Urgent Field Safety Notice (FSN)

Date: DD Month YYYY

To

<<Customer name>>

<<Customer address>>

<<Customer contact details>>

Dear Madam, Sir,

Subject: iSTAR Medical issues this Field Safety Notice to inform you about a device related issue concerning the use of MINIject® S devices supplied to your facility, along with the associated actions.

Information on Affected Devices
Device Commercial Name: **MINIject® S** Product Reference/Model/Catalogue: **FG2001ZA; FG2001ZB**
Description of the product problem:
Under the current implantation procedure, it was observed that some implants were misplaced into the ciliary body instead of the supraciliary space. This misplacement was undetected intraoperatively. iSTAR Medical received 06 complaints on device misplacement in the ciliary body that were confirmed by Optical coherence tomography (OCT) device for misplacement of the implant in the ciliary body.
Background on the issue:
To ensure patient safety, the commercial launch of the MINIject S was limited to specific sites. In total, there were 09 sites where the MINIject S was implanted, all of which were operated by surgeons who had prior experience with earlier versions of the MINIject device. Initially, there were 06 reported cases of device misplacement in the ciliary body that were confirmed using Optical Coherence Tomography (OCT), which verified the misplacement of the implant. A modified surgical technique was implemented, but this did not entirely resolve the device misplacement issue.

Hazard associated with the problem:
Six (6) misplaced devices of 78 devices implanted in total resulted in the overall misplacement rate of 7.7%. Potentially related post-operative complications included a case of elevated IOP and a case of cystoid macular edema, both of which responded to medical therapy. The shortest duration of misplaced implant is 14 days and the longest duration is 8 months, as of February 2025. However, there are device-related complications that could possibly occur in patients with misplaced implant in ciliary body, including but not limited to, the risk of hemorrhage in the front or the back of the eye, as well as complications of the implant being placed into the vitreous cavity. In certain situations, such events could lead to temporary or permanent loss of function, including vision loss. Even if the risk of these possibilities is low, the severity of the possible hazard warrants issuing of this FSN.
Actions required to be taken by the user:
1) All patients previously implanted with MINIject S should be proactively followed with any change in clinical status properly reported to the manufacturer. 2) Review, complete, sign and return the enclosed customer reply form to acknowledge the receipt of this notice.
Actions taken by the manufacturer:
1) iSTAR Medical has confirmed that no MINIject S devices remain at customer sites and that no additional units will be distributed to customers. 2) iSTAR Medical will continuously monitor available data to detect potential harm to the implanted patients. iSTAR Medical has also initiated a Corrective Action and Preventive Action (CAPA) to investigate, document and report events associated with this issue.

This Field Safety Notice and the associated Field Safety Corrective action has been submitted to the national competent authority (<<name of the NCA>>).

For any additional information or questions regarding this notice, please get in touch with our sales representative, (<<name>>), at (<<contact email address>>) or (<<insert contact phone number>>).

We truly appreciate your support and trust in our MINIject devices, and we look forward to continued collaboration.

Signature:	Signature:
Zubair Hussain VP Regulatory Affairs at iSTAR Medical S.A	Sabine Gilbert VP Quality & PMS at iSTAR Medical S.A

Transmission of this Field Safety Notice
This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate)
Please transfer this notice to other organizations 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.

***** End of the document*****

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	FSN-2024-001
FSN Date	DD Month YYYY
Product/ Device name	MINIject® S
Product Code(s)	FG2001ZA; FG2001ZB

2. Customer Details	
Account Number	
Healthcare Organisation Name	
Organisation Address	
Contact Name	
Telephone number	
Email	

Customer action undertaken on behalf of Healthcare Organisation

Questionnaire	Yes	No	Not applicable (Please explain)
I confirm receipt of the Field Safety Notice and that I read and understood its content.	☐	☐	☐
I agree to perform all actions requested by the FSN.	☐	☐	☐
I have checked my stock and confirm that there are no remaining MINIject S devices	☐	☐	☐
The information and required actions have been brought to the attention of all relevant users.	☐	☐	☐
Other Action (Define):			

Completed by:

Name	
Signature	
Date	

Kindly return the completed and signed forms to our sales representative, (<<name>>), at (<<contact email address>>) or (<<insert contact phone number>>) no later than (<<DD Month YYY).

*****End of Document*****