# **KANEKA MEDICAL AMERICA LLC** 623 FIFTH AVENUE, 27th FLOOR

623 FIFTH AVENUE, 27th FLOOF NEW YORK, NY 10022

# KANEKA MEDICAL AMERICA LLC

TEL: (800) 526-3522

TEL: (212) 705-4340

Date (February 10, 2022)

# URGENT: 1 MEDICAL DEVICE RECALL<sup>2</sup>

# <LIPOSORBER® LA-15 SYSTEM Labeling>

#### (1) Attention to Customer:

Customer Name Liposorber LA-15 System Labeling Street Address Town, State, Zip Code

Dear Device Customer,

# (2) Purpose of this letter

The purpose of this letter is to advise you that <u>Kaneka Medical America LLC</u> is voluntarily recalling LIPOSORBER® LA-15 System Labeling for the following indications:

- for use in performing low density lipoprotein cholesterol (LDL-C) apheresis to acutely remove LDL-C from the plasma of the specified high risk patient populations for whom diet has been ineffective and maximum drug therapy has been either ineffective or not tolerated.
- for treatment of adult and pediatric patients with nephrotic syndrome associated with primary focal segmental glomerulosclerosis (FSGS) for specific reasons.

The labeling includes: Instructions for us (IFU-FH & FSGS), operators manuals (FH & FSGS), and patient guide (FSGS).

Note: Serious injuries have occurred or could occur due to the treatment with the Liposorber LA-15 LDL Adsorption Column under concomitant ACE inhibitor medication treatment associated with this recall. We have reports 2 serious injuries to the FDA.

<sup>1</sup> Recommended for Class I and II recalls. "Urgent" should be noted on both the letter and envelope as per 21 CFR 7.49(4)(b).

<sup>&</sup>lt;sup>2</sup> For radiation-emitting electronic products, a recall action is governed by 21 CFR 1004 – Repurchase, Repairs, or Replacement of Electronic Products – under which manufacturers are required to bring such products into conformity with applicable performance standards or correct any reported device defect at no charge to the user. Medical device recalls are governed by 21 CFR 806 – Reports of Corrections and Removals – which does not contain an equivalent requirement.



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#### (3) Reason for the Voluntary Recall:

Kaneka submitted a special PMA supplement to address the risk of potential severe anaphylactoid reactions including shock due to treatment with Liposorber LA-15 LDL Adsorption Column under concomitant ACE inhibitor medication treatment. FDA has approved the changes in January 2022, to the Liposorber IFU, guides, and manuals. Kaneka Medical America, determined that there are obsolete Liposorber IFU, guides, and manuals with the old Contraindications, Warnings, and Other Potential Adverse Events for ACE-I.

See Appendix A: FH Table of Modifications, and Appendix B: FSGS Table of Modifications.

- **Adverse events** (6 minor injuries and 2 serious injuries) with symptoms including:
  - Chest painHypertensionNausea
  - Difficulty
     breathing
     Hypotension
     Abdominal pain
     Flushing
  - o Tachycardia o Fainting

#### (4) Risk to Health:

The LIPOSORBER® LA-15 System must not be used in patients who are being treated with angiotensin-converting enzyme (ACE) inhibitors. Severe anaphylactoid reactions including shock have been observed in patients treated with the LIPOSORBER® LA-15 LDL Adsorption Column under concomitant ACE inhibitor medication. Temporal ceasing of ACE inhibitor intake to remove its bioactivity from the patient's blood may not always be sufficient to avoid such adverse reactions. The ACE inhibitors should be switched to another antihypertensive medication (for example, angiotensin II receptor blockers (ARBs)) at the medical discretion of the treating physician.

# (5) Actions to be taken by the Customer/User:

Please take the following actions:

- 1. Locate all Liposorber operator's manuals, patient guides, and IFUs in your facilities control and dispose of these documents.
- 2. Ensure the updated operator's manuals, patient guides, and IFUs are distributed to the necessary persons within the organization and that they are adhered to when selecting and using the Liposorber.
- 3. Retain this letter in a prominent position.
- 4. Acknowledge receipt of this notification and disposal of the documents with Kaneka Medical America via email or regular mail using an electronic or physical copy of the acknowledgement letter found at the bottom of this letter.

#### (6) Product and Distribution Information:

- See Appendix C: All Affected Product Identification Codes".
- The images below are of the covers for the Liposorber labeling being corrected by this recall:



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#### KANEKA MEDICAL AMERICA LLC

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**FSGS Operator Manual** 

#### Manual No. 1002en-Rx

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# **LIPOSORBER® LA-15 SYSTEM**

Operator's manual for use in the treatment of pediatric patients with primary focal segmental glomerulosclerosis (FSGS)

# \_\_\_\_\_ Humanitarian Use Device Authorized by Federal (USA) law for use in the treatment of pediatric patients with nephrotic syndrome associated with primary focal segmental glomerulosclerosis (FSGS) when: Standard treatment options, including corticosteroid and/or calcineurin inhibitors, are unsuccessful or not well tolerated and the patient's glomerular filtration rate (GFR) ≥ 60 ml/min/1.73 m² or The patient is post renal transplantation. The effectiveness of this device for this use has not been demonstrated.

