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## **Urgent Field Safety Notice**

**MEDICINA DIRECT DILATION KIT DD12fr, DD14fr, DD16fr**

**JUNE 2014**

**RECALL**

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**Attention:** All Nursing, Medical, and Technical staff using this device;

### **Reason for Safety Notice**

The reason for the FSN recall is that the MEDICINA DIRECT DILATION KIT does not meet certain regulatory requirements.

### **Details of Device**

All Medicina Direct Dilation Kit DD12fr, DD14fr, DD16fr should be returned to Medicina regardless of expiry date or lot/batch number.



### **Action to be taken**

If any of the Medicina Direct Dilation Kits DD12fr, DD14fr and DD16fr is identified we advise they should be quarantined and returned to Medicina as soon as possible.

The following steps should be taken:

1. Contact Medicina using the details below to arrange collection of the Medicina Direct Dilation Kit DD12fr, DD14fr, and DD16fr.
2. This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the affected devices have been transferred.

**Contact**

Carol Cole  
Quality Assurance Administrator  
Unit 2  
Rivington View Business Park  
Station Road  
Blackrod  
Bolton  
BL6 5BN  
Email: carol@medicina.co.uk  
Tel: 01204 695050  
Fax: 01204 697755

Please confirm you have received this notice by email or complete and return below Fax Back Form to Medicina.

Medicina confirms that this notice has been notified to the appropriate Regulatory Agency.

Yours Sincerely,



Carol Cole  
Quality Assurance Administrator  
Medicina Ltd.

**EMAIL/FAX BACK FORM**

**Field Safety Notice – JUNE 2014**

**RECALL MEDICINA DIRECT DILATION KIT DD12fr, DD14fr and DD16fr**

**Please email or fax back:** f.a.o. Carol Cole, Quality Assurance Administrator

**Email:** Carol@medicina.co.uk

**Fax:** 01204 697755

We hereby certify that we have received, read, and distributed this Field Safety Notice to anyone it may concern within our organisation.

Quantity of Affected Product/s:

Lot/batch :

Hospital:

Department:

Name (print):

Date:..... Signature.....