

## **FIELD SAFETY NOTICE**

**Endoscopic Instruments Scissors – Metzenbaum Curved Scissors** May 17, 2021

FSN No. AN-210517-01

**Attention: Lagis' Customers** 

Please forward this communication to all surgeons, surgical personnel, and any other potential users of the product.

Dear Valued Customer,

The purpose of this letter is to advise you that Lagis is voluntarily recalling specific production lots of Endoscopic Instruments Scissors – Metzenbaum Curved Scissors.

Lagis have received a report about something fallen when using the device during procedure. After investigation, Lagis discovered that the assembly deviation of the shear blades may result in the damage to the blades. And the metal shaving may on rare occasions fall from the device. However, Lagis have not received any reports of patient injuries resulting from these reports.

Those specific production lots related to the assembly process in question is listed as below table. We are requesting that the devices be returned to Lagis.

The related product lots are showed as below:

<b>Production Lots of EI-330S</b>				
	P2103095			
	P2103043			
	P2101069			
	P2101031			
	P2012071			
	P2012024			
	P2012023			
	P2011026			
	P2010015			
	P2007039			



## **REQUIRED ACTIONS:**

- 1. Immediately quarantine and discontinue use of the above affected devices.
- 2. Immediately forward a copy of this FSN to all sites to which you have distributed affected product and advise all users of Endoscopic Instruments Scissors Metzenbaum Curved Scissors of this FSN.
- 3. Please return affected product as follows:
  - A. Distributors that distributed product from the affected lots must forward this notification to their customers.
  - B. If customers purchased product from a distributor please contact your Distributor directly. All affected units must be returned through the Distributor.
- 4. Complete the <u>RECALL CONFIRMATION FORM</u> even if you do not have affected product at your site.

If you have any questions or concerns regarding the return process or product related questions, please do not hesitate to contact Lagis directly or your Lagis representative.

We appreciate your attention to this matter and apologize for this inconvenience and assure you that Lagis has implemented appropriate measures to protect against recurrence of this problem. Thank you for your business and continued support.

Cora Chen

Lagis Enterprise Co., Ltd.

**Quality Assurance** 



## **RECALL CONFIRMATION FORM**

customer •					
Please complete this form 6	even if you do not l	have affected	d in	ventory and send to:	
E-mail: <u>servic</u>	<u>e@lagis.com.tw</u> or	Fax: +886-4	-26	320766	
Multiple choice accepted)					
1. ☐ <b>YES</b> - I would like replacement product from alternative product.				Please continue to complete the Column for RETURNING PRODUCT	
2. ☐ <b>YES</b> - I would like credit.				INFORMATION.	
RET	URNING PRODUCT	INFORMAT	ION		
Product Code	Lot No. of Affect	ed Product Q'ty of Returning Product			
EI-330S	P2103095				
	P2103043				
	P2101069				
	P2101031				
	P2012071				
	P2012024				
	P2012023				
	P2011026				
	P2010015				
	P2007039				
□ <b>NO</b> - I do not have any o	of the affected prod	lucts in stock			
Do you consider proceeding Authority?	with official notifi	cation to the	lo	cal Competent	
☐ YES ☐ ☐ If YES, what action should be t	NO aken by LAGIS?				
Facility Name:		Facility Shipping Address:			
Department:		Date:			
Print Name:		Signature:			
Email:		Phone Number:			