

Medical Devices and Diagnostic Products that May Contain or Be Coated with Heparin

This list is not meant to be exhaustive and will be updated as additional information becomes available. It is for information purposes only. FDA does not mean to suggest, in any way, that the products herein have been or are affected by contaminated heparin. Items in red are in-vitro diagnostic products.

<u>Manufacturer or Distributor</u>	<u>Product</u>
3M Health Care	3M CDI Quick-Cells with Heparin Treatment 3M Sarns Flow Sensor , Centrifugal Control Module Sarns Arterial Cannulae with Duraflo Treatment Sarns Venous Return Catheters with Duraflo Treatment
A-Med Systems, Inc.	Heparin Coated Miniature Centrifugal Bypass Pump
AMO Groningen BV	CEEON Heparin Surface Modified UV Light-Absorbing Posterior Chamber IOLs CEEON Heparin Surface Modified UV Light-Absorbing Anterior Chamber IOLs
Akers Labs	Platelet Factor 4 RIA
Alsius	Coolgard and catheter thermal regulation system Thermogard System ICY Catheter Models IC3583 and IC3893 Quattro Catheter IC4593 Fortius Catheter
AM2 PAT Inc.	Sierra Heparin Flushes
American Bentley	Heparin Coated Arterial Blood Filters Heparin Coated Extracorporeal Circuits
American Edwards Laboratories	Heparin Coated Catheter Swan-Ganz Heparin Coated Catheter
American Bioproducts	Ptt-Lt Stachrom Heparin

American Dade	Lithium Heparinized Blood Collect-Tube Actin Fs APTT
American Diagnostica	Actichrome Heparin
Amsino Medical USA	Heparin Flushes
APP	Heparin Flushes
Argon Medical Corporation	Heparin Coated Stainless Steel and Teflon Heparin-Coated Guidewires Heparin Coated Thermodilution Catheters
Arrow International, Inc.	Arrow-Howes large bore multi-lumen central venous catheter HANDS-OFF Heparin Coated Thermodilution Catheters
Artefactos De Vidrio S.A. De C.V.	Ven-O-Vac Blood Collection Vacuum Tubes
Atrium Medical	Atrium Heparin Coated Catheters
Avecor Cardiovascular Inc.	Affinity Hollow Fiber Oxgenator with Trillium Biopassive Surface
Avitro LLC	Heparin Flushes
B. Braun of America	H.E.L.P System Heparin Flushes
Baxter Bentley Laboratories	Duraflo II Heparin Treated Suction Wands Duraflo II Heparin Treated Femoral Cannulae
Baxter Edwards	Carpenter-Edwards Classic Ring with Duraflo Treatment
Baxter Healthcare Corp.	Hep-LOCK Heparin Flushes
Becton Dickson	B-D Heparinized Longdwel IV Catheter Heparin Coated Thermodilution Catheter Heparin Coated Luminal Pacing Catheter Heparin Flushes

	<p>Vacutainer Brand Plus Sodium Heparin Tube</p> <p>Bd Vacutainer Plus Pst Ii Tube</p> <p>Vacutainer Brand Blood Collection Syringe</p>
Bio/Data Corp	Cephalinex APTT
Biosensors Intl PTE, LLC	Heparin Coated Thermodilution Catheters
Biotrack, Inc	Biotrack APTT
Boston Scientific Corp	Constellation Multiple Electrode Pacing and Recording System
Cardiac Assist, Inc.	TandemHeart Transseptal Cannula Set-EF
Cardiovascular Diagnostic Services	Aoag-1 APTT Test Card
Cardiovascular Diagnostics	(Tas) Low Range Heparin
Careside Hematology	APTT
Celsus	Heparin Flushes
Ciba Corning Diagnostics Corp.	Ciba Corning Blood Collection Capillary Tube
Coaxia Inc	Coaxia Neuroflo Catheter
COBE Laboratories	<p>Heparinized Arterial Screen Blood Filter</p> <p>Sentry Smarxt 43 Micron Arterial Filter</p> <p>Smarxt BMR 1900 Closed Venous Reservoir Bag</p> <p>Smarxt VVR 4000 Filtered Hardshell Venous Reservoir</p> <p>Smarxt VVR4000I Plus Filtered Hardshell Venous Reservoir</p> <p>Smarxt HVR 4000 Surface Modified Hardshell Venous Reservoir</p> <p>Closed Venous Reservoir Bags with Smarxt</p> <p>Sorin Biomedica Smarxt BCD Vanguard Surface Modified Blood Cardioplegia System</p> <p>Smarxt Optimin Surface Modified Hollow Fiber Membrane Oxygenator</p> <p>Smarxt Optima XP Surface Modified Hollow Fiber Membrane Oxygenator</p> <p>CML Duo with Smarxt Surface Modified Membrane Oxygenator</p>

