

INDICATIONS FOR USE

For use in right atrial electrophysiology procedures to assist in the diagnosis of complex arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e., linear mapping catheters). The Constellation® Multiple Electrode Recording and Pacing Catheter System may also be used for delivery of externally generated pacing stimuli.

CONTRAINDICATIONS

Both the heparin-coated and uncoated version of the Constellation® Catheter and the SoftTip Sheath are contraindicated in patients who cannot be anticoagulated or infused with heparinized saline.

Additionally, use of the Constellation® Catheter is contraindicated in patients with any of the following:

- Permanent leads or prosthetic or stenotic valves present;
- Active systemic infection;
- Echocardiographically-confirmed visual presence of thrombus;
- For whom the inability of obtaining vascular access exists;
- Heparin-induced thrombocytopenia;
- Hemodynamic instability or shock.

WARNINGS AND PRECAUTIONS

- 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 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 that 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.
- This device has not been shown to be safe and effective for use in any cardiac chamber except the right atrium.
- Maintain activated clotting time (ACT) levels above 300 seconds at all times during the procedure and monitor throughout Constellation® Catheter use. Failure to do so may increase the risk of thrombus formation, which could lead to complications.
- Do not leave the catheter in situ more than three hours for the cumulative duration of catheter placement.
- Catheter mapping procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic defects in both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Catheter mapping should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure, and steps have been taken to minimize this exposure. The use of this device in conjunction with radiofrequency ablation, as part of the diagnosis and treatment of cardiac arrhythmias, may pose an increased risk of adverse events, such as cardiac perforation, myocardial infarction, air embolism, and hematoma requiring surgical repair and/or blood transfusion.

PRECAUTIONS SPECIFIC TO CONSTELLATION® CATHETER

- Preclinical and clinical testing show that small thrombi may attach to the basket and splines at locations where there is an abrupt change in geometry. However, there were no clinical sequelae. Ensure the patient is appropriately anticoagulated to ensure thrombus formation is minimized.
- As with percutaneous placement of any large diameter sheath, carefully monitor the vascular puncture site.
- To minimize risk of air embolus, flush the SoftTip Sheath to remove all air before introduction into vasculature. The introduction of the Constellation® Catheter into the SoftTip Sheath also has the potential to introduce air into the SoftTip Sheath. Therefore, during the introduction of the Constellation® Catheter into the SoftTip Sheath, again aspirate fluid to expel any air.
- If other catheters are used concurrently with the Constellation® Catheter, remove those catheters before removing or repositioning the Constellation® Catheter.
- The Constellation® Catheter is NOT intended for use as an ablation catheter.
- Carefully manipulate the catheter to avoid causing cardiac damage, perforation, or tamponade. Advance the catheter under fluoroscopic guidance. Do not advance or withdraw the catheter against excessive resistance. Do not torque the catheter while it is fully deployed.
- Excessive bending or kinking of the catheter shaft may damage internal wires.
- Manual pre-bending of the distal assembly can damage the basket assembly and may cause patient injury. Precautions During Catheter Use Cardiac mapping procedures should be performed only by physicians thoroughly trained in the electrophysiologic techniques in a fully equipped electrophysiology laboratory.
- The soft tip of the SoftTip Sheath has limited radiopacity. Do not advance against resistance.
- Use only isolated amplifiers, pacing equipment, and ECG equipment or patient injury or death may occur. Leakage current from any connected device to the patient must not exceed 10 microAmps under any circumstances.
- Catheter materials are not compatible with magnetic resonance imaging (MRI).
- 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 or connectors could result in electrocution of the patient or operator. Use of components with shrouded pins is highly recommended. Those who use components with unprotected male pin connectors must exercise extreme caution during device setup to prevent patient or operator injury.

INSPECTION PRIOR TO USE

Carefully inspect the package prior to use for any breach of the sterile barrier or damage to the contents. If the sterile barrier integrity is compromised or the contents damaged, contact your Boston Scientific representative.

ADVERSE EVENTS

OBSERVED ADVERSE EVENTS

The Constellation® Catheter was studied in 84 patients undergoing electrophysiologic (EP) mapping and ablation. The number of patients with adverse events (major or minor) was 12 of 84 (14.3%). The difference of 14.3% has a 95% confidence interval of [7.2%, 21.4%].

Constellation®

Full Contact Mapping Catheter



Get the whole picture in a heartbeat.

**Boston
Scientific**

Delivering what's next.™

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For more information about
the Constellation® Catheter,
call Customer Service at
1-888-272-1001

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Constellation[®]

Full Contact Mapping Catheter

Proven Effective and Efficient

- Unique, flexible basket design conforms to atrial anatomy to aid in accurate placement and to save repositioning time
- 64 electrodes provide comprehensive, real-time 3-D information in a single beat
- High resolution electrograms facilitate identification of earliest activation site(s)
- Remote display allows precise orientation of ablation catheter

Comprehensive, Full-Contact Mapping

- Provides comprehensive, real-time mapping in just one heart cycle
- Pacing capabilities facilitate the assessment of entrainment, conduction velocity studies, and refractory period
- Simultaneous longitudinal and circumferential signals for more accurate 3-D mapping
- Super-elastic alloy spline construction

Efficiently map focal arrhythmias *in real-time*

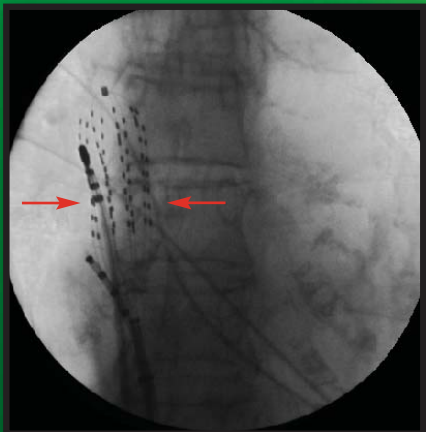
Switching/Locating Remote Display

- Provides comprehensive, real-time visual feedback and efficient 3-D mapping
- Facilitates ablation catheter positioning
- Enables more accurate ablation
- Reduces need for fluoro

D7-8



Fully deployed Constellation Catheter in right atrium



Necking of Constellation Catheter positioned in the SVC Ostium

