LIPOSORBER®

Getting Your FH Patients to their Recommended Therapeutic Targets

Familial Hypercholesterolemia (FH) and Elevated Lp(a)

FH and high lipoprotein(a) are genetically inherited and are not related to diet or exercise. If a patient has FH or an elevated Lp(a), it's likely that at least one parent has FH and/or high Lp(a).

An estimated **1 in 250** Americans have FH however **90% have not been accurately diagnosed**.

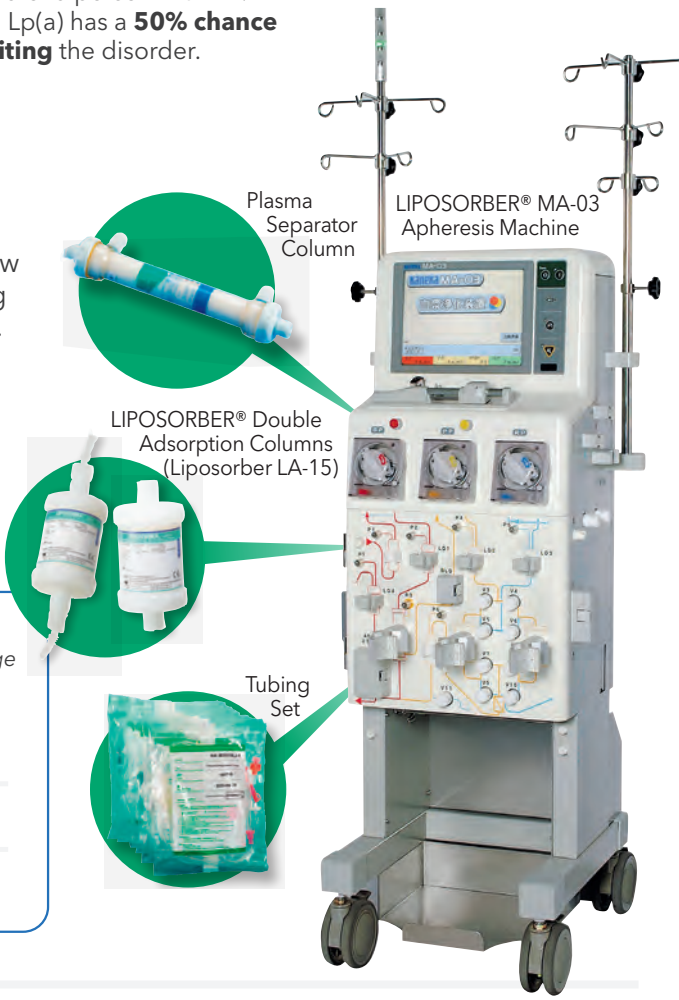
Nearly **1 in 5 individuals** are affected by elevated Lp(a) in the US.

Untreated FH patients have **20x** the risk of developing CAD, compared to general population.

Each child of a person with FH/ elevated Lp(a) has a **50% chance of inheriting** the disorder.

LIPOSORBER® as a Treatment Option

LIPOSORBER is an extracorporeal therapy, developed to treat cardiovascular diseases by selectively removing Low Density Lipoprotein Cholesterol (LDL-C), Lipoprotein(a) [Lp(a)], and Very Low Density Lipoprotein (VLDL) from the blood, significantly decreasing the progression of atherosclerotic cardiovascular disease (ASCVD).



Indications For Use

LIPOSORBER is indicated for use in clinically diagnosed FH patients with either documented Coronary Artery Disease (CAD)* or Peripheral Artery Disease (PAD)†, if:

- **LDL-C ≥100 mg/dL** -or-
- **Lp(a) ≥60 mg/dL and LDL-C ≥100 mg/dL**

And if diet and maximum tolerable combination lipid-lowering drug therapies have failed to achieve the established therapeutic targets per professional guidelines.

Treatment Frequency

Each treatment lasts 2-4 hours on average

LDL-C Level	Regimen
≥ 300 mg/dL	1 Session Every Week
100-200 mg/dL	1 Session Every 2 Weeks
Lp(a) ≥ 60 mg/dL & LDL-C ≥ 100 mg/dL	1 Session Every 2 Weeks

*Documented CAD: Diagnosed by: - Invasive OR CT Coronary Angiography; Electron Beam CT (EBCT); History of: Myocardial Infarction, Percutaneous Coronary Intervention, Coronary Artery Bypass Grafting † Documented PAD: Diagnosed by: - Symptoms and/or Physician exam; Ankle-Brachial Index (ABI); Ultrasound Exam; Pulse Volume Recording (PVR); Peripheral Vascular Angiography; History of: Peripheral Vascular Intervention/Peripheral Vascular bypass surgery/minor or major amputation. (Reference: FDA Approval/IFU 4.21.2020)

