum number of uses the EzFill Dispenser has been evaluated for is 5,000 uses. Careful inspection of the Green Device Valve function between uses, replacement of batteries every 2000 hours, and servicing of the digital gauge 2 years from initial calibration is required to maintain the serviceable life of the Dispenser until the 5,000 uses has been met.

Inflation Can

- Each Inflation Can must be used on or before the expiration date specified on each Inflation Can label.
- The Inflation Can should be stored according to the Product Specifications table.
- Dispose of each Inflation Can after each use. DO NOT REUSE.

CLEANING

EzFill Dispenser

Wipe the EzFill Dispenser and the digital gauge with a 70% Isopropyl alcohol wipe between uses.

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PRODUCT SPECIFICATIONS

EzFill Dispenser (PN 4200)	
Materials	Stainless Steel, 6061 AL, Brass, Acetal, Silicone
Pressure Range	Refer to the label on the EzFill Dispenser
Storage Temperature Storage Humidity Storage Altitude	-0.40 °F to 131 °F (-18 °C to 55 °C) 30 to 85% RH 0 to 9,843 ft (0 to 3,000 m)
Operating Temperature Operating Humidity Operating Altitude	59 °F to 77 °F (15°C to 25°C) 30 to 85% RH Refer to the label on the EzFill Dispenser
Wetted Materials	Type 316L SS
Housing Materials	Black polycarbonate front and back cover, anodized aluminum extruded housing with recessed grooves, polycarbonate overlay, Buna-N O-rings, 316L SS sensor construction
Accuracy	0.25% full scale
Sample Rate	2 seconds
Power Requirements	Two AAA batteries
Battery Life	2000 hours typical; low battery indicator
Auto Shut-off	25 minutes; Backlight 2 minutes
Inflation Can (PN 8200)	
Inflation Gas	Nitrogen-sulfurhexafluoride
Total Volume	156cc
Maximum Pressure	420 kPa
Materials	Aluminum, Steel, Plastic, Rubber
Storage Temperature Storage Humidity Storage Altitude	32 °F to 104°F (0 °C to 40°C) 30 to 85% RH 0 – 12,001 ft. (0 to 3,658 m)
Operating Temperature Range	59 °F to 77 °F (15°C to 25 °C)

The EzFill Dispenser/Inflation Can is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment:	
Electromagnetic Immunity	Compliance Level and Guidance
Electromagnetic Environment Guidance Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV Contact ± 15kV Air *, The relative humidity should be at least 5%
Electromagnetic Environment Guidance Power frequency (50/60Hz) Magnetic field 61000-4-8	3 A/m Power frequency magnetic fields should be at levels characteristic of a typical location in a commercial or hospital environment
Electromagnetic Environment Guidance Radiated RF 61000-4-3	3 V/m Portable and mobile RF communications equipment should be used no closer to any part of the EzFill Dispenser Digital Gauge, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field Strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

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Guidance and manufacturer's declaration – electromagnetic emissions			
The device is intended for use in the electromagnetic environment specified below. The customer or user of the device should assure that it is used in such environment.			
Emission Test	Compliance	Electromagnetic environment - guidance	
RF emissions CISPR 11	Group 1	The EzFill Dispenser Digital Gauge use RF energy only for internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class B	The EzFill Dispenser Digital Gauge is suitable for use in all establishments, including domestic establishments and those connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.	
Harmonic emissions IEC 61000-3-2	Not applicable		
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable		
Recommended separation distances between portable and mobile RF communications equipment and the EzFill Dispenser/ Inflation Can			
The EzFill Dispenser/Inflation Can are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 KHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance <i>d</i> in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations.			

MR Safety Information

The Obalon Balloon is MR Conditional.

The Obalon Inflation System (Dispenser and Can) is MR unsafe and are known to pose hazards in all MR imaging environments.

Essential Performance

EzFill Dispenser to have digital gauge accuracy with adequate accuracy to ensure final balloon pressure is attained.

Instruction for maintaining BASIC Safety and Essential performance for the expected Service life

NOTE: Do not change the gauge due to EMC Immunity test levels as described in the tables above (IEC 60601-1-2:2014).

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Additional information	
Single Use Only	
Storage/Operating Temperatures	
Storage / Operating Humidity	
Caution	
Non-Sterile	
Do not use if package is damaged	
Keep dry	
Refer to instruction manual/booklet	
Manufacturer	
Expiration	
Lot number	
Serial Number	
Part Number	
Type BF Applied Part	
MR Unsafe	

Manufacturer:



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