	Smarxt Tubing and Connectors
Cook, Inc	Amplatz Heparin Coated Catheter
Cordis	BX Velocity with Hepacoat Coronary Stent
Covidien	Heparin Flush Solutions Palindrome Emerald 14.5 Fr Chronic Hemodialysis Catheter with Heparin Coating 14.5 Fr Chronic Hemodialysis Catheter with Heparin Coating and Silver Impregnated Sleeve (Palindrome Sapphire)
Critikon Company, LLC	Heparin-Coated Balloon Thrombolysis Catheters
Current Technologies Inc.	Arterial Micro Collection Kit Prefilled Arterial Blood Sampling Syring
Dade Behring, Inc.	Dimension Vista System Drugs of Abuse Calibrator
Dade, Baxter Travenol	Heparin Assay
Daig Corp	Heparin Bonding for Catheters
Datascope Corp	Percluder-DL Occluding Balloon Heparin Coated
Diagnostica-Stago	Rotachrom Heparin
Dupont Medical Products	Dupont Apc Blood Collection Container With Lithium
Edwards Lifesciences	Embol-X Intra-Aortic Filter Heparin Coated Arterial Blood Filters Retrograde Cardioplegia Cannula with Duraflo PediaSat Oligon Oximetry Catheters with AMC Thromboshield Heparin Coating PreSep Oligon Oximetry Catheters with AMC Thromboshield Heparin Coating Polyethylene Central Venous Catheter with Heparin Coating Swan-Ganz and Edwards Laboratories Heparin Coated Catheters Edwards Vantex Central Venous Catheter with Thromboshield Coating Edwards AVA 3Xi Device with Thromboshield Coating Edwards AVA High-Flow Device with Thromboshield Coating

	<p>Edwards IntroFlex Percutaneous Sheath Introducer with Thromboshield Coating</p> <p>Venous Reservoir Bag Model No. BMR-800 with Heparin</p> <p>Venous Reservoir /Cardiotomy Autotransfusion Filter</p> <p>Duraflo II Heparin Oxygenator Model Univox Gold</p> <p>Univox Gold Membrane Oxygenator with Duraflo</p> <p>Extracorporeal Circuit with Duraflo II Heparin Treatment</p> <p>Sarns Centrifugal Pump with Duraflo II Treatment</p> <p>Jackson-Pratt Gold Wound Drains with Duraflo II</p> <p>Bentley Quick-Prime Hemoconcentrator with Duraflo Treatment</p>
Electro-Catheter Corp	<p>Elecath Heparin-Coated Catheters</p> <p>Elecath Heparin-Coated Temporary Pacing Catheters</p> <p>Elecath Heparin-Coated Thermal Dilution Catheters</p>
Em Diagnostics	<p>Easy-Test PTT</p>
Embol-X, Inc.	<p>Embol-X Aortic Filters</p> <p>Aortic Cannula Metal J-Tip (24 Fr)</p> <p>Embol-X Aortic Occlusion and Carioplegia Cannula</p> <p>Embol-X Introducer Model CF00200</p>
Emisphere Technologies, Inc	<p>Heparin Flushes</p>
EV3	<p>Spiderfx Embolic Protection Device</p>
Excelsior Medical	<p>Heparin Flushes</p>
GISH Biomedical, Inc.	<p>GISH Tubing and Connectors with GBS Coating</p> <p>GISH Arterial Filter with GBS Coating</p> <p>GISH ATR2900 and CAP35 Series Reservoirs with GBS Coating</p> <p>V-Bag with GBS Coating</p> <p>GISH CAPVRF44 Hardshell Venous Reservoir Ba with GBS Coating</p> <p>Soft Venous Reservoir (SVRXX) with GBS Coating</p> <p>IBC Flopump with GBS Coating</p> <p>Vision Blood Cardioplegia System and Extracorporeal Heat Exchanger with GBS Coating</p>
Gould, Inc.	<p>Heparin Coated Thermodilution Catheters</p>

Greiner Bio-One	Greiner Vacuette Blood Collection Tube W/Lithium Vacuette Evacuated Blood Collection Tubes
Greiner Mediatech Inc.	Greiner Minicollect Li Heparin Gel Greiner Minicollect Lithium Heparin Gel Blood Col
Guidant Corp	NeuroLink System
Helena Laboratories	Chrom Z-Heparin APTT-ES
Hospira, Inc.	Opticath Central Venous Oximetry Probes Latex-free Advanced Sensor Catheters Flow-Directed Heparin Coated Thermodilution Catheter Opticath Catheter Opticath Heparin Coated Flow Directed Catheter Oximetry Flow Directed Thermal Dilution Catheter
Hyphen Biomed	Biophen Heparin 3,6
Infusaid Corp	Heparin Lock Maintenance Kit
Innerdyne, Inc.	Innerdyne Radially Expanding Vascular Access System
Instrumentation Laboratory Co	Heparinized Flow Directed Thermal Dilution Catheter II Test Coamatic Heparin
International Technidyne (ITC)	Hemochron Jr Hemochron Kaolin-Activated Heparin
Intervascular, Inc.	Intergard Knitted Collagen Coated and Heparin Bonded Vascular Protheses Intergard Knitted Ultra-Thin Collagen Coated and Heparin Bonded Vascular Protheses
J-Lloyd Medical, Inc.	Flow Direct Thermodilution Balloon Catheter with Heparin Coating