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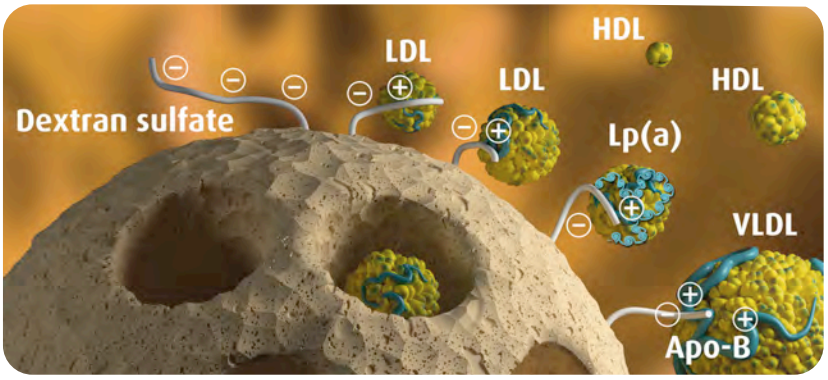
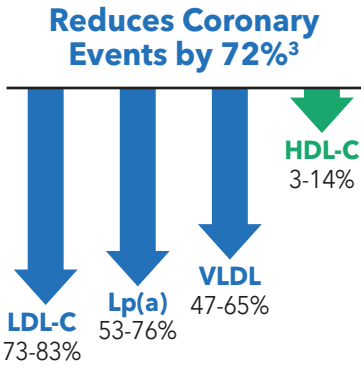
LIPOSORBER Selectivity Feature





The system's adsorbent columns are made up of **dextran sulfate cellulose beads**, which provide specific binding to certain Apo-B lipoproteins (such as LDL-C, Lp(a), and VLDL) associated with serious cardiovascular disease and vascular complications in FH patients.

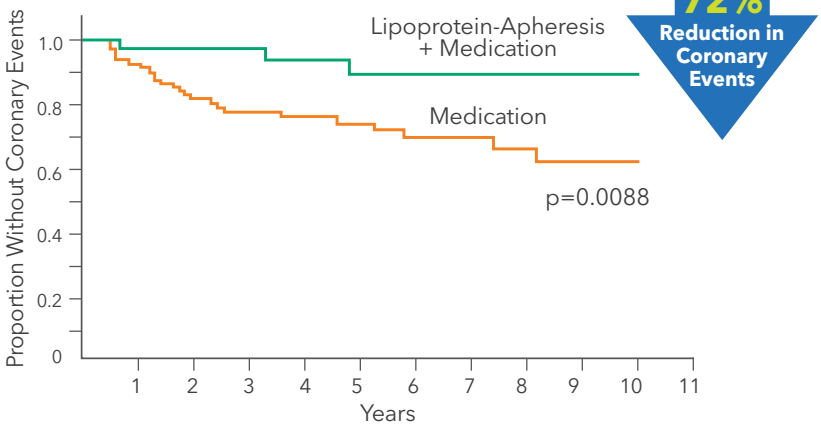
These harmful lipoproteins are **selectively removed** by the electro-static interaction between the negatively charged dextran sulfate and positively charged moiety of Apo-B.

Unlike therapeutic plasma exchange (TPE), LIPOSORBER minimally affects other blood components and is shown to reduce coronary events by 72% in 6 years.[1,3]

LIPOSORBER® Clinical Outcomes

Long-term efficacy of low-density lipoprotein-apheresis (LA) on coronary heart disease in familial hypercholesterolemia was studied. Investigators examined long-term efficacy and safety of LA in heterozygotes familial hypercholesterolemia (HeFH) patients with history of CHD. LA was shown to be an effective and well tolerated treatment for HeFH: **58% acute reduction in LDL-C levels and 72% reduction in total coronary events.**[3]

Long-Term Efficacy of LIPOSORBER



Consider LIPOSORBER for your FH patients with elevated Lp(a) levels when drug therapies (statins, PCSK9is) fail to achieve the recommended therapeutic targets.

ADVERSE EVENTS: The most common adverse events are hypotension (0.8%), nausea/vomiting (0.5%), and flushing/blotching (0.4%). Other adverse reactions include angina/chest pain, shortness of breath, fainting, lightheadedness and anemia.[1] *Please see **liposorber.com** for a full list of adverse events.

CONTRAINDICATION: Angiotensin converting enzyme [ACEI(s)] inhibitors are contraindicated with LIPOSORBER® due to possible bradykinin reaction. ACEI(s) should be replaced with angiotensin II receptor blockers (ARBs) or any other antihypertensive agent as determined by the prescribing physician.[2]

References:

1. Palcoux et al., 2008, Therapeutic Apher Dial; 12(3):195-201; Hudgins et al., 2008, American Journal of Cardiology; 102(9):1199-1204; Koga 1999, Therapeutic Apheresis; 3(2): 155-160; Gordon et al., 1998, American Journal of Cardiology; 81(4): 407-411; Parker, 1994, Chem Phys Lipids; 67-68, 331-338; Yokoyama S. et al. Arteriosclerosis. 1985 Nov-Dec; 5(6):613-22. Rubba S et al. Circulation. 1990 Feb;81(2):610-6.
2. Kaneka Medical America LLC., 2021, LIPOSORBER®LA-15 SYSTEM Operator's Manual No.1002en-R4.
3. Mabuchi, H et al. "Long-term efficacy of low-density lipoprotein apheresis on coronary heart disease in familial hypercholesterolemia." Hokuriku-FH-LDL-Apheresis Study Group. The American journal of cardiology vol. 82,12 (1998): 1489-9 doi:10.1016/s0002-9149(98)00692-4

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