

Field Safety Notice/Recall Form

OMNIMATE

Field Safety Notice No: FSN-202005

Document Date: 2020.06.03

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE **Medical Device Field Safety Notice for Recall**

Affected Devices: Sure-Spec disposable vaginal speculum

Type of Action: Removal

Date: Jun 03, 2020

Attention: Clinicians, Distributors, and Healthcare Providers utilizing use of the Sure-Spec disposable vaginal speculum

Affected Devices: The following Model Number and Lot Number are potentially affected by this issue:

| Model Number | Name | Unique Device Identifier (UDI-DI) | Lot Number | |
|--------------|---|-----------------------------------|--|--|
| D5302 | Sure-Spec disposable vaginal speculum #S Size | 4719872870036 | 20170307 20180206 20181112 001943101 | 20170725 20180417 201949101 301950101 |
| D5303 | Sure-Spec disposable vaginal speculum #M Size | 4719872870029 | 20170313 20180209 20181119 001943102 | 20170808 20180419 201949102 301950102 |
| D5304 | Sure-Spec disposable vaginal speculum #L Size | 4719872870012 | 20170306 20180213 201949103 301950103 | 20170810 20180418 001943103 |

Dear Customer,

The purpose of this Field Safety Notice (FSN) is to advise you that Omnimate Enterprise Co., Ltd. has initiated a voluntary Field Safety Corrective Action (FSCA) for 3 specific model number and 23 lot number of listed above. Model and lot number information of specific affected product shipped to you can be found on the Field Safety Notice Distributor / Importer Reply Form accompanying this notice.

REASON FOR RECALL :

Notified Body informs that the product has not passed the certification and will not issue a certificate. Any order, production and shipment of this product must be stopped immediately. Will not be shipped to any EU country for any products without appropriate certificate until it is obtained.

Field Safety Notice/Recall Form

OMNIMATE

Field Safety Notice No: FSN-202005

Document Date: 2020.06.03

RISK TO HEALTH :

The safety of the product has not been approved, and it may cause harm to patients / end users during use.

Omnimate has received no reports of any injuries related to this issue.

Action Required:

1. Locate and quarantine the affected Sure-Spec disposable vaginal speculum in your possession by referring to the attached Field Safety Notice Distributor / Importer Reply Form. This form identifies the specific lot number and quantity Omnimate distributed to your facility.
2. Complete the attached Urgent Field Safety Notice Response Form within 7 days of receipt, returning it to omni.mate@msa.hinet.net . The form must be returned even if you do not have any affected product in your possession. Product credit will be processed once the Urgent Field Safety Notice Response Form is received.
3. All affected product must be returned to Compliance at Omnimate for processing. Include a copy of your completed Response Form inside the package of returned product to facilitate processing. Make sure packages are sealed and labeled with your facility name prior to shipping to Omnimate.
4. If you have distributed potentially affected devices to your customers, please immediately notify them of this field notification by providing the information detailed in the Field Safety Notice along with the accompanying Response Form. All communication to Omnimate must be completed by the distributor. Please do not permit your end user to respond directly or return devices to Omnimate.

Omnimate is committed to providing quality products and service to its customers. We apologize for any inconvenience this situation may cause.

If you have any questions regarding this notification, please contact Omnimate via email at omni.mate@msa.hinet.net.

Sincerely,

OMNIMATE ENTERPRISE CO., LTD

General Manager: Stephen Shan _____



Date: 2020.06.03

Enclosure: Field Safety Notice Distributor / Importer Reply Form

Please bring this notice to the attention of all personnel you deem need to be made aware of this safety issue. If you have forwarded the affected product(s) listed above, please provide a copy of this field safety notice to them.