Caution: Federal law restricts this device to sale by or on the order of a physician.

#### Important:

Be sure to carefully read this operator's manual before use Keep this manual by the machine for immediate reference.

This manual is applicable to the KANEKA MA-03 with the software version 1.2. The software version is displayed on the KANEKA MA-03's screen.

KANEKA PHARMA AMERICA LLC NEW YORK, NY

#### FSGS Instruction for use

#### LIPOSORBER® LA-15

LDL ADSORPTION COLUMNS

#### **Humanitarian Use Device**

- Authorized by Federal (USA) law for use in the treatment of adult and pediatric patients with nephrotic syndrome associated with primary focal segmental glomerulosclerosis (FSGS) when:

   Standard treatment options, including cordicosteroid and/or calcineurs inhibitors, are unsuccessful or not well tolerated and the patient's glomerular filtration rate (GFR) ≥ 60 ml/min/1.73 m² or

   The patient is post renal transplariation.
- The effectiveness of this device for this use has not been demonstrated.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Carefully review the "LIPOSORBER" LA-15 System Operator's Manual for use in the treatment of adult and pediatric patients with primary focal segmental glomerulosclerosis (PSGS)" and use only under the direction of a licensed physician with appropriate training.

#### kaneka

Distributed by
KANEKA PHARMA AMERICA LLC
KANEKA PHARMA Floor New York, New York 10036

Manufactured by
KANEKA CORPORATION

- \*\* Makanoshima Kita-ku, Osaka 530-8288, Japan

XXXX-X

#### **FSGS Patient Guide**

#### A PATIENT GUIDE TO THE LIPOSORBER® LA-15 SYSTEM

#### Humanitarian Use Device

Authorized by Federal (USA) law for use in the treatment of pediatric patients with nephrotic syndrome associated with primary focal segmental glomerulosclerosis (FSGS) when:

Standard reatment options, including corticosteroid and/or calcineurin inhibitors, are unsuccessful or not well tolerated and the patient's glomerular filtration rate (GFR) ≥ 60 m/min/1.73 m² or

The patient is post renal transplantation.

The effectiveness of this device for this use has not been demonstrated.

rber® LA-15 System is approved for pediatric patients with focal segmental glomerulosclerosis (FSGS). All references to "you" in this booklet refer to "you", if you are legally allowed to give your own consent (i.e., if you are age 18-21 years old). If you are providing consent on behalf of a child under the age of 18 "you" refers to your child.

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#### (7) Type of Action by the Company:

Please find attached the revised operator's manual, patient guides, and IFU in PDF format. Please notify us if you would like us to send to you a paper copy of these documents.

#### (8) OTHER INFORMATION:

Authorized by:

Ahmad Al-Sattari

Director of Sales and Marketing

- If you have any question or concerns about this recall please contact Kaneka Medical America LLC. Monday through Friday, 8:00 AM to 4:30 PM, Eastern Time, at:
  - o Phone: (212) 705-4355
  - o Email: Ahmad.Al-Sattari@kaneka.com
- Please reference the following attachments:
  - Acknowledgement and Receipt Form
  - Instruction for use (FH)
  - Instruction for use (FSGS)

- Operation Manual (FH)
- Operation Manual (FSGS)
- Patient Guide (FH)
- Patient Guide (FSGS)

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

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# MEDICAL DEVICE RECALL RETURN RESPONSE Acknowledgement and Receipt Form

Response is Required

#### **Customer Information:**

Customer Name Street Address Town, State, Zip Code

# LIPOSORBER® LA-15 SYSTEM Labeling

Any adverse events associated with recalled product labeling? Yes _ No _	
If yes, please explain:	

Affected Product Information: Please note in the table below if the described labeling is at your facility, and if you will dispose of it by check the appropriate box.

Document Type	None at your facility	Dispose all copies at this facility
FSGS Operator Manual		
FSGS Instruction for use		
FSGS Patient Guide		
FH Operator Manual		
FH Instruction for use		



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Return Response Box:			
Please provide any	additional information, if applicable.		
☐ Please have Cus	tomer Service contact me.		
We certify that we wi	ll dispose of all affected labeling as identified by the recall notice received on		
<u> </u>			
Signature of Recipier	nt:		
Name/Title	Recipient		
Telephone			
Email address			

# PLEASE EMAIL COMPLETED RESPONSE FORM TO:

Yu. Tanaka@Kaneka.com

Subject: Recall

OR MAIL TO:

Kaneka Medical America LLC.

ATTN: Recall

623 Fifth Ave, 27th FL New York, NY 10022

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**Appendix A: FH Table of Modifications** 

Appendix A: FH Table of Modifications			
Labeling Name	Page	Original (current)	Modified (proposed)
IFU for LIPOSORBER LA-15 LDL	FH 4/10	patients who have been treated with angiotensin-converting enzyme (ACE) inhibitors within	patients who are being treated with angiotensin-converting enzyme (ACE) inhibitors;
Adsorption Columns FH		the past 24 hours; Severe anaphylactoid reactions including shock have been observed in patients treated with the LIPOSORBER® LA-15 LDL Adsorption Column under concomitant ACE inhibitor medication. The risk of an anaphylactoid reaction may be minimized by withholding the administration of ACE inhibitors for approximately 24 hours before each LDL-apheresis procedure. The time period to withhold ACE inhibitors should be prolonged, if determined by the treating physician, considering each individual's renal function and the biological half-life of the ACE inhibitor currently in use. If required, ACE inhibitor administration may be resumed on the day of the apheresis treatment but only after the apheresis treatment is complete.	Severe anaphylactoid reactions including shock have been observed in patients treated with the LIPOSORBER® LA-15 LDL Adsorption Column under concomitant ACE inhibitor medication. Temporal ceasing of ACE inhibitor intake to remove its bioactivity from the patient's blood may not always be sufficient to avoid such adverse reactions. The ACE inhibitors should be switched to another antihypertensive medication (for example, angiotensin II receptor blockers (ARBs)) at the medical discretion of the treating physician.
	FH 4/10	LDL-apheresis treatment of patients who have taken any antihypertensive drugs within 24	LDL-apheresis treatment of patients who have taken any antihypertensive drugs may
	FH	hours of treatment may cause hypotension in such patients. When clinically feasible, patients should not receive antihypertensive drugs during the 24 hour period prior to undergoing the LDL-apheresis procedure. Before each treatment, physicians should determine when patients took their last dose of such medication.  Patients on antihypertensive drugs,	cause hypotension in such patients (for ACE inhibitors, see VI. Contraindications). When clinically feasible, patients should not receive antihypertensive drugs prior to undergoing the LDL-apheresis procedure on the day of receiving the apheresis. Before each treatment, physicians should determine when patients took their last dose of such medication. Patients on antihypertensive drugs,
	10/10	such as diuretics, calcium	such as diuretics, calcium



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		Original	
Labeling Name	Page	(current)	Modified (proposed)
Labeling Name	Page	Original (current)  antagonists, beta blockers and ACE inhibitors, are at increased risk of hypotensive reactions occurring during therapy. ACE inhibitors have been associated with severe hypotension associated with flushing, dyspnea, and bradycardia. Therefore, ACE inhibitor should not be administered for 24 hours or longer preceding each apheresis procedure. (See Contraindications.) In order to minimize the potential risks which also may be associated with other anti-hypertensive medications, it is recommended that patients refrain from taking antihypertensive drugs at least the day before the LDL-apheresis procedure, when clinically feasible. Before each treatment, patients should be requested to advise the attending physician when they last took a dose of such medication. One of the hypotensive events reported in Table 1.1 was attributed to the administration of ACE inhibitors. The administration of ACE inhibitors in conjunction with	antagonists, beta blockers and ACE inhibitors, are at increased risk of hypotensive reactions occurring during therapy. ACE inhibitors have been associated with severe hypotension associated with flushing, dyspnea, and bradycardia. Therefore, patients who are being treated with any ACE inhibitor should not be treated with the LIPOSORBER® LA-15. (See VI. Contraindications). In order to minimize the potential risks which also may be associated with other anti-hypertensive medications, it is recommended that patients refrain from taking antihypertensive drugs prior to undergoing the LDL-apheresis procedure on the day of receiving the apheresis, when clinically feasible. Before each treatment, patients should be requested to advise the attending physician when they last took a dose of such medication. One of the hypotensive events reported in Table 1.1 was attributed to the administration of ACE inhibitors. The administration
		ACE inhibitors in conjunction with therapy with the device also has been associated with the occurrence of tachycardia, and three of the reported tachycardia events (two in an emergency use patient) were attributed to the administration of ACE inhibitors.	of ACE inhibitors. The administration of ACE inhibitors in conjunction with therapy with the device also has been associated with the occurrence of tachycardia, and three of the reported tachycardia events (two in an emergency use patient) were attributed to the administration of ACE inhibitors.
IFU for SULFLUX KP- 05 PLASMA SE- PARATOR FH	FH - 4 -	patients who have been treated with angiotensin-converting enzyme (ACE) inhibitors within the past 24 hours; Severe anaphylactoid reactions including shock have been observed in patients treated with the LIPOSORBER® LA-15 LDL Adsorption Column under concomitant ACE inhibitor medication. The risk of an anaphylactoid reaction may be	patients who are being treated with angiotensin-converting enzyme (ACE) inhibitors; Severe anaphylactoid reactions including shock have been observed in patients treated with the LIPOSORBER® LA-15 LDL Adsorption Column under concomitant ACE inhibitor medication. Temporal ceasing of ACE inhibitor intake to remove its



