

December 15, 2020

**RE: Latex Content**

**To Whom It May Concern:**

Based on information currently available from our raw material suppliers, the following products provided by Merit Medical Systems, Inc. are not made with natural rubber latex. Testing has not been conducted to confirm the presence or absence of natural rubber latex in the finished product.

Products to which this declaration applies:

**Cardiac Intervention**

- Access
  - Radial Approach Accessories Rad Board® Radial Arm Board  
Rad Board Xtra™  
Rad Trac®  
Rad Rest®
  - Needles & Scalpels Merit Advance® Angiography Needles  
Merit Advance® Angiographic Safety Needle  
Merit Majestik® Series Angiographic Needles  
Futura® Safety Scalpels
  - Sheath Introducers PreludeIdeal™ (Reinforced Thin Wall) Sheath Introducer  
PreludeEASE™ Hydrophilic Sheath Introducer  
Prelude® Radial Sheath Introducers – Mini Access  
PreludePRO™ Sheath Introducers  
Prelude® Sheath Introducer with Merit Advance® Needle  
Prelude® Sheath Introducers  
PreludeACT™ Sheath Introducer  
Prelude Choice™ Hemostasis Valve Adapter  
Exacta® Percutaneous Sheath Introducer Sets
  - Obturator & Guide Wires Prelude® Obturators  
Prelude® Guide Wires
- Angiography
  - Diagnostic Cardiology Catheters Performa® Diagnostic Cardiology Catheters  
Performa Multipack™ and MultipackPLUS™ Angiographic Cardiology Catheters  
Merit Diagnostic Cardiology FEP Catheters
  - Diagnostic Guide Wires InQwire® Guide Wires  
Go2Wire Guide Wires
  - Hydrophilic Guide Wires Merit H2O™ Hydrophilic Guide Wires  
Merit Laureate® Hydrophilic Guide Wires
  - Guide Wire Accessories Merit® Torque Devices (PinVise)  
Merit® Guide Wire Insertion Tool  
Merit RingMaster™ Guide Wire Basin  
H2O Torq™ Torque Device  
SeaDragon™ Torque Device  
SeaDragon 2™ Torque Device
  - Fluid Management & Tubing Miser® Contrast Management Systems  
Fluid Administration Systems  
High Pressure Tubing (Rigid PVC and Flexible Braided Polyurethane)  
Pressure Monitoring Tubing  
PIB – Pressure Infusor Bag™  
Connecta PE Pressure Lines

## Cardiac Intervention

- Manifolds, Stopcocks & Adapters
  - Merit® Manifolds
  - Devos™ Manifolds
  - TRAM® / TRAM-P™ Manifold with Integral Transducer
  - Marquis® Stopcocks
  - Airless Rotating Adapters
- Syringes
  - CCS™ Coronary Control Syringes (Inject8™ and Inject10n™ Coronary Control Syringes) and SmartTip™ syringes
  - RXP® Flushing Syringe
  - VacLok® Vacuum Pressure Syringes
- Transducers & Accessories
  - Meritrans® Pressure Transducers
  - Meritrans DTXPlus® Disposable Transducers
  - Meritrans DTXPlus® Accessories
  - TRAM® / TRAM-P™ Manifold with Integral Transducer
  - Meritrans® Accessories (Mentor™ Pressure Simulator)
  - Transducers Interface Cable
  - Transducer Mounting Background
  - Snap-On TMM Cable Organizer
  - CO In-Line Sensor
  - Cardiac Output Cable
- Intervention
  - Arterial Catheters
    - Careflow™ Arterial Catheters
  - Central Venous Catheters
    - Careflow™ Central Venous Catheters
    - Secalon-T™ Central Venous Catheters
    - Hydrocath Assure Central Venous Catheter
    - Secalon Seldy Central Venous Catheter
  - Aspiration Catheters
    - ASAP® Aspiration Catheter
    - ASAPLP™ Aspiration Catheter
  - Guiding Catheters
    - ConcierGE® Guiding Catheters
  - Steerable Microcatheters
    - SwiftNINJA® Steerable Coronary Microcatheters
  - Pericardiocentesis
    - Pericardiocentesis Kit
  - Hemostasis Valves & Accessories
    - MBA™ and MBAplus™ Hemostasis Valves\*
    - Passage® Hemostasis Valve\*
    - DoublePlay™ Large Bore Hemostasis Valve
    - FLO30™ Hemostasis Valve
    - FLO40™ Hemostasis Valve
    - FLO40XR™ Hemostasis Valve
    - FLO50™ Hemostasis Valve
    - Honor® Hemostasis Valve
    - Access-9™ and AccessPLUS™ Hemostasis Valve\*
    - PhD™ Hemostasis Valve
    - \*Includes hemostasis valves with bonded extension tubing
  - Inflation Devices
    - Merit Angioplasty Packs (MAP™)
    - BasixCompak™ Inflation Device
    - BasixTouch™ Inflation Device
    - Blue Diamond™ Inflation Device
    - Fluid Dispensing Syringes
    - IntelliSystem® Inflation Device and Accessories
    - Monarch® Inflation Device
  - Stent Positioning System
    - OstialPRO® Stent Positioning System
  - Thermodilution & Pulmonary Artery Catheters
    - Critikit™ Ice/Room Temperature Injectate Systems and Accessories
- Hemostasis
  - Compression Devices
    - SafeGuard® Pressure Assisted Device
    - Safeguard Radial™ Compression Device

