**Urgent Field Safety Notice**
**Device Commercial Names as provided in Appendix 1**

To the kind attention of:

*List of will be part of the FSN in the different destination countries*

- Customer Name,
- Address
- Postal code, City name
- e-mail
- Telephone

**Urgent Field Safety Notice (FSN)**
**Device Names as provided in Appendix 1**

This letter contains important information which require your **immediate attention**.

| 1. **Information on Affected Devices*** | |
|---|---|
| 1. | 1. Device Type(s)* |
| | See Appendix 01 |
| 1. | 2. Commercial name(s) |
| | See Appendix 01 |
| 1. | 3. Unique Device Identifier(s) (UDI-DI) |
| | Not available |
| 1. | 4. Primary clinical purpose of device(s)* |
| | See Appendix 01 |
| 1. | 5. Device Model/Catalogue/part number(s)* |
| | See Appendix 01 |
| 1. | 6. Software version |
| | Not relevant |
| 1. | 7. Affected serial or lot number range |
| | See Appendix 01 |
| 1. | 8. Associated devices |
| | Unknown. |

| **2 Reason for Field Safety Corrective Action (FSCA)*** | |
|---|---|
| 2. | 1. Description of the product problem |
| | C.G.M. Divisione Medicale Meta is the legal manufacturer of the following devices:<br>1. sterile scraper for use as a collecting bone flakes in oral surgical operations.<br>2. Set for Uterine Suction with tube and canula<br>3. membrane fixation tacks for oral surgical operations<br>4. Umbilical Cord Clamp<br>5. Closed Circuit Urine Bag<br>6. Amniotic Membrane Perforator<br>7. Magnetic Mat for Surgical Instrument<br><br>Those products are supplied to the market in sterile status, following the Etylene Oxide sterilization process performed overtime by Steril Milano Srl, one of the largest EO sterilization service providers in Italy.<br>C.G.M. Divisione Medicale Meta has become aware of sterilization issues notified by the contract sterilizer Steril Milano, with potential impact on efficacy of the Ethylene Oxide (EtO) sterilization processes at the contract sterilizer Steril Milano and sterile status of the devices placed on the market.<br>According to our investigation, we have identified certain batches for which we are unable to guarantee the primary sterility, even though, for the time being, based on our |

| | |
|---|---|
| | test results, we have no evidence of non-sterile status of the goods. Those batches are listed in the attached **Appendix 1 "List of Impacted Batches"**. |
| 2. | 2. Hazard giving rise to the FSCA |
| | The falsification of relevant data, especially linked to the preconditioning cycle and the sterilization cycle, could play a crucial role in the functionality and effectiveness of the devices' sterilisation processes. As specified in the risk analysis of the technical files, the ineffective sterilization of the devices listed above, could have consequences for patient's health with potential side effects linked to unsterile products, patient infection and worsening of their health conditions. C.G.M. Medical Division META didn't receive any notification of adverse events or serious patient harm associated with this safety corrective action. Even in the past years, our company didn't receive claims for adverse events referred to the millions of devices sold. Based on the following reasons, no specific patient follow-up activities are required for the product used:1) a preventive antibiotic therapy is prescribed before surgery procedures, 2) low level of microbial contamination of the products - detected by periodic Bioburden Tests - guarantee good disinfection of devices,3) no adverse events occurred for over 2 Million products sold in over 20 years, 4) Several Sterility Tests performed on devices sterilised with batches affected by this FSN resulted "sterile". 5) The sterilization colour change indicators are always checked during incoming controls and no deviation was never detected.All the products identified as potentially not sterile delivered to your Company are listed in Appendix 1 "List of Impacted Batches of the present FSN". |
| 2. | 3. Probability of problem arising |
| | All analysis performed in the past shown that the products were correctly sterile. Right now, further analysis is ongoing. Therefore we can't define a percentage, yet. |
| 2. | 4. Predicted risk to patient/users |
| | From the Health Hazard Evaluation of our devices, exposure to microbiological contamination could lead to bacterial infection and worsening of the patient health conditions. |
| 2. | 5. Further information to help characterise the problem |
| | NA |
| 2. | 6. Background on Issue |
| | NA |
| 2. | 7. Other information relevant to FSCA |
| | NA |

