

INSTRUCTIONS TO CUSTOMERS IN RELATION TO FIELD SAFETY NOTICE

Commercial Name of the Affected Product: GIS-10 OxyBloc Bite Block Device

GI Supply Ref Number: FSN14-001

Distribution: GI Supply OxyBloc EU Distributors and End Users

Implementation: Immediate

Type of Action: Destruction of Stock

Date: April 25, 2014

Description of the problem:

Diagmed Healthcare Ltd has become aware that the GIS-10 OxyBloc device was not properly classified for marketing and distribution in the European Union. This represents an inaccuracy in the CE labeling. There have been no potential hazards identified and no associated risk to patients associated with use of the OxyBloc Bite Block device. The manufacturer requested all EU Distributors to quarantine all stock on 21 February 2014 and issued a follow up letter on 18 March 2014.

Instruction on action to be taken by the End User:

Our records show that you have taken delivery of the affected product since January 2011.

Please destroy any remaining stock that you have and notify Diagmed Healthcare of this action using the attached form. We can arrange for appropriate replacements to be sent upon receipt of this notice.



Transmission of the Field Safety Notice:

Diagmed Healthcare apologises for any inconvenience this may cause and requests that you share this notice with all relevant OxyBloc Bite Block Device users. If you have any questions, please contact Diagmed Healthcare contact reference person listed below.

Name/Organization:

David Atkinson
Customer Support Technician

Address:

Unit 5, Moxon Court,
Thurston Road,
Northallerton,
North Yorkshire,
DL6 2NG

Email: david@diagmed.co.uk

Tel: (01609) 768515



NOTICE OF DESTRUCTION QUESTIONNAIRE

Diagmed Healthcare OxyBloc User:

Name	Address	OxyBloc Quantity	OxyBloc Quantity Destroyed

Distributor Customer Notification:

Instructions for Destruction of the OxyBloc Bite Block Devices Provided to Customers	Date of Notification: 25.4.14
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Name and Position: _____

Signature: _____

Date: _____

Please send the completed form to david@diagmed.co.uk.