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		Original	
Labeling Name	Page	(current)	Modified (proposed)
Labeling Name  IFU for TUBING	Page	(current) minimized by withholding the administration of ACE inhibitors for approximately 24 hours before each LDL-apheresis procedure. The time period to withhold ACE inhibitors should be prolonged, if determined by the treating physician, considering each individual's renal function and the biological half-life of the ACE inhibitor currently in use. If required, ACE inhibitor administration may be resumed on the day of the apheresis treatment but only after the apheresis treatment is complete.  patients who have been treated	Modified (proposed)  bioactivity from the patient's blood may not always be sufficient to avoid such adverse reactions. The ACE inhibitors should be switched to another antihypertensive medication (for example, angiotensin II receptor blockers (ARBs)) at the medical discretion of the treating physician.
SYSTEM FOR	-6-	with angiotensin-converting	with angiotensin-converting
PLASMAPHERESIS		enzyme (ACE) inhibitors within	enzyme (ACE) inhibitors;
NK-M3R(UL) FH		the past 24 hours;	Severe anaphylactoid reactions
		Severe anaphylactoid reactions	including shock have been
		including shock have been observed	observed in patients treated with
		in patients treated with the	the LIPOSORBER® LA-15 LDL
		LIPOSORBER® LA-15 LDL Adsorption	Adsorption Column under
		Column under concomitant ACE inhibitor medication. The risk of an	concomitant ACE inhibitor
		anaphylactoid reaction may be	medication. The risk of an anaphylactoid reaction may be
		minimized by withholding the	minimized by withholding the
		administration of ACE inhibitors for	administration of ACE inhibitors
		approximately 24 hours before each	before each LDL-apheresis
		LDL-apheresis procedure. The time	procedure. The time period to
		period to withhold ACE inhibitors	withhold ACE inhibitors should be
		should be prolonged, if determined	prolonged, if determined by the
		by the treating physician,	treating physician, considering
		considering each individual's renal	each individual's renal function
		function and the biological half-life	and the biological half-life of the
		of the ACE inhibitor currently in use.	ACE inhibitor currently in use.
		If required, ACE inhibitor	Temporal ceasing of ACE inhibitor
		administration may be resumed on	intake to remove its bioactivity
		the day of the apheresis treatment	from the patient's blood may not
		but only after the apheresis	always be sufficient to avoid such
		treatment is complete.	adverse reactions. The ACE
			inhibitors should be switched to
			another antihypertensive
			medication (for example,
			angiotensin II receptor
			blockers (ARBs)) at the medical
			discretion of the treating physician.



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	- D	Original	10.10
Labeling Name	Page	(current)	Modified (proposed)
LIPOSORBER	1-3	patients who have been treated	patients who are being treated
LA-15 SYSTEM		with angiotensin-converting	with angiotensin-converting
OPERATOR's		enzyme (ACE) inhibitors within	enzyme (ACE) inhibitors;
MANUAL		the past 24 hours;	Severe anaphylactoid reactions
FH		Severe anaphylactoid reactions	including shock have been
		including shock have been observed	observed in patients treated with
		in patients treated with the	the LIPOSORBER® LA-15 LDL
		LIPOSORBER® LA-15 LDL Adsorption	Adsorption Column under
		Column under concomitant ACE	concomitant ACE inhibitor
		inhibitor medication. The risk of an	medication. Temporal ceasing of
		anaphylactoid reaction may be	ACE inhibitor intake to remove its
		minimized by withholding the	bioactivity from the patient's blood
		administration of ACE inhibitors for	may not always be sufficient to
		approximately 24 hours before each	avoid such adverse reactions. The
		LDL-apheresis procedure. The time	ACE inhibitors should be switched
		period to withhold ACE inhibitors	to another antihypertensive
		should be prolonged, if determined	medication (for example,
		by the treating physician,	angiotensin II receptor blockers
		considering each individual's renal	(ARBs)) at the medical discretion of
		function and the biological half-life	the treating physician.
		of the ACE inhibitor currently in use.	
		If required, ACE inhibitor	
		administration may be resumed on	
		the day of the apheresis treatment	
		but only after the apheresis	
		treatment is complete.	
	1-4	LDL-apheresis treatment of	LDL-apheresis treatment of
		patients who have taken any	patients who have taken any
		antihypertensive drugs within 24	antihypertensive drugs may
		hours of treatment may cause	cause hypotension in such
		hypotension in such patients. When	patients (for ACE inhibitors, see
		clinically feasible, patients	1.3 Contraindications). When
		should not receive antihypertensive	clinically feasible, patients should
		drugs during the 24 hour period prior to undergoing the LDL-apheresis	not receive antihypertensive drugs prior to undergoing the LDL-
		procedure. Before each treatment,	apheresis procedure on the day of
		physicians should determine when	receiving the apheresis. Before
		patients took their last dose of such	each treatment, physicians should
		medication.	determine when patients took their
			last dose of such medication.
	1-10	Patients on antihypertensive drugs,	Patients on antihypertensive drugs,
		such as diuretics, calcium	such as diuretics, calcium
		antagonists, beta blockers and ACE	antagonists, beta blockers and ACE
		inhibitors, are at increased risk of	inhibitors, are at increased risk of
		hypotensive reactions occurring	hypotensive reactions occurring
		during therapy. ACE inhibitors have	during therapy. ACE inhibitors
		been associated with severe	have been associated with severe
		hypotension associated with flushing,	hypotension associated with



