Motiva®

QID®

FACTS FOR RADIOLOGISTS & MRI TECHNICIANS

Patients with Motiva Implants® with Qid® can be scanned safely with 1.5- and 3-Tesla (T) Magnetic Resonance Imaging (MRI)[1] under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only.
- Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m)(extrapolated).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode."

Qid® is intended to be an implantable device compatible with all imaging modalities. It consists of a passive radiofrequency identification (RFID) microtransponder embedded in the implant during its manufacturing. It is located near the patch area of the implant and is held in place by the cross-linked, highly viscoelastic silicone gel.

Qid® benefits are satisfactorily verified when a surgeon quickly obtains the 15-digit Electronic Serial Number (ESN) that is linked to information about the implant, such as date of manufacture, size, and volume, providing 100% accurate verification over time through a non-invasive procedure.

The FDA referenced this type of technology as a possible method to directly "mark" an implant with a Unique Device Identification (UDI) by affixing a permanent tag to the device[2] that provides peace of mind by being fully traceable, thereby assuring rapid and error-free implant identification.

Establishment Labs® has conducted different tests in accordance with international methodologies, complying with the most stringent ASTM International (formerly known as the American Society for Testing and Materials) standards and regulations.

The microtransponder components are:

- A readable memory RFID microtransponder
- A metallic micro-antenna that receives reader signal and transmits the specific information
- A ferrite core to strengthen the data transmission distance
- A hermetic biocompatible glass capsule

This innovative technology has been proven to be both safe and effective and is activated externally by the reader (as a passive RFID). Because it doesn't require a battery, its life expectancy is indefinite.

Safety and performance of Motiva Implants® with Qid® in specific tests

Magnetic field interactions

Motiva Implants® will not present an additional risk or hazard to a patient up to a 3-Tesla MRI environment regarding translational attraction or migration, according to the ASTM acceptance criteria for deflection angle.

Different studies have demonstrated that MRI can be performed safely in patients with metallic objects that are "weakly" ferromagnetic and minimally attracted by the magnetic field (e.g. passive RFID devices), such that the magnetic field interactions are insufficient to move or dislodge them in situ[3], and that they remain fully functional after exposure to electromagnetic environments[4].

MRI-related heating

MRI-related heating tests were conducted on the RFID-M. Under experimental conditions, a maximum rise of 1.5° C is expected after 15 minutes of continuous scanning with 1.5 Tesla (exceeding the time of a conventional pulse sequence)[5].

Magnetic susceptibility artifacts

Ferromagnetic materials have a strong positive magnetic susceptibility that produces an artifact effect in some magnetic resonance images.

In non-clinical testing, the image artifact caused by Qid® extends approximately 15 mm from its location within the implant when imaged using a gradient echo (GRE) pulse sequence and a 3-Tesla MRI system[5].

When patients undergo MRI, a small area posterior to the implant is obscured (see images 1 and 2).

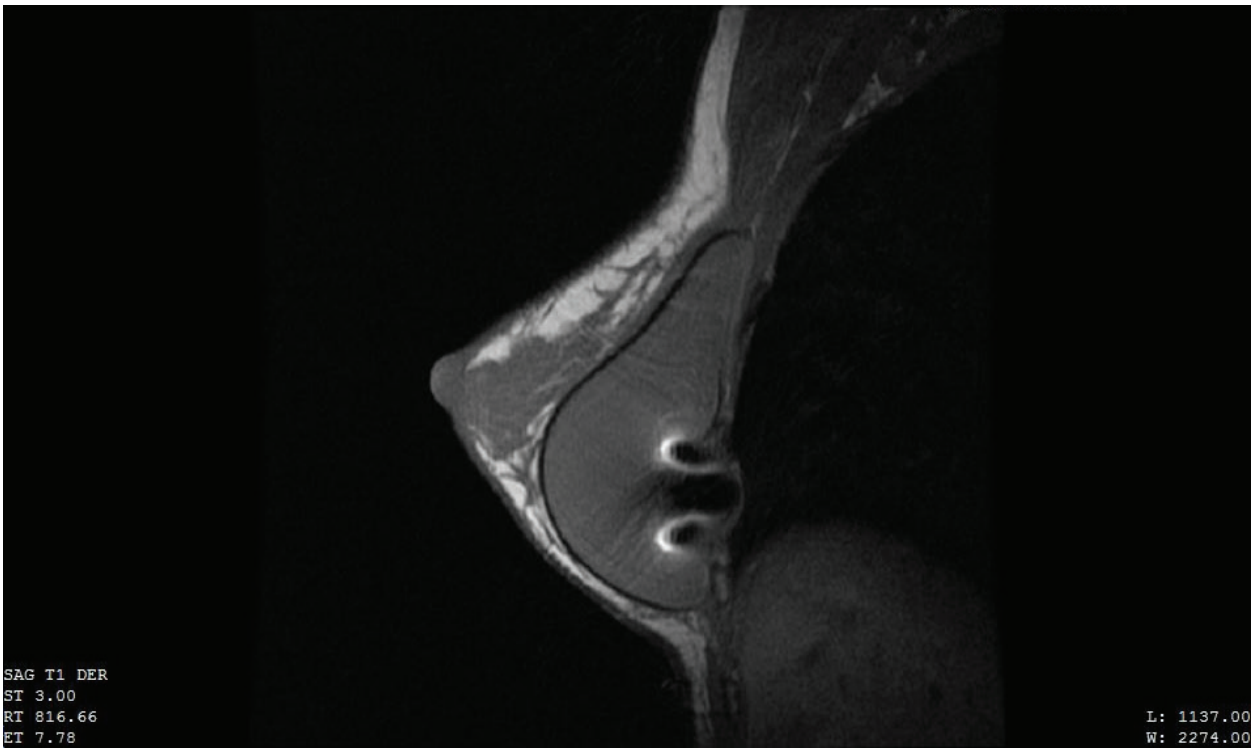

Image 1. MRI – T1-weighted sequence of the right-side breast showing the microtransponder-related artifact.

