

IF YOU HAVE THE WILL TO LOSE THE WEIGHT, WE HAVE THE WAY!

get OBAL N

The Obalon Balloon System is intended for adults with a body mass index (BMI) of 30 to 40 kg/m² (30 to 100 pounds overweight) willing to follow a diet and exercise program. All Obalon balloons must be removed in six months. Patients with prior weight loss surgeries are not eligible. The most common side effects reported were mild abdominal pain and nausea which typically resolved within two weeks. You must take daily acid-blocking medicine prescribed by your doctor. For full Important Safety Information go to www.Obalon.com/safety-information or call your doctor.

DISCOVER OBALON



WHAT IS THE OBALON 3-BALLOON SYSTEM?

The **FIRST** and **ONLY** swallowable, **FDA-approved** balloon system for weight loss.



The Obalon Balloon System facilitates weight loss by taking up space in your stomach so you eat less.

- Non-surgical
- Light weight, gas-filled, 3-balloon system
- 6-month treatment, combined with supervised diet and exercise program

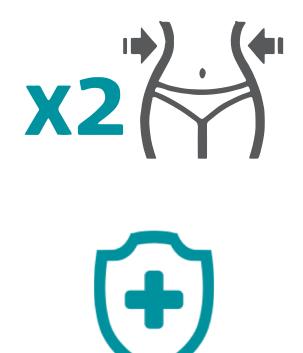
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- No downtime—return to normal activities
- Discreet

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WHY OBALON?

Results and Safety



Proven Weight Loss Patients with the Obalon Balloon System and diet and exercise lost **2 times** as much weight as those with diet and exercise alone.

Jump Start Long-Term Results The Obalon Balloon System helps jump start your weight loss journey.

Safe The most common side effects reported were mild abdominal pain and nausea which typically resolved within two weeks. *Less than 1%* of adverse events were severe or serious in nature.

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WHY OBALON?

Cost and Convenience



Convenient

The placement of each balloon typically takes *less than 10 minutes* and requires no surgery or sedation.



Affordable

With patient financing your treatment cost is broken down into smaller monthly payment options.

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OBALON RESULTS



WEIGHT LOSS EXPECTATIONS



In clinical trials, when used in combination with a professionally managed nutrition and exercise program:

Patients lost **2 times as much weight** than with diet and exercise alone.

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REAL RESULTS

"This was one of the best decisions I ever made."



One year weight loss results, six months with Obalon Balloon Therapy

Source: Obalon data on file.

LISA W. — REAL PATIENT. LOST 91 LBS.

"The Balloon System helped jumpstart my weight loss. Even after the balloons were removed, I continued a diet and exercise program and have lost 91 pounds to date."

Click here to watch Lisa's story

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REAL RESULTS

"This is a lifestyle change; this is not a diet."



Six-month weight loss results with Obalon Balloon Therapy

Source: Obalon data on file.

DANA G. — REAL PATIENT. LOST 43 LBS.

"The quick diet fixes never worked for me. This is the first time I was eating normal, losing weight and seeing results. The balloon placement itself was easy in and out, maybe 10 minutes at the most."

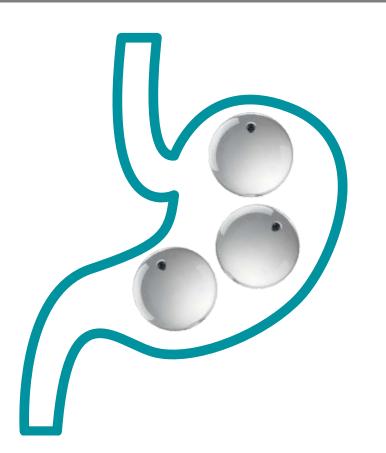
<u>Click here</u> to watch Dana's story

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HOW OBALON WORKS



WHY THREE BALLOONS?



- Lose more weight—patients lost 4.4 times the weight with three balloons vs. two balloons
- Demonstrated increase in weight loss after each balloon placement
- Placing three individual balloons gives the stomach time to adjust and helps to minimize side effects

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HOW ARE THE BALLOONS PLACED?

