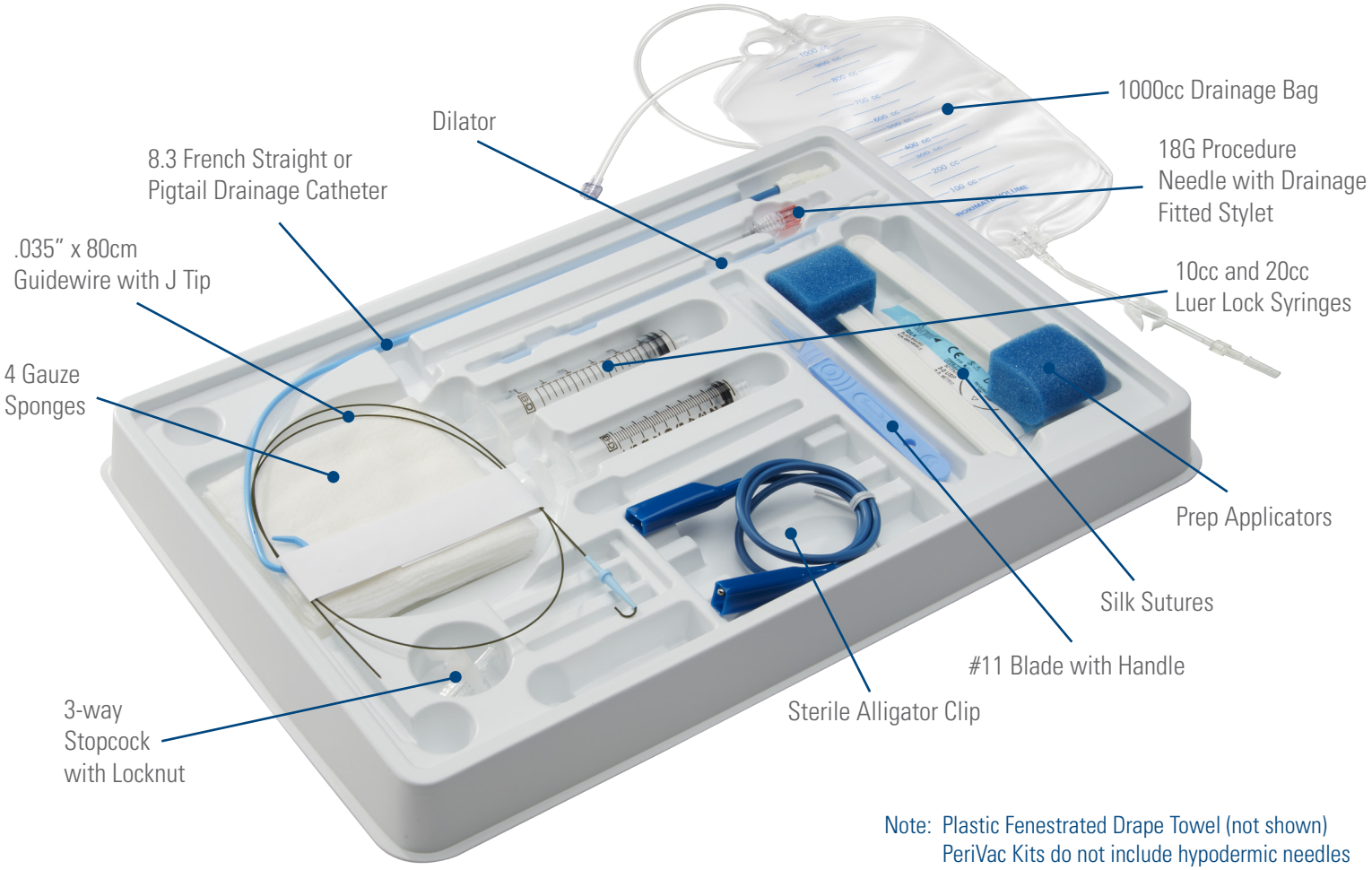
Boston Scientific
Advancing science for life™

PERIVAC™
PERICARDIOCENTESIS KITS

PRE-ASSEMBLED KIT FOR PERICARDIAL DRAINAGE PROCEDURES



Note: Plastic Fenestrated Drape Towel (not shown)
PeriVac Kits do not include hypodermic needles

PROVIDES THE ESSENTIALS FOR PERICARDIAL DRAINAGE/ASPIRATION

Featuring the Flexima® Pigtail Drainage Catheter

8.3F Catheter size with sideholes for drainage

To Order, Call Boston Scientific
Customer Service at 1-888-272-1001

PERIVAC™
PERICARDIOCENTESIS KITS

Ordering Information

Model	Description	Quantity
M004 4305 1	PeriVac with 8.3F / Pigtail Catheter plus Clip	Box of 3 Kits
M004 4315 1	PeriVac with 8.3F / Straight Catheter plus Clip	Box of 3 Kits
M004 400 1	Spare 1000cc Drainage Bag (individually sterilized)	Box of 3 Kits

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PERIVAC™ KIT from Boston Scientific INDICATIONS FOR USE: The PeriVac Kit is intended for use in pericardial aspiration and drainage in the presence of pericardial effusion or tamponade.

