

October 14, 2004

Dear Customer:

Proposition 65 requires that individuals must be warned of exposure to certain chemicals identified by the State of California to cause cancer or reproductive effects. Chemicals are listed by the State even if these effects occur only at extremely high exposure levels.

The State of California has identified ethylene oxide and the other listed chemicals as substances that cause cancer and reproductive effects.

COBE Cardiovascular, Inc. is a manufacturer of cardiopulmonary and cardiovascular devices. As does most of the healthcare industry, COBE Cardiovascular, Inc. uses ethylene oxide to sterilize its medical devices. This exposure results in a small amount of residual ethylene oxide in the packaging and product. Our medical devices meet all applicable federal and state regulations concerning ethylene oxide residuals. Typical user contacts with these products do not expose the user to levels of ethylene oxide, which are outside applicable federal standards.

In addition, other listed chemicals may be contained or used in the manufacture of some COBE Cardiovascular products. California law requires COBE Cardiovascular, Inc. to provide the following warning to our customers.

**Warning:**  
***This product contains a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.***

While COBE Cardiovascular products may contain detectable amounts of these chemicals, our products meet the requirements under the U.S. Food, Drug and Cosmetic Act for safety and effectiveness.

The Proposition 65 warning requirements may require you to review this information with others on your medical staff and/or patients, as appropriate.

COBE Cardiovascular, Inc. believes that such information is best provided to the patient by the healthcare provider as part of informed consent so as not to cause confusion or alarm. All COBE Cardiovascular devices, which use the aforementioned chemicals, have been tested for biological safety. The biocompatibility tests used are internationally recognized, conducted by a certified contract laboratory, and required by the U.S. Food and Drug Administration prior to their granting permission to market these types of devices.

Please be assured that COBE Cardiovascular, Inc., will continue to provide you with the highest quality products available. If you have any questions concerning this matter, please contact me at 1-800-221-7943, extension 6306.

Sincerely,

Jack Ellison  
Director of Quality and Regulatory

Prop 65 Listing

Following is the list of COBE Cardiovascular, Inc. manufactured devices that COBE CV is aware may contain a chemical identified by the State of California as known to cause cancer, birth defects, or other reproductive harm:

CHEMICAL	APPLICATION	PRODUCT LINE
ACRYLONITRILE		Resins
CHROMIUM <i>(hexavalent compounds)</i>	Component	Cardiotomy Reservoirs Flat Sheet Oxygenators Hollow Fiber Oxygenators Venous Reservoirs
DICHLOROMETHANE <i>(methylene chloride)</i>	Adhesive Cleaning agent	Cardioplegia Accessories Cardioplegia Table Lines Cardiotomy Reservoirs Crystalloid Recirculation Sets Crystalloid/Single Pass Set CSC 14 Cardioplegia Delivery Systems Flat Sheet Oxygenators Hemoconcentration Packs Hollow Fiber Oxygenators Overpressure Relief Line Pressure Monitoring Separator Lines PTS/Custom Tubing Packs Topical Cooling Devices Vacuum Relief Check Valve Vanguard Cardioplegia Delivery Systems Venous Reservoirs Versaplegia Delivery Systems

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CHEMICAL	APPLICATION	PRODUCT LINE
METHYLENE CHLORIDE		50/50 cement Bowl line Chem Mix Model Shop VP, 3700 Reservoir
DOP (DEHP)	Tubing plasticizer	BCHY (Blood Cardioplegia Hemoconcentrator Y Adapter) BCJ (Bonchek Cardiac Jacket) Blood Management Accessories Cardioplegia Table Lines Crystalloid Recirculation Sets Crystalloid/Single Pass Set CSC 14 Cardioplegia Delivery Systems ELS (Extension Line) Hemoconcentration Packs MPHL (Pump Head Line) MREK (Monolyth Reservoir Extension Kit) Overpressure Relief Line Pressure Monitoring Separator Lines PTS/Custom Tubing Packs PVC Tubing Rapid Prime Lines Resins SAFPL (Arterial Filter Purge Line) SCCA (Coronary Cardioplegia Adapter) SMA PVC Tubing Topical Cooling Devices Vanguard Cardioplegia Delivery Systems Versaplegia Delivery Systems
ETHYLENE DICHLORIDE (1, 2 dichloroethane)	Adhesive	50/50 cement Cardiotomy Reservoirs Chem Mix CSC 14 Cardioplegia Delivery Systems PTS/Custom Tubing Sets Topical Cooling Devices Vanguard Cardioplegia Delivery Systems Venous Reservoirs

CHEMICAL	APPLICATION	PRODUCT LINE
ETHYLENE OXIDE	Sterilant	Arterial Filters ASA (Arterial Stopcock Adapter) Autotransfusion Filters Autotransfusion Wash Sets BCHY (Blood Cardioplegia Hemoconcentrator Y Adapter) BIC/VIC (Vein Irrigation Cannula) Blood Management Accessories BRAT Disposables BRAT Packs BRAT Procedure sets BSVD (Bonchek Vein Distention System) Cannula, Catheters, Suckers Cardioplegia Table Lines Cardiotomy Reservoirs Centrifugal pumphead (Centriflow) Crystalloid Recirculation Sets Crystalloid/Single Pass Set CSC 14 Cardioplegia Delivery Systems CSD (Cardioplegia Solution Delivery Set) Disposable temperature probes ELS (Extension Line) Flat Sheet Oxygenators Hemoconcentration Packs Hemoconcentrator Hollow Fiber Oxygenators MASLE (Monolyth Arterial Sampling Line Extension) MPHL (Pump Head Line) MREK (Monolyth Reservoir Extension Kit) Overpressure Relief Line Oxygen Filter Pressure Monitoring Separator Lines PTS/Custom Tubing Sets Rapid Prime Lines Revolution Centrifugal Pump SAFPL (Arterial Filter Purge Line) SAT/HCT Connectors SCCA (Coronary Cardioplegia Adapter) SMA PVC Tubing Sterile Connectors Topical Cooling Devices Vacuum Relief Check Valve Vanguard Cardioplegia Delivery Systems Venous Reservoirs Versaplegia Delivery Systems

CHEMICAL	APPLICATION	PRODUCT LINE
<p><b>FORMALDEHYDE</b> <i>(gas)</i></p>	Cleaning agent	CSC 14 Cardioplegia Delivery Systems Flat Sheet Oxygenators Hollow Fiber Oxygenators Vanguard Cardioplegia Delivery Systems
<p><b>LEAD</b></p>	Component	Temperature Probes
<p><b>NICKEL AND CERTAIN NICKEL COMPOUNDS</b></p>	Component	Cardiotomy Reservoirs CSC 14 Cardioplegia Delivery Systems Flat Sheet Oxygenators Hollow Fiber Oxygenators SCCA 14 Temperature Probes Vanguard Cardioplegia Delivery Systems Venous Reservoirs
<p><b>URETHANE</b></p>	Adhesive	Arterial Filters Autotransfusion Filters Cardiotomy Reservoirs CSC 14 Cardioplegia Delivery Systems Flat Sheet Oxygenators Hollow Fiber Oxygenators Kardia PTS/Custom Tubing Sets Vanguard Cardioplegia Delivery Systems Venous Reservoirs Versaplegia Delivery Systems