Johnson & Johnson	Arterial 20/40 Micron Filters with Heparin Coating
KMA Inc.	Heparin Coated Thermodilution Catheter
Maquet Cardiopulmonary AG	Jostra Quadrox D Diffusion Membrane Oxygenator with Bioline Coating
Mansfield Scientific	Heparin Coated Temporary Pacing Electrode
Martech Medical Products Inc.	Marksman Arterial Blood Gas Syringe
Medefil, Inc.	Heparin Flushes
Medelec Intl. Corp.	Blood Specimen Collection Devices
Medical Components, Inc	MedComp DUO-COAT Catheter Double Lumen
Medrad, Inc.	Benzalkonium-Heparin Coated Guidewires
Medtronic	Trillium Bio Disposable Blood Flow Probe Trillium Tri-Optic Measurement Cell Trillium Affinity NT Cardiotomy Venous Reservoir Trillium Biopump Plus Model BPX80T Affinity 20 Micron Arterial Filter with Trillium Biosurface Affinity 38 Micron Arterial Filter with Trillium Biosurface Select 3D (and CAP) Arterial Cannula with Carmeda Boactive Surface Affinity Pediatric Arterial Filter Affinity NT Hollow Fiber Oxygenator Trillium Myotherm XP Cardioplegia Delivery System Tubing and Connectors with Trillium Biopassive Surface Carmeda or Trillium Coated Myotherm Blood Cardioplegia System Carmeda Coated Intersept Pediatric Arterial Filter Minimax/Maxima Hollow Fiber Oxygenators Minimax Oxygenation System
Mentor Corp	Mentor Tissue Expanders with TDMAC Coating
Microbio-Medics Inc.	Microtek Medical`S Blood Collection Kit

Millenia Healthcare, Corp.	Heparin Flushes
Morris innovative Research, Inc.	Femoral Introducer Sheath and Hemostasis (FISH) Device 5, 6, and 8 French
Nova Medical Speicialties	Heparin Coated Balloon Thermodilution Catheters
Novalung GMBH	Novalung Surgical Lung Assist (SLA) Membrane Lung
Organon Teknika	MDA Heparin Anti-X
Ortho	Synthafax
Oximetrix Inc.	Opticath Heparin Coated Flow Direct Catheter
Pacific Hemostasis	Thromboscreen APTT
Parke-Davis Co.	Deseret Heparin Coated Flow Catheters
Parker Pharmaceutical, Inc.	Heparin Flushes
Physician Industries, Inc.	PICC Insertion Tray with Hep-LOCK Heparin Flush
Precision Biologicals	APTT Reagent
Radiant Medical	Radiant Medical Endocatheter Temperature Probe Setpoint Endovascular Temperature Management System Relieve Endovascular Termperture Therapy System
Radiometer Medical Aps	Safepico
Ram Scientific	Safe-T-Fill Capillary Blood Collection System
Research Industries Corp.	Duraflo II Heparin Treated Cannulae
Research Medical. Inc.	TDMAC-Heparin Coated RMI Carotid Bypass Shunt

Rocap/Sabratek Corp	Heparin Flushes
Roche Diagnostics	CoaguChek
Safety Diagnostics Inc.	Pinset
Shapes	Heparin Flushes
Shelhigh, Inc	Delcol Heparinized Pericardial Substitute
Sherwood Medical Co.	Argyle Griffith TDMAC Heparinized Venovenous Shunt Heparinized Wound Suction Tubing Heparinized Saratoga Sump Drain Heparinized Penrose Tubing Heparinized Intravenous Cannula Lancer Coagent APTT Monoject Sample Capillary Plasma Sep W/Lith Hepar Monoject Samplette Capillary Blood Coll Monoject Sps Blood Collection Tube
Sigma	APTT Reagent
Sims Portex Inc.	Pro-Vent Pulsator Arterial Blood Sampling Syringe
Smith's Healthcare Manufacturing	Injection Adaptor Heparin Lock
Smiths Industries Medical Systems In	Sims Pro-Vent 250 (500) Plus Arterial Blood Sample
Smith's Medical ASD	Injection Adaptor Heparin Lock
Solo Pak Labs	Heparin Flushes
Sorenson Research	Flow-Directed Heparin Coated Thermodilution Catheter
Spectramed, Inc.	Heparin Coated Luminal Pacing Catheter
Spire Biomedical, Inc.	15.5 Fr Decathalon Coated Catheters

Starplex Scientific Inc.	Vacuplus Tubes With Green Stoppers
Statspin Technologies	Statspin Statsampler
Sunscope Intl, Inc.	Heparin Coated Thermodilution Catheter and Accessories
Terumo Corp.	Capiject Sys Capillary Blood Collect Venoject Ii Blood Collection Tubes
Vital Scientific	APTT
Vital Signs, Inc	Heparin Flushes
W.L. Gore & Associates, Inc.	Gore Propaten Vascular Graft Gore Viabahn Endoprosthesis with Heparin Bioactive Surface
Wako Intl. Inc.	Seri-Sep Serum/Plasma Isolator