Less than 10 minutes—no sedation or anesthesia







- 1. Balloon capsule is swallowed, attached to the micro-catheter
- 2. Capsule location is confirmed with digital imaging
- **3.** Capsule dissolves and the balloon is inflated with gas
- 4. Micro-catheter is removed quickly and smoothly

<u>Click here</u> to watch how it works

THE SAME PROCESS IS REPEATED FOR 2ND & 3RD BALLOON PLACEMENTS

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WHAT TO DO WHILE THE BALLOONS ARE IN PLACE



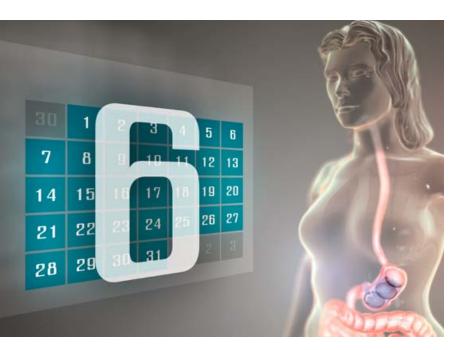
- Return to normal activities
- Follow your physician's recommended diet and exercise program

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- Return for follow up visits with your physician and registered dietitian
- Continue to take medications as prescribed

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HOW ARE THE BALLOONS REMOVED?



Six months after the first balloon placement, all three balloons are removed during a brief endoscopic procedure under light, conscious sedation (no intubation required).

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YOUR COMMITMENT TO LIFESTYLE MODIFICATION



- The Obalon balloons take up space in your stomach so you eat less
- Healthy diet and exercise are critical to your success
- Work with your physician and registered dietitian to develop a program that will support your weight loss

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YOUR OBALON TREATMENT



GETTING STARTED

It starts with...



- **1.** A review of your medical, health, diet and lifestyle history
- 2. A discussion about your weight loss goals
- **3.** Determine your readiness and commitment to follow a diet and exercise program

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- 4. Pre-treatment screening
 - Pregnancy testing
 - Upper GI series
 - H. pylori test
 - Two successful placebo capsule swallows

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PLACEBO CAPSULE SWALLOW



Before your balloon placements, you will complete **two placebo capsule swallows**.

- Looks and feels just like an Obalon Balloon capsule but it is filled with table sugar
- Replicates the experience of swallowing the balloon capsule

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In order to proceed with your Obalon treatments, you must be able to successfully swallow the placebo capsule.

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PREPARING FOR YOUR OBALON BALLOON PLACEMENT

Diet and medication guidelines



- Start prescribed medications 24 hours prior to placement
- Avoid use of any gastric irritants including aspirin and NSAIDs (Advil,[®] Motrin,[®] Toradol,[®] Aleve,[®] naproxen) for entire six-month therapy
- Fast and limit liquids for at least eight hours before balloon placements

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MEDICATIONS & HOMEOPATHIC AIDS



REQUIRED MEDICATIONS:

Start one day prior to your first balloon placement and continue for the full six months:

• **Proton Pump Inhibitor**—a drug whose main action is to reduce gastric acid production in the stomach

Start one day prior to your balloon placements and continue up to five days after placement:

- Nausea Medication—a drug that helps relieve the feeling of stomach sickness and the urge to vomit
- Antispasmodic—a drug that reduces muscle spasms in the stomach which can cause discomfort

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Other medications may be prescribed as needed.

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BALLOON PLACEMENT DAY

Here are a few tips for your placement days:



- Avoid wearing clothing that has metal in or on it such as buttons, zippers, or an underwire bra
- Remove any jewelry or piercings
- Remove lipstick or lip gloss
- Deep breathing will help you relax
- If you feel nervous, concentrate on squeezing stress balls
- Avoid biting, talking or clenching the catheter upon swallowing and until the balloon has been inflated and the catheter removed

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Remember...you already swallowed two placebo capsules successfully!

