KANEKA MEDICAL AMERICA LLC
623 FIFTH AVENUE, NEW YORK, NY 10022
TEL: (800) 526-3522 or (212) 705-4340

New York, January 29, 2025

LETTER TO HEALTH CARE PROVIDERS

CHANGE LABELING OF LIPOSROBER® TO EXPAND INDICATION FOR USE DUE TO FDA APPROVAL P910018/S039

Dear Health Care Provider:

We are pleased to announce an important update regarding Kaneka's LIPOSORBER® LA-15 System indications for clinically diagnosed Familial Hypercholesterolemic patients. As part of our ongoing commitment to advance patient care and support healthcare providers in properly managing these patients, we have received approval for indications that enhance the utility of our system in clinical settings.

This update affects Group C and Group D of the indications and have been updated as follows:

Prior Indication	Updated Indication
Group C. Clinically diagnosed Familial Hypercholesterolemic Heterozygotes with LDL-C ≥ 100 mg/dL and either documented coronary artery disease or documented peripheral artery disease; and	**Group C.** Clinically diagnosed Familial Hypercholesterolemic Heterozygotes with LDL-C ≥ 70 mg/dL and either documented coronary artery disease or documented peripheral artery disease; and
Group D. Clinically diagnosed Familial Hypercholesterolemic Heterozygotes with LDL-C ≥ 100 mg/dL, lipoprotein(a) [Lp(a)] ≥60 mg/dL and either documented coronary artery disease or documented peripheral artery disease.	**Group D.** Clinically diagnosed Familial Hypercholesterolemic Heterozygotes with lipoprotein(a) [Lp(a)] ≥60 mg/dL (or 130 nmol/L) and either documented coronary artery disease or documented peripheral artery disease.

These updates are expected to broaden the application of the LIPOSORBER LA-15 System in treating clinically diagnosed Familial Hypercholesterolemic patients with elevated LDL-C and/or Lp(a) who have documented cardiovascular disease.

We are committed to supporting you throughout this transition and will be providing further information and resources about the updated indications, including training opportunities and revised clinical support materials.

FDA approved our premarket approval application (PMA) 180-day supplement for this labeling change on January 24, 2025.

The revised labeling of the LIPOSORBER LA-15 System will now include the following **Indications for Use Statement**:

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The LIPOSORBER® LA-15 System is indicated for use in performing low density lipoprotein cholesterol (LDL-C) apheresis to acutely remove LDL-C from the plasma of the following high risk patient populations for whom diet has been ineffective and maximum drug therapy has been either ineffective or not tolerated:

Group A - Clinically diagnosed Familial Hypercholesterolemic Homozygotes with LDL-C > 500 mg/dL;
Group B - Clinically diagnosed Familial Hypercholesterolemic Heterozygotes with LDL-C ≥ 300 mg/dL;
Group C - Clinically diagnosed Familial Hypercholesterolemic Heterozygotes with LDL-C ≥ 70 mg/dL and either documented coronary artery disease or documented peripheral artery disease; and
Group D - Clinically diagnosed Familial Hypercholesterolemic Heterozygotes with lipoprotein(a) (Lp(a)) ≥ 60 mg/dL (or 130 nmol/L) and either documented coronary artery disease or documented peripheral artery disease.

If you have any questions or require further assistance, please do not hesitate to reach out to your Sales Account Representative, Medical Affairs Representative, or contact our Customer Support Team at (713) 213-9486 or ahmed.elagouz@kaneka.com.

Thank you for your continued trust in our products and commitment to patient care.

Sincerely,

Takuji Hasegawa
Executive Vice President