

## **Information on Battery Passivation**

### **Background**

All PhysioTel™ Digital Implants are manufactured with lithium batteries. Lithium batteries offer many advantages including high energy density, and a low self-discharge rate. These advantages come with a price as all lithium batteries are affected by a phenomenon known as passivation.

Passivation serves to protect the lithium in the battery from discharging on its own when the device is turned off. However, passivation that builds up over time can decrease the battery voltage to an un-useable level until this passivation layer can be burned off.

DSI seasons all lithium batteries upon receipt. The seasoning process in combination with the manufacturing process and on-time during surgery will burn off the accumulated passivation and allow the implants to function as intended during a study. However, the passivation layer will reform after an extended period of time in the off state (>1 month), and it will form quicker if stored at higher temperatures or when implanted.

Typically it takes a matter of seconds to burn off the passivation layer, but it can take over an hour. During this time, the PhysioTel Digital implants are not receiving a usable voltage from the battery. Therefore, the communication between the implant and the system will make it appear that the device is no longer functional. Eventually the passivation will burn off, the device will then attempt to join the system.

### **Mitigation**

To avoid the possibility of passivation DSI recommends turning the implants on once a month. Implants should be turned on with a magnet and configured to a PhysioTel Digital system. This limited amount of use will prevent a large amount of passivation to be formed.

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