San Possidonio, July 8th[rd], 2024

To:
Mermaid Medical A/S
Frydenbergsvej 25
Stenløse 3660
Denmark
Tél: +33 (0) 2 41 27 01 06

Kind attention: Ashley Cannone

Subject : Field Safety Notice FSN-02-2024

Dear Valued Customer,
Company MEDAX – manufacturer of the device – UNIMAG 18G X 250 MM - is initiating a voluntary recall of the lot number indicated in the table below.

Code	Lot	Description
UM18250-00	07653-22	UNIMAG 18G X 250 MM Soft tissue biopsy needle compatible with Argon Medical Pro-Mag™ Ultra 2.5 biopsy system

Our records show that your facility has purchased the affected lot.

Important note:
This notice must be transmitted to any structure where the potentially affected devices may have been transferred.

Problem description:
The plastic protection tube has fallen of the needle and it has perforated the pouch with loss of sterility.

Potential risk:
Perforation of the primary packaging and loss of sterility.
Risk for the safety of the Patient and/or User.

Nationl Authorities Competent have been informed about this FSN.

Required Actions by Distributors and Users:

- Please identify and quarantine any devices of the affected lot in your inventory.
- Provide a copy of this FSN and FSN response to all users/hospitals who may have received affected devices.
- Ask these users/hospital personnel to complete the FSN response form and return it to you.
- Confirm to Medax that you have completed the required activity for all of your impacted customers.

Upon receipt of the completed FSN response form, MEDAX will contact you to arrange the return of the affected devices and the provision of replacement devices.

Medax places utmost importance to product quality and safety of our patients.
We appreciate your attention to this matter and apologize for any inconvenience this issue may have caused. If you have any question or concerns regarding this recall, please contact your MEDAX Customer Service and Quality Assurance teams by email at:

sales@medax.it
customercare@medax.it
qa@medax.it
quality3@medax.it

We will remain at your entire disposal for any further information or clarifications you may require.

We thank you for your attention and cooperation

Best Regards

Stefano Cavalieri
Quality Assurance
Medax S.r.l. Unipersonale