Establishment Labs S.A. / Motiva USA, LLC (Collectively, "ESTA")

Directions for Use

Motiva® Inflatable Balloon

Table of Contents

INTRODUCTION

Device Description
The Motiva® Inflatable Balloon is a hand-held, single-use, intraoperative device designed for use by qualified surgeons to create a surgical space through soft tissue expansion. Once placed in the surgical space the Motiva® Inflatable Balloon is gradually inflated and later deflated and removed.

Intended Use
The Motiva® Inflatable Balloon is a manual, handheld, intraoperative, single-use device intended to create a surgical space in the body by dissecting layers of soft tissue and providing intraoperative tissue expansion.

Indications for Use
The Motiva® Inflatable Balloon is indicated in augmentation and reconstruction surgical procedures including correction of congenital deformations, cosmetic defects, scar revisions, and anomalies.

Contraindications
The Motiva® Inflatable Balloon should not be used in patients with a history of abscess or infection in the surgical area.

Warnings
The device should only be used by qualified surgeons.

Only use the device in a sterile environment.

DO NOT use the product if particulate contamination, damage, or loss of shell integrity is present. If present, the device must NOT be used and be disposed of in accordance with standard procedure.

Precautions
DO NOT modify the Motiva® Inflatable Balloon.

DO NOT introduce the handle of the device into the incision site. The incision should be of appropriate length to insert the Balloon. This will reduce potential excessive stress on the soft tissue.

DO NOT apply external pressure to the area of expansion. This may interfere with the ability of air to enter the Balloon, and consequently failure to inflate the device.

DO NOT remove the Balloon from the surgical pocket before deflating to avoid injury. Deflate the Balloon prior to removal.

INSTRUCTIONS FOR USE
This device is intended for single-use only. Do not reuse.

Sterile Product
Each Motiva® Inflatable Balloon is supplied in a sealed sterile barrier primary package. Sterility is maintained only if the package seals are intact. Use standard procedures to maintain sterility during transfer of the device to the sterile field.

How to Open Sterile Product Package
DO NOT expose the Motiva® Inflatable Balloon to talc gloves, sponges, towels, or other contaminants.

1. Remove the thermoformed package, and use the pull-tab to open the lid on the inner thermoformed package.
2. Inside the sterile field, remove the tray's content.
3. Examine for any particulate contamination or damage or loss.
4. Use the device within the sterile field.

Intraoperative Instructions
The components of the Motiva® Inflatable Balloon are shown below in Figure 1.

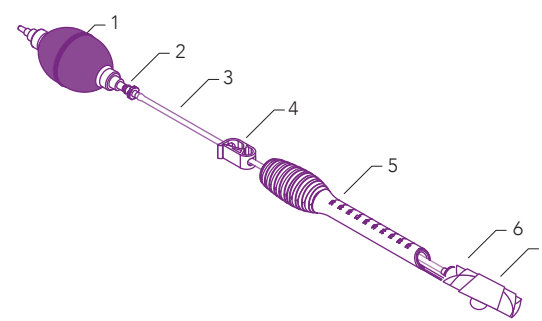

Figure 1. Motiva® Inflatable Balloon Components

1. **Manual Pump:** Inflates and deflates the Balloon as required. The two-way pump inflates using the clear tip and deflates using the black tip.
2. **Female Luer Lock:** Connects the tubing and the Manual Pump.
3. **Tubing**: Connects the Manual Pump to the Balloon, creating the path for airflow.
4. **Pinch Clamp:** Controls airflow in both directions (inflation and deflation) to allow Balloon to remain inflated or deflated.
5. **Introducer:** Provides rigid support for Balloon placement into the soft tissue. This component includes a Handle (distal end) and a Ruler for measurement marking.

6. **Balloon:** After insertion, the Balloon is inflated via the Manual Pump to create the desired surgical space.
7. **Strap:** Keeps the Balloon folded while in its package and is removed prior to use.

Steps for use of the Motiva® Inflatable Balloon

1. Remove the Strap from the Balloon, unfold the Balloon, and hydrate with sterile saline.
2. Refold the Balloon prior to insertion.

Placement

3. Holding the Handle (distal end) of the Introducer, gently insert the Balloon into the soft tissue, with the Ruler facing up, to guide the Balloon to desired space.