CONTRAINDICATIONS: There are no known contraindications for pericardial aspiration, although recurrent effusion or unresolved tamponade may warrant surgical intervention.

WARNINGS: Pericardiocentesis should be performed only by physicians thoroughly trained in invasive cardiology and in the techniques of pericardiocentesis and in the specific approach to be used, in the Special Procedures Laboratory or Cardiac Catheterization Laboratory, utilizing equipment capable of cardiac monitoring. When performed at bedside, electrocardiographic monitoring should be employed continuously. Coagulation therapy may be required for patients that have been anti-coagulated to prevent excessive bleeding. The risk of bleeding (which can occur due to needle laceration of the heart, or from other causes) should therefore be weighed carefully vs. the risks and benefits of anticoagulation and any treatment given to reverse the anticoagulation before proceeding with the pericardiocentesis.Take proper care to ensure that all patient-contact electrical equipment is properly isolated and grounded and to ensure that there is no electrical potential difference and that the cardiac monitor meets relevant safety standards to reduce the risk of inadvertent arrhythmia induction and/or electrical shock to the patient and staff. If a current of injury pattern is observed on the ECG V lead connected to the procedure needle, withdraw the procedure needle as this indicates myocardial contact has occurred. Carefully advance the pericardial needle, guidewire and/or catheter into the pericardial sac to avoid inadvertent injury to adjacent structures. Do not reintroduce effluent to patient. Do not leave the pigtail catheter in the patient for longer than 24 hours. If a pigtail catheter is left in the patient for drainage, it should not be left in place for longer than 24 hours due to the hazard of introducing sepsis. Ensure that the external portion of the guidewire is stabilized prior to catheter introduction to reduce the risk of inadvertent advancement resulting in perforation.If resistance is encountered during advancement or withdrawal of the catheter, STOP. DO NOT CONTINUE without first determining the cause of the resistance and taking remedial action. Vascular damage and/or cardiac perforation are risks with any intracardiac catheter. If it is necessary to reintroduce the guidewire, use extreme caution to assure that the guidewire exits through the end hole. Damage to the catheter may occur if the guidewire exits through a side hole and may cause fracture to the catheter and/or guidewire that may result in an unretrieved device fragment or catheter/guidewire entrapment. The occurrence of either complication may necessitate surgical intervention and/or repair of injured tissue. If hemorrhagic fluid is aspirated, confirm, if possible using contrast media and fluoroscopic guidance, that the needle tip is in the pericardial space and not within the right or left ventricle or coronary artery. Movement of the patient with the straight catheter in place is not recommended due to risk of cardiac perforation. Patients undergoing pericardiocentesis procedures should be closely monitored during and post procedure for clinical manifestations of arrhythmias, embolism, hemorrhage, pericarditis, sepsis and/or recurrent pericardial effusions/tamponade.

PRECAUTIONS: Before use, inspect contents of the kit for physical damage including electrical insulation on the cables and other damage on the shaft of the catheter. Replace damaged components. If no drainage is seen accumulating over several hours, the lumen of this catheter may be obstructed by cellular debris. Gentle flushing of the catheter with sterile saline may be requested by the physician. Careful attention to aseptic technique should be employed. Do not wipe catheter with organic solvents (e.g. alcohols, ethers, esters, phenols, etc.) CT scan, fluoroscopic, or echocardiographic examinations are recommended to evaluate needle and catheter placement.

ADVERSE EVENTS: Potential adverse events (in alphabetical order), that have been or may be associated with pericardial drainage procedures:

- Allergic reaction
- Arrhythmias
- Death
- Edema
- Embolism
- Endocarditis
- Hemorrhage
- Hemothorax or Pneumothorax
- Hypotension/Hypertension
- Pain/Discomfort
- Pericardial Effusion
- Pericarditis
- Perforation of the Ventricle, Atrium, Coronary Vessel or other cardiac structure
- Sepsis/Infection
- Surgical intervention
- Tamponade.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

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EP-143805-AB SEP2015