Urgent Field Safety Notice

Commercial name/Model: Hemoclip AG-51044-2300-090-16
Lot No.510160810, 510160912
FSCA-identifier: FSCA-510-161201
Type of action: Recall

Jan.5, 2017

Dear Customer

Origin

We have received the feedback from distributor and hospital about the problem of our 16mm hemclip impossible release, which may cause lesion tearing bleeding, and it involved the batch no. 510160810, 510160912

Cause analysis

The size of individual product is wrong due to adjustment of mould of a component after analysis, which may result in the problem of impossible release when rotating hemoclip under the bending of endoscope beyond 135°.

Corrective and preventive actions

It was decided to establish a voluntary recall; all products will be replaced. In parallel, preventive actions has been set so to ensure product conformity.

Caution implement

Today the concerned lots are not sold any more.

If your institution has in stock a product concerned please return it for exchange.

If you received this product and it has been placed on a patient, there is no residual risk for the patient, no specific action is to be implemented.

Hemoclip to return

If you have some hemoclips to return, you should contact your supplier, who will inform you of their return procedure:

Support Engineer – Alan Sheng

Organization:

Hangzhou AGS MedTech Co., Ltd.

Tel: 0086-571-87671223-8070

Fax: 0086-571-87671225

Please ensure all the health professionals in your hospital, who use these devices (and in particular the endoscopy operating room) are informed of this recall.
You will also find attached an 'acknowledgement of receipt' for this important recall, please complete and return as soon as possible.

This Notice has been notified the appropriate Regulatory Agency.

For any additional information regarding this safety notice, please contact the Quality Control Department at Hangzhou AGS MedTech Co., Ltd.(E-mail:shengyy@bioags.com)

We apologise for the inconvenience caused by this notice, although it is aimed at guaranteeing patient safety and customer satisfaction and we thank you for your co-operation and understanding in this matter.

(Closing paragraph)

Signature:

2017.1.5

Alan Sheng
Quality Center

Building 6,Kangxin Road No.597,Qianjiang Economic
Development Area, Hangzhou, Zhejiang, 311106 , P.R.China
Tel: 0086-571-87671223-8070
Fax: 0086-571-87671225
Email: shengyy@bioags.com

Customer - City - Country

ACKNOWLEDGEMENT OF RECEIPT – to return by fax at: 0086-571-87671225
I confirm that I have received the safety notice which has been communicated to the users in my centre.

The hemoclips shown in the table below have been billed to your center. If they have already been placed in a patient, there is no risk for him.

No.	Lot No.	Specification	Production quantity	delivery date	delivery quantity	Distributor /Hospital	Contact person	Address	Telephone	Email
1 .	510160810	AG-51044 -2300-090-16	2000	2016/9/8 2016/9/14	3575	Life Partners Europe	Amélie Merle	161, Avenue Galliéni/ 93170 BAGNOLET France	+33 149 88 85 62	a.merle@lifeurope.com
2	510160912	AG-51044 -2300-090-16	4000	2016/9/29	2000	Life Partners Europe	Amélie Merle	161, Avenue Galliéni/ 93170 BAGNOLET France	+33 149 88 85 62	a.merle@lifeurope.com

Person in charge of this safety notice:

Surname-First Name: _____

Position: _____

Department: _____

E-mail address: _____

Direct phone: _____

Date: _____ Signature and stamp: