

Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/39

Issued: 5 August 2004

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION REQUEST	✓



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
Medical Device/Equipment: Hi-Tec® BARG TF Vaginal Tape Tension Free	▶ ①
Problem: Hi-Tec® BARG TF vaginal tape may be available in the UK. This product is uncontrolled, carries a false CE marking and presents an unknown risk to patients. It imitates a bona fide product called Hi-Tex® BARG P8 manufactured by Textile Hi-Tec.	▶ ②
Action by: Supplies and Purchasing departments and all clinical staff involved in the use of vaginal tape.	▶ ③
Action: <ul style="list-style-type: none"> • Be aware that Hi-Tec® BARG TF vaginal tape may be available in the UK. • Check stocks of vaginal tape to ensure that you do not have any of this product. Information that may assist identification of this tape is attached. • Do not purchase or use Hi-Tec® BARG TF vaginal tape. If this product is identified, report this to NIAIC. 	▶ ④
Distributed by NIAIC to: <ul style="list-style-type: none"> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers 	▶ ⑤
Contacts NIAIC contacts for technical aspects.	▶ ⑥
Feedback Requirements to NIAIC Report any complications that could be due to the implantation of Hi-Tec® BARG TF tape to NIAIC.	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

The Hi-Tec® BARG TF polypropylene mesh vaginal tape imitates a polypropylene mesh called Hi-Tex® BARG P8, manufactured by Textile Hi-Tec in France.

2. PROBLEM:

NIAIC has been informed of the availability of Hi-Tec® vaginal tape which carries a false CE-marking. Its labelling and instructions for use are in English and it is thus possible that it is being offered for sale on the UK market. The product imitates an existing, bona fide vaginal tape named Hi-Tex® which is manufactured and sold by Textile Hi-Tec. The labelling of Hi-Tec® differs from that of the bona fide product in several ways as described in the table below. See Appendix for pictures of the labelling of both products.

	Imitation product	Bona fide product
Product name	Hi-Tec® BARG TF	Hi-Tex® BARG P8
Label	Orange label – black letters	White label – black and green letters
Sterilisation method claimed	Gamma irradiation	Ethylene oxide
Language	English	French
Product size	1.2 x 60 cm	180 x 60 mm or 10 x 500 mm

3. ACTION BY:

Supplies and Purchasing departments and all clinical staff involved in the use of vaginal tape.

4. ACTION:

- Be aware that Hi-Tec® BARG TF vaginal tape may be available in the UK.
- Check stocks of vaginal tape to ensure that you do not have any of this product. Information that may assist identification of this tape is attached.
- Do not purchase or use Hi-Tec® BARG TF vaginal tape. If this product is identified, report this to NIAIC.

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Risk Managers
- Clinical Governance Leads
- Medical Directors
- Nurse Directors
- Obstetric and Gynaecology Surgeons
- Supplies Staff (RSS)
- Theatre Managers
- Urology Surgeons
- Independent Health Care Providers – Private Clinics through HSS Board R&I Units

6. CONTACTS:

Enquires to NIAIC should quote reference number MDEA(NI)2004/39 and be addressed to:
Northern Ireland Adverse Incident Centre (NIAIC)

Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

Report any complications that could be due to the implantation of Hi-Tec® BARG TF tape to NIAIC.



Brian Godfrey
NIAIC Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2004/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety

Imitation product labelling:



Bona fide product labelling:

