


Document Number
1056640

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2

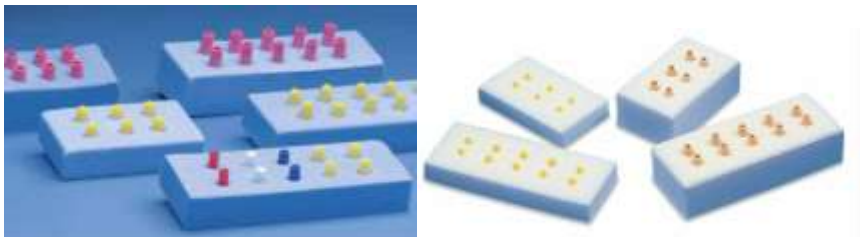
TECHNICAL DATA SHEET

Alt. Doc. Number
N/A

Effective Date
13Apr2023

SUTURE AID BOOTIES

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Product Family	Suture Aid Booties
Intended Use	Suture Aid Booties are intended to protect, tag, and help locate sutures
Description	<p>Suture Aid Booties – A sterile cover, used in pairs, fitted onto the distal working end (the jaws) of artery forceps, vascular clamps, or similar surgical instruments, to provide improved grip for delicate sutures</p> <p>It is typically tube-like with a closed, rounded tip and composed of radiopaque silicone materials. It is available in various sizes and may be straight or curved</p> <p>This is a single-use device</p>
Picture of Device	
Manufacturer Name and Address	<p>Aspen Surgical Products, Inc. 6945 Southbelt Dr. SE Caledonia, MI 49316, USA</p> <p>Duns #027680821 Tax ID #38-3448946</p>
Certifications	<p>ISO 13485 CE 612363 MDSAP 690516 UKCA 776645</p> <p>Available on Aspen 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>



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European Union Classification	MDD: Class IIa under Rule 7 per Annex IX MDR: Class IIa under Rule 7 per Annex VIII
Authorized Representative of the European Union	Emergo Europe Westervoortsedijk 60 6827 AT Arnhem The Netherlands
EU Notified Body	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam Notified Body Number: 2797
Canadian Classification and License Number (If applicable)	Class II, Rule 1 Medical Device License 80609
FDA Regulatory Class and Product Code Registration #	21 CFR 878.4800, Instrument, Surgical, Disposable Medical Device Listing Number: D358980 Product Code: KDC Product Class: I 510K Submission Type: Exempt
Instruction Insert (IFU)	20180029 Generic Aspen Suture Aid Booties NS eIFU 70050-003 Suture Aid Booties Sterile eIFU Available with product and on Aspen's website: https://www.aspensurgical.com/education/instructions-for-use/
Material Composition	Suture Aid Booties Configuration: Suture Aid Booties Pad: Foam: Minicel Adhesive: Modified Acrylic Liner: Densified Kraft Suture Aid Booties: Medical Grade Vinyl Barium Sulfate Suture aid booties do not contain reportable amounts of: <ul style="list-style-type: none"> • Natural latex rubber • Polyvinylchloride (PVC) • Bis (2-ethyhexyl) phthalate (DEHP) • Bisphenol A (BPA) • Potential contamination by bovine or transmissible spongiform encephalopathies (BSE/TSE).



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	<ul style="list-style-type: none"> 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	Diisononyl phthalates (DINP) are found within suture aid booties and the user will receive a clear and reasonable warning
Biological/Biocompatibility Report	<p>The following tests were performed per ANSI/AAMI/ISO 10993:</p> <p>Cytotoxicity per ISO 10993-5:2009</p> <p>Sensitization / Delayed-type hypersensitivity</p> <p>Irritation (including intracutaneous reactivity)</p> <p>Acute Systemic Toxicity</p> <p>Material-Mediated Pyrogenicity</p> <p>Conclusion: Devices do not pose biological risk</p>
GMDN Number and EMDN Number, if applicable	<p>GMDN: 35257, Vascular Boots</p> <p>EMDN: H9099, Suture Devices-Other</p>
Shelf Life	5 years
Country of Origin	USA
Tariff Codes	<p>HTS: 9018.90.2000</p> <p>HS: 9018.90.8000</p>
Radiopaque	Product is radiopaque