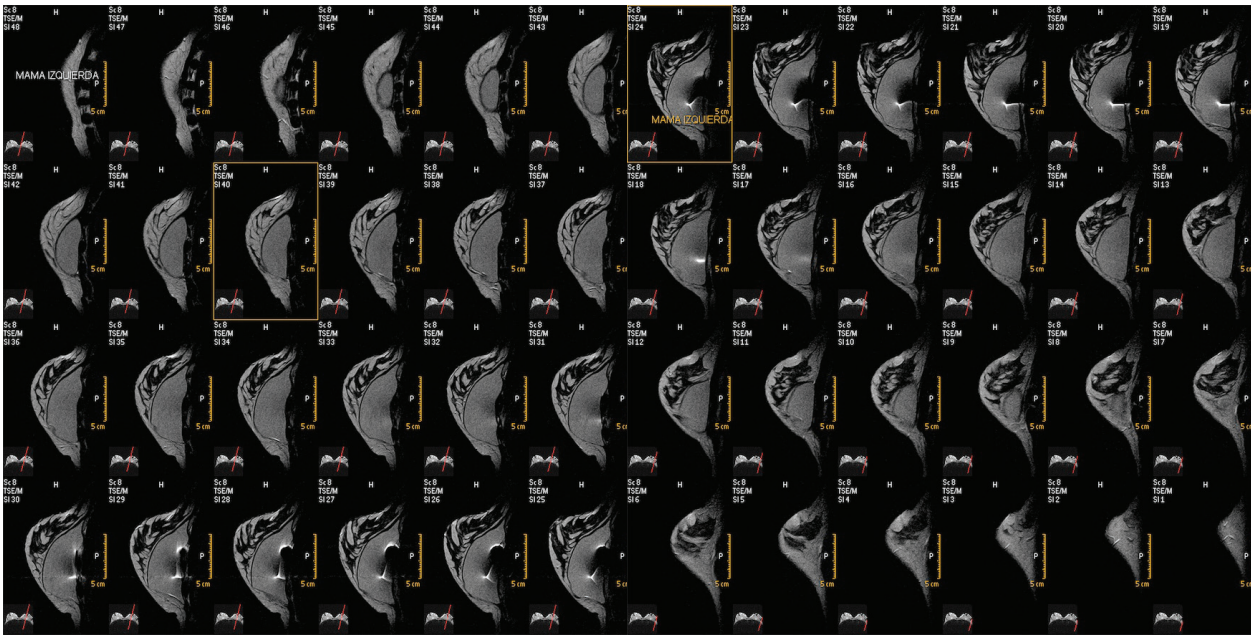

Image 2. MRI of the left-side breast showing the microtransponder-related artifact in approximately 25% of the images (12/48).

Management of MRI protocols and microtransponder-related artifact

Establishment Labs® recommends using conventional MRI protocols to study the implant's integrity and surrounding breast tissue, despite the occurrence of image artifacts due to magnetic susceptibility differences between substances. While these cannot be eliminated entirely, they can be minimized by strategically selecting the pulse sequence (when possible) and specific sequence parameters[6].

Several techniques are commonly used to reduce the severity of metal susceptibility artifact, including simple concessions such as increasing the frequency encoding bandwidth (BW)[7].

Artifact reduction strategies in MRI include:

· Strategically selecting the pulse sequence (see image 3)

· Reducing slice thickness to 1 or 2 mm

· Reducing the echo time (ET)

· Increasing the receiver bandwidth (range of frequencies collected per pixel)

· Applying artifact reduction advanced software, if available (depending on MRI vendor)

· When possible, utilizing inversion recovery sequences (short tau inversion recovery, or STIR) for fat suppression

· Acquiring GRE or fast GRE for contrast-enhanced MRI with gadolinium when screening for breast cancer

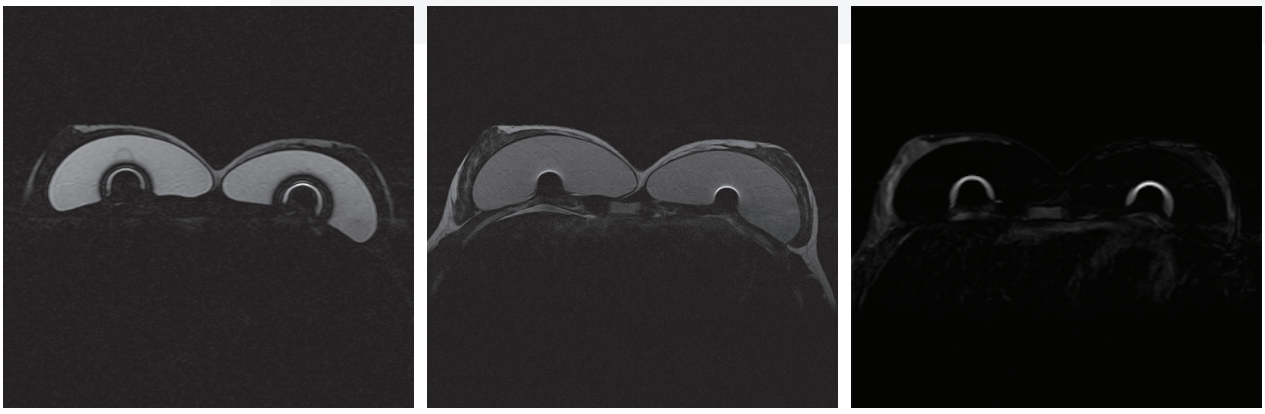

Image 2. Axial "silicone only", T2-weighted, and T2 SPIR (spectral pre-saturation with inversion recovery) sequence comparison showing the microtransponder-related artifact.

Technical artifacts are frequent and have been also described for other devices such as surgical and biopsy breast tissue clips[8-10]. It is imperative that images, regardless of the methodology used, are evaluated by a qualified radiologist with significant expertise in breast imaging.

