**Medical Product Safety Network (MedSun)**

**Small Sample Survey**
**Topic: Breast Tissue Expander (BTE) and Implantable Cardioverter-Defibrillator (ICD) Interference Final Report**
**Year Conducted: 2015**

## Introduction

A common breast reconstruction technique is tissue expansion, which involves expansion of the breast skin and muscle using a temporary breast tissue expander (BTE). A breast tissue expander is an inflatable breast implant designed to stretch the skin and muscle to make room for a future, more permanent implant. Recently, two articles were published describing cases where implanted BTEs with magnetic port locators came in close proximity to the patient's implantable cardioverter-defibrillator (ICD), which may have caused a suspension of tachycardia therapies. These articles suggest there may be an interaction between the BTE's magnetic injection port and the ICD.

The FDA conducted a small sample survey with cardiac electrophysiologists, breast reconstruction surgeons, medical directors, and risk managers to learn about their experiences with BTEs and ICD interference. The survey questions focused specifically on whether the hospital has experienced interactions between BTE magnetic injection ports and ICDs in patients who have both implants, and whether this issue is considered common knowledge in the hospital community. The survey was intended to help determine if healthcare professionals in the U.S. are aware of or have experienced these issues in their patients.

## Methodology

A sample of health care providers from hospitals that participate in FDA's Medical Product Safety Network (MedSun) were queried to obtain detailed perspectives about possible interference between BTEs and ICDs. Respondents from fourteen different hospitals located in all regions of the U.S. participated in the voluntary survey. Ten hospitals involved in the survey have between 100-399 beds and four hospitals have between 400-900 beds. All respondents have experience with BTEs or ICDs.

## Overview of Responses

### *BTE and ICD Interference*

Of fourteen respondents, none have experienced an interaction between the BTE magnetic injection ports and ICDs in patients who have both implants. All respondents also say this issue is not considered common knowledge in their professional community. One respondent said even though they haven't had direct issues with BTEs they are aware of the potential interaction because it's noted in their hospital's cardiac and vascular department policy. This policy says BTEs are not recommended for patients with pacemakers or ICDs due to the possibility that the magnet may suspend ICD therapy or change pacemaker function.

One respondent says that even though the article case studies seem like random occurrences, anything is possible when you place a magnet or metal near an ICD. If a patient is pacemaker dependent, the metal or magnet in the BTE could theoretically shut off the pacemaker causing the patient to faint or die. This respondent also notes that Medtronic now has a magnetic resonance imaging (MRI) compatible ICD and pacemaker, and that St. Jude Medical and Boston Scientific are working on MRI compatible ICDs. Another hospital echoes the previous respondent by saying even though this interaction is not well known, there should be awareness amongst cardiologists and electrophysiologists that anything that creates an electromagnetic field in the immediate vicinity of an ICD could cause temporary interference.

## Summary

Overall, fourteen hospitals responded to the survey and none have experienced possible interference between BTEs and ICDs. All respondents also say this is not a widely known issue in their professional communities. One respondent is aware of the possible interaction because their hospital policy says BTEs are not recommended for patients with pacemakers or ICDs.

Even though respondents say this specific interaction is uncommon, there should be general awareness amongst cardiologists and electrophysiologists that any object capable of creating an electromagnetic field while near an ICD could cause temporary interference. One hospital also notes that several medical device companies are either working on or already have ICDs or pacemakers that are MRI compatible.

## Survey Limitations

Although the findings add to FDA's knowledge of clinical experiences, and provide perspectives about possible interference between BTEs and ICDs, the small sample size of the survey limits the findings. In view of this limitation, the respondents' perspectives may not represent the perspectives of all cardiac electrophysiologists, breast reconstruction surgeons, medical directors, and risk managers. Therefore, these findings represent only one piece of information. No conclusions can be made about possible interference between BTEs and ICDs based on this report alone. Instead, the report should be considered along with other information that may include adverse event reports, scientific publications, enforcement/compliance information, and other data sources that are part of FDA's monitoring of device performance.

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*Surveying device users is one of many tools the FDA uses to evaluate the public health impact of potential problems associated with the use of medical devices. Typically, small sample surveys are used to collect qualitative information on post-market experiences of clinicians or facilities with medical device performance or use. The FDA selects survey respondents based on their experience with the topic or device, their availability, and their willingness to participate.*

*The FDA makes our scientific, medical, nursing, and engineering staff aware of the survey results as needed. If the FDA believes there is a significant risk of adverse events as noted from the survey, we will combine those results with data gained from other sources. The FDA will*

*work with the manufacturers and health care provider organizations to make important information known to the clinical community. Additionally, the FDA continues to work with manufacturers to ensure the development, testing, and promulgation of methods for reducing the risk associated with these devices and to minimize the complications from adverse events that may occur in the course of normal usage. If the results of any survey raise serious concerns about the safety of these devices, the FDA may convene a group of clinical, scientific, and regulatory experts to discuss any necessary action.*