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LIFE WITH OBALON AND BEYOND

DIET RECOMMENDATIONS POST-PLACEMENT

Be sure to meet with your registered dietitian and follow your diet and exercise program Day 1: Clear liquids only the first 24 hours

- Day 2: Puréed foods such as non-fat yogurt or low-fat/low-sodium soups
- Day 3: Slowly introduce regular food and begin to follow your diet and exercise program

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OTHER IMPORTANT REMINDERS



- Take prescribed medications to minimize side effects
- Call our office if you are having:
 A sudden onset of stomach pain
 - A lack of feeling full—you may need your next balloon
 - Cramps that cause you to soothe by eating
- While balloons are in place, avoid permanent relocation to an altitude more than 4,000 feet higher or 2,500 feet lower than treatment site
- Avoid SCUBA diving, skydiving, or travel in an unpressurized aircraft

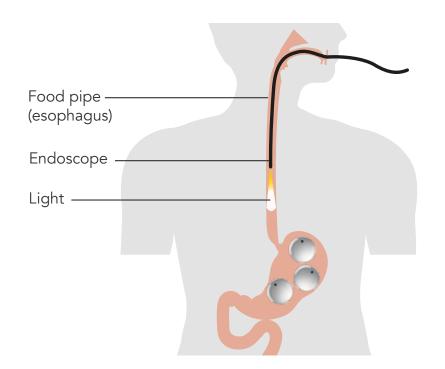
YOUR OBA

• Avoid use of NSAIDs

Follow the recommended diet and exercise program and return for scheduled follow up visits.

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BALLOON REMOVAL



Six months after placement of the first balloon, all three balloons are removed during a brief endoscopic procedure under light, conscious sedation.

During endoscopy, a thin scope with a lighted camera is used to locate and deflate each balloon in the stomach. Each balloon is then removed one at a time.

You will need a ride home from your balloon removal procedure.

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Image courtesy of: Cancer Research UK / Wikimedia Commons

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LIFE AFTER BALLOON REMOVAL

Will I regain the weight that I lose?



Long term success depends on you!

• Continue your healthy diet and exercise habits

 In a large clinical study, an average of 89% of the total weight lost was maintained six months after the balloons were removed. Patients continued to follow their supervised diet and exercise program.

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FAQS AND SAFETY INFORMATION

FREQUENTLY ASKED QUESTIONS

Who can get the Obalon Balloon System?

You are a candidate for the Obalon Balloon System if you have a body mass index (BMI) from 30 to 40 kg/m² (30 to 100 pounds overweight) and are 22 years or older. The program begins with the placement of the Obalon Balloons in your stomach for up to six months. The program should be accompanied with a healthy diet and exercise program during the time you have the balloons and is recommended for six months after the balloons are removed.

Who cannot get the Obalon Balloon System?

Please see the Patient Safety Labeling section.

How large is the Obalon Balloon?

A fully inflated single balloon has a volume of 250 cc, weighing approximately three grams (less than a penny) and about the size of a small orange. Therefore, all three balloons have a combined volume of 750 cc.

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FREQUENTLY ASKED QUESTIONS, cont.

What should I expect when using the Obalon Balloon System?

Your physician will work closely with you to help develop healthy eating and exercise habits, such as making the right food choices and limiting yourself to appropriate portion sizes. Because the balloons take up space in your stomach, you won't be able to eat the same quantity of food you previously consumed.

Will the balloons stretch my stomach?

No. Stomach volume differs from person to person but an average stomach can hold 1.5–4.0 L of volume. That's 1500–4000 cc of food. It is a muscular organ and chronic overeating can stretch the stomach over time.* The total volume for all three Obalon balloons is 750 cc.

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*Sources: Curtis, Helena & N. Sue Barnes. Invitation to Biology. 5th Edition. New York: Worth, 1994:529. Radcliffe, Donald V. "Stomach." Compton's Encyclopeadia Online v3.0. The Learning Company, 1998. Johnson, George B. Holt Biology: Visualizing Life. Orlando: Holt, Rinehart & Winston, 1994:769.

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FREQUENTLY ASKED QUESTIONS, cont.

What happens after I get the Obalon Balloon System?

It is important that you listen to the instructions provided by your physician and their staff who are available to assist you in your weight loss efforts. They will develop a follow-up schedule to further support your weight loss routine. As you become aware that you are eating less, it is important to adopt a healthy lifestyle by making healthy food choices and making exercise a priority.

