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XXth December 2014

**FIELD SAFETY NOTICE:**
**VOLUNTARY RECALL OF ENDOREC® MEDICAL DEVICES FROM ASPIDE MEDICAL**

Object : risk of sterile packaging breakage.

Dear Madam, dear Sir,

ASPIDE MEDICAL decided to perform a voluntary recall of all lots of Endorec® medical devices (reference MTERPACK). This single-use medical device is an endo-rectal trocar used for interventional endoscopy and rectum surgery, to screen out or/and treat defects. It is a short term invasive medical device used through a body orifice. This device is placed on the market under sterile condition, packaged under double blister and then put in cardboard box.

Further to transport testing simulating extreme conditions shipment and handling corresponding to tropical and desert climates, ASPIDE MEDICAL noted that the sealing of the outer blister can be weakened.
Please note that ASPIDE MEDICAL did not receive any complaint nor incident report from any country regarding sterile ENDOREC® packaging breakage. Moreover, ASPIDE MEDICAL found no sterile packaging breakage in the products that have been shipped and handled under normal conditions.
However, ASPIDE MEDICAL cannot preclude a situation in which a product would undergo extreme conditions in the shipping and handling process. Any sealing breakage of the external blister could lead to non-sterile inner blister. Use of non-sterile inner blister on the sterile operating field presents a risk of contamination and consequently patients' infection.
ASPIDE MEDICAL decided to perform a voluntary recall due to technical reason of all lots of Endorec® medical devices.

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred (if appropriate).

ANSM (French Competent National Authority) has been informed about this recall and will inform other European Competent Authorities.

As a precaution, ASPIDE MEDICAL recommends the following actions to be taken:

1. Check your stock and identify any involved product.

2. If appropriate, identify and quarantine the device.

3. Pass this notice on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred (if appropriate).

4. Fill in the ACKNOWLEDGMENT OF RECEIPT FORM, **even if you do not have involved product**.

5. **Within 17th December 2014**, send back to the distributor a signed copy of the ACKNOWLEDGMENT OF RECEIPT FORM attached to this Field Safety Notice, by fax, or by scanning it and sending it by e-mail to [Distributor] :

    - E-mail : [Distributor e-mail]
    - Fax : [Distributor fax]

6. Upon receipt of your ACKNOWLEDGMENT OF RECEIPT FORM filled in, [Distributor] will contact you if necessary and arrange with you the formalities of products return.

7. Send back all ENDOREC®.

A credit note will be issued for distributors holding one or more device(s) concerned by this recall. Any product returned after 15th February 2015 will not receive credit note.

For any question, please contact [Distributor] at :

- E-mail : [Distributor e-mail]
- Phone : [Distributor phone]

The company ASPIDE MEDICAL is aware of the inconvenience this may cause you, and will endeavor to restock urgently, according to availability.

Feel free to contact us for any question.
Best regards.

David HOUOT
Regulatory Affairs
ASPIDE MEDICAL

**FIELD SAFETY NOTICE:**
**VOLUNTARY RECALL OF ENDOREC® ASPIDE MEDICAL's MEDICAL DEVICE**

**ACKNOWLEDGMENT OF RECEIPT FORM**

ASPIDE MEDICAL decided to perform a voluntary recall of all lots of Endorec® medical devices (reference MTERPACK).

**Please fill in this acknowledgment of receipt form, and send it back to :**

- E-mail : [Distributor e-mail]
- Fax : [Distributor fax]

**Device in stock (please thick the box):**

☐ No ENDOREC® medical device to send back.
☐ Medical device ENDOREC® to send back:

| Reference number | Lot number | Quantity to send back |
|---|---|---|
| | | |
| | | |
| | | |

Date of acknowledgment of receipt of the field safety notice : ……
I, Mr/Mrs/Miss……..……
Function: ……..……..……
Phone: ……..……
Fax : ……..……
E-mail : ……..……..…
hereby certify I have read the field safety notice the (date)…….....……, and commit myself to communicate it to staff potentially using the product in our establishment or in other establishment(s) in which the device would have been transferred.

Done in ……,
Date……
Establishment stamp Signature…….