Motiva®

QID®

FACTS FOR SURGEONS

MATERIAL INTENDED FOR SURGEONS EDUCATION ONLY

Motiva Implants® with Qid®

Fig. 1. Motiva Implants® with the embedded microtransponder.

Qid® is compatible with all imaging modalities required to study a clinical condition or assess implant integrity.

Motiva Implants® are available with Qid® to assure full traceability of the implant and secure access to implant-specific data, advancing patient care and safety by using a radiofrequency identification device (RFID). This technology has shown potential for multiple FDA-cleared uses, including intraoperative localization of nonpalpable breast lesions[1,2].

RFID transponders for use in breast, prostate, and other soft tissues can also be of great help to dosimetry information[3-5] on tumor treatment.

Moreover, the FDA referenced this technology as a possible method to directly mark an implant with a Unique Device Identification (UDI) by "affixing" a permanent tag to the device[6].

Technology Information

Qid® consists of a passive radiofrequency 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.

The RFID microtransponder uses radio waves to provide an Electronic Serial Number (ESN) that may be retrieved externally from a handheld reader. This serial number may be used to identify the implant's essential information, including the serial number, manufacturer name, date of manufacture, implant style, and volume.

The ESN is encoded into the RFID circuitry as part of a 3-point authentication system (microtransponder + reader + database). This authentication system prevents association with any patient's personal information.

The microtransponder components are:

- A readable memory
- 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

Fig. 2. Image of a microtransponder in which all its components can be seen.

BENEFITS TO PATIENTS WITH QID®

TRANSPONDER

+ READER

+ DATA BASE =

3-POINT AUTHENTICATION SYSTEM

100% ACCURATE IDENTIFICATION FOR BEST-IN-CLASS TRACEABILITY

Accurate and precise medical records have proven to be crucial in past cases involving product recalls and safety action notices. The PIP (Poly Implant Prothèse) breast implant recall, for example, significantly diminished the quality of life in women with breast implants, regardless of whether they had the impacted model or another brand.

Questionnaires completed by 115 women seeking elective replacement indicated that the pre-operative mean anxiety level in these patients was comparable or slightly higher than previously described for breast cancer patients[7].

Motiva Implants® with Qid® are fully traceable and assure rapid error-free identification by the handheld reader. This technology can provide confidence to patients that their implants are identifiable at any time, regardless of the availability of the patient ID Card or medical history records.

100% VERIFICATION FOR PATIENT PEACE OF MIND

Patients benefit from 100% accurate verification of breast implants over time through a non-invasive and free procedure.

Immediately following surgery, patients can thoroughly verify that they have received the implants they chose before the procedure, including the brand, model, size, volume, and authenticity of the device.

This holds its value over time. When considering a breast augmentation or reconstruction revision surgery, information about the current implant is vital for surgical planning.

SECURE PATIENT ACCESS TO IMPLANT INFORMATION
THROUGH THE MOTIVAIMAGINE® APP

The ESN retrieved by the handheld reader allows access to a secure database containing the device information that may be accessed through the MotivaImagine® App. Medical staff can securely access to this implant-specific information through our various digital platforms.

EXTENDED WARRANTY PROGRAM FOR QID®

The possibility of precisely identifying all records with a simple scan of the breast through a serial number that may be entered in a registration database represents an enhanced tool for actuarial and epidemiological analysis that opens the opportunity for additional benefits linked directly to the product.

With this enhanced data and precise actuarial analysis, Establishment Labs has provided additional benefits to patients who receive Motiva Implants® with Qid® in the event of reoperation. In addition to the replacement product, the patient may also receive financial assistance for each affected implant, appliable to the cost of the revision surgery in the case of a rupture or capsular contracture (Baker grades III and IV). In the case of rupture, it also includes financial assistance for imaging tests[b].

a. € 2500 / Euro Zone £ 2500 / U.K.$2500 / Rest of the world

b. € 500 / Euro Zone£ 500 / U.K.$500 / Rest of the world

BEST PRACTICES WITH MOTIVA WITH QID®

CONFIRMING IMPLANT RUPTURE

Implant rupture is a well-known long-term complication potentially less common with high cohesive gels[8]. Mammography and ultrasonography are the standard first steps in the diagnostic workup.