Moreover, there are multiple imaging modalities at radiologists' disposal to complement and achieve a satisfactory evaluation of the breast region, ensuring the suitable use of available resources[11] as shown in table 1.

	BREAST IMPLANT RUPTURE	BREAST CANCER SCREENING	BREAST CANCER SURVEILLANCE
MAMMOGRAPHY	Usually appropriate in suspected implant complication in women > 30 years old	Usually appropriate in average-risk women	Usually appropriate in surveillance to rule out local recurrence
ULTRASOUND	Usually appropriate in suspected implant complication	It may be appropriate in average-risk women	It may be appropriate in surveillance to rule out local recurrence
MRI	Usually appropriate in suspected implant complication	Usually not appropriate in average-risk women	It may be appropriate in surveillance to rule out local recurrence

Table 1. American College of Radiology (ACR) Appropriateness Criteria for different imaging modalities according to clinical ambit[12-14].

Detection of Breast Implant Rupture: Implant Integrity Study

MRI is commonly accepted as the imaging study of choice to definitively evaluate implant integrity, with sensitivity and specificity ranging from 64% to 89% accuracy in both asymptomatic and symptomatic patients with suspected rupture[12,15].

1.5- and 3-Tesla devices are widely used for clinical evaluation of breast-augmented patients.

In 2006, the FDA recommended women with silicone gel breast implants undergo MRI screening to detect silent ruptures three years after implantation, and every two years thereafter[16].

However, a research review identified methodologic biases in prior studies that resulted in overestimation of this imaging modality benefit[17]. Therefore, the FDA recommendations should be interpreted with caution[18], considering other optimal and more budget friendly strategies[19].

The latest published ACR Appropriateness Criteria for breast implant evaluation does not usually consider breast MRI appropriate for evaluation of silicone breast implants in asymptomatic patients[12].

Breast ultrasound (US) represents a valid, first-level technique for evaluating implant integrity. It is non-invasive, relatively inexpensive, easily available, and well accepted by patients.

Sonographically, the microtransponder becomes visible inside the implant mass due to its good echogenicity. Aside from making its presence evident inside the implant, Qid® will not interfere in any way with such an examination, its results, or a consequent diagnosis (see image 4).

