



May 5th, 2021

URGENT: FIELD SAFETY NOTICE

MONOBLUE NafX (manufacturer: ARCADOPHTA)

- Voluntary recall -

FSN Ref.: **FSN-2021-01**

FSCA Ref.: **FSCA-2021-01**

For attention of Distributors and Users,

ARCADOPHTA is issuing this Field Safety Notice to inform you about a potential issue that may affect MONOBLUE NafX, a sterile single use medical device for retinal surgery identified below.

2. Information on Affected Devices*	
1.	7. Device Type(s)* Sterile, single use, ophthalmic staining solution composed 0.15% of Trypan Blue, 2.5% of Mannitol, 5% D2O, Phosphate buffer QS 0.75 mL in a 2.5 mL type I glass syringe, packaged with a connector in an individual pouch. The pouch is sterilized by autoclave. A box contains 5 pouches and 5 tuberculin syringes.
1.	8. Commercial name(s) MONOBLUE NafX
1.	9. Unique Device Identifier(s) (UDI-DI) (01)13760130640289(17)220400(10)9447091
1.	10. Primary clinical purpose of device(s)* Ophthalmic staining solution for use as an aid for retinal surgery
1.	11. Device Model/Catalogue/Part number(s)* 615
1.	12. Affected serial or lot number range 9447091

3 Reason for Field Safety Corrective Action (FSCA)*	
2.	3. Description of the product problem* On April 27th, 2021, ARCADOPHTA has been advised MONOBLUE NafX boxes might contain syringes of NafX staining solution in unsealed pouch (batch 9447091), due to a weakness of the sealing. None of these products has been injected as the defect was observed before use (labelling alerts the user to not use the device if the sterile barrier is damaged).
2.	4. Hazard giving rise to the FSCA* As this pouch (bag) is the sterile barrier system, decision was taken to voluntary recall this batch to avoid any risk of intra-ocular infection for the patient, while labelling alerts the user to not use the device if the sterile barrier is damaged and no other complaint was reported so far on this batch since placement on the market (May 2020).

ARCADOPHTA SARL – 11 rue Antoine Ricord – 31100 TOULOUSE – FRANCE

Tél : + 33.(0)5.61.40.52.35

Email : InfoArcadophtha@bvimedical.com

SAS au capital de 1 000 000 € – SIRET : 440 530 558 00020 –APE/NAF : 3250A – ID VAT : FR54440530558

5. Action to be taken		
3.	4. Action To Be Taken by the User* <p> <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p>5. Stop IMMEDIATELY using MONOBLUE Nafx, batch 9447091. Examine your inventory and quarantine products from this batch subject to this voluntary recall.</p> <p>6. If you have further distributed this product, please identify your customers and notify them of this voluntary product recall. Consider all potential users of this product in your user supply chain. Please provide them with a copy of the present Field Safety Notice (FSN).</p> <p>7. Complete the Attachment 1 “Reply Form” and return it by email to: mmillan@bvmedical.com, not later than 5 working days after receipt, even if you do not have product to return.</p> <p>8. Return all quarantined products, from the affected batch (9447091) to ARCADOPHTA, 12 rue Louis Courtois de Viçose, Portes Sud, Bat. 3, 31100 Toulouse, FRANCE. Your account will be credited when the products are received. If you need further assistance, you can contact us using the information below: Email: mmillan@bvmedical.com</p>	
3.	5. Is customer Reply Required? *	Yes
	(If yes, form attached specifying deadline for return)	
3.	6. Is the FSN required to be communicated to the patient /lay user?	No

6. General Information*		
4.	6. FSN Type*	New
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	ARCADOPHTA
	b. Address	11 rue Antoine RICORD, 31100 TOULOUSE, FRANCE
	c. Website address	Arcadophtha.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Att. 1: Reply Form
4.	10. Name/Signature	Insert Name and Title here and signature below Catherine CHAUDRON, <i>Quality Affairs / Regulatory Affairs Director</i> ARCADOPHTA



Attachment 1: Reply Form
ARCADOPHTA FSN Ref: FSN-2021-01

Please complete and return this response form not later than 5 working days after receipt

5. Field Safety Notice (FSN) information	
FSN Reference number*	FSN-2021-01
FSN Date*	05/05/2021
Product/ Device name*	MONOBLUE NafX
Product Code(s)	615
Batch/Serial Number (s)	9447091

6. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

7. Return acknowledgement to Sender	
Email	mmillan@bvimedical.com
Postal Address	11 rue Antoine RICORD, 31100 TOULOUSE, FRANCE
Web Portal	Arcadophta.com
Deadline for returning the Distributor/Importer reply form*	<u>Not later than 5 working days after receipt</u>

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8. Distributors/Importers (Tick all that apply)		
<input type="checkbox"/>	*I confirm the receipt, the reading and understanding of the Field Safety Notice FSN-2021-01 .	Distributor/Importer to complete or enter N/A
<input type="checkbox"/>	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
<input type="checkbox"/>	I have identified customers that received or may have received this device	
<input type="checkbox"/>	I have informed the identified customers of this FSN	Date of communication:
<input type="checkbox"/>	I have received confirmation of reply from all identified customers	
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form)
<input type="checkbox"/>	Neither I nor any of my customers has any affected devices in inventory	
Print Name*		Distributor/Importer print name here
Signature*		Distributor/Importer sign Here
Date *		

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.