

## Implantable Pacing Leads and Risk of Cardiac Perforation

**Product Update** articles provide clinical and/or technical information focused on the performance of Boston Scientific Cardiac Rhythm Management (CRM) products.

### Executive Summary

Permanent cardiac pacing leads serve as an electrical pathway between an implanted pacemaker and the heart. As described in device labeling, one potential complication of lead positioning is cardiac perforation, which can have severe clinical consequences including pericardial effusion, cardiac tamponade, pneumothorax and death. This Product Update (first published on November 1, 2005) provides further emphasis regarding the possible clinical consequences of heart wall perforation, summarizes risk factors for perforation, and offers measures from literature and device labeling to reduce the risk of perforation. Furthermore, while cardiac perforation is not unique to Boston Scientific leads, this update presents relative perforation rates for various Boston Scientific lead fixation types. The potential advantages in placement, fixation, and removal of extendable helix leads need to be balanced against an observed increased risk of cardiac perforation compared with alternative permanent pacing leads.

### Products Referenced\*

Boston Scientific Sweet Tip® Rx, Sweet Picotip® Rx, FLEXTEND®, FINELINE® II Sterox®, FINELINE II Sterox EZ, Selute® Picotip permanent pacing leads.

\*Products referenced herein may not be approved in all geographies.

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### Background

Although rare, cardiac perforation during pacing lead placement can have serious clinical consequences. Indicators of cardiac perforation include lead impedance changes, poor sensing or capture thresholds, diaphragmatic pacing, and/or patient symptoms of chest pain and hypotension. Most perforations are mitigated by the “self-sealing” properties of cardiac tissue<sup>1</sup>. On rare occasion, re-sealing is not accomplished, and life-threatening cardiac tamponade may result. While perforations are most often observed at implant, late complications are a possibility and may be fatal if perforation is not immediately recognized.<sup>2</sup>

The actual rate of cardiac perforation depends on a number of clinical, procedural and technical variables, and may be subject to substantial underreporting. Reporting statistics may be further impacted by the lack of a consistent definition of perforation (symptomatic versus asymptomatic, prospective versus retrospective identification, etc). While some hospital case studies report perforation rates as high as 2%, Sivakumaran et al<sup>3</sup> reported four perforations in 1,021 lead placements (0.4%) with one fatal tamponade. In a recent article entitled *Incidence and Predictors of Cardiac Perforation after Permanent Pacemaker Placement*<sup>4</sup>, Mayo Clinic physicians reported their experiences with another manufacturer’s leads, noting 50 perforations out of 4,280 lead placements (1.2%) with no associated deaths.

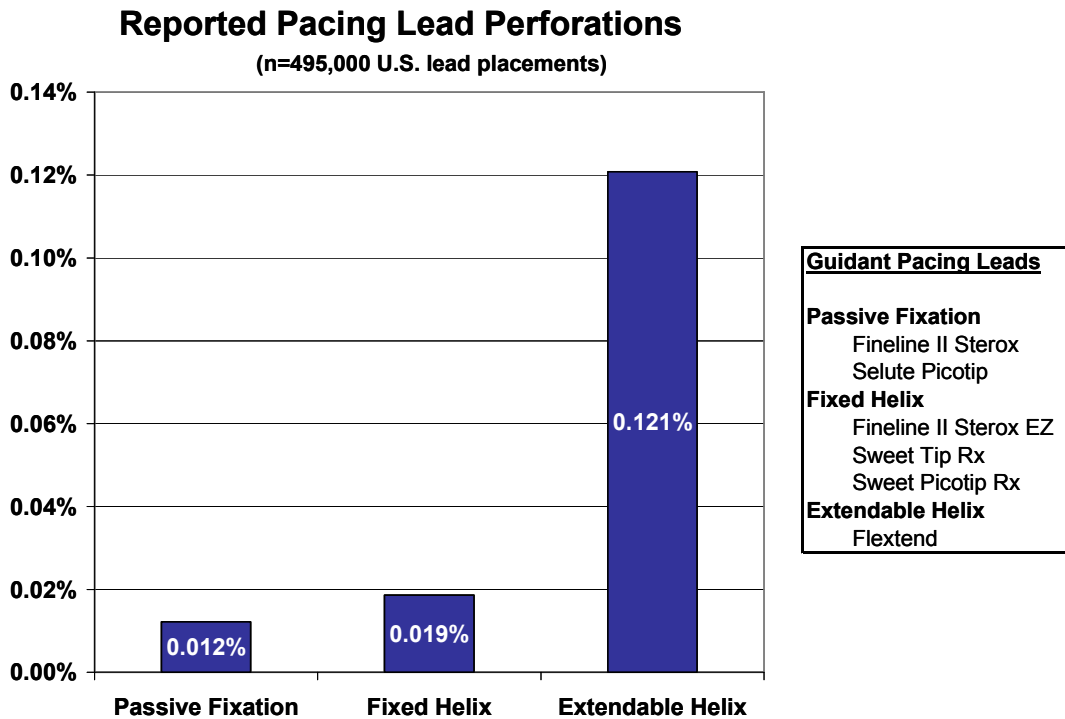
### Boston Scientific pacing lead performance

Analysis of Boston Scientific pacing lead performance data over the past 10 years (United States only) has identified 205 reports of lead perforation out of 495,000 leads placed, which equates to a reported perforation rate of 0.04% per lead implanted. Boston Scientific recognizes that the actual perforation rate may be greater than the reported rate. In

none of these reported instances has there been any confirmed failure of lead integrity relative to design specifications. Included in these 205 reports are 18 medical device reports (8.8% of reports) filed with the United States Food and Drug Administration in which lead perforation has been implicated as the cause of death.

As depicted in Figure 1 below, Boston Scientific lead performance data indicate that lead fixation type (extendable helix versus fixed helix versus passive tines) is a risk factor for cardiac perforation. This observation parallels findings of Mayo Clinic physicians who reported that, with another manufacturer’s leads, extendable helix leads increased the risk of perforation by a factor of 1.4 to 3.8 times when compared to passive fixation leads<sup>4</sup>.

**Figure 1.** Reported lead perforations associated with Boston Scientific leads (United States data as of November 1, 2005)



	Passive Fixation	Fixed Helix	Extendable Helix
Reported perforations	17	44	144
Lead placements	139,000	237,000	119,000
Perforation rate	0.012%	0.019%	0.121%
Reports of patient death associated with perforation	2/17 (11.8%)	5/44 (11.4%)	11/144 (7.6%)

Recent reports<sup>2</sup> have drawn attention to delayed appearance of patient symptoms associated with lead perforation. Boston Scientific analysis of reported perforations indicates that approximately two-thirds were observed in the immediate implant period (within one week), while one-third were reported beyond the first week. Lead fixation type does not appear to impact this ratio.

## Risk factors for cardiac perforation

Several variables have been identified in literature as risk factors for cardiac perforation<sup>1,2,3,4</sup>

### Patient/clinical factors

- Heart wall thickness
- Use of oral steroid within 7 days preceding lead implantation
- Patient age
- Female gender
- Coagulation status
- Body mass index (BMI) less than 20

### Technical/procedural factors

- Lead/stylet stiffness
- Use of a temporary pacemaker
- Use of extendable helix lead fixation
- Lead placement techniques, including over-torque of helix mechanisms
- Number of lead repositionings

## Reducing the risk of cardiac perforation

The following measures have been suggested in literature and/or recommended in device labeling to reduce the likelihood of perforation during permanent lead placement:

- Leads with a fixed helix or passive tines have a lower reported rate of perforation than those with an extendable helix.<sup>4</sup>
- A septal wall position may reduce the risk of extracardiac perforation, particularly for patients with thin ventricular walls.<sup>5,6</sup>
- Exercise caution when utilizing a temporary pacing wire, as risk may be increased by the presence and/or the stiffness of a temporary wire.<sup>4</sup>
- Among patients in whom steroid administration is necessary, minimization of other risk factors should be considered.<sup>4</sup>
- To minimize the force applied when positioning the distal tip of an extendable helix lead against tissue prior to fixation, partially withdraw the stylet.<sup>6</sup>
- Avoid excessive turns of an extendable helix to minimize tissue damage and wall penetration.<sup>6</sup>

Early recognition and appropriate treatment of pericardial effusion are essential in assuring a good patient outcome and avoiding surgical intervention.<sup>7</sup> Easy access to echocardiography and availability of physicians adept at pericardiocentesis are key to minimizing morbidity and mortality.

## Reporting adverse events

Boston Scientific investigates all lead perforation events to identify ways to further mitigate their occurrence. If you should encounter either acute or delayed perforations associated with the use of Boston Scientific leads, please report immediately to your Boston Scientific sales representative or to Boston Scientific Technical Services.

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### References

- <sup>1</sup> Vlay SC. Complications of Active-Fixation Electrodes. PACE Aug 2002; Vol. 25, no.8: 1153-1154.
- <sup>2</sup> Ellenbogen KA, Wood MA, Shepard RK. Delayed complications following pacemaker implantation. PACE Aug 2002; Vol. 25, no.8:1155-1158.
- <sup>3</sup> Sivakumaran S, Irwin ME, Gulamhusein SS, Senaratne MP. Postpacemaker implant pericarditis: incidence and outcomes with active-fixation leads. Pacing Clin Electrophysiol 2002; 25:833-837.
- <sup>4</sup> Mahapatra S, Bybee KA, Espinosa RE, Sinak LJ, McGoan MD, Hayes, DL. Incidence and predictors of cardiac perforation after permanent pacemaker placement. Heart Rhythm 2005; 2:907-911.
- <sup>5</sup> Ellenbogen KA, Wood MA. Techniques of pacemaker implantation and removal. Fourth Edition of "Cardiac Pacing and ICDs"; Blackwell Publishing; 5:218
- <sup>6</sup> Boston Scientific instructions for use, FLEXTEND Model 4086/4087/4088, FLEXTEND II Model 4095/4096/4097.
- <sup>7</sup> Leloir P. Accidents will happen (so be prepared); Editorial commentary; Heart Rhythm 2005; 2:912-913.