



TERUMO MEDICAL CORPORATION

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MATERIALS OF CONCERN DECLARATION

PINNACLE® Introducer Sheath	GLIDESHEATH™ Introducer Sheath
PINNACLE® TIF TIP™ Introducer Sheath	GLIDEACCESS® System
PINNACLE® R/O II HiFlo Introducer Sheath	DESTINATION® Guiding Sheath
PINNACLE® R/O II Radiopaque Marker Introducer Sheath	R2P™ DESTINATION SLENDER™ Guiding Sheath
PINNACLE PRECISION ACCESS SYSTEM® Sheath	SOLOPATH® Balloon Expandable TransFemoral System
RADIFOCUS® Introducer Sheath	SOLOPATH® Re-collapsible Balloon Access System
RADIFOCUS® R/O II Introducer Sheath	ANGIO-SEAL® Vascular Closure Device
RADIFOCUS® R/O II HiFlo Introducer Sheath	FEMOSEAL® Vascular Closure Device
GLIDESHEATH SLENDER® Introducer Sheath	TRBand® Radial Compression Device
GLIDESHEATH SLENDER® Tibial Pedal Introducer Sheath	

Please be advised that the above medical devices manufactured by Terumo Medical Corporation do not contain the following compounds unless noted in the exceptions below:

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|---------------------------------------|------------------------------------|
| BPA | Heparin |
| Murine Antibody | Albumin |
| Swine Aortic Valve | Urokinase |
| Swine Cardiac Valve | Hyaluronic acid |
| Equine Pericardial Membrane | Casein |
| Bovine Pericardial Membrane | Vitamins |
| Silver Protein (or Silver Protainate) | PVC |
| Ovine Antibody | Mercury |
| Collagen | DEHP** Di (2-ethylhexyl) phthalate |

Exceptions:

- PINNACLE® R/O II HiFlo Introducer Sheath contains DEHP
- RADIFOCUS® R/O II HiFlo Introducer Sheath contains DEHP
- DESTINATION® Guiding Sheath contains BPA and DEHP
- R2P™ DESTINATION SLENDER™ Guiding Sheath contains BPA and DEHP
- ANGIO-SEAL® Vascular Closure Device contains Collagen
- TRBand® Radial Compression Device contains BPA and PVC

DEHP is known by many other chemical names in the industry. Please cross reference the following list:
1,2-Benzenedicarboxylic acid bis(2-ethylhexyl) ester; Octoil; Ethyl hexyl phthalate; 2-Ethylhexyl phthalate; bis-(2-ethylhexyl) 1,2-benzenedicarboxylate; octyl phthalate; phthalic acid dioctyl ester; BEHP; bisoflex 81; bisoflex dop; compound 889; DAF 68; ergoplast fdo; eviplast 80; eviplast 81; fleximel; flexol dop; flexol plasticizer dop; good-rite gp 264; hatcol dop; hercoflex 260; kodaflex dop; mollan o; nuoplaz dop; palatinol ah; Pittsburgh px-138; platinol ah; platinol dop; rc plasticizer dop; reomol dop; reomol d 79p; sicol 150; staflex dop; truflex dop; vestinol ah; vinicizer 80; witicizer 312; Benzenedicarboxylic acid; bis(2-ethylhexyl) ester; Union carbide flexol 380.

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John Boselli
Sr. VP of Quality and Regulatory Affairs