



Document Number
1096426

Revision Number
4

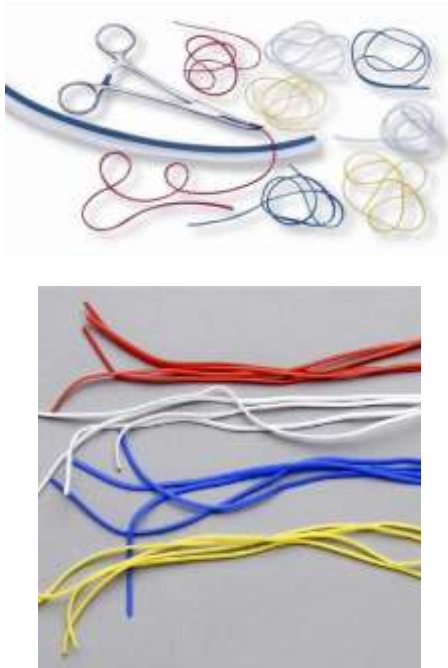
TECHNICAL DATA SHEET

Alt. Doc. Number
N/A

Effective Date
14Apr2023

VESSEL LOOPS

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Product Family	Vessel Loops
Intended Use	Intended to be used to occlude, retract, and identify arteries, veins, tendons, and nerves in surgical procedures
Description	Surgical Vessel Loop is a sterile, non-implantable cord intended to be used during a surgical procedure to assist a surgeon to identify, retract and occlude blood vessels, tendons, and nerves. It is constructed of synthetic polymer and is typically colored to facilitate visualization. This is a single—use device. Duration of use is up to 8 hours
Picture of Device	 <p>Vessel Loops</p>
Manufacturer Name and Address	<p>Aspen Surgical Products, Inc. 6945 Southbelt Dr. SE Caledonia, MI 49316, USA</p> <p>DUN #027680821 Tax ID #383 448 946</p>



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Certifications	<p>ISO 13485 FM703042 CE 612363 MDSAP 690516 UKCA 775545</p> <p>Available on Aspen's website: https://www.aspensurgical.com/compliance/certificates/</p>
Sterilization Information	<p>Ethylene Oxide (EtO): Sterilization Services of Virginia (SSV) 5674 Eastport Blvd Richmond, Virginia 23231, USA</p>
European Union Classification and Conformity Route	<p>MDD – Class IIa under Rule 7 per Annex IX MDR – Class IIa under Rule 7 as per Annex VIII</p>
Authorized Representative of the European Union	<p>Emergo Europe Westervoortsedijk 60 6827 AT Arnhem The Netherlands</p>
EU Notified Body	<p>BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam Notified Body Number: 2797</p>
Canadian Classification and License Number (If applicable)	<p>Class II, Rule 1 Medical Device License: 61095</p>
FDA Regulatory Class and Product Code Registration #	<p>21 CFR 878.4800, Instrument, Surgical, Disposable Medical Device List Number: D358980 Product Code: KDC Product Class: Class 1 510k Submission Type: Exempt Registration # 1836161</p>



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Instruction Insert (IFU)	<p>Vessel Loop Instructions for Use, Sterile: 70010-001 Vessel Loop Instructions for Use, Non-Sterile: 20180030 Vessel Loops Sterile IFU: 20210013 Vessel Loops, Non-Sterile IFU: 20210014</p> <p>Available with product and on Aspen's website: https://www.aspensurgical.com/education/instructions-for-use/</p>
Material Composition	<p>Vessel Loops: Silicone Rubber Barium Sulfate</p> <p>Vessel Loop Card: ABS Plastic</p> <p>Neither Configuration contains reportable amounts of:</p> <ul style="list-style-type: none"> • Natural latex rubber • Polyvinylchloride (PVC) • Phthalates • Bis (2-ethyhexyl) phthalate (DEHP) • Bisphenol A (BPA) • Potential contamination by bovine or transmissible spongiform encephalopathies (BSE/TSE). • Substances which are carcinogenic, mutagenic, or toxic to reproduction ('CMR') of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council
RoHS under DIRECTIVES 2011/65/EU as amended by Directives 2015/863 & 2017/2102	Not Applicable. This device does not consist of any electrical & electronic equipment
REACH Regulation 1907/2006	Aspen confirms that to the best of our knowledge that none of these products or product packaging contain any Substances of Very High Concern (SVHC) as noted on the REACH Candidate List in a concentration above 0.1% by weight allowable limit. This list will continue to be monitored for additions or modifications
California Proposition 65	At this time, this product does not contain chemicals listed on California's Safe Drinking Water & Toxic Enforcement Act, commonly known as California Proposition 65. This list will continue to be monitored for additions



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Biological/Biocompatibility Report	<p>The following tests were performed per ANSI/AAMI/ISO 10993:</p> <p>Cytotoxicity per ISO 10993-5</p> <p>Dermal Sensitization per ISO 10993-10</p> <p>Irritation/Intracutaneous per ISO 10993-10</p> <p>Acute Systemic Toxicity per ISO 10993-11</p> <p>Conclusion: This device poses no biological risk</p>
GMDN Number and EMDN Number, if applicable	<p>GMDN: 61916, Surgical Vessel Loop</p> <p>EMDN: V9012, Surgical Instruments, Not Specialistic Surgery, Single use</p>
Shelf Life	5 Years
Country of Origin	USA or Israel (For Country of Origin, See Product Label)
Tariff Codes	<p>HTS: 9018.90.2000</p> <p>HS: 9018.90.8000</p>
Radiopaque	Yes, product is radiopaque