ST. JUDE MEDICAL™

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# Effects of Therapeutic Radiation on St. Jude Medical Implantable Cardiac Rhythm Devices

**Background**
Therapeutic radiation such as that used in cancer treatment can affect the operation of implantable cardiac rhythm devices, including both pacemakers and implantable cardioverter defibrillators (ICDs).

Today's implantable device technology uses complementary metal-oxide semiconductor (CMOS) integrated circuits. Low current consumption CMOS circuits are a breakthrough in the implantable device industry due to their inherent low current consumption, allowing for greater device longevity while keeping the size of devices small. However, these circuits can be more susceptible to therapeutic doses of radiation such as those used in cancer treatment. The damage can occur when cumulative doses of radiation affect the small silicon and silicon oxide insulators within the transistors.

While the risk of effects on device operation increases with increasing cumulative radiation exposure, no exact threshold for damage has been determined. Temporary effects on the pacing and sensing circuitry are outlined below and can be mitigated by taking some precautionary measures. Permanent damage to devices is rare.

**Sources of Therapeutic Radiation**
Radiation therapy is frequently used as a treatment in many types of cancer. There are three typical ways this radiation may be administered—radioactive cobalt, linear accelerators, and betatrons. Note that linear accelerators and betatrons produce strong electromagnetic fields as well as radiation, which can also affect device operation.

**Potential Effects**
The modes of interaction or failure as a result of exposure to radiation therapy are random. The effects can be temporary or permanent. A summary of potential effects is provided in the table below and is based on device testing at St. Jude Medical, clinical experience and a review of the scientific literature.

| Potential Effect | Estimated Frequency | |
|---|---|---|
| | Pacemakers | ICDs |
| Permanent damage | Rare | Rare |
| Temporary loss of sensing | Uncommon | Uncommon |
| Temporary device inhibition | Uncommon | Uncommon |
| Temporary loss of capture | Uncommon | Uncommon |
| Temporary increased sensor rate | Common | Common |
| Temporary rate changes | Uncommon | Uncommon |
| Device reset or reversion to backup VVI pacing | Uncommon | Uncommon |

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**Recommendations**
St. Jude Medical recommends that ionizing radiation not be used in the vicinity of an implanted device. If a patient requires radiation therapy directly over a device, it may be necessary to move the device to another location. However, if it must be used in the vicinity of the implanted device, the following recommendations will help in patient management:

**Patient Management Before Therapy**
- Coning the radiation field to avoid the pacer region helps reduce overall received dosage.
- For ICDs, if clinically appropriate for the patient, deactivating the tachyarrhythmia detection and response functions before delivering radiation therapy will ensure that the device does not oversense the radiation energy and potentially deliver inappropriate therapy. Tachycardia detection and therapy delivery can also be suspended by placing a magnet over the device for the duration of the radiation therapy session. Additionally, the device may be programmed to “Tachy Therapy Disabled”, “All Functions Off”, “Defib Off” or “Brady Pacing Only” using the appropriate St. Jude Medical programmer. During magnet placement, the bradycardia pacing features of an ICD are not affected. Once the treatment session is completed, the magnet should be removed or the device should be re-programmed as appropriate for the patient.
- For rate-adaptive devices, if the sensor is ON, exposure to therapeutic radiation may cause the device to pace at rates up to the programmed maximum sensor rate, and will gradually return to the Base Rate after therapy has ended. To prevent such transient rate increases, the sensor can be programmed to PASSIVE or OFF before administering the radiation therapy.

**Patient Management During Therapy**
- ECG monitoring is an advisable procedure in order to ensure proper device function during therapeutic radiation treatments. During the initial therapy sessions, the clinician can determine if there is any interaction between the device and the radiation equipment. The clinician can decide if subsequent ECG monitoring during each therapy session is necessary.
- If inhibition or other forms of oversensing occur during the initial procedures, the clinician may want to consider programming the device to an asynchronous pacing mode or using a magnet to inhibit sensing, during subsequent treatments.
- In the event any device-related symptoms occur during the course of radiation therapy, the patient should have the pacemaker or ICD interrogated and all real-time measurements, real-time electrograms, and pacing thresholds evaluated.

It is recommended to monitor and record the cumulative radiation dosage to which a device has been exposed. The pacemaker-dependent patient should undergo a detailed evaluation of the pacing system once or twice during the course of the treatment. A change in the capture or sensing threshold may reflect an early problem with the pacing system. While the risk of effects on device operation increases with increasing cumulative radiation exposure, no exact threshold for damage has been determined. Current devices have been tested to 30 gray (3,000 rads) without any adverse effects. This testing was performed using a low dose radiation source such as x-ray. No correlation testing to high dose sources presently used, such as linear accelerators or betatrons, has been performed. Cumulative dosage levels of 20 gray (2,000 rads) are seldom encountered by the pacemaker or ICD when situated outside the irradiated field.

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**Patient Evaluation following Completion of Radiation Therapy**

Following completion of the course of therapeutic radiation, the clinician may want to consider a detailed device evaluation. This should include device interrogation, evaluation of pacing and sensing function, and analysis of device diagnostics. For ICD patients induction testing should also be considered to evaluate the high-voltage functions of the device.

If you have any questions on this topic, please contact St. Jude Medical Technical Services at 800-722-3774.