BARD®

Cardiovascular Fabrics, Surgical Felts and Pledgets

Proven to be Successful in Surgery

BARD | PERIPHERAL VASCULAR

BARD FULL LINE OF CARDIOVASCULAR FABRICS...

...offers the surgeon a choice of synthetic patch materials which have been proven to be successful in surgery for the repair of septal defects and for patch grafting.

CARDIOVASCULAR FABRICS

Product/Indications	Product Code	Size (cm)	Nominal Thickness (mm)	Size (inches)	Units/Box
Knitted Polyester					
BARD® SAUVAGE® Filamentous Fabric Recommended for patch graft angioplasty such as in carotid endarterectomy procedures and ASD/VSD repairs	007940	1.0 x 15.2	0.61	3/8 x 6	10
	007942	2.5 x 10.2	0.61	1 x 4	10
	007943	5.1 x 5.1	0.61	2 x 2	10
	007944	5.1 x 10.2	0.61	2 x 4	10
	007828	10.2 x 10.2	0.61	4 x 4	5
	007829	15.2 x 15.2	0.61	6 x 6	5
BARD® DEBAKEY® Double Velour Fabric Used for patch graft angioplasty and repair of intracardiac defects	007937	2.5 x 10.2	1.50	1 x 4	10
	007939	5.1 x 10.2	1.50	2 x 4	10
	007826	10.2 x 10.2	1.50	4 x 4	5
	007827	15.2 x 15.2	1.50	6 x 6	5
BARD® DEBAKEY® Elastic Knit Fabric Used for patch graft angioplasty and repair of intracardiac defects	007830	10.2 x 10.2	0.57	4 x 4	5
	007831	15.2 x 15.2	0.57	6 x 6	5
Woven Polyester					
BARD® DEBAKEY® Woven Fabric A thin, lower permeability fabric for use in outflow tract repairs, patch graft angioplasty, and septal defects	007957	5.1 x 10.2	0.28	2 x 4	10
	007955	10.2 x 10.2	0.28	4 x 4	5
	007956	15.2 x 15.2	0.28	6 x 6	5
Knitted PTFE					
BARD® Edwards Outflow Tract Fabric Lower permeability material used for aortic and pulmonary outflow tract patching and intracardiac defects	007979	5.1 x 10.2	0.91	2 x 4	10
	007834	10.2 x 10.2	0.91	4 x 4	5
	007835	15.2 x 15.2	0.91	6 x 6	5

For the purpose of tissue approximation, as a temporary or permanent ligature, and to retract vessels during a surgical procedure.

BARD SELECTION OF SURGICAL FELTS...

...gives the surgeon several options in material thickness and permeability. These felts are used in various ways in cardiac surgery, most commonly as a patch, a buttress for sutures, and a material used in procedures that reinforce large segments of the left ventricular myocardium.

SURGICAL FELTS

Product/Indications	Product Code	Size (cm)	Nominal Thickness (mm)	Size (inches)	Units/Box
BARD® Polyester Felt Used as a buttress for sutures and friable tissue	008972	15.2 x 15.2	1.65	6 x 6	5
BARD® Low Porosity PTFE Felt Low porosity helps to control bleeding	007021	2.5 x 2.5	1.85	1 x 1	5
	007838	10.2 x 10.2	1.85	4 x 4	5
	007839	15.2 x 15.2	1.85	6 x 6	5
BARD® PTFE Felt Used as a buttress for sutures and friable tissue	007974	0.6 x 5.1	1.65	1/4 x 2	10
	007975	1.3 x 10.2	1.65	1/2 x 4	10
	007973	2.5 x 2.5	1.65	1 x 1	10
	007968	2.5 x 10.2	1.65	1 x 4	10
	007976	2.5 x 15.2	1.65	1 x 6	10
	007977	5.1 x 5.1	1.65	2 x 2	10
	007836	10.2 x 10.2	1.65	4 x 4	5
	007837	15.2 x 15.2	1.65	6 x 6	5
BARD® PTFE Felt (Thick) Extra thickness provides added support to tissue	007018	1.0 x 15.2	2.87	3/8 x 6	20
	007019	2.5 x 2.5	2.87	1 x 1	5
	007958	10.2 x 10.2	2.87	4 x 4	5
	007959	15.2 x 15.2	2.87	6 x 6	5

PTFE FELT PLEDGETS

Product/Indications	Product Code	Size (mm)	Nominal Thickness (mm)	Size (inches)	Units/Box	Shape	Size Guide (1:1)
BARD® PTFE Felt Pledgets Used as buttresses under sutures when there is a possibility of sutures tearing through tissue. These pledgets are used in various surgical suturing procedures, such as vascular closure, septal repair, myocardial closure, and valvular suturing	007970	4.8 x 6.0	1.65	3/16 x 1/4	250	Rectangle	
	007963	4.8 x 9.5	1.65	3/16 x 3/8	250	Rectangle	
	007972	7.9 x 7.9	1.65	5/16 x 5/16	250	Square	
	007965	6.0 x 6.0	1.65	1/4 x 1/4	250	Square	
	007969	4.8 x 6.0	1.65	3/16 x 1/4	250	Oval	
	007984	4.8	1.65	3/16	250	Round	
BARD® PTFE Felt Pledgets (Thick)	007971	6.0	2.87	1/4	250	Round	

PTFE Felt Pledgets are packed 10 per sterile pouch, 25 pouches per box.