## Cardiac Intervention

- Clo-Sur P.A.D.® and Clo-SurPLUS P.A.D.™ Antimicrobial Barrier
- Finale® Radial Compression Device
- RADstat® Radial Artery Compression Device
- PreludeSYNC™ Radial Compression Device
- EP & CRM
  - Electrophysiology HeartSpan® Fixed Curve Braided Transseptal Sheath
  - HeartSpan® Transseptal Needle
  - HeartSpan® Steerable Sheath Introducer
  - Cardiac Rhythm Management Hydrophilic PreludeSNAP™
  - PreludeSNAP™ Splittable Hemostatic Introducer
  - Classic Sheath™ Splittable Hemostatic Introducer
  - Worley™ Advanced LV Lead Delivery System (Worley™ Advanced Lateral Vein Introducer, Worley™ Advanced Coronary Sinus Guide, Worley™ Vein Selector, Worley™ Advanced Contrast Administration Kit)
- Solutions
  - Pen & Labels PAL™ Pen and Label Sets
  - Procedure Trays, Packs and Kits Rapid Response Kits and Angiography Kits \*
  - Pericardiocentesis Kits
  - Patient Cover / Radial Drapes
  - Radiation Scatter Drapes
  - Safety & Waste Management Dualcap® Disinfection and Protection Systems
  - MiniStop® and MiniStop+™ Disposal Systems
  - DriPAD™ Super Absorbent Pad
  - BackStop® and BackStop+™ Disposal Systems
  - DugOut® Closed Waste Basin
  - ShortStop®, ShortStop Advantage® and ShortStop Grandstand® Temporary Sharps Holders

## Peripheral Intervention

- Access
  - Accessories Merit® HVA – Hemostasis Valve Adapter
  - BowTie™ Guide Wire Insertion Device
  - Introducers & Dilators Merit PAK™ Pedal Access Kits
  - Merit MAK™ Mini Access Kits and Accessories (Mini Guide Wires)
  - Merit S-MAK™ Kits and Accessories (Mini Guide Wires)
  - Prelude® Dilators
  - Vessel Dilators
  - Prelude® Marker Tip Sheath Introducer
  - Prelude® Short Sheath Introducers
  - Prelude Choice™ Hemostasis Valve Adapter
  - A-S-K Merit Access Safety Kit®
  - Needles Merit Advance® Angiographic Needles
  - Renal Therapies & Accessories HeRO® Graft, Super HeRO®
  - HeRO® Ally
  - Peritoneal Dialysis (PD) (Flex-Neck®) Catheters and Kits (Insufflation, repair, Y-TEC® Catheter Implantation) and Accessories (connectors, caps, implantation stylettes, embedding tools, trocar, Y-TEC® system components)
  - PD Catheter Implantation System
  - Centros® and CentrosFLO® Hemodialysis Catheters
  - ProGuide™ Chronic Dialysis Catheters
  - Impress® 30cm Catheters
  - Merit Advance® Curved Needles
  - OuTake® Catheter Extractor
  - Covered Stent/Endoprosthesis Slip-Not® Suture Retention Device