Will the Obalon Balloon System limit my activity?

Patients usually resume normal activities immediately after the balloon placement procedure. You cannot take any stomach irritating medicines like non-steroidal antiinflammatory drugs (NSAIDs) or aspirin while the balloons are in your stomach. Some examples of NSAIDs are Motrin or Advil. You cannot have the balloons placed if you plan to live in a place at an altitude more than 4000 feet higher or 2500 feet lower than where your doctor places your balloons. Avoid SCUBA diving, skydiving, and travel in an unpressurized aircraft. See the Safety Information section and Patient Labeling for contraindicated activities with the Obalon Balloon System.

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IMPORTANT SAFETY INFORMATION

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Belly cramping/pain, nausea, vomiting, bloating, and/or diarrhea are common the first few days after balloon placement.

Please visit www.obalon.com/safety-information for complete safety information.

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PATIENT SAFETY LABELING

You are *not* a candidate for the Obalon Balloon System if:

- You have any problems with swallowing, or have had any prior surgeries that would make it difficult to swallow the Obalon balloon capsule.
- You take prescription aspirin, anti-inflammatory agents (such as Advil or Motrin), anticoagulants (blood thinner), or other gastric irritants daily. Taking these drugs on a daily basis increases the possibility of gastric irritations and ulcers when you have the balloons in your stomach.
- You have had prior surgeries or conditions that may have led to a narrowing or blockage of your gastrointestinal (GI) tract. If one or more of the balloons deflates and passes into your intestines, it will cause a blockage, also known as an obstruction, and must be surgically removed. This bowel obstruction can lead to serious injury and even death.
- You have ever had weight loss surgery such as a gastric sleeve or lap band. This does not include the other stomach balloons. Failure to follow this warning may result in damage to your stomach or intestines that may require surgery to repair.
- You have an untreated *Helicobacter pylori* infection. Having this infection increases the possibility of gastric irritations and ulcers.
- You are unable or unwilling to take prescribed proton pump inhibitor medication for the duration of the device implant. Not taking these medications increases the possibility of gastric irritations and ulcers.
- You have allergies to products/foods of porcine origin. You might experience an allergic reaction to the capsule.
- You have been diagnosed with (including but not limited to) bulimia, binge eating disorder, or compulsive overeating disorder, or your daily diet includes very high-calorie liquids. The balloons may not help you lose weight if you have these eating disorders or these habits.

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You are *not* a candidate for the Obalon Balloon System if:

- You have a history of structural or functional disorders of the stomach, including gastroparesis (stomach emptying disorder), gastric ulcer, chronic gastritis (stomach irritation), gastric varices (veins in your stomach that bleed), large hiatal hernia (>2 cm), cancer, or any other disorder of the stomach. If you have one of these disorders you may not be able to swallow the Obalon Balloon capsule, or the balloon may not inflate properly or you will have increased risk of gastric irritations and ulcers.
- You require the use of anti-platelet drugs or other agents affecting the normal clotting of blood. Use of these drugs may cause you to bleed more during the removal process of the balloons.
- You have a history of irritable bowel syndrome, Crohn's disease, or other diseases of your bowel system. If one or more of the balloons deflates and passes into your intestines, it will cause a blockage, also known as an obstruction, and must be surgically removed. This bowel obstruction can lead to serious injury and even death.
- You are taking medications on specified hourly intervals that may be affected by changes in gastric emptying, such as anti-seizure or anti-arrhythmic medications. Placement of the balloons in your stomach may further affect gastric emptying and motility.
- You have untreated or unstable alcohol or illicit drug addiction.
- You are pregnant or nursing.

Your doctor will discuss this and other important information with you to see if you are a candidate for the Obalon Balloon System.

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Things you must do to avoid serious harm (Warnings and Precautions)

WARNING: RETURN at six months to have the Obalon Balloons taken out. If you wait until after six months, one or more of the balloons may deflate and move from your stomach into your intestines and may cause a blockage, also known as an obstruction, which must be surgically taken out. This bowel obstruction can lead to serious injury and even death.