| | 3. Type of Action to mitigate the risk |
|---|---|
| 3. | **1. Action To Be Taken by the User**<br><br>☒ Identify Device ☒ Quarantine Device ☒ Return Device, when requested by C.G.M. Divisione Medicale Meta ☒ Destroy Device, when requested by C.G.M. Divisione Medicale Meta<br><br>☐ On-site device modification/inspection<br><br>☐ Follow patient management recommendations<br><br>☐ Take note of amendment/reinforcement of Instructions For Use (IFU)<br><br>☐ Other ☐ None<br><br>Once received this official notification, in order to prevent potential impact of the medical procedure, each user shall:<br>1) Identify and segregate all items listed in Appendix 01, still available at their premises,<br>2) Translate FSCA and Acknowledgment letter for Healthcare Facilities, provided in Annex 03, in your national languages,<br>3) Fill in the acknowledgment letter provided in the Appendix 02, including the number of segregate devices and returned devices,<br>4) Within 5 working days from receiving the official notification, return to C.G.M. Divisione Medicale Meta premises, E.Villa n.7, I-42124 Reggio Emilia (RE) – Italy, or destroy all the segregated devices, according to instruction provided by META,<br><br>As required, we have provided this notification to the relevant Regulatory Agencies of the countries where the devices have been distributed.<br><br>Please refer to your local sales agent for any further information you may need or, in alternative, contact directly C.G.M. Divisione Medicale Meta customer service at telephone number +39 0522 502311 or mail helpdesk@metahosp.com |
| 3. | **2. By when should the action be completed?**<br><br>Within 5 (five) calendar days from the issue date |

| ID# | Actions description | By when |
|---|---|---|
| 1 | Identify and segregate all items listed in Appendix 01, still available at your premises | Immediately or within 1 calendar day |
| 2 | Translate FSCA and Acknowledgment letter for Healthcare Facilities, provided in Annex 03, in your national languages | Immediately or within 3 calendar day |

| | | | |
|---|---|---|---|
| | 3 | Fill the Acknowledgment Letter provided in the Appendix 02, including the number of received devices, used or sold devices, remaining and segregated devices. | Within 7 calendar days from the receipt of the present communication |
| | 4 | Return to C.G.M. Divisione Medicale Meta premises, Via E.Villa n.7, I-42124 Reggio Emilia (RE) – Italy, or destroy all the segregated devices, according to instruction provided by META | Within 15 calendar days from receiving the official notification |

| | | |
|---|---|---|
| 3. | **3. Particular considerations for:**<br><br>N/A | |
| 3. | **4. Is customer Reply Required?**<br>See Acknowledgment Letter in Appendix 02, to be returned within 7 calendar days from the issue date. | |
| **3.** | **5. Action Being Taken by the Manufacturer**<br><br>☒ Product Removal ☐ On-site device modification/inspection<br>☐ Software upgrade ☐ IFU or labelling change<br>☐ Other Device re-working ☐ None<br><br>Based on the evaluation and sterility test performed, as conservative approach and a protective measure to maintain patient health, we decided to replace the devices listed in Appendix 01.<br>C.G.M. Divisione Medicale Meta has sent a Field Safety Notice to all affected customers. The Field Safety Notice identifies the problem, the affected products, the risk factors and the actions that must be taken by the users and distributors. | |
| 3 | **6. By when should the action be completed?** | Before 30 calendar days from the issue date |
| 3. | **7. Is the FSN required to be communicated to the patient /lay user?** | No |
| 3 | **8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?** | |
| | No Not appended to this FSN | |

