



# Q Inside<sup>®</sup> Safety Technology

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## FACTS FOR SURGEONS

### Motiva Implants<sup>®</sup> with Q Inside<sup>®</sup> Safety Technology

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Fig. 1. Motiva Implants<sup>®</sup> with the embedded microtransponder

Cleared by the US Food & Drug Administration (FDA) in 2004, Q Inside<sup>®</sup> Safety Technology (also known as Qid<sup>®</sup>) is intended for use in humans and is compatible with all imaging modalities required to study a clinical condition or to assess implant integrity.

Motiva Implants<sup>®</sup> are available with Q Inside<sup>®</sup> Safety Technology to assure full traceability and secure access to implant-specific data. This technology advances patient care and safety by using radiofrequency identification device (RFID) technology and has showed potential for multiple FDA-cleared uses, including intraoperative localization of nonpalpable breast lesions.<sup>1,2</sup>

RFID transponders for use in breast, prostate, and other soft tissues can also be of great help to dosimetry information<sup>3,4,5</sup> on tumor treatment.

Moreover, the FDA recently 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.<sup>6</sup>

# Technology Information

Q Inside® Safety Technology consists of a passive radiofrequency microtransponder safely 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 key information about the implant, 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 of the patient's personal information and is compliant with all governmental 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



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

## BENEFITS TO PATIENTS WITH Q INSIDE® SAFETY TECHNOLOGY

**TRANSPONDER**  
**+ READER**  
**+ DATA BASE =**  
**3-POINT AUTHENTICATION SYSTEM**



## 100% ACCURATE IDENTIFICATION FOR BEST-IN-CLASS TRACEABILITY

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Accurate and precise medical records have proven to be of extreme importance 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 entirely. Knowing with certitude that a product recall is not applicable to your specific case provides significant piece of mind.

Questionnaires completed by 115 women seeking elective replacement indicated that the pre-operative mean anxiety level in these patients was comparable, or even slightly higher than previously described for breast cancer patients.<sup>7</sup> Motiva Implants® with Q Inside® Safety Technology are fully traceable and thereby assures rapid and error-free identification if necessary by the handheld reader. This technology can provide complete confidence to patients that their implants are identifiable at any time, regardless of availability of the patient ID Card or medical history records.

## 100% VERIFICATION FOR PATIENT PEACE OF MIND

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

Immediately following surgery and thereafter, patients are able to fully verify that they have received the implants they chose before the procedure, including the brand, model, size, and volume, as well as authenticity of the device.

With RFID technology, the cost of this foolproof verification to the patient is zero and puts the patient at no risk of an invasive verification procedure.

## SECURE PATIENT ACCESS TO IMPLANT INFORMATION THROUGH THE MOTIVAIMAGINE® APP

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The electronic serial number 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 secure access to this implant-specific information through a web service.

## EXTENDED WARRANTY PROGRAM FOR Q INSIDE® SAFETY TECHNOLOGY

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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 of additional benefits linked directly to the product.

With this enhanced data and precise actuarial analysis, Establishment Labs has been able to provide additional benefits to patients who receive Motiva Implants® with Q Inside® Safety Technology in the event of reoperation. In addition to the replacement product, the patient may also receive financial assistance for each affected implant<sup>a</sup>, applicable 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<sup>b</sup>.

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

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

# BENEFITS TO PATIENTS WITH Q INSIDE® SAFETY TECHNOLOGY

## SCREENING FOR REVISION SURGERY

When planning a breast augmentation or breast reconstruction revision surgery, information about the current implant is important for medical verification and surgical planning.

Q Inside® Safety Technology benefits are satisfactorily verified when a surgeon quickly obtains the 15-digit Electronic Serial Number (ESN) that is linked to information regarding the implant, such as date of manufacture, size, and volume, all of which are significant when considering and planning a revision surgery.

To turn on the reader, press and then release the Start button located at the back of the reader.

