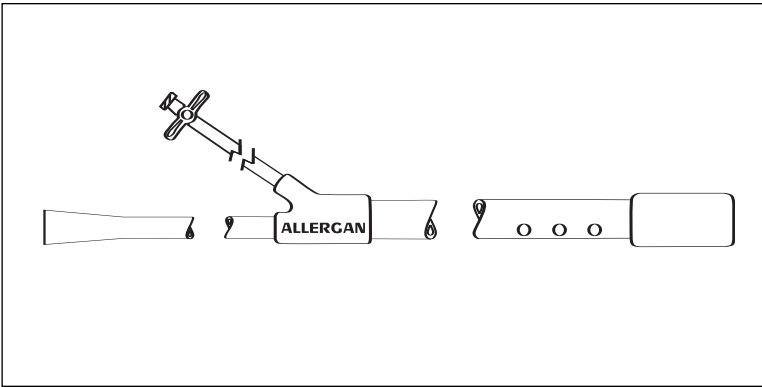


Gastric Balloon Suction Catheter

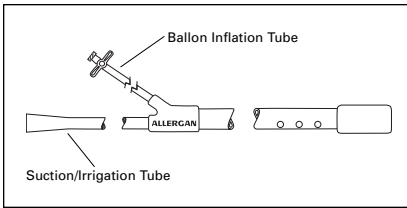
DIRECTIONS FOR USE (DFU)



Rx Only



Gastric Balloon Suction Catheter



The Gastric Balloon Suction Catheter is a flexible gastric tube designed to be used in gastric and bariatric surgical procedures including gastrectomy, fundoplication, gastric banding, vertical banded gastroplasty and gastric bypass. The catheter provides visible and tactile delineation of the antrum of the stomach along with the ability to decompress the stomach, drain and remove gastric fluid and size a gastric pouch.

DESCRIPTION

Gastric Balloon Suction Catheter Catalog No. B-2020

The dual lumen Gastric Balloon Suction Catheter utilizes one lumen for drainage, suction and irrigation and the second lumen to inflate/deflate the fixation/calibration balloon. The catheter is 32 French and 53 cm long with centimeter markings every 5 cm from 30 cm to 50cm. The catheter is attached to a 3/8 inch suction tubing and a 6-inch tubing with a stopcock for filling the balloon.

INDICATIONS

The Gastric Balloon Suction Catheter is indicated for use in gastric and bariatric surgical procedures to decompress the stomach, drain and remove gastric fluid and size the gastric pouch.

CONTRAINDICATIONS

The Gastric Balloon Suction Catheter is contraindicated when general or bariatric surgical procedures are contraindicated.

COMPLICATIONS

Complications which may result from the use of this product include the risks associated with the medications and methods utilized in the surgical procedure, the risks associated with any surgical procedure and the patient's degree of intolerance to a gastric tube.

SURGICAL PROCEDURE

Decompression

The Gastric Balloon Suction Catheter tube is inserted into the esophageal passage and advanced into the stomach. Once in the stomach, the distal end of the catheter is connected (with the suction/irrigation tubing connector) to standard low vacuum suction and the stomach is decompressed, removing air and/or gastric fluid.

Pouch Calibration

After decompression is completed and all air and fluids removed, the balloon attached to the catheter (with the one-way stopcock) is inflated with 15-25 cc of air or saline and drawn up to the cardia. The bulge created by the balloon can be seen and a visible boundary is established for gastric dissection, band placement or staple resection. After gastric dissection, band placement or staple resection, the balloon is deflated and the catheter is removed. The surgical procedure is then completed using standard techniques.

HOW SUPPLIED

The Gastric Balloon Suction Catheter is supplied non-sterile and for single use only.

Note: Do not autoclave the Gastric Balloon Suction Catheter, as this will damage the device.

RETURNED GOODS POLICY

Authorization must be received from your distributor prior to return of the merchandise. Merchandise returned must have all the manufacturer's seals intact to be eligible for credit or replacement. Products returned may be subject to restocking charges.

LIMITED WARRANTY, LIMITATION OF LIABILITY AND DISCLAIMER OF OTHER WARRANTIES

Allergan warrants that reasonable care was used in the manufacture and production of this product. Because Allergan has no control over the conditions of use, patient selections, surgical procedure, post-surgical stresses, or handling of the device after it leaves our possession, Allergan does not warrant either a good effect or against an ill effect following its use. Allergan shall not be responsible for any incidental or consequential loss, damage or expenses directly or indirectly arising from the use of this product. Allergan's SOLE responsibility in the event that Allergan determines the product was defective when shipped by Allergan, shall be replacement of the product. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for use.

AUTHORIZED TRAINING PROGRAM AND PRODUCT ORDERING INFORMATION










For additional information, please contact your local distributor or:

Manufacturer
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5540 Ekwil St.
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Telephone (805) 683-6761
Fax (805) 681-5765
www.allergan.com

CAUTION: This device restricted to sale by or on the order of a physician.

The Gastric Balloon Suction Catheter contains no latex or natural rubber materials.

The Gastric Balloon Suction Catheter has US and international Patents Pending.

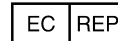
STYLE	Device Style
	Attention! See instructions for use.
	Single Use Only. Do Not Reuse.
	Lot Number
	Use By Year & Month
	Manufacturer
	Date of Manufacture, Year & Month
SN	Serial Number
REF	Catalog Number
	Authorized Representative in the European Community
	Contains no latex
	This device restricted to sale by or on the order of a physician.



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