

BLAZER™ Dx-20

BIDIRECTIONAL DUODECAPOLAR DIAGNOSTIC CATHETER

Built on the trusted Blazer platform

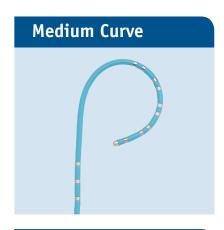


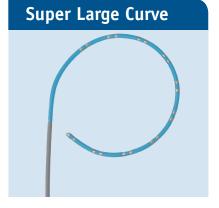
Bidirectional steering to facilitate CS access and advancement



Technical Information

Description	Specifications
Shaft Diameter	7F
Usable Length	109cm / 100cm
Electrode Material	Platinum/Iridium
Curve Size	Super Large / Medium
Curve Direction	Bidirectional/Symmetric
Configuration	Duodecapolar
Curve Diameters	Super Large = 56mm Medium = 25mm





Suggested catheter configurations are illustrative representations only and may not reflect actual performance.

Cable model no. M004 20S 0 can be 10x resterilized using EO (Ethylene Oxide) and Sterrad processes.

BLAZER[™] **Dx-20**

BIDIRECTIONAL DUODECAPOLAR DIAGNOSTIC CATHETER

Ordering Information

BLAZER Dx-20 Steerable Diagnostic Catheter for Alternative CS RA Placement

Model Number	Electrode Configuration	Electrode Spacing (mm)	Cable Model Number
M004 20ML222 0	Duodecapolar	2/2/2	M004 20S 0
M004 20M252 0	Duodecapolar	2/5/2	M004 20S 0
M004 20M21035 0	Duodecapolar	2/10/2/10/2/10/2/10/2/35/2/10/2/10/2/10/2/10/2	M004 20S 0
M004 20M25505 0	Duodecapolar	2/5/2/5/2/5/2/5/2/50/5/5/5/5/5/5/5/5/5	M004 20S 0

Note: All BLAZER Dx-20 Catheter Medium Curve models are 109 cm in length.

Ordering Information

BLAZER Dx-20 Steerable Diagnostic Catheter for Standard Placement

Model Number	Electrode Configuration	Electrode Spacing (mm)	Cable Model Number
M004 20SL222 0	Duodecapolar	2/2/2	M004 20S 0
M004 20SL252 0	Duodecapolar	2/5/2	M004 20S 0
M004 20SL555 0	Duodecapolar	5/5/5	M004 20S 0
M004 20SL282 0	Duodecapolar	2/8/2	M004 20S 0
M004 20SL2102 0	Duodecapolar	2/10/2	M004 20S 0
M004 20SL2860 0	Duodecapolar	2/8/2/8/2/8/2/8/2/80/2/8/2/8/2/8/2/8/2	M004 20S 0
M004 20SL22025 0	Duodecapolar	2/20/2/2/2/2/2/2/2/2/2/2/25/2/25/2/25/2	M004 20S 0

Note: All BLAZER Dx-20 Catheter Super Large Curve models are 100 cm in length.

Blazer Dx-20 Bidirectional Steerable Diagnostic Catheter from Boston Scientific INTENDED USE: The Blazer Dx-20 Catheter is ise in electrophysiology studies for intracardiac stimulation (pacing) and/or recording of electrical potentials CONTRAINDICATIONS: Caution should be exercised, in the use of these or any other catheters, in patients with prosthetic valves. Patients with recurrent sepsis or with hypercoaguable state should not be considered candidates for transvascular catheters, since the catheter could serve as a focal point for septic or blood thrombus formation. Care should be taken during placement and removal of this or any diagnostic catheter, so as to avoid disturbing permanent internal pacing/defibrillation leads. The Blazer Dx-20 Catheter is contraindicated for transseptal approach in patients with atrial thrombus or myxoma, or interatrial baffle or patch. The Blazer Dx-20 Catheter is contraindicated for use from the femoral approach in patients who have vena cava embolic protection filter devices or known femoral thrombus. WARNINGS: The device(s) should be used by physicians thoroughly trained in the techniques of invasive cardiology and in the specific approach to be used. Care must be taken to ensure that any equipment used in connection with the BSC Catheter meet IEC 60601-1 electrical safety and IEC 60601-1-2 electromagnetic compatibility requirements, be type CF, be defibrillation proof, system configurations meet IEC 60601-1-1 electrical safety requirements and comply with local regulatory requirements for the specified intended use. No modification of this equipment is allowed. The use of catheters or cables with unprotected male pin connectors presents a risk of electrical hazard. Inadvertent attachment of pin connectors to power supply sockets of connectors could result in electrocution of the patient or operator. Do not use Blazer Dx-20 Catheter as an internal defibrillation catheter. Doing so may result in perforation, arrhythmias, embolism, thrombus, and/or patient death. Diagnostic electrophysiology involves x-ray exposure that presents the potential risk for somatic and genetic effects to both patients and laboratory staff due to the x-ray beam and intensity and duration of the fluoroscopic imaging Steps should be taken to minimize this exposure as much as possible. Careful catheter manipulation must be performed to avoid cardiac damage, perforation, or tamponade. Catheter advancement should be performed under fluoroscopic guidance. Do not use excessive force to advance or withdraw the catheter when resistance is encountered. Stimulation of cardiac tissues caused by pacing stimuli may lead to inadvertent induction of arrhythmias. These arrhythmias may require defibrillation that could also result in skin burns. Do not use if package is opened or damaged. This catheter is not indicated for use in Cardiac Ablation or Coronary Artery Mapping. **PRECAUTIONS:**• Excessive bending or kinking of the catheter shaft may damage internal wires. Manual prebending of the distal curve can damage the steering mechanism and/or electrical wires and may cause patient injury. • Before using, check shelf life. Do not use catheter after expiration date. ADVERSE EVENTS: The following potential risks or discomforts may be associated with diagnostic BSC procedures. The frequency and severity of these adverse events can vary and may necessitate additional medical intervention, including surgery.

**Allergic reaction **Arrhythmias **Cardiac or respiratory arrest **Cardiac valve damage **Catheter entrapment/entanglement **Chest pain ** Damage to vessel intima or cardiac structures • Death • Embolus, air embolus • Hematoma/ecchymosis • Hemorrhage • Hypotension • Infection • Myocardial infarction • Pericardial effusion • Pericarditis/pleuritis • Pneumothorax • Pseudoaneurysm • Pulmonary edema • Sinús or AV node injury • Stroke • Tamponade • Thrombosis • Vasovagal reaction • X-ray exposure CAUTIÓN: 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. 91163156 (Rev AA)



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