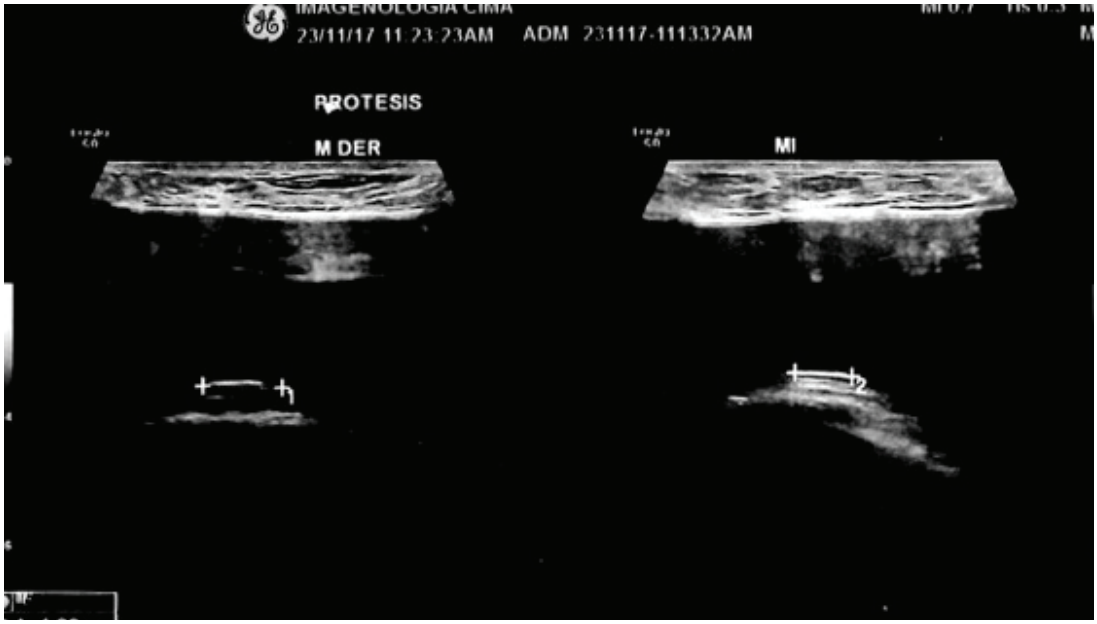

Image 4. Breast ultrasound showing the RFID in both right and left implants.

Breast Cancer Screening

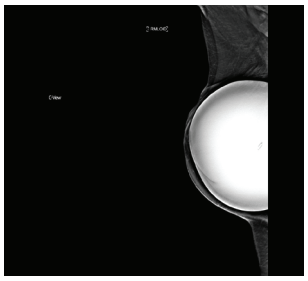

Image 5. Digital breast tomosynthesis of a patient with Motiva Implants® and Qid®

From a historical perspective, mammography has been the recommended imaging tool for screening the general population of women. Five major medical organizations formulated the current screening guidelines in the United States, mostly based on mammography indications[20].

Diagnostic breast MRI is not usually recommended before clinical breast examination, and conventional breast imaging is performed and interpreted. Screening MRI should be used in addition, not as an alternative, to screening mammography and/or tomosynthesis in clinically indicated patients[14,18].

The ferrous core microtransponder produces an artifact that will affect a small portion of the chest wall in MRI images. It is recommended that ultrasound examination is used as an adjunct to further visualize this area[21].

A risk impact assessment on a high-risk population determined that when an artifact is present, dual-modality (MRI and US) imaging has a reduced risk of a missed cancer diagnosis compared to that of MRI alone without artifact[21].

Breast Cancer Surveillance and Chest Wall Imaging Examination

There are no clear guidelines on post-breast reconstruction radiological surveillance[22-24].

Mammography is recommended for surveillance after primary breast cancer treatment[20,25,26] to examine residual breast tissue after breast conservation surgery and the contralateral breast. However, it is not generally recommended for surveillance of the reconstructed breast after mastectomy[24,27].

Patients with breast cancer are at risk of recurrence over many years after their initial disease in the subcutaneous tissue, flap, or chest wall; or regionally in the lymph nodes[26].

Locoregional recurrences (LRRs) occur at a rate of 8–12% (within 10 years) after conservative surgery or mastectomy and adjuvant radiotherapy[28].

Clinical examination plays an important role in post-operative surveillance. However, when a patient has undergone a flap or implant reconstruction, radiological surveillance may be recommended to examine any residual breast tissue behind the reconstructed area, especially in high-risk patients[29].

Current reconstructive techniques will use local flaps or prosthetic material to cover the lower pole of the implant, or even place the implant in a pre-pectoral plane with added fat grafts. This will place the mastectomy plane and potential local recurrence site behind the implant[30], undetectable by clinical examination. Thus, radiological surveillance is often utilized after implant reconstruction. US and MRI are currently the recommended modes of radiological examination[29].

The RFID microtransponder creates an artifact seen on MRI imaging and will conceal a small area of the chest wall behind the breast implant that can be viewed with ultrasound. Thus, in reconstruction patients, dual-mode imaging (using both artifact-reduction protocol MRI and US) is the recommended radiological surveillance protocol after reconstruction with Motiva Implants® with Qid®.

QID® RFID TECHNICAL SPECIFICATIONS

Weight: 0.06 grams

Length: 9 mm

Diameter: 2.1 mm

Frequency: 134.2 ± 4 KHz; Read Range: >10 cm

Operating Temperature Tolerance: -20°C to + 70°C

Validated safety and performance when exposed to 1.5 and 3.0 Tesla MR imaging systems.

MR Conditional classified items have been shown to pose no known hazards in a specified MR environment with specified conditions of use.

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