Urgent Field Safety Notice – Recall

Diathermy Suction Devices

Product codes S113, S114, S115, S116, S117, S118, S119, S136, S195, S437, S438 & S448

Please pass this Field Safety Notice (FSN) to all persons in your organisation who need to be aware of it.

Type of Action:	To communicate an identified issue with electrical standards compliance and recall of all device models
Device:	Diathermy Suction Devices
Manufacturer:	Eakin Surgical Limited, Cardiff, UK
Date of Issue:	16th Feb 2023
For Attention of:	Healthcare professionals working in hospitals and all others to whom potentially affected devices have been transferred, including distributors.
Scope of Action:	**Device Model recall**
Keywords:	Diathermy Suction Devices

Summary

Testing of the Diathermy Suction Devices has revealed non-compliance with IEC 60601-2-2-2017 standard: Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories. A health hazard assessment has been conducted and has determined that the risk of harm to patient or user is remote. To date there have been no complaints or adverse events reported related to this potential nonconformity and Eakin Surgical do not believe that it is likely to lead to any patient or user injury.

These devices are being recalled because they do not fully comply with IEC 60601-2-2-2017.

This notice needs to be passed to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. Please transfer this notice to other organisations on which this action has an impact.

All devices detailed in Table 1 should be taken out of clinical use and returned to Eakin Surgical.

Action to be taken by Users

Eakin Surgical are performing a voluntary recall of the devices listed in Table 1 below. Users are requested to review the list of potentially affected devices and return the completed FSN response form to Eakin Surgical or to an appointed distributor.

Customers are being asked to complete and return the below customer return form via email to QARA@eakinhealthcare.com and return the devices the address below.

Eakin Surgical Limited, Greypoint, Cardiff Business Park, Cardiff CF14 5WF, UK

Field Safety Corrective Action

This Field Safety Notice is published to facilitate a full device model recall. See Table 1 for detail of all Product codes and LOTs of finished medical devices that are subject to recall under this FSN.

Description of Action

All devices identified in Table 1 should be returned to Eakin Surgical or disposed of.

Table 1. Affected Devices

Products impacted		
Product Code	**Description**	**Lot**
S113	Diathermy Suction 9fg 22cm Fenestrated	181658, 190352, 200240, 210470, 210605, 201288ES, 210164ES, 210920
S114	Diathermy Suction 9fg 27cm	176056, 180065, 181544, 182008, 190001, 190397, 200926, 210466, 201192ES, 210380ES, 210892, 211139, 211279, 230019
S115	Diathermy Suction 9fg 20cm	176072, 190749, 200076, 200092, 211052, 211277
S116	Diathermy Suction 9fg 13cm	176096, 176351, 181250, 181537, 181652, 190021, 190506, 200156, 200157, 200158, 210734, 210778, 201232ES, 210184ES, 210354ES, 210379ES, 211053, 211162, 220188, 220282, 220299, 223085, 223229, 223331, 223424, 223589, 230088
S117	Diathermy Suction 9fg 9cm Frazier	176349, 181251, 181498, 181653, 190111, 190820, 200811, 210267ES
S118	Diathermy Suction 9fg 13cm Fenestrated Rounded	All Lots past 5 year expiry
S119	Diathermy Suction 9fg 13cm Fenestrated Rounded	176107, 176347, 180038, 181110, 181301, 181738, 181880, 182064, 190004, 190326, 190341, 190494, 190626, 190891, 190892, 190893, 201091, 210570, 176142, 201191ES, 210012ES, 210360ES, 210378ES, 210901, 211107, 211122, 211261, 220096, 223169, 223201, 223252, 223269, 223407, 223487, 230063
S136	Diathermy Suction 9fg 9cm Rounded	176110, 176214, 176348, 181135, 181739, 182127, 190221, 190461, 200923, 200924, 210530, 210781, 210867, 210368ES, 210982, 211174, 220024, 220177, 223037, 223389
S195	Diathermy Suction 12fg 19cm	181178, 181538, 182156, 190163, 190265, 190651, 190886, 210591, 201208ES, 210167ES, 210922, 210963, 211224, 220271
S437	9fg 23cm 90°	All Lots past 5 year expiry
S438	Diathermy Suction 9fg 17cm 70˚	176088, 176290, 181238, 182198, 210468, 210032ES, 210044ES, 211036, 211140
S448	Diathermy Abbey Needle with Suction 6fg 10cm	180044, 182116, 190425, 190623, 190819, 190953, 200034, 200075, 200102, 200103, 210527, 210782, 201291ES, 210960, 211110, 223051, 223137,223190, 223406, 223477, 230005

Eakin Surgical Limited has made relevant communication to the UK Competent Authority - Medicines and Healthcare Products Regulatory Agency (MHRA) and the Competent Authorities in other jurisdictions where the device is sold into.

Field Safety Notice Response Form

FSN Reference: ESL-2301 Date: 16 Feb 2023

Hospital or Delivery Location Name: _____

Hospital or Delivery Location Address: _____

_____

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Please complete the information below and return to QARA@eakinhealthcare.com. For commercial queries please telephone Eakin Surgical on 00 44 (0)29 2076 7800 and ask for Eakin Surgical Customer Service.

☐ We confirm that we have received this FSN and have distributed it to relevant individuals or departments within our organisation.

Please also tick one of the following options:

☐ We do not have remaining stock of the affected products

☐ We have stock of affected products and confirm that they have been quarantined for return to Eakin Surgical (FAO QA or Rachael Beattie-Hinton). Quantity of stock for return:

_____ (full boxes of 10 units),

_____ (part boxes) with _____ (individual units)

☐ **Eakin Surgical Distributors Only:** We confirm that we have received this FSN and have distributed it to all customers that have been supplied with the products listed in Table 1.

Form Completed by:

Name: _____

Department or Position: _____

e-mail Address: _____

Date: _____