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	Page	Original	Modified (proposed)
Labeling Name	rage	(current)	Wodified (proposed)
		dyspnea, and bradycardia. Therefore,	flushing, dyspnea, and bradycardia.
		ACE inhibitor should not be	Therefore, patients who are being
		administered for 24 hours or	treated with any ACE inhibitor
		longer preceding each apheresis	should not be treated with the
		procedure. (See	LIPOSORBER® LA-15. (See 1.3
		Contraindications.) In order to	Contraindications). In order to
		minimize the potential risks which	minimize the potential risks
		also may be associated with other	which also may be associated
		anti-hypertensive medications, it is	with other anti-hypertensive
		recommended that patients refrain	medications, it is recommended
		from taking antihypertensive	that patients refrain from taking
		drugs at least the day before the	antihypertensive drugs prior to
		LDL-apheresis procedure, when	undergoing the LDL-apheresis
		clinically feasible. Before each	procedure on the day of receiving
		treatment, patients should be	the apheresis, when clinically
		requested to advise the attending	feasible. Before each treatment,
		physician when they last took a dose	patients should be requested to
		of such medication. One of the	advise the attending physician
		hypotensive events reported in Table	when they last took a dose of such
		1.1 was attributed to the	medication. One of the hypotensive
		administration of ACE inhibitors.	events reported in Table
		The administration of ACE inhibitors	1.1 was attributed to the
		in conjunction with therapy with the	administration of ACE inhibitors.
		device also has been associated with	The administration of ACE
		the occurrence of tachycardia, and	inhibitors in conjunction with
		three of the reported tachycardia	therapy with the device also has
		events (two in an emergency use	been associated with the occurrence
		patient) were attributed to the	of tachycardia, and three of the
		administration of ACE inhibitors.	reported tachycardia events (two in
			an emergency use patient) were
			attributed to the administration of
			ACE inhibitors.



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**Appendix B: FSGS Table of Modifications** 

