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FSCA Ref: QA-FSN-2020-0006

Date: 2020-11-03

Urgent Field Safety Notice
**STOPCON Disposable Valves Set (EN10229, EN10229.1,
EN10229.2), STOPCON Suction Valve (EN10232)**

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Contact details of local representative (name, e-mail, telephone, address etc.)*

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STOPCON Disposable Valves Set (EN10229, EN10229.1, EN10229.2), STOPCON Suction Valve (EN10232)

1. Information on Affected Devices*																								
1	1. Device Type(s)*																							
.	<p>The STOPCON Suction Valve (EN10232) is intended to be fitted to endoscope working channel/port to enable an endoscope operator to control its function. When the valve is being pressed, the suction valve can provide air/fluid passage through the apertures on the stem.</p> <p>The STOPCON Disposable Endoscope Valves Set (EN10229.2) consists of one suction valve and one air/water valve. The valve sets are intended to be fitted to multiple endoscope working channels/ports to enable an endoscope operator control the function of the working channels/ports.</p> <p>The STOPCON Disposable Endoscope Valves Set (EN10229) consists of one suction valve, one air/water valve and one biopsy valve. The valve sets are intended to be fitted to multiple endoscope working channels/ports to enable an endoscope operator control the function of the working channels/ports.</p> <p>The STOPCON Disposable Endoscope Valves Set (EN10229.1) consists of one suction valve, one air/water valve, one biopsy valve and one auxiliary water connector. The valve sets are intended to be fitted to multiple endoscope working channels/ports to enable an endoscope operator control the function of the working channels/ports.</p> <p>* The Suction Valve is the only affected device. This device is also included in the valves set series EN10229, EN10229.1 and EN10229.2.</p>																							
1	2. Commercial name(s)																							
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1	3. Unique Device Identifier(s) (UDI-DI)																							
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1	4. Primary clinical purpose of device(s)*
.	<p>The single use STOPCON Air/Water Valve is used to control the air / water function of an endoscope during GI endoscopic procedures. The air / water valve in the endoscopic system provides backflow prevention function to the air / water channel. Not using the air / water channel can cause potential contamination to the air / water system.</p> <p>The single use STOPCON Suction Valve is used to control the suction function of an endoscope during GI endoscopic procedures.</p> <p>The single use STOPCON Biopsy Valve is used to cover the opening to the biopsy/suction channel of Olympus® gastrointestinal endoscopes. The Biopsy Valve provides access for endoscopic device passage and exchange, helps maintain insufflation, minimizes leakage of biomaterial from the biopsy port thought the endoscopic procedure and provides access for irrigation</p> <p>The single use STOPCON Auxiliary Water Connector is used in conjunction with irrigation tubing, intended to provide irrigation via irrigation fluids such as sterile water supplied to the Olympus® GI endoscope during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump. The Auxiliary Water Connector is manufactured with a one-way valve to minimize the risk of cross-contamination of the irrigation system.</p>
1	5. Device Model/Catalogue/part number(s)*
.	<p>EN10232 EN10229 EN10229.1 EN10229.2</p>
1	6. Software version
.	Not applicable, the device does not contain software.
1	7. Affected serial or lot number range
.	<p>EN10232: 20070701, 20073107 EN10229: 19101124, 19111420, 19112504,19120607, 19120609, 20021162, 20021163, 20021164, 20042803, 20050703, 20072103, 20072415, 20080609, 20073103 EN10229.1: 19101125, 19111421, 19112801, 19121830, 20021154, 20031112, 20031604, 20061102,20061103, 20070311, 20072416, 20073104,20080610 EN10229.2: 20021709, 20072417, 20073105</p>
1	8. Associated devices
.	N/A

2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem*
.	The suction button may be sticky and/or broken during or after the procedure.
2	2. Hazard giving rise to the FSCA*
.	Patient injury unlikely happened per problem nature and hazardous evaluation.
2	3. Probability of problem arising
.	Analysis has estimated the probability of device failure to be low.



