**MATERIALS OF CONCERN DECLARATION**

<table>
<thead>
<tr>
<th>PINNACLE® Introducer Sheath</th>
<th>GLIDESHEATH™ Introducer Sheath</th>
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<tbody>
<tr>
<td>PINNACLE® TIF TIP™ Introducer Sheath</td>
<td>GI IF: FACCFS® System</td>
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<tr>
<td>PINNACLE® R/O II HiFlo Introducer Sheath</td>
<td>DESTINATION® Guiding Sheath</td>
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<tr>
<td>PINNACLE® R/O II Radiopaque Marker Introducer Sheath</td>
<td>R2P™ DESTINATION SLENDER™ Guiding Sheath</td>
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<tr>
<td>PINNACLE PRECISION ACCESS SYSTEM® Sheath</td>
<td>SOLOPATH® Balloon Expandable TransFemoral System</td>
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<tr>
<td>RADIFOCUS® Introducer Sheath</td>
<td>SOLOPATH® Re-collapsible Balloon Access System</td>
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<td>RADIFOCUS® R/O II Introducer Sheath</td>
<td>ANGIO-SEAL® Vascular Closure Device</td>
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<tr>
<td>RADIFOCUS® R/O II HiFlo Introducer Sheath</td>
<td>FEMOSEAL® Vascular Closure Device</td>
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<tr>
<td>GLIDESHEATH SLENDER® Introducer Sheath</td>
<td>TRBand® Radial Compression Device</td>
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<td>GLIDESHEATH SLENDER® Tibial Pedal Introducer Sheath</td>
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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:

- BPA
- Murine Antibody
- Swine Aortic Valve
- Swine Cardiac Valve
- Equine Pericardial Membrane
- Bovine Pericardial Membrane
- Silver Protein (or Silver Proteinate)
- Ovine Antibody
- Collagen
- Heparin
- Albumin
- Urokinase
- Hyaluronic acid
- Casein
- Vitamins
- PVC
- Mercury
- 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; bisolex 81; bisolex dop; compound 889; DAF 68; ergoplant fdo; eviplast 80; eviplast 81; fleximel; flexol dop; flexol plasticizer dop; good-rite gp 264; hatcol dop; hercoflex 260; kodaflex dop; mollan o; mnuoplast dop; palatinol ah; Pittsburgh ps-138; platinol ah; platinol dop; re plasticizer dop; roemol dop; roemol d 79p; sicol 150; stafl ex dop; truxel dop; vestinol ah; vinicizer 80; witcizer 312; Benzenedicarboxylic acid; bis(2-ethylhexyl) ester; Union carbide flexol 380.

Sincerely,

John Boselli
Sr. VP of Quality and Regulatory Affairs

PM-01029