Expansion

4. Using the clear tip, connect the Pump to the Luer Lock and manually inflate until the desired volume is reached.
5. Close the Pinch Clamp to keep the Balloon inflated and remove the Pump.
6. Maintain Balloon inflation for approximately 5 minutes.

Deflation

7. Using the black tip, connect the Pump to the Luer Lock and open the Pinch Clamp.
8. Manually deflate the Balloon using the Pump, removing all air.
9. Slide the Pinch Clamp to the end of the Introducer and close it.

Removal

10. Once completely deflated, carefully remove Balloon. It must be deflated before removing to avoid tissue injury while the Balloon is being removed.
11. Properly dispose of the device using the facility's single-use device precautions.

ADDITIONAL PRODUCT-SPECIFIC INFORMATION

Storage

Keep the device dry and away from sunlight. No additional considerations or special storage and/or handling conditions are required.

Expiration

The Motiva® Inflatable Balloon should not be used after the labeled expiration date (see package labeling for expiration date). ESTA does not guarantee sterility if the device is used after the expiration date.

Sterilization

The Motiva® Inflatable Balloon is sterilized by Electron Beam sterilization method (E Beam).

Returned Mechandise Policy

Product returns should be handled through Motiva USA, LLC Customer Care. Contact Customer Care at:
1-800-924-5072 or email customercare@motivausa.com.

All package seals must be intact for product to be eligible for return. Returned products may be subject to a restocking charge. For more information, please contact the local Motiva USA, LLC representative.

Product Warranty

ESTA warrants that this product is free of manufacturing defects at the time of shipment. ESTA shall not be responsible for any incidental or consequential loss, damage, or expenses directly or indirectly arising from the use of this product. In the event ESTA determines a product is defective at the time of shipment, the sole remedy will be the replacement of the product. ESTA assumes no further liability. 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, suitability for use, or performance.

Product Ordering

To order directly in the U.S.A. or for product information, please contact Motiva USA, LLC at 1-800-924-5072 or email customercare@motivausa.com

Access to Electronic Directions for Use Information

The electronic version of this Directions for Use (DFU) can be found on the QR code provided on the box label and on the Motiva USA, LLC website at www.motivausa.com/support/. For a paper copy of this DFU, free of charge, contact Motiva USA, LLC at 1-855-236-0910.

Reporting Problems

The FDA requires manufacturers, device user facilities (such as hospitals), and importers to report serious injuries involving medical devices to submit voluntary reports about serious adverse events that may be associated with a medical device, as well as user errors, product quality issues, and therapeutic failures. These reports, along with data from other sources, can provide critical information that helps improve patient safety. In addition, the patient can voluntarily report injuries or complications directly to FDA's MedWatch. You can report by telephone to 1-800-FDA-1088 (1-800-332-1088); by FAX, use Form 3500 to 1-800-FDA-0178 (1-800-332-0178); electronically at www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting; or by mail to MedWatch Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-9787. Keep a copy of the completed MedWatch form for your records. This information reported to MedWatch is entered into databases to be used to follow safety trends and to determine whether further follow-up of any potential safety issues related to the device is needed. You are also required to report any product problem or serious adverse effect to Motiva USA Customer Care 1-800-924-5072.

Device Manufacturer
The Motiva® Inflatable Balloon is manufactured by Establishment Labs S.A. and imported to the US by Motiva USA, LLC.

Patent Pending
The Motiva® Inflatable Balloon is subject to a pending patent application filed with the USPTO.

CONTACT INFORMATION
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Manufacturing Site
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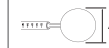
QTY	Quantity of accessories or medical devices included in the package.		Balloon diameter dimensions
	Manufacturer	MD	Medical device
SN	Serial Number	REF	Catalogue number
UDI	Unique Device Identifier		Date of manufacture
	Use-by date	STERILE R	Sterilized using radiation
	Do not resterilize		Do not use if package is damaged
	Fragile, handle with care		Keep away from sunlight
	Keep dry		Do not re-use
	Request instructions for use information		Caution
	This way up		Importer
	Refer to instruction manual/booklet		Single sterile barrier system with protective packaging outside
	Country of manufacturer		Consult electronic instructions for use
	Temperature limit		Non-pyrogenic

Motiva®

www.motivausa.com

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