The display screen will show "Reading" and the reader will emit a single beep.

Place the reader next to the skin (see figure 3). When an ESN is located, you will hear a beep, followed by a 15-digit numeric sequence shown on the display screen.

If no ESN is found, try the reading again, but this time, move the reader lower and at different directions, varying the angle of the reader on the area to be read.

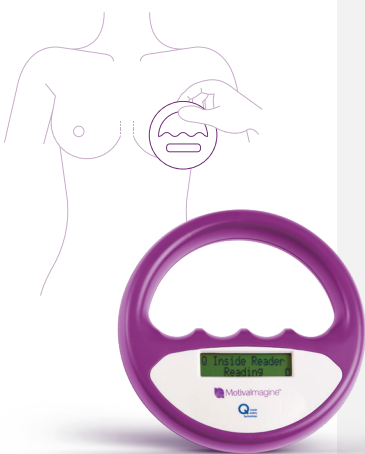


Fig. 3. Image showing how the scan should be performed and the Motivalmagine® reader.

## SCREENING FOR IMPLANT RUPTURE

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

Magnetic Resonance Imaging (MRI) is also a very useful imaging modality for the characterization of breast implants because of its high spatial resolution and contrast between implants and soft tissues, as well as the absence of ionizing radiation. MRI is the most sensitive imaging examination for the evaluation of rupture in silicone gel breast implants. It provides a reliable way to assess implant integrity and is highly sensitive for the detection of both intracapsular and extracapsular rupture.<sup>9</sup>

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

Imaging voids or artifacts are commonplace when implanted medical devices are present.<sup>10,11,12,13</sup> The RFID used in the Q Inside® Safety Technology feature has been determined not to cause any imaging voids or artifacts with X-ray or ultrasound imaging.



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

The MRI study consists of an ordered combination of RF and gradient pulses used to acquire multiple image series correlated to variable parameter settings. These are 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, but 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.

The use of contrast agents in MRI studies for assessment of breast implant integrity is not recommended.

## SCREENING FOR BREAST CANCER

Breast cancer screening is used to identify women with asymptomatic cancer, with the goal of enabling women to undergo less invasive treatments that lead to better outcomes, ideally at earlier stages before the cancer progresses.<sup>14</sup>

Guidelines for who should undergo breast cancer screening vary within and among countries.<sup>15</sup>

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 the sensitivity of breast cancer detection and diagnosis, and 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 leads to reduced mortality and improved patient outcome.<sup>16</sup>

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 by means of an implant displacement technique to better evaluate the breast tissue.

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

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.

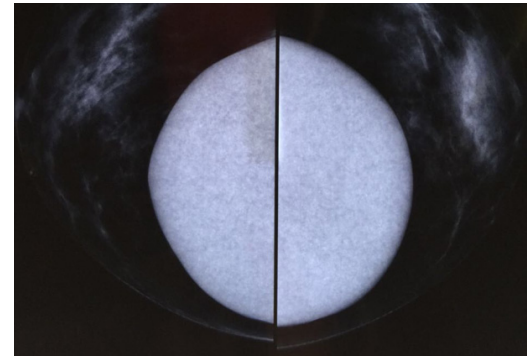


Fig. 5. Right and left breast mammography showing Motiva Implants® breast implants.



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

Women who have been treated for breast cancer are at risk of developing a second breast cancer, such as tumor recurrence in the ipsilateral breast, or a newly developed cancer in the contralateral breast.<sup>14</sup> A different approach is also recommended for women with increased risk of breast cancer, including those with a personal history of breast cancer.

Additional supplemental screening with breast MRI with contrast may be considered for special high-risk populations.<sup>14,18,19</sup>

Annual screening mammography (non-implanted patients) 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.<sup>20</sup>

## Q INSIDE® SAFETY TECHNOLOGY 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

## Q INSIDE® SAFETY TECHNOLOGY 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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