

K904814

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SUMMARY OF SAFETY AND EFFECTIVENESS  
BIPORE ACCUFLEX™ PERCUTANEOUS SHEATH INTRODUCER  
November 26, 1996

**Trade Name:** Bipore AccuFlex™ Percutaneous Sheath Introducer

**Manufacturer:** Bipore, Inc.  
31 Industrial Parkway  
Northvale, NJ 07647  
Tel: (201) 767-1993 Fax: (201) 767-0435

**Device Generic Name:** Sheath Introducer

**Classification:** Class II, Performance Standards

**Predicate Device:** Arrow Super Arrow-Flex™ Percutaneous Sheath Introducer  
510(k): K924607

**Description of Device:** The Bipore AccuFlex™ Percutaneous Sheath Introducer is a wire-reinforced flexible tube with an integral side port/hemostasis valve at the proximal end.

**Indications for Use:** The Bipore AccuFlex™ Percutaneous Sheath Introducer is designed to be used for the percutaneous introduction of various devices into arteries and/or veins for diagnostic and therapeutic procedures.

**Safety and Performance:** Information concerning adverse health effects for this type of product is presented here and in the Instructions for Use. Generally, the potential complications for devices of this type are:

Vessel wall perforation	Bacteremia
Pleural and mediastinal injuries	Septicemia
Air embolism	Thrombosis
Thoracic duct laceration	Nerve damage
Inadvertant vessel puncture	Hematoma formation
Hemorrhage	Dysrhythmias

**Conclusion:** Based on the indications for use, technological characteristics, and mechanical tests the Bipore AccuFlex™ Percutaneous Sheath Introducer is safe and effective for its intended use.