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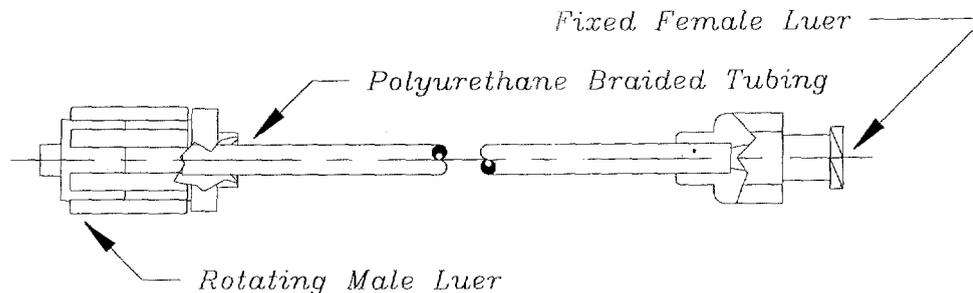
Summary of Safety and Effectiveness
for
ASC High Pressure Braided Tubing
submitted by
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Identification of a Legally Marketed Predicate Device

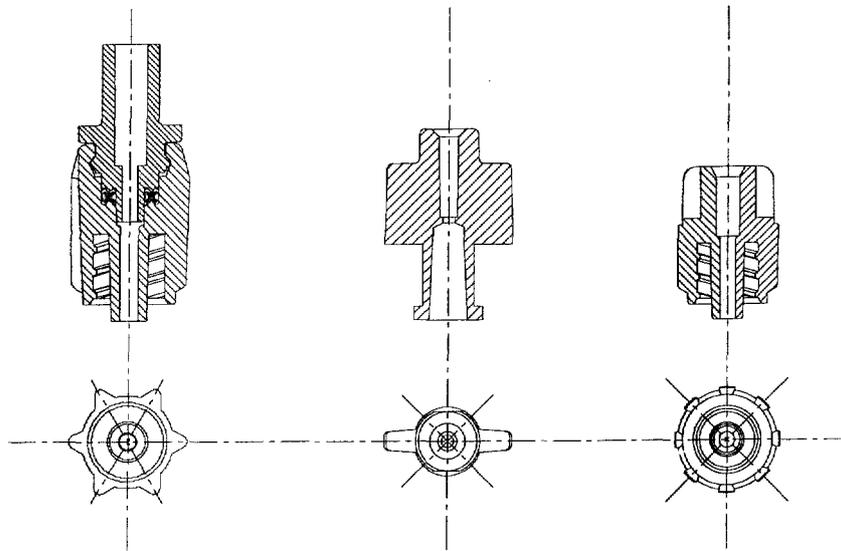
The Adam Spence Corporation High Pressure Braided Tubing (HPBT) is substantially equivalent to the High Pressure Catheter Connector that is manufactured and marketed by the USCI® Bard Corporation.

Device Description

The HPBT are sterile, single use, disposable devices, that are delivered non-toxic and non-pyrogenic. The HPBT consists of braided polymeric tubing terminated at both ends with luer connectors. The luer connector may be one of three types: male, male rotating, or female. A typical HPBT is shown below. Cross-sectional views of the three luer connectors are shown on the next page. The tubing has three sub-components: extrusion base coat, reinforcement nylon braid, and extrusion top coat.



Typical HPBT



Cross-sectional Views

Intended Use

ASC High Pressure Braided Tubes are accessory devices to angiographic catheters intended to provide an extended luminal connection between an angiographic injector and an angiographic catheter for the purpose of delivering radiopaque contrast medium to selected sites in the vascular system.

Summary of Technological Characteristics

The table below compares the technological characteristics of the HPBT to the predicate device.

Feature	HPBT	Predicate Device
Manufacturer	Adam Spence Corporation	USCI [®] Bard Corporation
Sterile packaging	Mylar [®] and Tyvek [®] heat seal pouch	Mylar [®] and Tyvek [®] heat seal pouch
Sterilization method	Ethylene Oxide Gas	Ethylene Oxide Gas
Pyrogenicity	Non-pyrogenic	Non-pyrogenic
Shelf life	3 years	Not shown in labeling
Available with rotating or non-rotating male luer lock connectors	Yes	Non-Rotating Only
Available working lengths (inches)	10, 16, 20, 30, and 48	10 and 20

Feature	HPBT	Predicate Device
Intended use	ASC High Pressure Braided Tubes are accessory devices to angiographic catheters intended to provide an extended luminal connection between an angiographic injector and an angiographic catheter for the purpose of delivering radiopaque contrast medium to selected sites in the vascular system.	USCI® Catheter Connectors are designed to provide an extension from an angiographic catheter to a standard automatic contrast media (dye) injector.
Nominal Inside Diameter (Inches)	0.071	0.105
Nominal Outside Diameter	0.142	0.208
Luer material	Polycarbonate	Polycarbonate
Reinforcement braid material	Nylon	Non-braided
Tubing material	Polyurethane	Vinyl
Rated pressure (PSI)	1200	1100

Summary of Performance Data

The HPBT complies with the following standards, practices, and guidances:

- Medical Devices—Validation and Routine Control of Ethylene Oxide Sterilization, ANSI/AAMI/ISO 11135-1994, Approved March 24, 1994 by the American National Standards Institute, Inc.
- Ethylene Oxide, Ethylene Chlorhydrin, and Ethylene Glycol, Proposed Maximum Residue Limits and Maximum Levels of Exposure, 21 CFR, § 821.100, Proposed Rule, June 23, 1978
- Biological Evaluation of Medical Devices—Part 7: Ethylene oxide sterilization residuals, American National Standard, ANSI/AAMI/ISO 10993-7:1995
- Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment — General Requirements: International Standards Organization Reference Number 594-1:1986 (E)
- Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment — lock fittings: International Standards Organization Reference Number 594-2:1991 (E)
- Biological Evaluation of Medical Devices, ISO-10993-1

The HPBT is substantially equivalent to High Pressure Catheter Connector which is legally marketed by the USCI[®] Bard Corporation. This has been demonstrated by extensive bench testing of both devices. Testing includes component tensile strength, static burst strength, and luer compatibility. Furthermore, the device has similar technological characteristics to High Pressure Catheter Connector which is legally manufactured by the USCI[®] Bard Corporation.

All direct and indirect blood contact materials used to fabricate the HPBT pass the testing required by ISO-10993-1. These materials are currently used in many disposable medical devices.

Since the HPBT meets the requirements of the stated standards and embodies technological characteristics essentially identical to the predicate device, we believe the device is safe and effective and performs as well as or better than the predicate device. The HPBT will be manufactured per specifications and good manufacturing practices that ensure the device is safe and effective for its intended use.