Unit 18, 21/F, Metropole Square,
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www.GAhealth.net

FSCA Ref: <Reference Number>

Date: <Date>

Urgent Field Safety Notice
Andorate® Disposable Valves Set (GAR004, GAR004C)

For Attention of*: <Customer Company, Address, Contact Details>

Contact details of local representative (name, e-mail, telephone, address etc.)*
Terry Ngan **GA Health Company Limited** **Unit 18, 21/F, Metropole Square, 2 On You Street, Shatin, N.T., Hong Kong** **Telephone: +852 2833 9010** **Email: terry@gahealth.net**

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Urgent Field Safety Notice
Andorate® Disposable Valves Set (GAR004, GAR004C)

1. Information on Affected Devices*

1.1. Device Type(s)*

The Andorate® Disposable Endoscope Valves Set (GAR004C) 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.

The Andorate® Disposable Endoscope Valves Set (GAR004) 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.

* The Suction Valve is the only affected device. This device is also included in the valves set series GAR004, GAR004C.

1.2. Commercial name(s)

Product Code	Product Name
GAR004	Andorate® Disposable Endoscope Valves Set contains Air/water Valve, Suction Valve and Biopsy Valve
GAR004C	Andorate® Disposable Endoscope Valves Set contains Air/water Valve, Suction Valve

1.3. Unique Device Identifier(s) (UDI-DI)

Product Code	Unit Label UDI-DI	Box Label UDI-DI	Cartoon Label UDI-DI
GAR004	04897106950225	14897106950222	24897106950229
GAR004C	04897106950232	14897106950239	24897106950236

1.4. Primary clinical purpose of device(s)*

The single use 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.

The single use Suction Valve is used to control the suction function of an endoscope during GI endoscopic procedures.

The single use Biopsy Valve is used to cover the opening to the biopsy/suction channel of Olympus® gastrointestinal endoscopes. The Biopsy Valve provides access for

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	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.
1.	5. Device Model/Catalogue/part number(s)*
	GAR004 GAR004C
1.	6. Software version
	Not applicable, the device does not contain software.
1.	7. Affected serial or lot number range
	GAR004: 19111119, 19111121, 20021927 GAR004C: 20022006
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.
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 Andorate® 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 Andorate® 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***
	☒ Identify Device ☐ Quarantine Device ☐ Return Device ☒ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU)

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	☐ Other ☐ 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
3.	**5. Action Being Taken by the Distributor** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other Discard remaining inventory ☐ 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:	

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	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	

	Transmission of this Field Safety Notice
	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) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. 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.