

Date: 2022-09-06

Urgent Field Safety Notice
Infusion set with backcheck valve

For Attention of*:Customers of the EU importer who have received the medical device with affected batch.

Contact details of local representative (name, e-mail, telephone, address etc.)*
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Wolfram Droh GmbH, Dammweg 11, 55130 Mainz // service@droh.de

Urgent Field Safety Notice (FSN)
Infusion set with backcheck valve
stop selling and
recall all affected products

1. Information on Affected Devices*	
1	1. Device Type(s)*
.	Infusion set with backcheck valve // Spike without wings and red cap, 62mm drip chamber with filter, 180 cm tube, safety roller clamp, luer lock + vented cap, with additional 10 pcs inner bag
1	2. Commercial name(s)
.	Infusion set with backcheck valve
1	3. Unique Device Identifier(s) (UDI-DI)
.	-
1	4. Primary clinical purpose of device(s)*
.	The pressure infusion product is used for rapid fluid delivery using an increased infusion rate by means of pressure.
1	5. Device Model/Catalogue/part number(s)*
.	E-0497
1	6. Software version
.	-
1	7. Affected serial or lot number range
.	21/502087
1	8. Associated devices
.	-

2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem*
.	In a user report, it was determined that the designated product "Infusion System for Pressure Infusion with Check Valve," model E-0497, designated batch 21/502087, may break at the check valve between the patient valve and the infusion system
2	2. Hazard giving rise to the FSCA*
.	no Connection to an access is possible/ no use on patient possible
2	3. Probability of problem arising
.	The error has been reproduced by the manufacturer and occurs in about 20% of the goods.
2	4. Predicted risk to patient/users
.	-
2	5. Further information to help characterise the problem
.	-
2	6. Background on Issue
.	-
2	7. Other information relevant to FSCA
.	-

3. Type of Action to mitigate the risk*	
3.	<p>1. Action To Be Taken by the User*</p> <p> <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input checked="" 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>
3.	<p>2. By when should the action be completed?</p> <p style="text-align: center;">Immediate y</p>
3.	<p>3. Particular considerations for:</p> <p>Is follow-up of patients or review of patients' previous results recommended? No -</p>
3.	<p>4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)</p> <p style="text-align: right;">Yes</p>
3.	<p>5. Action Being Taken by the Manufacturer</p> <p> <input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p style="text-align: center;">-</p>
3	<p>6. By when should the action be completed?</p> <p style="text-align: center;">Immediate y</p>
3.	<p>7. Is the FSN required to be communicated to the patient /lay user?</p> <p style="text-align: right;">No</p>
3	<p>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?</p>

4. General Information*	
4.	1. FSN Type* New
4.	2. For updated FSN, reference number and date of previous FSN -
4.	3. For Updated FSN, key new information as follows: -
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: -
4	6. Anticipated timescale for follow-up FSN -
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)
	a. Company Name Shandong LeeMed Technology Co., Ltd.
	b. Address No.10, Sanying Road, 255000 Zibo, China
	c. Website address www.leemedcn.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *
4.	9. List of attachments/appendices: -
4.	10. Name/Signature 

Transmission of this Field Safety Notice	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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..*</p>

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



www.droh.de

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Ansprechpartner	Telefon	Fax	E-Mail	Datum	Kundennummer
Andrea Knaf	06131 62319-22	06131 62319-11	rc@droh.de	07.09.2022	166189

DRINGEND - Produktrückruf des Herstellers
RÜCK22/0039
Infusionssystem für Druckinfusion

Art der Maßnahme: Außerverkehrnahme

Belegnummer: BNR22/000960

Rückmeldeformular - bitte ausfüllen und per E-Mail, Fax oder postalisch zurücksenden

Bitte veranlassen Sie keine Warenrücksendung. Bitte bestätigen Sie uns die Vernichtung der vom Rückruf betroffenen Ware mit dem nachfolgenden Formular, damit wir Ihnen eine entsprechende Gutschrift ausstellen können.

Die betroffenen Artikel wurden aus dem Verkehr gezogen und vernichtet.

[bitte ankreuzen]

Name der Einrichtung	
Anschrift der Einrichtung	Telefonnummer & E-Mail-Adresse
Formular ausgefüllt durch	Stempel
Unterschrift und Datum	

Wolfram Droh GmbH
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Amtsgericht Mainz 90 HRB 8220
Geschäftsführer: Wolfram Droh
USt.-IdNr.: DE149142666
Gerichtsstand Mainz

DB Privat- und Firmenkundenbank
NL Postbank Dortmund
IBAN: DE04 4401 0046 0753 5974 65
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Folgend finden Sie die Liste der vom Rückruf betroffenen Produkte, die Sie von uns bezogen haben.

Bitte tragen Sie ihre Restbestände in die Spalte "Lagerbestand" ein.

Lieferscheindatum	Lieferschein	Artikel	Referenznummer	Charge	Menge	Lagerbestand
26.01.2022	LIE22/273831	E-0497	P21301BWS	21/502087	2.000 Stück	
04.03.2022	LIE22/276356	E-0497	P21301BWS	21/502087	2.000 Stück	
05.07.2022	LIE22/283992	E-0497	P21301BWS	21/502087	1.000 Stück	
26.08.2022	LIE22/286765	E-0497	P21301BWS	21/502087	1.000 Stück	

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