



## 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 RECALL CONFIRMATION FORM 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.

A handwritten signature in blue ink that reads "Cora Chen".

Cora Chen  
Lagis Enterprise Co., Ltd.  
Quality Assurance