## Peripheral Intervention

- Angiography
  - Diagnostic Guide Wires Merit WRAPSODY™  
Merit MAK™ Guide Wires  
InQwire® Diagnostic Guide Wires
  - Diagnostic Peripheral Catheters Performa® Angiographic Catheters  
Performa® Vessel-Sizing Catheters  
Impress® Diagnostic Peripheral Catheters  
Impress® Hydrophilic Catheters  
Performa® Diagnostic Peripheral Catheters
  - Fluid Management & Tubing High Pressure Flow Control Switch  
Contrast Transfer Sets
  - Guide Wire Accessories SPINR™ High Performance Guidewire Controller  
SeaDragon™ Torque Device
  - Hydrophilic Guide Wires Merit Laureate® Hydrophilic Guide Wires  
TrueForm Shapable Guide Wires
  - Syringes VacLok® Vacuum Pressure Syringes
- Intervention
  - Balloon Catheters Advocate™ 0.018" PTA Catheter
  - Support Catheters Merit SureCross™ Support Catheters
  - Inflation Devices BasixTOUCH40™ Inflation Device  
BasixCompak™ Inflation Device  
BasixTouch™ Inflation Device  
Blue Diamond™ Inflation Device  
IntelliSystem® Inflation Device and Accessories  
Monarch® Inflation Device
  - Snares & Accessories EN Snare® Endovascular Snare System  
ONE Snare® Endovascular Snare System
  - Therapeutic Infusion Systems Fountain® Infusion Systems  
Squirt® Fluid Dispensing System  
Pulsed Infusion Kits  
Mistique® Infusion Catheters
  - Venous Solutions ClariVein® IC Infusion Catheter  
FibroVein
- Drainage & Biopsy
  - Access Accessories MAK-NV™ Introducer System  
Valve Adapter for MAK-NV™  
Merit Drainage Depot™ Drainage Bags  
Revolution™ Catheter Securement Device  
EPI-FIX™ and StayFIX® Fixation Devices  
VacLok® Vacuum Pressure Syringes  
Marquis® Series Stopcocks  
Drainage Tubing  
Connecting Tubes  
FastBreak™ Breakaway Connector
  - Biopsy CorVocet™ Biopsy System  
Westbrook™ Bone Biopsy System  
Kensington™ Guide Wire Bone Biopsy System  
Bedford™ Guided Hard Bone Biopsy System  
Madison™ Perforating Bone Biopsy Kit with Drill  
Huntington™, Guided, Perforating Bone Biopsy System with Drill  
Preston™ Bone Biopsy Needle  
Preston™ Hard Bone Access Needle with Drill  
Preston™ Transpedicular Introducer  
Preston™ Bone Filler

## Peripheral Intervention

		Preston™ Transpedicular Drill
		Bone Marrow Aspiration Needle (Mallarme) – (Outside US Only)
		Muscle Biopsy Needle (Outside US Only)
		Original Temno™ Biopsy Device
		Temno Evolution® Biopsy Device
		Tru-Cut® Biopsy Needle
		Achieve® Automatic Biopsy Device
	Complete Solutions	ReSolve® Locking Drainage Catheter Trays (includes catheter, MAK-NV Introducer, Drainage Depot and Dilators)
		Safety Paracentesis Procedure Tray
		Thoracentesis & Paracentesis Set
		Aspira® Drainage System
	Intervention	ReSolve® and ReSolve+™ Biliary Locking Drainage Catheters
		ReSolve® and ReSolve® Plus Locking Drainage Catheters
		ReSolve® Non-Locking Drainage Catheters
		ReSolve® CirQ Nephrostomy Catheter
		ReSolve® MINI Drainage Catheter
		One-Step™ Centesis Catheters
		Valved One-Step™ Centesis Catheters
		Cen-Step Centesis Catheters
•	Solutions	
	Hemostasis Accessories	Access-9™ Hemostasis Valve
		Hemostasis Valve Adapter
		FLO30™ Hemostasis Valve
	Procedural Trays, Packs & Kits	Myelogram Tray
		Vein Closure Tray
		Vein Closure Syringe
		Patient Cover
		Radiation Scatter Drapes
	Safety & Waste Management	Merit Disposal Depot™ Waste Bags
•	Transradial Access – Peripheral	
	Set-up	Rad Board® Radial Arm Board 2
		Rad Board Accessories (Rad Board Xtra™, Rad Trac®, Rad Rest®)
		Radial Drapes
	Access	Advance® Needles
		Two-Part Access Needle
		Prelude® Guide Wires
		Prelude IDeal™ (Reinforced Thin Wall) Sheath Introducer
		PreludeEASE™ Hydrophilic Sheath Introducer
		Prelude® Radial Sheath Introducer – Mini Access
		Prelude Choice™ Hemostasis Valve Adapter
	Angiography	Merit Maestro® Microcatheters
		Performa® Diagnostic Peripheral Catheters
		Performa® Diagnostic Cardiology Catheters
		Pursue Microcatheters
		ConcierGE® Guiding Catheters
	Intervention	Embosphere® Microspheres
		QuadraSphere® Microspheres
		Bearing™ nsPVA Embolization Particles
		EmboCath® Plus Microcatheters
		Inject8™ and Inject10n™ Coronary Control Syringes
		BasixTOUCH™ Inflation Device
	Hemostasis	Safeguard Radial™ Compression Device
		Radstat®
		Clo-Sur P.A.D.® & Clo-Sur PLUS P.A.D.™ Antimicrobial Barrier

