

# How MRI Conditionality of an SCS System Could Impede Screening for Breast Cancer

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## Introduction

One in 8 women will develop breast cancer. To aid in better detection of breast cancer, new regulations were announced by the FDA in 2023 requiring “mammogram providers to inform patients about the density of their breasts.” This notice relates to research showing that the risk of cancer increases up to 4-fold in women with dense breast tissue when compared to average-risk women, and their cancers are more likely to be occult on a mammogram.<sup>1</sup>

- MRI can identify disease occult on mammography and ultrasound.<sup>1</sup>
- MRI for breast screening continues to rise, for example increasing between 300% and 1600% between 2000 and 2011 in the United States.<sup>2</sup>

Women represent a significant, if not the majority, of patients implanted with spinal cord stimulation (SCS) systems.<sup>3,4</sup>

A publication on neuromodulation and the epidemiology of cancer acknowledged that breast MR screening was likely in high-risk female populations and that MR use would be “higher than average utilization” for on-going surveillance.<sup>5</sup> The authors recommended MR conditional systems particularly for women with BRCA mutations, a first degree relative with a BRCA mutation, a lifetime risk of breast cancer of more than 20%, dense breast tissue, and patients under the age of 50 years.

**With the increasing use of MRI to diagnose breast cancer and the high use of spinal cord stimulation in women, we explored the recommendations for breast scanning and the conditions required for scanning SCS systems in an MRI environment.**

The review found that conditions for some MR Conditional SCS devices do not include scanning in a prone position, which may prohibit diagnostic breast scans for women with certain SCS MR Conditional devices.

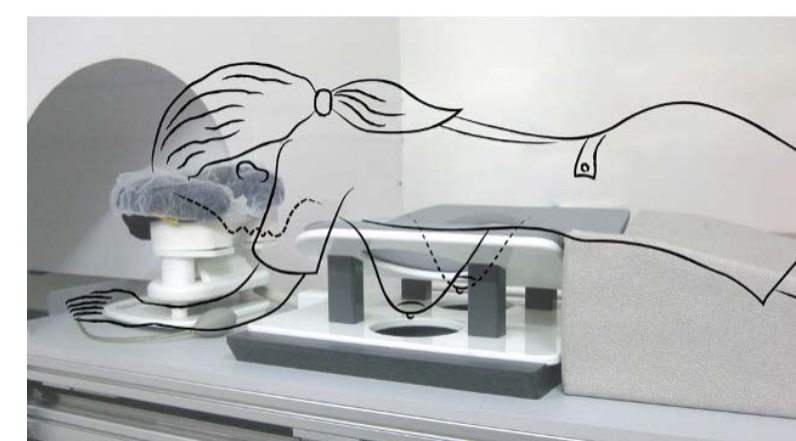
## Methods

Literature searches were conducted through PubMed, Embase, and Google Scholar to understand 1) society recommendations for MRI scanning of breast tissue and 2) the recommendations for MRI conditions for scanning breast tissue. MRI labeling for SCS systems was also reviewed to understand whether conditions could be met for breast MRI scanning in patients with SCS MR conditional systems. These data were not collected as a part of a clinical study, and thus are exempt from institutional review board approval under applicable law.

## Results: Literature on Breast Scans

**MRI scanning of breast tissue.** The American College of Radiology recommends that women with a high lifetime risk of breast cancer be screened annually using MRI, and other high-risk women may also benefit from MRI scans. MRI is “the most sensitive, currently available method for detection of breast cancer” and is indicated for high-risk populations, evaluation of newly-diagnosed cancer for surgical planning and management, and to assess the response to chemotherapy.<sup>1</sup> In addition, the number of MRI-guided breast biopsies is expected to double over the next 10 years.

**Best practices for MRI scanning of breast tissue.** Breast scans are generally performed with the patient in a prone position to improve diagnostic accuracy and visibility of deep breast tissue.<sup>6</sup> MRI in a supine position is not ideal due to “low accuracy of tumor diagnosis due to motion artifacts and low contrast MRI.”<sup>6</sup>



Nissan N et al. Tracking the mammary architectural features and detecting breast cancer with magnetic resonance diffusion tensor imaging. J Vis Exp. 2014 Dec 15;(94):52048. doi: 10.3791/52048. Figure 5 of the article. No changes were made to the image. Used under a CC BY-NC-ND 3.0 DEED: <https://creativecommons.org/licenses/by-nc-nd/3.0/>

## Results: MRI Labeling, SCS Devices

Labeling for most SCS systems did not have restrictions against scanning a patient in prone position. However, the MRI conditions for the SCS systems of one company did restrict against scans in the prone position:<sup>7</sup>

**Patient position:** Supine, patient’s arms must be at his or her sides

**Warning:** Any prone patient positions or “superman” positions (where the patient’s arm is raised above his or her head) are excluded and have not been tested.

The proportion of women with an implanted SCS system needing an MRI scan is unknown. However, the proportion of patients expected to need an MRI performed on the chest, spine, pelvis, heart or breast after 1 year has been reported to be 44% with increasing numbers at 2 years (55%), 3 years (62%), and 4 years (69%). The estimated need for MRI outside of the head or extremities over 5 years is 72-74%; within 10 years of implant 79-87% of patients are expected to need an MRI outside head or extremities.<sup>8</sup>

## Conclusions: Impact of being MRI Ineligible

**Scanning position is one example of condition that must be considered for some SCS MR Conditional systems. In this scenario, if a woman is implanted with an MR Conditional SCS system that does not allow for scans to be conducted in a prone position, she may be prohibited from optimal healthcare. The inability to conduct the scan may delay a woman’s diagnosis and treatment for breast cancer.**

**Case reports demonstrate MRI detects masses not visible through mammography or ultrasound.<sup>9</sup> Not conducting MRI due to SCS system restrictions could have critical implications in diagnosing and treating a woman for breast cancer.**

## Awareness; Other MR Conditions

Out-of-range impedance is another condition that may lead to MRI ineligibility. In 3 case studies,<sup>10</sup> high impedance impeded optimal patient care by:

- Preventing stroke treatment
- Delaying treatment for new pain and led to device explant
- Cancelling of MRI scans needed for metastatic melanoma

Furthermore, a recent study reported that by 5 years after SCS implant, 43% of patients had high impedance in at least 1 contact.<sup>11</sup> Although these patients all had MR Conditional SCS systems, they would be ineligible for MRI due to high impedance.

Understanding the conditions for each MR Conditional SCS system is important since they vary. Some systems do allow prone scans and some systems can undergo an MRI scan without an impedance check.

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## Disclosure

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