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Bard Vascular Systems Division
C.R. Bard, Inc.
25 Computer Drive
Haverhill, MA 01832
508-373-1000



510(k) SUMMARY FOR THE BARD® GRAFT SIZER

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter Information

Submitter's Name: Bard Vascular Systems, C.R. Bard Inc.
Address: 25 Computer Drive, Haverhill, MA 01832
Phone #: (508) 373-1000
Fax #: (508) 374-6200
Contact Person: Sandra L. Perreand
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B. Device Name

Trade Name: Bard® Vascular Graft Sizer
Common/Usual Name: graft sizer
Classification Name: vascular graft prosthesis, 6mm greater accessory

C. Predicate Device

Trade Name: Meadox Graft Sizer

D. Device Description

This vascular graft sizer is a caliper-type design consisting of two parts: a graft sizer scale and a graft sizer pointer. These are joined together with an eyelet to allow the pointer to rotate. This device may measure inner diameter (I.D.) Of a blood vessel from 6mm to 38mm and the outer diameter (O.D.) From 2mm to 38mm. In addition, on the opposite side, there is a 9cm ruler, graded to a 1mm scale.

E. Intended Use

The Bard® Vascular Graft Sizer is designed to assist the physician in determining the relationship between the inner and outer diameter of the patient's blood vessel and the appropriate vascular graft diameter. The ruler may also aid in determining vessel/graft lengths.

F. Technological Characteristics Summary

Both the Bard graft sizer and the Meadox graft sizer are intended to be used in assisting the physician in measuring a patient's blood vessel(s) in order that he/she may select a vascular graft of appropriate size. Both devices are hand held, manually operated devices which obtain measurements by aligning the edges of the device to the inner or outer edge of the vessel, however, the Bard Graft Sizer is of a different design and is manufactured using slightly different materials than the Meadox Graft Sizer. For a comparison of the two device designs and material characteristics see Table VI-I below.

Table VI-I Comparison of General Characteristics

CHARACTERISTICS		BARD GRAFT SIZER	MEADOX GRAFT SIZER
Indications For Use (from the device's IFU)		The Bard [®] Vascular Graft Sizer is designed to assist the physician in determining the relationship between the inner and outer diameter of the patient's blood vessel and the appropriate vascular graft diameter. The ruler may also aid in determining vessel/graft lengths.	The MEADOX Graft sizer is designed to aid the physician in determining the relationship between the size of the patient's blood vessel and the appropriate graft diameter.
Contraindications		None	None
Packaging		Peel Pull style pouch. Each unit is placed in it's own unit box.	Peel Pull style pouch. Each unit is boxed with a vascular graft.
Sterilization		Gamma Radiation	Gamma Radiation
Method of Operation		Manual	Manual
Range of Measure		From 6mm-38mm ID From 2mm-38mm OD	Obturator available in sizes 5,6,7,8,9,10,11,12,14,16,18 20,22,and 24 mm.
Component Materials	Pointer	Polyester	N/A
	Scale	Polystyrene	N/A
	Eyelet	brass	N/A
	Pointer silkscreen	Medical Grade PVC ink	N/A
	Scale Silkscreen	Medical Grade PVC ink	N/A
	Meadox obturators	N/A	polystyrene

G. Performance Data

The Bard Vascular Graft Sizer was subjected to biocompatibility testing as outlined in FDA's May 1, 1995 General Program memorandum- #G95-1 Attachment A. All testing was successfully completed.