Magnetic Resonance Imaging (MRI) is also a beneficial imaging modality for the characterization of breast implants because of its high spatial resolution and contrast between implants and soft tissues and the absence of ionizing radiation. MRI provides a reliable way to assess implant integrity and is highly sensitive for detecting both intracapsular and extracapsular rupture[9].

When using MRI, a small image void (referenced as an "artifact") is created by the presence of the Qid® microtransponder (see figure 4). This is a known effect that can be managed with a combination of radiological expertise in breast imaging and additional imaging techniques (such as mammography or ultrasound) recommended to complement the visualization of the artifact-affected region.

Imaging voids or artifacts are a common finding when implanted medical devices are present[10-13]. The RFID used in the Qid® has been determined not to cause any imaging voids or artifacts with X-ray or ultrasound imaging.

However, it will create a small artifact when used with MRI. There have been a series of specific strategies developed to maintain the effectiveness and safety of the exam, which will be presented later in this document.

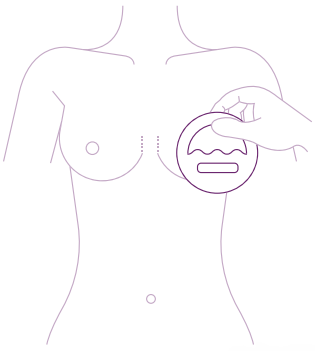

Fig. 3. MotivaImagine® reader.

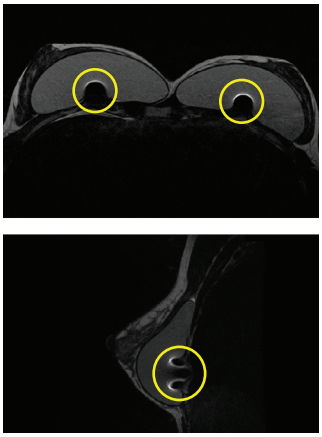

Fig. 4. Images of an axial and sagittal view of MR images depicting the microtransponder's artifact.

The MRI study consists of multiple image series also known as sequences. A "selective silicone" sequence present in many of the vendors' MRI software is commonly used to evaluate breast implant integrity because of its specific capacity to enhance the silicone signal. However, it will also produce a larger void image or a more intense microtransponder-related artifact.

Therefore, to mitigate this causative image distortion, it is recommended to use typical sequences without fat suppression, such as the T1- or T2-weighted Turbo Spin Echo.

SCREENING FOR BREAST CANCER

Breast cancer screening is used to identify women with asymptomatic cancer, to enable them to undergo less invasive treatments that lead to better outcomes, ideally at earlier stages before the cancer progresses[14].

Guidelines for who should undergo breast cancer screening vary within and among countries[15].

Breast cancer screening modalities include clinical and physical breast exams as well as mammographic or breast ultrasound imaging.

Ongoing improvements in imaging technologies have enhanced breast cancer detection and diagnosis sensitivity. Each modality is most useful when utilized according to individual traits such as age, risk group, and breast density.

Screening mammography for women with an average risk of breast cancer results in early detection of breast cancer and reduces mortality[16].

In either its 2-D or 3-D variants (tomosynthesis), silicone gel breast implants are visible in the resulting images. Radiologists capture additional images of the breasts employing an implant displacement technique to evaluate the breast tissue better.

Studies have shown that ultrasound can detect mammographically occult breast cancer in women with dense breast tissue[16]. In these cases, the combination of ultrasound and mammography may still identify the majority of cancers when they are node negative[17].

The microtransponder is visible inside the implant mass due to its good echogenicity. Aside from making its presence evident inside the implant, the microtransponder will not interfere in any way during the exam, its results, or a consequent diagnosis.

Women treated for breast cancer are at risk of developing second breast cancer, such as tumor recurrence in the ipsilateral breast or a newly developed cancer in the contralateral breast[14]. A different approach is also recommended for women with an increased risk of breast cancer, including those with a personal history of breast cancer.

