Field Safety Notice (FSN)
SYNIMIX VTP MIXER

FSN Ref: SYFSN24001
FSCA Ref: SYFSCA24001

26th November 2024

SYNERGIE INGÉNIERIE MEDICALE performs Field Safety Corrective Action for a batch of the device **SYNIMIX VTP MIXER**.

Attention customers and distributors of the affected batch of medical devices. Others: physician, clinician or hospital administrator.

1. Information on Affected Devices*

1. 1. Device Type(s)*

Vacuum mixer for vertebroplasty cements; class Is, sterile, non-invasive, single use.

1. 2. Commercial name(s)*

SYNIMIX VTP MIXER SYSTEM

1. 3. Unique Device Identifier(s) (UDI-DI)

03700448201386

1. 4. Primary clinical purpose of device(s)*

The Synimix vacuum mixer has been developed for the preparation of a wide range of cements intended for verteroplasty.

1. 5. Device Model/Catalogue/part number(s)*

880440 SYNIMIX VTP MIXER SYSTEM

1. 6. Software version

n.a.

1. 7. Affected serial or lot number range

43456

1. 8. Associated devices

Cements for verteroplasty

1. 9. Details of device putting on the market (See Distribution list)

Account Number	Ref. Number	Product Designation	Batch number	GTIN	Invoice number	Purchased quantity	Delivery date
FUT002	880440	SYNIMIX VTP MIXER SYSTEM	43456	03700448201386	FC14146	12	31/05/2024
PAL001	880440	SYNIMIX VTP MIXER SYSTEM	43456	03700448201386	FC14213	5	20/06/2024
PAL001	880440	SYNIMIX VTP MIXER SYSTEM	43456	03700448201386	FC14389	5	05/09/2024

2. Reason for Field Safety Corrective Action (FSCA)*

2. 1. Description of the product problem*

This product has been on the market since 26 May 2024 without complying with the requirements of REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards transitional provisions relating to certain medical devices and certain in vitro diagnostic medical devices.

The product was not included in the contract signed with the notified body for MDR certification and therefore cannot be placed on the market after May 26, 2024.

It is informed that Synimed will no longer market this product with immediate effect.

2. 2. Hazard giving rise to the FSCA*

The product does not present any risk since it was manufactured on September 2, 2022 in compliance with the applicable regulatory requirements.

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2.	3. Probability of problem arising
	n.a.
2.	4. Predicted risk to patient/users
	No risk has been identified
2.	5. Further information to help characterise the problem
	Product classification confusion and lack of communication
2.	6. Background on Issue
	The cause of this issue is due to the fact that there was a misunderstanding with the notified body CNCps nº0318 on the part of those responsible for managing the contract signed for the certification of the product in MDR 2017/745, withdrawing the SYNIMIX VTP from the list, thinking that it was not a medical device. The relevant persons of Synimed were not informed of this decision.
2.	7. Other information relevant to FSCA
	Withdrawal of unused product and safety information if it has been used.

	3. Type of Action to mitigate the risk*	
3.	**1. Actions To Be Taken by the User***	
	X Identify Device **X** Quarantine Device **X** Return Device ☐ Destroy Device - Locate the units, keep them in quarantine and when all are located, return the devices to Synimed, by completing the form **F-PR031-004** attached to this Filed Safety Notice. - Devices must be returned to the following address: ***Synimed Synergie Ingénierie Médicale*** ***Zone d' Activité de l'Angle, 19370 Chamberet, Francia*** - Synimed must be informed of the users or persons to whom this device has been made available, using the form attached to this Field Safety Notice. - In the event that the product has been used, inform the final user that the product does not carry any type of risk. - It is informed that Synimed will no longer market this product with immediate effect.	
3.	2. By when should the action be completed?	1 week - maximum ten working days weeks
3.	3. Particular considerations for: n.a. Choose an item. Is follow-up of patients or review of patients' previous results recommended? No	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes (10 working days)

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3.	**5. Action Being Taken by the Manufacturer***	
	X Product Removal ☐ Software upgrade ☐ Other Provide further details of the action(s) identified.	☐ On-site device modification/inspection ☐ IFU or labelling change ☐ None
3.	6. By when should the action be completed?	10 working days
3.	7. Is the FSN required to be communicated to the patient /lay user?	N/A
3.	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	No n.a. Choose an item.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	n.a.
4.	3. For Updated FSN, key new information as follows:	
	Summarise any key difference in devices affected and/or action to be taken.	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	tracking of the device located on the market and withdrawal within a maximum of 2 weeks	
4.	6. Anticipated timescale for follow-up FSN	daily
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	SYNERGIE INGÉNIERIE MEDICALE
	b. Address	Z.A. De L´Angle, Chamberet 19370 France
	c. Website address	www.synimed.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes, ANSM Agence Nationale de Securite du Medicament et des Produits de Santé Ref. FSCA (ANSM): **R2433463** Synimed Reference (FSCA) SYFSCA24001	
4.	9. List of attachments/appendices:	SYFSCA24001 F-PR031-004 CUSTOMER REPLY FORM

4.	10. Name/Signature	Magda Bresó
		Firmado digitalmente por MARIA MAGDALENA BRESO PERIS - NIF:25419308 DN: cn=MARIA MAGDALENA BRESO PERIS - NIF:25419308 gn=MARIA MAGDALENA c=ES ou=ACCV o=HC SUDAMANOS Motivo:Soy el autor de este documento Ubicación: Fecha: 2024-11-27 15:52:40 00

	Transmission of this Field Safety Notice
	This FSN has been transmitted to the followings: ANSM Agence Nationale de Sécurité des Médicaments dt Produits de Santé **Synimed Quality Responsible** **Synimed Manager** **Recall/vigilance Committee** **Sales and Administrative persons** **Customers included in the Distribution list** **Involved Health Authorities** (Agencia Española de Medicamentos y Productos Sanitarios AEMPS SPAIN/ National Agency for Medicines and Medical Devices of Romania) **Notified body No.0318** CNCps Spain.

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.