

M. A. ARAIN & BROTHERS (PVT.) LTD.

Manufacturers & Exporters of fine quality Surgical, Electrosurgical & Diagnostic Instruments



Dated:15.03.2013



CIGMPI FDA. U.S.A.

CERTIFIED

Urgent Field Safety Notice

Catalogue Numbers of Teleflex

670067-0000** (Reusable Laryngoscope Handle)

Reference Number: M.A RE 13.01

LOT-Number of affected Products:

- 031511
- 041511
- 040811 This Field Safety Corrective Action affects this LOT-Number which is not indicated on the label of the products.
- 123011
- 011012
- 030812
- 032112
- 073012
- 083112
- 103112
- 111512

Description of the problem:

The products are being subject of this recall due to flickering and intermittent lightning. This problem may occur in some products during use. The described failure may cause a delay during use of the device.

Advise on action to be taken by the user:

Stop using the above indicated products immediately.

Please send back affected products for replacement and check similar other products intend to the same issue before use as per the IFU.

MEMBERS





MAILING ADDRESS: P.O. BOX 432, SIALKOT-PAKISTAN FACTORY: WAZIRABAD ROAD, SIALKOT. TEL: +92-52-4264926, 4264571 FAX: +92-52-4264759, 4264026 E-mail: info@maarain.com URL: http://www.maarain.com



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Transmission of this Field Safety Notice:

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

The undersigned confirms that the appropriate competent authorities have been advised of the FSCA.

ISO 14001:2004 (E) C(GMP) FDA, U.S.A.

CERTIFIED

Mr. Waqas Akbar

Director Marketing and QA

MEMBERS



