Date: 25.07.2022

Urgent Field Safety Notice

Silaro Exchange Kit

For Attention of:

Physicians, users, and OR staff in the field of urology

Contact details of local representative (name, e-mail, telephone, address etc.)
BMEDIC ApS Stensgårdsvej 47 7000 Frederica Denmark Tel: +45 30882500 Email: info@bmedic.dk web: www.bmedic.dk

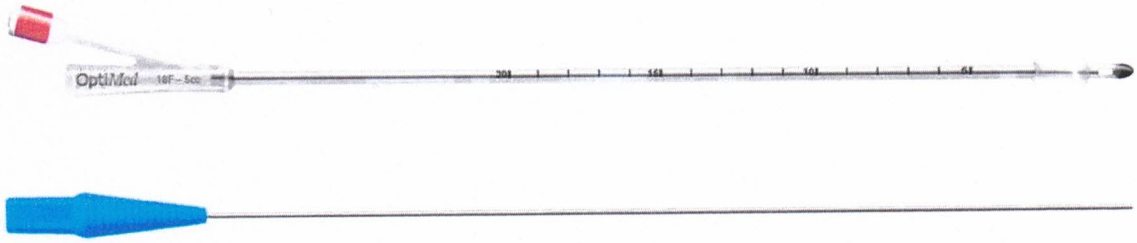

Fig. 1: Optimed Silaro Exchange Kit

Urgent Field Safety Notice (FSN)
Silaro Exchange Kit

1. Information on Affected Devices*	
1.	1. Device Type(s)
	Silaro Exchange Kit (siehe Abb. 1 oben)
1.	2. Commercial name(s)
	Silaro Exchange Kit
1.	3. Unique Device Identifier(s) (UDI-DI)
	n/a
1.	4. Primary clinical purpose of device(s)
	Transkutaner Nephrostomie Katheter
1.	5. Device Model/Catalogue/part number(s)
	1346-1203
1.	6. Software version
	n/a
1.	7. Affected serial or lot number range
	6000221004
1.	8. Associated devices
	n/a

2 Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	We were informed of a case where the obturator belonging to the packaging unit was not included.
2.	2. Hazard giving rise to the FSCA
	We were informed of a case with a missing obturator. An internal review concluded that this error occurred in one batch. There is no risk to patients and users as the product cannot be used without the obturator. There is only the possibility of an extended intervention period in order to use a replacement product.
2.	3. Probability of problem arising
	Only one lot with a total of 50 products is affected, the complaint rate of the last three years for this product group is 0,659%.
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
	n/a
2.	7. Other information relevant to FSCA
	The cause has been identified as an error during packaging of the lot. Other lots of this item number and other item numbers are not affected.

	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	**Frank Wohkittel, PRRC**

	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.