Appendix B: FSGS Table of Modifications				
	Door	Original	M- 1:C-1 (1)	
Labeling Name	Page	(current)	Modified (proposed)	
IFU for	FSGS	patients who have been treated	patients who are being treated	
LIPOSORBER	3/19	with angiotensin-converting	with angiotensin-converting	
LA-15 LDL		enzyme (ACE) inhibitors within	enzyme (ACE) inhibitors;	
Adsorption		the past 24 hours;	Severe anaphylactoid reactions	
Columns		Severe anaphylactoid reactions	including shock have been	
FSGS		including shock have been	observed in patients treated with	
		observed in patients treated with	the LIPOSORBER® LA-15	
		the LIPOSORBER® LA-15 LDL	LDL Adsorption Column under	
		Adsorption Column under	concomitant ACE inhibitor	
		concomitant ACE inhibitor	medication. Temporal ceasing of	
		medication. The risk of an	ACE inhibitor intake to remove	
		anaphylactoid reaction may be	its bioactivity from the patient's	
		minimized by withholding the	blood may not always be	
		administration of ACE inhibitors	sufficient to avoid such adverse	
		for approximately 24 hours before	reactions. The ACE inhibitors	
		each LDL-apheresis procedure.	should be switched to another	
		The time period to withhold ACE	antihypertensive medication (for	
		inhibitors should be prolonged, if	example, angiotensin II receptor	
		determined by the treating	blockers (ARBs)) at the medical	
		physician, considering each	discretion of the treating	
		individual's renal function and the	physician.	
		biological half-life of the ACE		
		inhibitor currently in use. If		
		required, ACE inhibitor		
		administration may be resumed on		
		the day of the apheresis treatment		
		but only after the apheresis		
		treatment is complete.		
	FSGS	LDL-apheresis treatment of	LDL-apheresis treatment of	
	4/19	patients who have taken any	patients who have taken any	
		antihypertensive drugs within 24	antihypertensive drugs may	
		hours of treatment may cause	cause hypotension in such	
		hypotension in such patients.	patients (for ACE inhibitors,	
		When clinically feasible, patients	see VI. Contraindications).	
		should not receive	When clinically feasible, patients	
		antihypertensive drugs during the	should not receive	
		24 hour period prior to undergoing	antihypertensive drugs prior to	
		the LDL-apheresis procedure.	undergoing the LDL-apheresis	
		Before each treatment, physicians	procedure on the day of	
		should determine when patients	receiving the apheresis. Before	
		took their last dose of such	each treatment, physicians	
		medication.	should determine when patients	
			took their last dose of such	
			medication.	
	FSGS	Hypersensitivity (anaphylactoid)	Hypersensitivity (anaphylactoid)	
	18/19	reaction: Use of ACE inhibitors	reaction: Use of ACE inhibitors	



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	_	Original	
Labeling Name	Page	(current)	Modified (proposed)
		within 24 hours of therapy with the device can cause an increase in bradykinin levels, resulting in severe hypotension. ACE inhibitors should not be taken within 24 hours of therapy with the device.	with the device can cause an increase in bradykinin levels, resulting in severe hypotension.  Patients who are being treated with any ACE inhibitor should not be treated with the LIPOSORBER® LA-15 (See V. Contraindications).
IFU for SULFLUX KP- 05 PLASMA SE- PARATOR FSGS	FSGS -4-	patients who have been treated with angiotensin-converting enzyme (ACE) inhibitors within the past 24 hours; Severe anaphylactoid reactions including shock have been observed in patients treated with the LIPOSORBER® LA-15 LDL Adsorption Column under concomitant ACE inhibitor medication. The risk of an anaphylactoid reaction may be minimized by withholding the administration of ACE inhibitors for approximately 24 hours before each LDL-apheresis procedure. The time period to withhold ACE inhibitors should be prolonged, if determined by the treating physician, considering each individual's renal function and the biological half-life of the ACE inhibitor currently in use. If required, ACE inhibitor administration may be resumed on the day of the apheresis treatment but only after the apheresis treatment is complete	patients who are being treated with angiotensin-converting enzyme (ACE) inhibitors; Severe anaphylactoid reactions including shock have been observed in patients treated with the LIPOSORBER® LA-15 LDL Adsorption Column under concomitant ACE inhibitor medication. Temporal ceasing of ACE inhibitor intake to remove its bioactivity from the patient's blood may not always be sufficient to avoid such adverse reactions. The ACE inhibitors should be switched to another antihypertensive medication (for example, angiotensin II receptor blockers (ARBs)) at the medical discretion of the treating physician.
IFU for TUBING SYSTEM FOR PLASMAPHERESIS NK-M3R(UL) FSGS	FSGS -6-	patients who have been treated with angiotensin-converting enzyme (ACE) inhibitors within the past 24 hours; Severe anaphylactoid reactions including shock have been observed in patients treated with the LIPOSORBER® LA-15 LDL Adsorption Column under concomitant ACE inhibitor medication. The risk of an anaphylactoid reaction may be minimized by withholding the administration of ACE inhibitors for approximately 24 hours before each	patients who are being treated with angiotensin-converting enzyme (ACE) inhibitors; Severe anaphylactoid reactions including shock have been observed in patients treated with the LIPOSORBER® LA-15 LDL Adsorption Column under concomitant ACE inhibitor medication. Temporal ceasing of ACE inhibitor intake to remove its bioactivity from the patient's blood may not always be sufficient to avoid such adverse reactions. The ACE inhibitors should be switched