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2	4. Predicted risk to patient/users
.	The disassembly of suction valve may cause prolonged procedure. It is determined that such impact will not be a major issue in procedure and therefore immediate corrective action for on field product is not required.
2	5. Further information to help characterise the problem
.	No.
2	6. Background on Issue
.	GA Health Company Ltd. (hereinafter referred to as "GA Health") became aware that suction valve from STOPCON disposable endoscope valves set was sticky and/or broken during or after procedure due to recent complaint. The root cause was related to overlook the wrong practice of workers who do not follow the SOP. GA Health is voluntarily recalling suction valve and its related valves set.
2	7. Other information relevant to FSCA
.	No.

3. Type of Action to mitigate the risk*	
3. 1. Action To Be Taken by the Customer*	<input checked="" type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input checked="" type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None Provide further details of the action(s) identified.
3. 2. By when should the action be completed?	Customer is advised to identify and discard the device immediately. The Field Safety Notice Customer Reply Form should be returned to GA Health Company Ltd. or her local distributor of number of affected devices for replacement or credit note.
3. 3. Particular considerations for:	N/A, the device is not an IVD device. Is follow-up of patients or review of patients' previous results recommended? No
3. 4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes



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3.	5. Action Being Taken by the Distributor	
	<input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input checked="" type="checkbox"/> Other Discard remaining inventory <input type="checkbox"/> None	
	Please fill-in the attached Field Safety Notice Customer Reply Form to report number of affected devices in the inventory and return the form back to GA Health Company Ltd.	
3	6. By when should the action be completed?	Distributor is advised to identify and discard the device immediately. The Field Safety Notice Distributor/Importer Reply Form should be returned to GA Health Company Ltd. of number of quarantined devices for replacement or credit note.
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	N/A	


4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Same as page 1 of this FSN
	b. Address	Same as page 1 of this FSN
	c. Website address	Same as page 1 of this FSN
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes.	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	



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Transmission of this Field Safety Notice	
	<p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.</p>



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Field Safety Notice Distributor/Importer Reply Form

Distributor/Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	QA-FSN-2020-0006
FSN Date*	2020-11-03
Product/ Device name*	STOPCON Disposable Valves Set STOPCON Suction Valve
Product Code(s)	1 EN10229 2 EN10229.1 3 EN10229.2 4 EN10232
Batch/Serial Number (s)	EN10232: 20070701, 20073107 EN10229: 19101124, 19111420, 19112504,19120607, 19120609, 20021162, 20021163, 20021164, 20042803, 20050703, 20072103, 20072415, 20080609, 20073103 EN10229.1: 19101125, 19111421, 19112801, 19121830, 20021154, 20031112, 20031604, 20061102,20061103, 20070311, 20072416, 20073104,20080610 EN10229.2: 20021709, 20072417, 20073105

2. Distributor/Importer Details (Sales Input)	
Company Name*	Key Surgical GmbH
Account Number	
Address*	Zum Windpark 1 23738 Lensahn Germany
Shipping address if different to above	
Contact Name*	Tanja Dreesch
Title or Function	
Telephone number*	Direct: +49.4363.90590.130 Mobile: +49.160 97822205
Email*	tanja.dreesch@keysurgical.de

3. Return acknowledgement to Sender	
Email	lewis@gahealth.net
Distributor/Importer Helpline	+852 2833 9010
Postal Address	Unit 18, 21/F, Metropole Square, 2 On You Street, Shatin, N.T., Hong Kong
Web Portal	N/A
Deadline for returning the Distributor/Importer reply form*	7 calendar days upon receipt the field safety notice.

4. Distributors/Importers (Tick all that apply)		
<input type="checkbox"/>	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A



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<input type="checkbox"/>	*I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
<input type="checkbox"/>	*I have identified customers that received or may have received this device	
<input type="checkbox"/>	*I have attached completed RMA list	
<input type="checkbox"/>	*I have informed the identified customers of this FSN	Date of communication:
<input type="checkbox"/>	*I have received confirmation of reply from all identified customers	
<input type="checkbox"/>	*I have destroyed affected devices – enter number destroyed and date complete.	Refer to RMA list for details.
<input type="checkbox"/>	Neither I nor any of my customers has any affected devices in inventory	
Print Name*		Distributor/Importer print name here
Signature*		Distributor/Importer sign Here
Date *		

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.