

Berenstein Occlusion Balloon Catheter (Large Lumen)

Advancing Vessel Occlusion

- Increased Strength and Reliability
 - Soft, compliant latex material is designed to increase balloon burst strength during multiple inflations
 - Stronger balloon bond increases reliability (6F and 7F)
 - Improved nylon material is designed to increase catheter shaft strength (6F and 7F)
- Greater Procedural Efficiency
 - Radiopaque catheter shaft is designed to improve visibility
 - Larger balloon lumen diameter is designed to allow for faster balloon deflation (6F and 7F)
 - Non-tapered catheter shaft facilitates the coaxial use of small catheters and infusion of embolics

Ordering Information

UPN	Order Number	French Size (F)	Lumens	Usable Length (cm)	Recommended Guidewire	Inflated Balloon Diameter
M001173010	17-301	6.0	Dual	80	.038	11.5

Indications

Boston Scientific Occlusion Balloon Catheters are designed for temporary vessel occlusion in applications including arteriography, preoperative occlusion, emergency control of hemorrhage, chemotherapeutic drug infusion and renal opacification procedures.

The Occlusion Balloon Catheter product line consists of two specific designs – Standard Occlusion Balloons and Berenstein Occlusion Balloon Catheters.

Only the Berenstein Occlusion Balloon Catheter has been designed for coaxial delivery of small catheters or embolic agents.

Contraindications

Boston Scientific Occlusion Balloon Catheters are not designed for use in embolectomy procedures.

Boston Scientific Occlusion Balloon Catheters are not designed for use as vascular flow-directed catheters (Swan-Ganz type).

Any use for procedures other than those indicated in the instructions is not recommended.

Warnings

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative. For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

LATEX: CAUTION: This product contains natural rubber latex which may cause allergic reactions.

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Potential Adverse Effects

The complications that may result from an occlusion balloon procedure include:

- vessel perforation
- vessel spasm
- hemorrhage
- hematoma
- hypotension
- pain and tenderness
- arrhythmias/bradycardia
- sepsis or infection
- systemic embolization
- endocarditis
- short-term hemodynamic deterioration or instability
- death
- vascular thrombosis
- drug reactions
- allergic reactions to contrast medium
- pyrogenic reaction
- arteriovenous fistula
- thromboembolic episodes
- vessel dissection
- air embolism

Cautions

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these and other instructions relevant to the procedure. Failure to do so may result in complications.

CAUTION: A thorough understanding of the technical principles, clinical applications, and risks associated with occlusion procedures is necessary before using this product.

**Boston
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Delivering what's next.™

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Ordering Information
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