
Urgent Field Safety Notice

Commercial name/Model: Sterile single use electro-surgical pencil/HCP-05

FSCA-identifier: Vk_20180416_14-011

Type of action: Recall

May. 2018

Attention:

Dear Sir or Madam,

This letter is intended to provide you with information as following:

Details on affected devices:

Hospital/Distributor Name	Commercial name	Model	batch number	Quantity (PCS)	Used quantity (PCS)	Stock quantity (PCS)
	Sterile single use electro-surgical pencil	HCP-05	P1718008			

Description of the problem:

Sealing of sterile pouch may not be intact .This is an individual case due to the unexpected or incorrect handling.

Advise on action to be taken by the Hospital administrator:

Please return the electro-surgical pencils of the concerted batch number.

Advise on action to be taken by the distributor:

Please transit this FSN to all hospitals which the concerted pencils was distributed to.

Transmission of this Field Safety Notice:

We would be grateful if you could confirm receipt of this letter. Please fill in below Acknowledgement Form and return via E-mail or Fax.

Contact reference person:

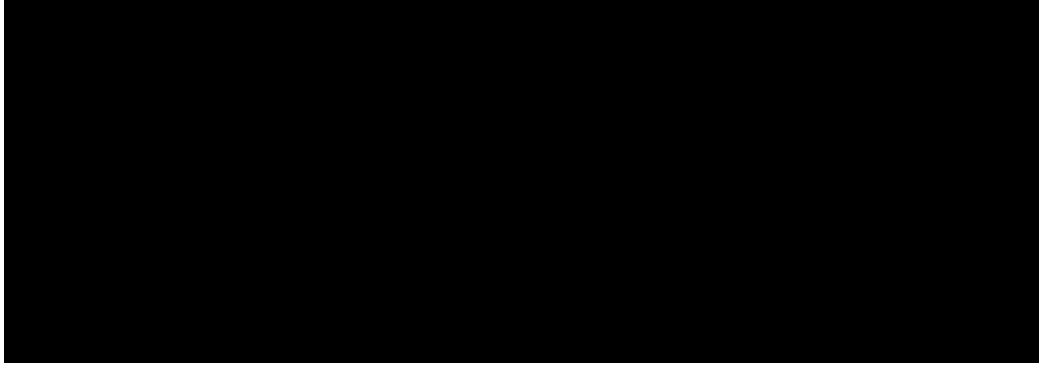
We apologize for the inconvenience caused by this situation. If you have any questions, please contact Wickimed Supply Company Ltd. Service Engineer or designated Technical Support Engineer – Himson Li

Organization:

Tel: 0086 139-22531086

Fax: 0086-752 386 3017
Email: himson_li@wickimed.com

Signature:



Acknowledgement Form

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Confirmation of Receipt of Field Safety Notice

Affected Products : HCP-05 (Lot :P1718008)

FSCA :

Type of FSCA : *Recall*

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Please fill in this form and return this confirmation by E-mail or Fax immediately.

Fax:

Email:

Name: _____

Tel. No.: _____

E-mail address: _____

Date and Signature: _____

Address of the Organization:

Appendix 1 List of Affected Devices.

We have identified that HCP-05 of batch P1718008 were manufactured by Wickimd Supply Company Ltd.

The commercial name and Lot number are HCP-05 Disposable Pencil ,Push Botton 5m cable,sterilzed, standard, P1718008

1. List of customers which distributed with equipments

Country	Equipment S/N	Commercial name/Model	Quantity	Distributor/Hospital	Contact person	Address	Telephone	Email
	P1718008	HCP-05						