

Contact Person:

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Date:

August 09, 2018

**Urgent Field Safety Notice
Transplant – Aspiration Needle / Biopsy Cannula SPI-CUT**

Dear Sir or Madam,

The purpose of this letter is to inform you that SOMATEX Medical Technologies GmbH is voluntarily recalling specific lots of the Transplant – Aspiration Needle (REF 180635) and of the Biopsy Cannula SPI-CUT (REF 180820, REF 180830, REF 180840, REF 180845, REF 180850, REF 180860, REF 180870). This recall has been initiated due to potentially compromised integrity of the sterile packaging. A complete list of all lots affected by this recall is provided further below. According to SOMATEX records, you have received one or more of the affected products. This issue does not affect any other SOMATEX products.

It is important to note that through August 9, 2018, SOMATEX received no customer complaints or reports of adverse events regarding compromised integrity of the sterile packaging and there is no reason to believe that any patients have been adversely impacted. The potential for a deficiency in the sterile packaging was discovered during internal packaging testing, which involves exposure to extreme transport conditions.

Despite the lack of field complaints associated with this issue, SOMATEX is taking precautions by executing this recall. If a device with a compromised package sterile barrier were to be used, there would be a possibility for a patient risk of infection. It would be difficult to visually identify a package with compromised integrity; therefore, although the risk is remote, customers are requested to return the potentially impacted lots prior to use. Patients who have received treatment with the affected lots should continue to be monitored in accordance with standard medical practice.

Our records indicate that your facility has received one or more of the affected units as defined by lot numbers indicated below. SOMATEX is asking you to take the following actions if not already completed:

- Immediately discontinue use of the potentially impacted lots that remain in your inventory.
- Complete the attached *Acknowledgement and Receipt Form* to facilitate the product return of any remaining product in inventory. SOMATEX Customer Service +49 30 319822500 will help you organize the transport and credit all of affected products.

Please share this notification with others in your organization as appropriate. If products within scope of this recall have been forwarded to another facility, please notify the facility of the issue and assist with the return of affected product.

The competent authority of your country has been notified of this action.

We sincerely apologize for any inconvenience that may arise, and thank you very much for the cooperation. This field action is consistent with our commitment to you and your patients. If you have additional questions, please feel free to contact us via safety@somatex.com or your Somatex Sales Representative.

Sincerely,



André Cerbe
Managing Director

AFFECTED MODEL AND LOT NUMBERS

Affected Transplant – Aspiration Needle (REF 180635) Lots:

| | | | | | | |
|--------------|--------------|--------------|--------------|--------------|--------------|--------------|
| 48513 | 49109 | 49334 | 49577 | 49648 | 49668 | 49829 |
| 49932 | 49997 | 50171 | 50202 | 50203 | 50251 | |

Affected Biopsy Cannula SPI-CUT (REF 180820) Lots:

| | | | | | |
|--------------|--------------|--------------|--------------|--------------|--------------|
| 49503 | 49580 | 49581 | 49743 | 49998 | 50432 |
|--------------|--------------|--------------|--------------|--------------|--------------|

Affected Biopsy Cannula SPI-CUT (REF 180830) Lots:

| | | | | | |
|--------------|--------------|--------------|--------------|--------------|--------------|
| 48679 | 48796 | 48797 | 48916 | 49025 | 49949 |
|--------------|--------------|--------------|--------------|--------------|--------------|

Affected Biopsy Cannula SPI-CUT (REF 180840) Lots:

| | | | | | | |
|--------------|--------------|--------------|--------------|--------------|--------------|--------------|
| 48762 | 48763 | 48787 | 48811 | 48816 | 49471 | 49579 |
| 49823 | 50192 | | | | | |

Affected Biopsy Cannula SPI-CUT (REF 180845) Lots:

| | |
|--------------|--------------|
| 49692 | 50268 |
|--------------|--------------|

Affected Biopsy Cannula SPI-CUT (REF 180850) Lots:

| | | | | |
|--------------|--------------|--------------|--------------|--------------|
| 48769 | 48802 | 48810 | 49122 | 49758 |
|--------------|--------------|--------------|--------------|--------------|

Affected Biopsy Cannula SPI-CUT (REF 180860) Lots:

| | | | | | | |
|--------------|--------------|--------------|--------------|--------------|--------------|--------------|
| 48915 | 49021 | 49166 | 49201 | 49254 | 49415 | 49416 |
| 49578 | 49895 | 50196 | | | | |

Affected Biopsy Cannula SPI-CUT (REF 180870) Lots:

| | | | | | |
|--------------|--------------|--------------|--------------|--------------|--------------|
| 49199 | 49547 | 49649 | 50132 | 50210 | 50234 |
|--------------|--------------|--------------|--------------|--------------|--------------|

ACKNOWLEDGEMENT AND RECEIPT FORM

Transplant – Aspiration Needle (REF 180635)
Biopsy Cannula SPI-CUT (REF 180820, REF 180830, REF 180840, REF 180845,
REF 180850, REF 180860, REF 180870)

I have read and understood the recall instructions provided in the August 9, 2018 letter.

Yes No

We have had adverse events not previously reported but associated with the recalled products.

Yes No

We have not found any of these devices in our inventory.

We have found the following devices:

| Product | REF | Lot Number | Quantity |
|---------|-----|------------|----------|
| | | | |
| | | | |
| | | | |

We will return the products immediately to you

Please pick up the goods.

We have further distributed subject devices to third parties.

We have informed the third parties about the recall.

The third parties have not located any of the subject devices.

The third parties have located the subject devices and will return them.

| | | | |
|--------------------|--|-------------------|--|
| Form completed by: | | | |
| Contact Name: | | Contact Facility: | |
| Contact Address: | | Contact Phone: | |
| | | Contact E-mail: | |

PLEASE COMPLETE AND FAX THIS FORM TO: +49 30 319 8225 99
OR EMAIL TO: safety@somatex.com