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		Original	
Labeling Name	Page	(current)	Modified (proposed)
		LDL-apheresis procedure. The time period to withhold ACE inhibitors should be prolonged, if determined by the treating physician, considering each individual's renal function and the biological half-life of the ACE inhibitor currently in use. If required, ACE inhibitor administration may be resumed on the day of the apheresis treatment but only after the apheresis treatment is complete.	to another antihypertensive medication (for example, angiotensin II receptor blockers (ARBs)) at the medical discretion of the treating physician.
LIPOSORBER LA-15 SYSTEM OPERATOR'S MANUAL FSGS	1-2	patients who have been treated with angiotensin-converting enzyme (ACE) inhibitors within the past 24 hours; Severe anaphylactoid reactions including shock have been observed in patients treated with the LIPOSORBER® LA-15 LDL Adsorption Column under concomitant ACE inhibitor medication. The risk of an anaphylactoid reaction may be minimized by withholding the administration of ACE inhibitors for approximately 24 hours before each LDL-apheresis procedure. The time period to withhold ACE inhibitors should be prolonged, if determined by the treating physician, considering each individual's renal function and the biological half-life of the ACE inhibitor currently in use. If required, ACE inhibitor administration may be resumed on the day of the apheresis treatment but only after the apheresis	patients who are being treated with angiotensin-converting enzyme (ACE) inhibitors; Severe anaphylactoid reactions including shock have been observed in patients treated with the LIPOSORBER® LA-15 LDL Adsorption Column under concomitant ACE inhibitor medication. Temporal ceasing of ACE inhibitor intake to remove its bioactivity from the patient's blood may not always be sufficient to avoid such adverse reactions. The ACE inhibitors should be switched to another antihypertensive medication (for example, angiotensin II receptor blockers (ARBs)) at the medical discretion of the treating physician.
	1-5	treatment is complete  LDL-apheresis treatment of patients who have taken any antihypertensive drugs within 24	LDL-apheresis treatment of patients who have taken any antihypertensive drugs may
		hours of treatment may cause hypotension in such patients. When clinically feasible, patients should not receive antihypertensive drugs during the 24 hour period prior to undergoing the LDL-apheresis procedure. Before each treatment, physicians should determine when patients took their last dose of such medication.	cause hypotension in such patients (for ACE inhibitors, see 1.3 Contraindications). When clinically feasible, patients should not receive antihypertensive drugs prior to undergoing the LDL- apheresis procedure on the day of receiving the apheresis. Before each treatment, physicians should determine when patients took their



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	I	Original	
Labeling Name	Page	Original (current)	Modified (proposed)
			last dose of such medication.
	1-9	Hypersensitivity (anaphylactoid) reaction: Use of angiotensin-converting enzyme inhibitors (ACEi) within 24 hours of therapy with the device can cause an increase in bradykinin levels, resulting in severe hypotension. ACE inhibitors should not be taken within 24 hours of therapy with the device.	Hypersensitivity (anaphylactoid) reaction: Use of ACE inhibitors with the device can cause an increase in bradykinin levels, resulting in severe hypotension.  Patients who are being treated with any ACE inhibitor should not be treated with the LIPOSORBER® LA-15 (See 1.3 Contraindications).
A PATIENT GUIDE TO THE LIPOSORBER LA-15 SYSTEM FSGS	Page 5,	your doctor is currently treating you with a medication called an angiotensin-converting-enzyme (ACE) inhibitor and believes that this medication cannot be stopped for at least a day before each treatment with the LIPOSORBER®.	your doctor is currently treating you with a medication called an angiotensin-converting-enzyme (ACE) inhibitor and believes that this medication cannot be stopped.

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# **Appendix C: All Affected Product Identification Codes**

# **Liposorber Disposables**

Product	Product	Lot#	Expiry
Number	Description	LOI#	Date
		LAP1498	02/28/22
		LAP1505	06/28/22
		LAP1509	07/28/22
		LAP1510	07/28/22
		LAP1523	09/28/22
		LAP1526	10/28/22
		LAP1527	10/28/22
		LAP1533	12/28/22
		LAP1534	12/28/22
		LAP1535	12/28/22
		LAP1536	12/28/22
		LAP1538	02/28/23
		LAP1543	07/31/23
		LAP1544	07/31/23
		LAP1547	09/30/23
		LAP1554	10/31/23
101785	LA-15 (AU) LDL Adsorption Column (Luer Lock Type)	LAP1555	10/31/23
		LAP1556	10/31/23
		LAP1558	11/30/23
		LAP1561	12/31/23
		LAP1568	02/29/24
		LAP1569	02/29/24
		LAP1578	06/30/24
		LAP1580	06/30/24
		LAP1581	07/31/24
		LAP1582	07/31/24
		LAP1585	07/31/24
		LAP1587	08/31/24
		LAP1588	08/31/24
		LAP1598	10/28/24
		LAP1599	10/28/24
		LAP1607	06/28/25
		LAP1609	09/28/25
		LAP1611	09/28/25



