



Hygeia Medical Company Limited

Address: Flat 13MN, Hechuan Tower, No. 2016, Yishan Road, Shanghai, China.

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Field Safety Notice

Commercial name/Model: Disposable Surgical Blades

FSCA-identifier:

Type of action:

March 2014

Attention: Distributor /Hospital Administrator

Details on affected devices:

The affected product is surgical blade # 10 & # 15 (Lot number 130630).

Description of the problem:

The hospital had an accident-in one operation one blade fractured and stayed in the patient stockmach, the blade is not shape.

Advise on action to be taken by the user:

A. For distributor

Stop selling, and contact the related local hospital to take back all bad surgical blades

B. For User/ Hospital Administrator.

Stop using these bad surgical blades, and return to the local distributor immediately.

Transmission of this Field Safety Notice:

This Notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected device(s) have been transferred.

Please transfer this Notice to other organizations on which this action has an impact.

Please maintain awareness on this Notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

For additional information please contact

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This Notice has been notified the appropriate Regulatory Agency.

(Closing paragraph)

Signature:

Quality Assurance

Hygeia Medical Co.,Ltd.

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