WARNING: CALL your doctor immediately if you start experiencing a new stomach pain that is different from the stomach pains that you felt when the balloon was put in, or if the pain does not go away. If you do not, one or more of the balloons may have deflated and moved from your stomach into your intestines, causing a blockage, also known as an obstruction, which must be surgically taken out. This bowel obstruction can lead to serious injury and even death.

WARNING: CALL your doctor immediately if you have a sudden loss of feeling of stomach fullness. If you do not, one or more of the balloons may have deflated and moved from your stomach into your intestines, causing a blockage that must be surgically taken out.

WARNING: TAKE daily acid-blocking medicine prescribed by your doctor (examples: Prilosec[®], Nexium[®]) while the balloon(s) are in your stomach. If you do not take this medicine daily, there is a higher risk of developing a stomach ulcer or small hole in your stomach.

WARNING: DO NOT take any stomach-irritating medicines like non-steroidal anti-inflammatory drugs (NSAIDs) or aspirin while the balloons are in your stomach. Some examples of NSAIDs are Motrin or Advil. Please read the warnings on any medicines that you might take to see if they can hurt your stomach. You might get ulcers or bleeding if you take these kinds of medications while the balloons are in your stomach.

WARNING: DO NOT have the balloons placed if you plan to live in a place that is at an altitude more than 4000 feet higher or 2500 lower than where your doctor places your balloons. Based on laboratory testing, changing where you live might cause the balloons to deflate. If the balloons deflate you may need to have an endoscopy to have them removed early from your stomach. If one or more of

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Things you must do to avoid serious harm (Warnings and Precautions)

the deflated balloons moves from your stomach into your intestines and causes a blockage, also known as an obstruction, they must be surgically taken out. This bowel obstruction can lead to serious injury and even death.

WARNING: DO NOT have the balloons placed if you plan on embarking on air travel in non-commercial aircraft. Based on laboratory testing, this type of travel might cause the balloons to deflate. If the balloons deflate you may need to have an endoscopy to have them removed early from your stomach. If one or more of the deflated balloons moves from your stomach into your intestines and causes a blockage, also known as an obstruction, they must be surgically taken out. This bowel obstruction can lead to serious injury and even death. There are no restrictions for commercial airplane travel.

WARNING: DO NOT SCUBA dive while you have the balloons in your stomach. SCUBA diving might cause the balloons to deflate. If the balloons deflate you may need to have an endoscopy to have them removed early from your stomach. If one or more of the deflated balloons moves from your stomach into your intestines and causes a blockage, also known as an obstruction, they must be surgically taken out. This bowel obstruction can lead to serious injury and even death.

WARNING: DO NOT bite the tubing that inflates the balloons. This might cause the balloons not to inflate. If the balloons do not inflate completely, you will require an endoscopy to have them taken out of your stomach early.

CAUTION: DO NOT have the balloons placed if you have type 1 diabetes or type 2 diabetes using insulin or other oral agents. The effects of this condition with use of the Obalon balloon are not known.

CAUTION: DO NOT have the balloons placed if you have severe coronary artery (blood vessels that supply the heart with blood) disease. The effects of this condition with use of the Obalon balloon are not known.

The Obalon Balloon System is intended for adults with a body mass index (BMI) of 30 to 40 kg/m² (30 to 100 pounds overweight) willing to follow a diet and exercise program. All Obalon balloons must be removed in six months. Patients with prior weight loss surgeries are not eligible. The most common side effects reported were mild abdominal pain and nausea which typically resolved within two weeks. You must take daily acid-blocking medicine prescribed by your doctor. For full Important Safety Information go to www.Obalon.com/safety-information or call your doctor.

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Things you must do to avoid serious harm (Warnings and Precautions)

CAUTION: DO NOT have the balloons placed if you have uncontrolled hypothyroidism, Cushing's disease or syndrome, end-stage renal disease or have required hemodialysis within the past six months, or uncontrolled hypertension. The effects of these conditions with use of the Obalon balloon are not known.

CAUTION: DO NOT have the balloons placed if you have severe, unstable/uncontrolled medical conditions of major organ systems. The effects of these conditions with use of the Obalon balloon are not known.

For full Important Safety Information including Patient Labeling, go to www.obalon.com/safety-information.

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