

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

Directions for Use

Motiva® Channel Separator



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INTRODUCTION

Device Description

The Motiva® Channel Separator is a handheld, single-use device designed for use by qualified surgeons to dissect layers of soft tissue along natural planes of separation within the body.

Intended Use

The Motiva® Channel Separator is a manual, handheld, intraoperative, single-use device intended to create a surgical channel within the body by dissecting layers of soft tissue.

Indications for Use

The Motiva® Channel Separator is indicated in augmentation and reconstruction surgical procedures including correction of congenital deformations, cosmetic defects, scar revisions, and anomalies.

Contraindications

The Motiva® Channel Separator should not be used near the central circulatory system and central nervous system.

Warnings

The device should only be used by qualified surgeons.

Only use the device in a sterile environment.

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

DO NOT use if package is damaged or compromised.

Precautions

DO NOT modify the Motiva® Channel Separator.

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

INSTRUCTIONS FOR USE

The Motiva® Channel Separator is shown below in Figure 1.



Figure 1. Motiva® Channel Separator

How to Use the Motiva® Channel Separator

1. Using sterile technique, open the sterile pack of the Motiva® Channel Separator in a sterile field.
2. Holding the handle (distal end), place the tip of the Motiva® Channel Separator at the soft tissue incision site.
3. Gently guide the tool along the natural plane of separation following the intended path until the device's tip reaches the intended channel endpoint, approximately 2 cm beyond the pre-defined border of the dissection channel.
4. Gently remove the Motiva® Channel Separator from the channel.
5. 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.

Expiration

The Motiva® Channel Separator 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.

Returned Merchandise Policy

Product returns should be handled through Customer Care. Contact Customer Care at 1-800-924-5072 or email customercore@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 express 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 at 1-800-924-5072 or email customercore@motivausa.com.

Access to Electronic Information

The electronic version of this Directions for Use can be found on the QR code provided on the box label and on the Motiva USA 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 use 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. Report can be made 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 <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>; 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 ESTA.

Device Manufacturer

The Motiva® Channel Separator is manufactured by DVL-op Medico Inc and distributed by Motiva USA, LLC.

Manufactured By:

DVL-op Medico Inc.
29021 Avenue Penn
Valencia, California 91355
Phone: 1-661-645-4405

Distributed By:

Motiva USA LLC
125 East De La Guerra Street Suite 203A
Santa Barbara, California 93101
Phone: US Customer Care 1-800-924-5072
Email: customercare@motivausa.com
Website: www.motivausa.com/support/

	Quantity of accessories or medical devices included in the package.		Batch Code		Consult Instructions for Use
	Manufacturer		Medical device		This way up
	Serial Number		Catalogue number		Refer to instruction manual/ booklet
	Unique Device Identifier		Date of manufacture		Temperature limit
	Use-by date		Single sterile barrier system with protective packaging outside sterilized using ethylene oxide		Caution
	Do not resterilize		Do not use if package is damaged		Humidity Limitation
	Fragile		Keep away from sunlight		
	Keep dry		Do not re-use		



www.motivausa.com

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