Date: April 6th, 2021

Urgent Field Safety Notice

Cemento Mini Set for Cemento-MP

For Attention of:

Physicians, users, and OR staff in the field of spine surgery

Contact details of local representative (name, e-mail, telephone, address etc.)
Macromed (UK) Ltd 4 Petre Road, Clayton Business Park, Clayton Le Moors, Accrington, Lancs BB5 5JB United Kingdom T: 0845 0345 160 F: 0845 0345 161 Email: admin@macromed.co.uk

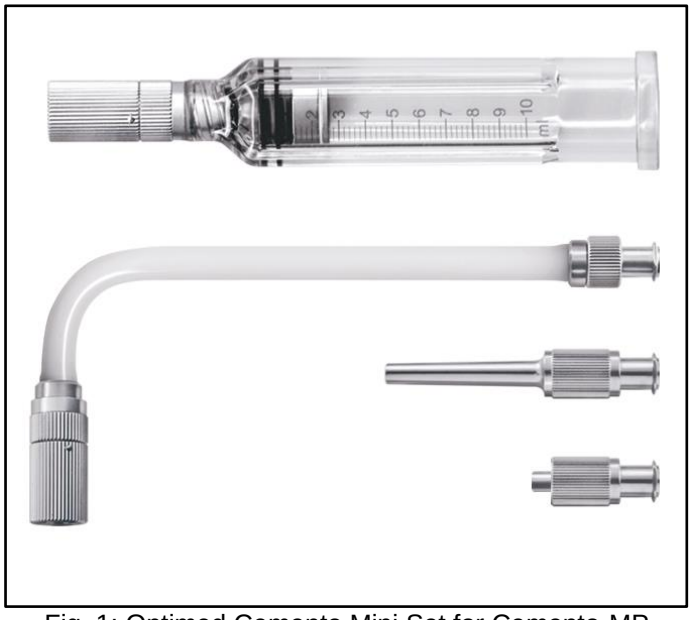


Fig. 1: Optimed Cemento Mini Set for Cemento-MP

Urgent Field Safety Notice (FSN)
Cemento Mini Set for Cemento-MP

1. Information on Affected Devices*	
1.	1. Device Type(s)
	Cemento Mini Set for Cemento-MP: complementary set with injection cylinder, connection hose, aspiration cannula, and Luer Lock adapter (see fig. 1 above)
1.	2. Commercial name(s)
	Cemento Mini Set for Cemento-MP
1.	3. Unique Device Identifier(s) (UDI-DI)
	n/a
1.	4. Primary clinical purpose of device(s)
	The optimed Cemento MP is an injection system for cemetoplasty / vertebroplasty.
1.	5. Device Model/Catalogue/part number(s)
	1382-0100
1.	6. Software version
	n/a
1.	7. Affected serial or lot number range
	13622, 13661, 13712, 13822
1.	8. Associated devices
	n/a

2 Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	In recent weeks, in very rare cases, an unexpected leakage of the cement mixture occurred at the distal luer lock of the connection hose (see fig. 2)
2.	2. Hazard giving rise to the FSCA
	We have been informed about 4 cases with cement leakage; none of the patients has been harmed. The user can clearly see the leakage of the cement because it happens outside the patient. When the user notices a leakage, he must use a new set. Since the cement cannot be applied into the patient in case of a leakage, there is no risk to the patient. We decided to recall the affected products, because the malfunction is not acceptable, even if there is no risk for the patients.
2.	3. Probability of problem arising
	There are four lots which may be affected by this leakage. 697 mini sets of these four lots has been delivered by optimed, and four cases of leakage has been reported. The complaint rate is 0.57%.
2.	4. Predicted risk to patient/users
	According to the available information, there is no risk for patients.
2.	5. Further information to help characterise the problem
	n/a
2.	6. Background on Issue
	The root cause was identified as a deviation in the tolerance during production of the rotatable Luer lock connection. Only products of the 4 above-mentioned lots can be affected by this manufacturing defect. Other lots are not affected by this possible defect.
2.	7. Other information relevant to FSCA
	Other lots of this part number and other products are not affected.

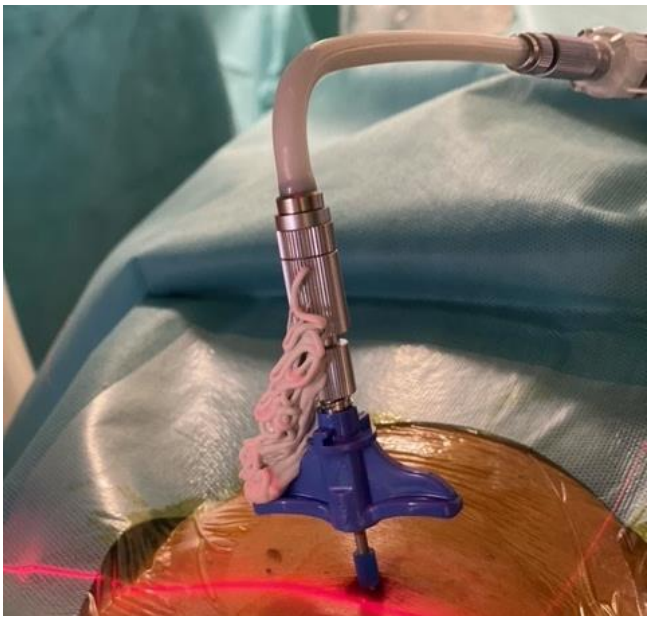
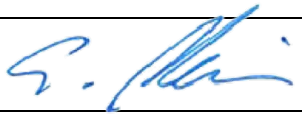


Fig. 2: Leakage at distal Luer Lock of the connection hose

	3. Type of Action to mitigate the risk	
3.	**1. Action To Be Taken by the User** ☒ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None The affected products should no longer be used on patients. Quarantine all affected products and return all products of the affected lot.	
3.	2. By when should the action be completed?	As soon as possible
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

3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None All affected products are separated at optimed and will be exchanged.		
3	6. By when should the action be completed?	As soon as possible	
3.	7. Is the FSN required to be communicated to the patient /lay user?		No
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?		
	n/a Choose an item. 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:	
	n/a	
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:	
	n/a	
4	6. Anticipated timescale for follow-up FSN	n/a
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Optimed Medizinische Instrumente GmbH
	b. Address	Ferdinand-Porsche-Str. 11, 76275 Ettlingen, Germany
	c. Website address	www.optimed.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	9. List of attachments/appendices:	n/a
4.	10. Name/Signature	**Dr. Ernst Nennig, PhD** **Health and Safety Officer for Medical Devices**
		06.04.2021 

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