| | **4. General Information*** | |
|---|---|---|
| 4. | 1. FSN Type* | New |

| | | |
|---|---|---|
| 4. | 2. For updated FSN, reference number and date of previous FSN | NA |
| 4. | **3.** For Updated FSN, key new information as follows: | |
| | NA | |
| 4. | 4. Further advice or information already expected in follow-up FSN? | No |
| 4 | 5. If follow-up FSN expected, what is the further advice expected to relate to: | |
| | NA | |
| 4 | 6. Anticipated timescale for follow-up FSN | NA |
| 4. | 7. Manufacturer information<br>(For contact details of local representative refer to page 1 of this FSN) | |
| | a. Company Name | C.G.M. Divisione Medicale Meta S.p.A. |
| | b. Address | Via E.Villa n.7, I-42124 Reggio Emilia (RE) – Italy |
| | c. Website address | http://www.metahosp.com/ |
| 4. | 8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.<br>Yes | |
| 4. | 9. List of attachments/appendices: | **1. <u>Appendix 01: List of affected devices</u>**<br>**2. <u>Appendix 02: Acknowledgment letter for Distributor</u>**<br>**3. <u>Appendix 03: FSCA and Acknowledgment letter for Healthcare Facilities</u>** |
| 4. | 4. Name/Signature | Insert Name and Title here and signature below |

| | **Transmission of this Field Safety Notice** |
|---|---|
| | This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)<br><br>Please transfer this notice to other organisations and to all users on which this action has an impact. (As appropriate)<br><br>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. |

| | |
|---|---|
| | Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback. |

**C.G.M. S.p.A. – Divisione Medicale META**
Via E. Villa n.7 - 42124 Reggio Emilia (RE) – Italy ☎ phone +39 0522 502305 website: www.metahosp.com
info@metahosp.com

Sede Legale: Via Modena 22/24 – 42015 Correggio (RE) – Italy - P.IVA 00678290354

# Appendix 02 - Acknowledgment Letter for Distributors

Please read in conjunction with FIELD SAFETY NOTICE FSCA-01-2021 and return completed and signed as soon as possible or within 5 days from its receipt to hepldesk@metahosp.com

| **Tick all that apply** | | |
|---|---|---|
| ☐ | I confirm this notice has been read, understood and that all recommended actions have been implemented as required. | Customer/Distributor/Importer to complete, sign or enter N/A |
| ☐ | I have checked my internal stock and our clients stock and quarantined all inventories | Customer/Distributor/Importer to complete, sign or enter N/A |
| ☐ | I have identified all Healthcare organization and all end users where the devices listed in Annex 1 have been shipped and on which this action has an impact, | Customer/Distributor/Importer to complete, sign or enter N/A |
| ☐ | I have informed the identified Healthcare organization and all end users of this FSN | Date of communication: |
| ☐ | I have received confirmation of reply from all identified Healthcare organization and all end users | Date of receiving last communication: |
| ☐ | I have filled-in the **Table 1**, with the number of remaining, segregated and returned/destroy devices to your premise. | Add quantity, Lot/REF/Date Returned (same information as requested by the Customer Reply form |
| ☐ | Our organization has none of the affected devices in inventory | |
| ☐ | Our Healthcare clients and end users has none of the affected devices in inventory | |

**Comments, if any**

| | | | |
|---|---|---|---|
| **Name of Trust / Organisation :** | | | |
| **Address :** | | | |
| **Postcode :** | | **Country :** | |
| **Telephone number :** | | **E-mail address :** | |
| **Name of your supplier for this product** | | | |
| **Name, title and signature of person completing this form**: | | | |

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.
Your organisation's reply is the evidence we need to monitor the progress of the corrective action

**C.G.M. S.p.A. – Divisione Medicale META**
Via E. Villa n.7 - 42124 Reggio Emilia (RE) – Italy ☎ phone +39 0522 502305 website: www.metahosp.com
info@metahosp.com

Sede Legale: Via Modena 22/24 – 42015 Correggio (RE) – Italy - P.IVA 00678290354

## Table 1: Mapping devices in inventory

| REF | Batch number | Quantity quarantined | Country |
|---|---|---|---|
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DISTRIBUTOR HEADED PAPER