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Product	Product		Expiry
Number	Description	Lot #	Date
		TJ3Z3K	03/18/22
		TJ5K5U	05/27/22
		TJ7X7J	07/17/22
		XJXNY1	10/30/22
		XK1X1L	01/19/23
		XK2H2R	02/24/23
101447	KP-05 Sulflux Plasma Separator	XK4S5E	05/14/23
101447	Kr -03 Sulliux Flasilia Separator	XK5K5T	05/27/23
		XK8R92	09/01/23
		XKXAXL	10/20/23
		FKZXZH	12/17/23
		FL1A1K	01/19/24
		FL3N42	03/31/24
		FL3P43	04/01/24
	NK-M3R(UL) Tubing (Luer Lock Type)	200210	01/28/23
		200302	02/28/22
		200401	03/28/22
		200502	04/28/22
		200528	04/28/22
		200624	05/31/22
101786		200720	06/30/22
		200813	07/31/22
		200907	08/31/22
		201005	09/30/22
		201105	10/28/22
		210222	01/28/23
		210301	02/28/23
		LAP1510	07/28/22
		LAP1526	10/28/22
		LAP1527	10/28/22
		LAP1535	12/28/22
		LAP1544	07/31/23
101700	HDE LA-15(AU) LDL Adsorption Column (Luer Lock Type)	LAP1547	09/30/23
101788		LAP1555	10/31/23
		LAP1558	11/30/23
		LAP1580	06/30/24
		LAP1585	07/31/24
		LAP1598	10/28/24
		LAP1599	10/28/24



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Product	Product	1 -4 #	Expiry
Number	Description	Lot #	Date
	HDE KP-05 Sulflux Plasma Separator	TJ3Z3K	03/18/22
		TJ7X7J	07/17/22
		XK1X1L	01/19/23
101473		XK2H2R	02/24/23
		XK5K5T	05/27/23
		XKXAXL	10/20/23
		FL1A1K	01/19/24
	HDE NK-M3R(UL) Tubing (Luer Lock Type)	200302	02/28/22
		200624	05/31/22
101789		200907	08/31/22
		201005	09/30/22
		210222	01/31/23

#### **MA-03 Machines**

Product	Product	SN #	Expiry
Number	Description		Date
There	138 systems in d	listribution	in US
		68007-01	
		68007-03	
		68007-04	
		68008-01	
		68008-02	
		68008-03	
		68008-04	
		68008-05	
		69005-01	NA
	MA-03 Machines	69005-02	
		69005-03	
101445		69005-04	
		69005-05	
		69006-04	
		70013-01	
		70013-04	
		70014-02	
		70014-03	
		70014-04	
		70014-05	
		70015-03	
		70015-04	



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Product	Product	CN #	Expiry
Number	Description	- SN #	Date
		70015-05	
		70016-01	
		70016-03	
		70016-04	
		70016-05	
		70017-04	
		70017-05	
		70018-02	
		70018-03	
		70018-05	
		71001-01	
		71001-02	
		71001-03	
		71002-01	
		71002-02	
	MA-03 Machines	71002-05	
101445		71003-01	NA
		71003-02	
		71003-03	
		71003-04	
		71004-01	
		71004-02	
		71004-03	
		71004-04	
		71005-03	
		71005-04	
		71005-05	
		71006-01	
		71006-04	
		71006-05	
		71007-01	
		71007-02	
		71007-03	
		71007-04	
		71008-01	
		71008-02	
		71008-03	
		71008-05	
		72001-01	



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Product	Product		Expiry
Number	Description	SN #	Date
		72001-02	
		72001-03	
		72001-04	
		72001-05	
		72002-01	
		72002-02	
		72002-04	
		72002-05	
		72003-01	
		72003-02	
		72003-03	
		72003-04	
		72003-05	
		72004-02	
		72004-03	
101445	MA-03 Machines	72004-04	NA
		72004-05	
		72005-01	
		72005-02	
		72005-03	
		72005-04	
		72005-05	
		72006-01	
		72006-02	
		72006-03	
		72006-04	
		72006-05	
		J1412335	
		J1412337	
		J1412338	
		J1412339	
		J1412615	
		J1412616	
		J1412617	
		J1412618	
		J1412619	
		J1501052	
		J1501053	
		J1501054	



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Product	Product	011 "	Expiry
Number	Description	SN #	Date
		J1501055	
		J1501056	
		J1501359	
		J1501360	
		J1501361	
		J1501362	
		J1501363	
		J1501676	
		J1501677	
		J1501678	
		J1501679	
		J1501680	
		J1501959	
		J1501961	
100445	MA-03	J1501962	NA
	Machines	J1501963	IVA
		J1502233	
		J1502236	
		J1502237	
		J1502501	
		J1502502	
		J1502504	
		J1502505	
		J1804799	
		J1804800	
		J1804801	
		J1804802	
		J1804803	
		J1804804	
		J1804805	
		J1804806	
		J1804807	
		J1804808	
		J1914653	
		J1914654	
		J1914655	
		J1914656	
		J1914657	