

Assisi 26/04/2022

FSCA Ref: FSCA\_18/22

## **URGENT FIELD SAFETY NOTICE M-CONNECT - Connecting tubes**

Commercial name: M-Connect - Connecting tubes  
Intended use: Connection to drainage bag  
Codes and lots: See Annex A  
FSCA ID: FSCA\_18/22  
Manufacturer: BETATEX SPA - ASSISI - ITALY  
SRN: EN-MF-000009955  
Type of action: Product recall

Dear Customer,

Betatex spa has undertaken a voluntary field safety corrective action recall for the **M-CONNECT** product codes, and kits containing such products, shown in Annex A.

### **Description of the problem and immediate action required**

Betatex has received a number of reports about the possibility of the M-Connect hose coming loose from the fittings while in use.

This can have a negative impact on room hygiene as liquids passing through the M-Connect, which should be directed towards the collection bag, fall into the surrounding area. If the device is used for chest drainage, the detachment of the tube, if it is left open for a long time, could cause air entrance into the drainage tube, which could lead to pneumothorax.

There are currently no reports of patient complications.

### **Action to be taken by the customer**

Stop using these products immediately.

Check your stocks, complete and return the form provided.

Return all involved and unused devices to Betatex spa.

**Betatex has informed all customers and distributors of this field safety corrective action.**





### **Transmission of this Field Safety Notice**

Please ensure that the contents of this safety notice are passed on to all those who may have received the products listed in Annex A.

If the products have been further distributed, identify the customers concerned and inform them immediately of this safety notice.

If you have distributed the products outside your country, notify Betatex immediately.

Betatex has informed the relevant authorities of the action taken.

### **What is Betatex doing?**

Betatex has already implemented appropriate corrective actions to ensure product safety.

For this reason, all batches produced since March 2022 do not have these anomalies.

Betatex has revised its Risk Management Plan according to this event.

### **Contact details**

Betatex spa:

CORRECTIVE ACTION RESPONSIBLE: Dr. Francesca Mondovecchio

Telephone: 0039. 075.8004872    email: [qa@betatex.com](mailto:qa@betatex.com) - [qacf@betatex.com](mailto:qacf@betatex.com)



BETATEX Spa

Sede Legale: Via Raffaello, 2

06081 S. MARIA degli ANGELI - Assisi (PG)

P.I. / C.F. 00440180545

Sede Produttiva e Commerciale:

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52044 TERONTOLA CORTONA (AR)

Tel. +39 (0575) 67172

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**URGENT FIELD SAFETY NOTICE  
M-CONNECT - Connecting tubes****RECEIPT FORM**

Please complete this form in its entirety and return it to Betatex Spa within 7 days.

- We confirm receipt of this FSN and that we have carried out the required actions as indicated on it. We confirm that we do NOT have in stock the devices involved in this field action.
- We confirm receipt of this FSN and that we have performed the required actions set out within it. We confirm that we HAVE in stock the devices involved in this field action. They have been identified and will be returned.

CLEARLY INDICATE THE QUANTITY OF PRODUCT

PRODUCT CODE	LOT NUMBER	QUANTITY TO BE RETURNED

CUSTOMER NAME \_\_\_\_\_

Email \_\_\_\_\_

Phone \_\_\_\_\_

DATE \_\_\_\_\_

SIGNATURE \_\_\_\_\_

**PLEASE RETURN THE COMPLETED FORM IMMEDIATELY TO FAX: 075.8004972 OR EMAIL:**

[qa@betatex.com](mailto:qa@betatex.com) - [gacf@betatex.com](mailto:gacf@betatex.com)



## ANNEX A

CODICE	LOTS INCLUDED BETWEEN THE FOLLOWING NUMBERS
WPV0006S	FROM 179085 TO 297295
WPV0002S	FROM 181302 TO 301937
WPV0031S	FROM 182266 TO 301982
WPV0034S	FROM 195203 TO 305556
WPV0025S	FROM 185221 TO 305562
WPV0029S	FROM 189106 TO 301975
WPV0026S	FROM 191754 TO 265711
WPV0030S	FROM 213674 TO 304320
WPV0009S	FROM 191682 TO 259847
WPV0024S	FROM 269945 TO 305559
WPV0054S	FROM 196732 TO 196732
WPV0059S	FROM 288866 TO 288866
SE1988SE	FROM 196060 TO 209491
SE2062SE	FROM 181285 TO 256744
SI1267SE	FROM 179065 TO 294921
SI1266SE	FROM 181318 TO 273576
SE2122SE	FROM 182245 TO 238895
SE2187SE1	FROM 181311 TO 244917
SE2510SE	FROM 185288 TO 187751

Example: code WPV0026S - LOT 259810 - *TO BE RETURNED BACK BECAUSE IT IS INCLUDED IN THE INDICATED NUMBERS.*



**TECNODRAPE**

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