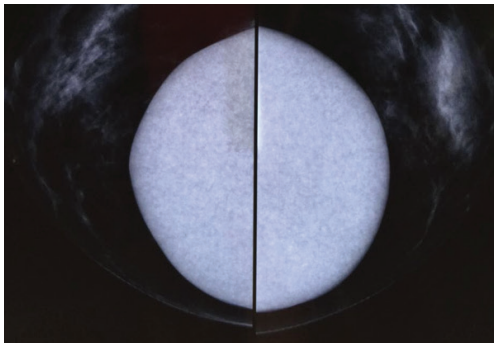

Fig. 5. Right and left breast mammography showing Motiva Implants® *in situ*.

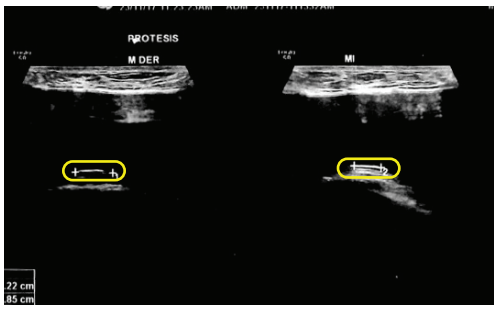

Fig. 6. Breast ultrasound showing the RFID in both right and left implants.

Additional supplemental screening with breast MRI with contrast may be considered for special high-risk populations[14,18,19]. Annual screening mammography and MRI starting at age 30 years are recommended for women with a known BRCA mutation, women who are untested but have a first-degree relative with a BRCA mutation, or women with an approximately 20% to 25% or greater lifetime risk of breast cancer based upon specialized breast cancer risk-estimation models[20].

MANAGEMENT OF MRI PROTOCOLS AND MICROTRANSPONDER-RELATED ARTIFACTS

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[21].

Several techniques are commonly used to reduce the severity of metal susceptibility artifacts, including simple concessions such as increasing the frequency encoding bandwidth (BW)[22].

Artifact reduction strategies in MRI include:

- Strategically selecting the pulse sequence (see figure 7).
- 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.

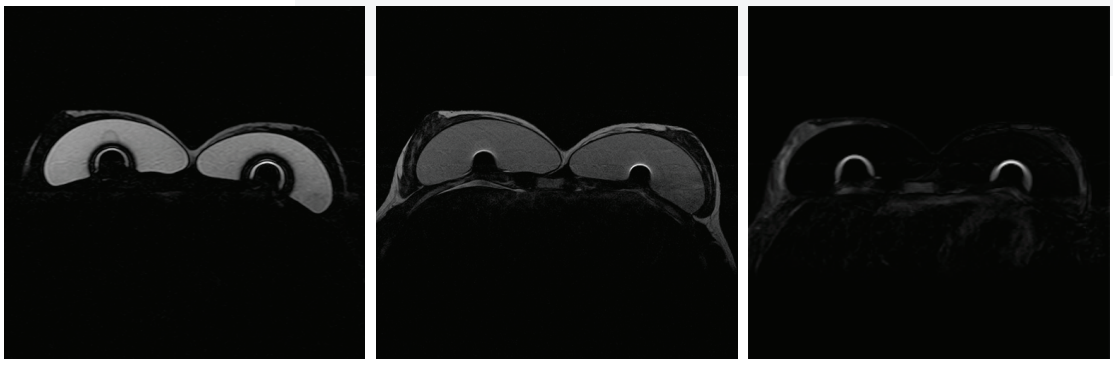

Fig. 7. Axial "silicone only", T2-weighted, and T2 SPIR (spectral pre-saturation with inversion recovery) sequence comparison showing the microtransponder-related artifact.

Technical artifacts are frequent and have also been described for other devices such as surgical and biopsy breast tissue clips[10,13,23].

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 appropriate use of available resources[24], 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 scenario[25-27].

QID® RFID TECHNICAL SPECIFICATIONS

Weight 0.06 g
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

QID® HANDHELD READER TECHNICAL SPECIFICATIONS

This device is ROHS compliant and meets ISO 11784 and 11785.
Dimensions: 135 mm diameter x 33 mm depth (5.315 in. diameter x 1.299 in. depth); Weight: 70 g (2.4962)
Reads per charge: 8 second scans x 1000 (battery capacity may vary with normal use); Charge time: 3.5 hours
Operating temperature: 0°C + 50°C (32°F to + 122°F)

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

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