## Interventional Oncology & Spine (IOS)

- Embolotherapy
  - Embolization Particles Bearing™ nsPVA Embolization Particles
  - Microspheres Embosphere® Microspheres
  - EmboGold® Microspheres
- Oncology
  - Hepatic Oncology HepaSphere® Microspheres (Outside US Only)
  - QuadraSphere® Microspheres (US Only)
  - Breast Oncology SAVI® SCOUT
  - SAVI® Brachy
- Spine Ablation STAR™ Tumor Ablation System
- Vertebral Compression Fracture (VCF) StabilIT® Vertebral Augmentation System
- StabilIT® MX Vertebral Augmentation System
- StabilIT® VP Vertebroplasty System
  - (Systems consist of: MultiPlex Controller, Activation Element, Hydraulic Assembly, Introducers, Delivery Cannula, Hand Switch Cable, AE Cable)
  - SPACE 360 Delivery System (Controller, Pressure Sensor, Cannula and Stylet Assembly, Hydraulic Assembly, Disposable Cable, Hand Switch, Power Cord)
  - Space CpsXL Bone Cement
  - Osseoflex® SB Steerable and Straight Balloons
  - Osseoflex® SN Steerable Needle
  - Osseoflex® Access Instruments
  - Osseoflex® Bone Cement & Delivery System
- Accessories
  - Guide Wires Tenor® Steerable Guidewires
  - Merit® Guide Wire Bowl
  - Microcatheters SwiftNINJA® Steerable Microcatheter
  - Merit Maestro® Microcatheters
  - EmboCath® Plus Microcatheters
- Complete Procedural Solutions Medallion® Syringes
- Biopsy Centesis Kits
- Medication Delivery Packs

\* Merit's Rapid Response and Convenience Kits and Procedure Trays do not include components which are known to contain latex. Exception: Custom kits may contain customer-specified component(s) which are manufactured with latex.

## Endoscopy

- Pulmonary
  - AERO® Tracheobronchial Stent
  - AEROMini® Tracheobronchial Stent
  - AERO DV® Tracheobronchial Stent
  - AEROSIZER® Tracheobronchial Stent Sizing Device
  - BAL Convenience Kit™
  - TRAP CAPtain™
  - TWISTER® PLUS Rotatable Retrieval Device
  - Elation™ Pulmonary Balloon
- Gastroenterology
  - EndoMAXX™ Esophageal Stent
  - ALIMAXX-ES™ Esophageal Stent
  - ALIMAXX-B® Biliary Stent
  - BiliQUICK™ Cholangiography Continuous Injection Kit
  - Elation™ Balloon Dilator
  - Elation™ Fixed Wire Balloon Dilation Catheter
  - Elation™ Wireguided Balloon Dilation Catheter
- Accessories
  - MAXXWIRE® Guide Wires
  - Brighton Bipolar Probe®
  - VacLok® Negative Pressure Syringe

**Endoscopy**

- Inflation Devices

TIO™ (Three-In-One) Bite Block  
DriPAD™ Super Absorbent Pad  
Segue™ Multipurpose TransProtection System  
BIG60™ Inflation Device  
Endotek Analog Inflation Device  
Endotek Digital Inflation Device

**Miscellaneous**

- Accessories

Convenience Towel Pack  
KanguruWeb® Disposable Contoured Web  
Surgical Prep Mitt  
Contamination Shield  
Contamination Sleeve  
NvisionVLE® Imaging System, with Real-time Targeting™

Merit is concerned with the safety and welfare of patients and healthcare professionals and appreciates your interest in our products.

Please note that we do not routinely test for any of these substances referenced above, nor do we intentionally add or use these materials in the manufacture or handling of the above product(s), at or above the restricted concentrations.

This information is accurate as of the date of this declaration and is subject to change without notice.

If you have any questions concerning this matter or if we can be of further assistance, please contact us at [qualitycompliance@merit.com](mailto:qualitycompliance@merit.com).

Sincerely,



John Hellgeth, Ph.D.  
Director, R&D Materials Sciences  
Merit Medical Systems, Inc.