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 a device related problem concerning the use of MINIject® S devices supplied to your facility.

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. All these 06 cases 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 MINIject® S was limited to 5 sites. Following the detection of 2 misplaced implantations at one site, 4 additional sites were allowed to make additional implantations to asses whether the misplacement was on account of one surgeon's technique alone, or whether it was more widespread. From the 4 additional sites, where the test implantations were performed, iSTAR Medical received 4 additional incident reports of device misplacement in the ciliary body, thus it was concluded that the device misplacement issue was more widespread and not surgeon dependent. Based on available information, there were two advisory meetings held with the outcome of the decision to evaluate the procedure with one additional surgical step for 10 cases (priming of the cleft with a blunt instrument) as part of the ongoing STAR-LIFE post-market clinical investigation. A formal advisory meeting is planned to discuss the outcome of the modified surgical technique and further actions.

Hazard associated with the problem:
There were no post-operative complications observed in relation to the 6 reported incidents. The shortest duration of misplaced implant is 14 days and the longest duration is 3 months, to date. 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 may 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) The hospitals where MINIject S was supplied under the limited launch are advised to perform implantation only in the frame of STAR-LIFE post-market clinical study. The investigators must follow the modified implantation procedure and continue to monitor patients according to the instructions provided in the updated Clinical Investigation Plan (CIP). Following the implantation of 10 patients, the data will be reviewed for further actions. 3) Review, complete, sign and return the enclosed customer reply form to acknowledge the receipt of this notice.
Actions taken by the manufacturer:
1) The manufacture follows recommendations from the advisory meetings to enroll 10 additional patients in the ongoing STAR-LIFE post market study to be treated with MINIject S with respect to modified surgical procedure to reduce the risk of device misplacement. 2) The manufacturer will continuously monitor available data to detect potential harm to the implanted patients. The manufacturer has also initiated a Corrective Action and Preventive Action (CAPA) to investigate the 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:
Zubair Hussain VP Regulatory Affairs 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 quarantined the available units.	☐	☐	☐
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*****