LeMaitre® VASCULAR

Your Peripheral Vision™

Germany
LeMaitre Vascular GmbH
Otto-Volger-Str. 5a/b
65843 Sulzbach/Ts.

Tel: +49-(0)6196-659230
Fax: +49-(0)6196-527072

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www.lemaitre.com

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United States · LeMaitre Vascular, Inc.
Tel: +1-781 221-2266 · Fax: +1-781 221-2223

Risk Management
<Customer Name>
<Address 1>
<Zip> <City> <State>
Country

Your reference:

Our reference
TM/Marketing

Telephone
+49-6196-65923-0

E-Mail
tmalcharczik@lemaitre.com

Date
17 February 2017

URGENT: MEDICAL DEVICE RECALL

Device: Reddick Cholangiogram Catheter

Dear Valued Customer:

This is to inform you of a product labeling issue involving the LeMaitre Vascular, Inc. Reddick Cholangiogram Catheter devices. **Our records indicate that you have received one or more devices listed below.** Therefore, we are asking that you read the following information, check your inventory, then complete the form on the last page and send it back to us.

REF # 2401-50 – Reddick Scoop Tip Cholangiogram Catheter

CATALOG #	LOT #	EXPIRATION DATE
2401-50	RST2404	2018-12
2401-50	RST2416	2019-02
2401-50	RST2424	2019-03
2401-50	RST2426	2019-03
2401-50	RST2442	2019-07

REF # 2401-51 - Reddick Scoop Tip Cholangiogram Stiffer Catheter

CATALOG #	LOT #	EXPIRATION DATE
2401-51	RST2405	2018-12
2401-51	RST2417	2019-02
2401-51	RST2425	2019-03
2401-51	RST2449	2019-08

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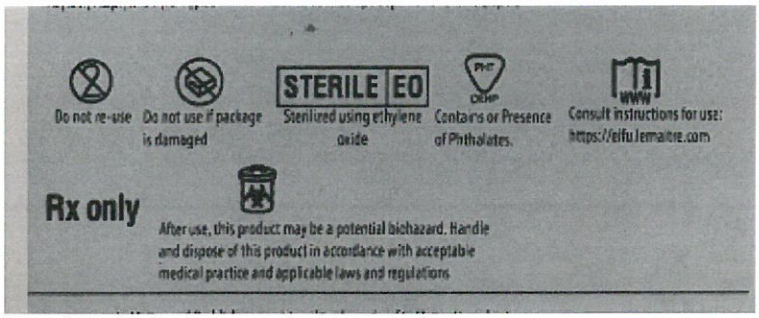
REF # 2401-52 - Reddick Scoop Tip Cholangiogram Catheter with Introducer

CATALOG #	LOT #	EXPIRATION DATE
2401-52	RST2394	2018-09
2401-52	RST2411	2019-01
2401-52	RST2412	2019-01
2401-52	RST2459	2019-10

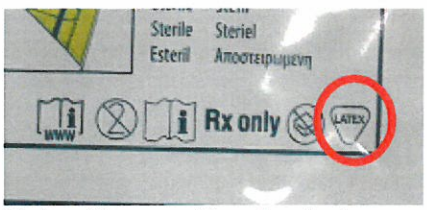
REF # 2401-53 - Reddick Scoop Tip Cholangiogram Stiffer Catheter with Introducer

CATALOG #	LOT #	EXPIRATION DATE
2401-53	RST2413	2019-01

This recall notice has been initiated due to a labeling error on the box and sterile product pouch. Since the Reddick Catheters contain a latex balloon, the product should be labeled with a warning that indicates that the product contains natural rubber latex. However, the 'Contains Latex' symbol was not printed onto the box label or the sterile (inner) product pouch. The product's instructions for use and foil storage pouch do have the warning symbol for latex contents. Individuals sensitive to latex may experience hypersensitivity, allergic reaction, localized reaction, rash, itching (pruritus), dyspnea, and anaphylaxis.



Box label—Latex symbol is missing.



Outer Storage Pouch—Latex symbol is present.

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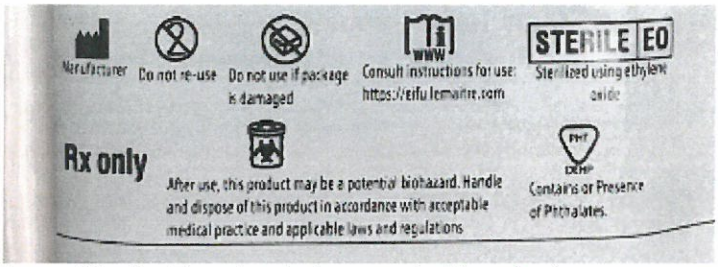

Inner Sterile Pouch—Latex symbol is missing.

Actions to be taken by the customer:

1. Complete the enclosed customer reply form, and return it to LeMaitre Vascular GmbH at csde@lemaitre.com or via fax +49 (0)6196-527072. **Please note that the form needs to be returned—even if you have 0 devices in inventory.**

2. If you distributed any affected product to other facilities, please forward this recall to the recipients.

3. If you are a dealer, wholesaler, or distributor/reseller that distributed any product to other facilities, please notify your customers of this communication in accordance with your customary procedures.

If you require replacement material:

- After our customer service department receives your completed form, they will contact you with an Return Goods Authorisation Number (RMA) and instructions on how to return the recalled product at no charge to you. **Please ensure that the RMA number is marked on the shipping box.**

- They will arrange for you to receive replacement product.

We sincerely apologize for the inconvenience that this incident may have caused you. If you have any questions concerning this recall, please contact me at +49 (0)6196-659230.

Sincerely,

LeMaitre Vascular GmbH

Tobias Malcharczik
Director, Marketing International

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Please complete this reply form and e-mail it to us at csde@lemaitre.com or Fax +49 (0)6196-527072.

The form should be returned even if you have zero devices in inventory.

Customer Number*	Customer Name*
<Account Number>	<Customer Name>

**If you are not the customer listed here, please include your facility information here. Also, please add a note if you received the devices from another facility.*

Contact Name (First and Last Name)	
Contact Email	
Contact Phone	
Signature	
Date	

CHECK ONE BOX BELOW ☑	DISPOSITION
☐	We will return devices for replacement.
☐	We have zero units in inventory.
☐	We acknowledge receipt but will not be returning any inventory.

Please record how many devices you have at your location:

REDDICK CATALOG #	LOT #	QUANTITY ON HAND (Write 0 if there are no devices.)

If a replacement is requested, LeMaitre Vascular Customer Service will contact you with further instructions upon receipt of this request.

Thank you for your cooperation.