**Urgent Field Safety Corrective Action (FSCA)**
**Device Commercial Names as provided in Attachment 01**

To the kind attention of:

*List of will be part of the FSN to each End User*

- Customer Name,
- Address
- Postal code, City name
- e-mail
- Telephone

DISTRIBUTOR HEADED PAPER

**Urgent Field Safety Corrective Action (FSCA)**
**Device Names as provided in Appendix 1**

This letter contains important information which require your **immediate attention**, concerning the devices listed in Attachment 01

| | **Reason for Field Safety Corrective Action (FSCA)*** |
|---|---|
| 2. | 1. Description of the product problem |
| | C.G.M. Divisione Medicale Meta is the legal manufacturer of the involved devices (see Attachment 01)<br><br>Those products are supplied to the market in sterile status, following the Etylene Oxide sterilization process, but the legal manufacturer C.G.M. Divisione Medicale Meta has become aware of sterilization issues notified by the contract sterilizer Steril Milano, with potential impact on efficacy of the Ethylene Oxide (EtO) sterilization processes. |
| 2. | 2. Hazard giving rise to the FSCA |
| | The ineffective sterilization cycle could play a crucial role respectively in the functionality and in the effectiveness of the sterilization processes of the devices, leading to consequences for patient's health with potential side effects linked to unsterile products, patient infection and worsening of their health conditions. |

| | **3. Type of Action to mitigate the risk** |
|---|---|
| **3.** | **1. Action To Be Taken by the User**<br><br>☒ Identify Device ☒ Quarantine Device ☒ Return Device to (distributor name, Adress and contact person)<br><br>☐ On-site device modification/inspection<br><br>☐ Follow patient management recommendations<br><br>☐ Take note of amendment/reinforcement of Instructions For Use (IFU)<br><br>☐ Other ☐ None<br><br>Once received this official notification, in order to prevent potential impact of the medical procedure, each user shall:<br>1) Identify and segregate all items listed in Attachment 01, still available at your premises,<br>2) Fill the acknowledgment letter provided in the Attachment 02, including the number of segregate devices and returned devices,<br>3) Within 20 working days from receiving the official notification, return to (DISTRIBUTOR NAME AND ADRESS)<br><br>Please refer to your local sales agent for any further information you may need |

3. **2. By when should the action be completed?**

Within 5 (five) calendar days from the issue date

| ID# | Actions description | By when |
|---|---|---|
| 1 | Identify and segregate all items listed in Attachment 01, still available at your premises | Immediately or within 1 calendar day |
| 2 | Fill the Acknowledgment Letter provided in the Attachment 02, including the number of received devices, used devices, remaining, segregated and returned devices. | Within 3 calendar days from the receipt of the present communication |
| 3 | Return to (DISTRIBUTOR NAME AND ADRESS | Within 20 calendar days from receiving the official notification |

3. **3. Is customer Reply Required?**
See Acknowledgment Letter in Attachment 02, to be returned within 3 calendar days from the issue date.

**3.** **4. Action Being Taken by the Manufacturer**

☒ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☐ IFU or labelling change
☐ Other Device re-working ☐ None

Provide further details of the action(s) identified.

| | | |
|---|---|---|
| 3 | **5. By when should the action be completed?** | Before 20 calendar days from the issue date |

| | | |
|---|---|---|
| 4. | 1. List of attachments/appendices: | **1. <u>Attachment 01: List of affected devices</u>**<br>**2. <u>Attachment 02: Acknowledgment letter for Healthcare Facilities</u>** |
| 4. | 3. Name/Signature | Insert Name and Title here and signature below |

| | **Transmission of this Field Safety Notice** |
|---|---|
| | This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)<br><br>Please transfer this notice to other organisations and to all users on which this action has an impact. (As appropriate) |

| | |
|---|---|
| | Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.<br><br>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback. |