BARD®

Cardiovascular Fabrics, Surgical Felts and Pledgets

BARD® Cardiovascular Fabrics

Indications for Use:
1) The knitted and woven polyester fabrics (BARD® SAUVAGE® Filamentous fabrics, BARD® DEBAKEY® Double Velour fabrics, BARD® DEBAKEY® Elastic Knit fabrics, BARD® DEBAKEY® Woven fabrics) are indicated for use in cardiovascular surgical procedures requiring patch graft angioplasty such as carotid endarterectomy. These fabrics are also indicated for repair of certain intracardiac anomalies such as septal defects. **2)** DEBAKEY® Woven Fabrics and Edwards Outflow Tract Fabrics are indicated for aortic and pulmonary outflow tract repair and repair of intracardiac defects.

Contraindications:
Due to the high permeability of the knitted polyester fabrics, they are contraindicated for use in patients requiring prolonged systemic or high dose heparinization except for use in repair of intracardiac defects.

Warnings:
1) These fabrics must be properly preclotted with non-heparinized blood prior to exposure to full arterial pressure to avoid unnecessary bleeding or blood loss. Preclotting is not required when the fabrics are used in the intracardiac position. **2)** While it is common practice to employ moderate doses of intraoperative heparin, care should be taken not to exceed the manufacturer's recommended dose for such procedures. Excessive amounts of heparin can result in bleeding. **3)** Due to variability in patient response to heparinization, it is essential that the adequacy of anticoagulation during surgery and the precision of neutralization at the conclusion of the procedure be closely monitored. Adherence to a strict protocol, determined by each hospital, can prevent excessive bleeding. **4)** As with any cardiovascular fabric, occasional difficulties with hemostasis may occur. In the event that hemostasis is not easily obtained, the surgeon may wish to consider the following: • Investigate for systemic coagulopathy and treat appropriately. • Compression, as necessary. • Additional sutures and/or pledgets at the anastomosis, as necessary. • Reversal of heparin with protamine sulfate, as necessary. • Utilization of topical coagulation therapy, e.g., thrombin, as necessary. **5)** As with all woven fabric constructions, care must be taken when trimming the fabric to minimize the potential for fraying at cut edges. Cautery is highly recommended for heat sealing on all woven patch edges. If the edges of the fabric are not heat sealed, then sutures must be at least 2 mm from the cut edge. **6)** Do NOT expose PTFE Fabrics to temperatures greater than 500°F (260°C). PTFE decomposes at elevated temperatures, producing highly toxic decomposition products.

Precautions:
1) STERILE, unless the package is opened or damaged. Single use only. **2)** These products are sterilized by ethylene oxide. DO NOT RESTERILIZE. **3)** Care should be taken when clamping the fabrics to avoid damage to the fibers and preclot. Only atraumatic, shod-type vascular clamps should be used. **4)** Taper point, noncutting needles are recommended so the fabric fibers will not be cut during suturing. **5)** After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Potential Adverse Reactions:
Adverse reactions that may occur with the use of these products or with any cardiovascular implant procedure include: • Anastomotic aneurysms • Implant bleeding • Infection • Perioperative hemorrhage • Tissue erosion

BARD® Surgical Felts and Pledgets

Indications for Use:
BARD® PTFE and Polyester Surgical Felts are used in various applications for general, vascular and cardiac surgery. They are most commonly used as a patch, a buttress for sutures, and as a material for replacement of segments of the ventricular myocardium after resection.

BARD® PTFE Felt Pledgets are used as buttresses under sutures when there is a possibility of sutures tearing through tissue. These pledgets are used in various surgical suturing procedures, such as vascular closure, septal repair, myocardial closure, hepatic repair and valvular suturing.

Contraindications:
None known.

Warnings:
1) When used as a permanent ligature, care should be taken with surgical tapes to insure that the knots are secure. **2)** Do NOT expose PTFE products to temperatures greater than 500°F (260°C). PTFE decomposes at elevated temperatures, producing highly toxic decomposition products.

Precautions:
1) STERILE, unless the package is opened or damaged. Single use only. **2)** These products are sterilized by ethylene oxide. DO NOT RESTERILIZE. **3)** Only atraumatic instruments should be used. **4)** Taper point, noncutting needles are recommended when surgical tapes are used as an implant material so the fibers will not be cut during suturing. **5)** Avoid excessive manipulation of the felt surface prior to use. **6)** To assure that felt fibers are cleanly cut and not pulled apart, it is important to use a sharp cutting device or scissors with sharp blades when cutting felt in to smaller pieces. **7)** After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Potential Complications:
Potential complications that may occur with the use of these products or with any vascular implant procedure include: • Infection • Tissue erosion

Please consult package insert for safety information and instructions for use.

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Additional information is available on request

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