# Q Inside Safety Technology

## Facts for Surgeons

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

## Motiva Implants® with Q Inside Safety Technology™

Q Inside Safety Technology™, cleared by the US Food & Drug Administration (FDA) in 2004, is intended for use in humans and compatible with all imaging modalities that could be required to study a clinical condition or to assess implant integrity.
Motiva Implants® are available with Q Inside Safety Technology™ to assure full traceability and secure access to implant specific data. This technology advances patient care and safety by a Radio Frequency Identification Device (RFID) technology and has showed potential for multiple FDA approved uses, including monitoring breast tumors and sentinel nodes localization. RFID transponders for use in breast, prostate, and other soft tissues can also be of great help to dosimetry information on tumor treatment. Moreover, this type of technology was recently referenced by the FDA as a possible method to directly mark an implant with a Unique Device Identification (UDI) by affixing a permanent tag to the device[1].

## Technology Information

Q Inside Safety Technology™ consists of a passive radio frequency microtransponder safely embedded in the implant during its manufacturing. It is located near the patch area of the implant and held in place by the cross- linked high visco-elastic silicone filling 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 serial number (ESN) is encoded into the RFID circuitry as part of a 3-point authentication system (microtransponder + reader + database). This authentication system prevents association to any personal information of the patient, and is compliant will all governmental regulations.

The microtransponder components are:

- A readable memory transponder
- A metallic micro-antenna that receives reader signal and transmits the specific information
- A ferrite core to strenghten the data transmision distance
- A hermetic biocompatible glass capsule

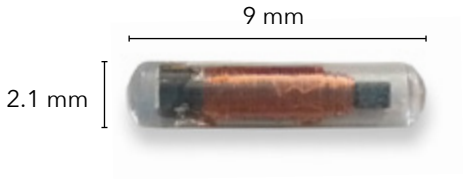


Fig.2. Image of a microtransponder where all its components can be seen.

# BENEFITS TO PATIENTS WITH Q INSIDE SAFETY TECHNOLOGY

TRANSPONDER
+ READER
+ DATA BASE =

3 POINT AUTHENTIFICATION SYSTEM


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

Accurate and precise medical records have proven to be of extreme importance in past cases involving product recalls and safety action notices. The PIP 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 care 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[2]. 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

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 to the patient of this full proof verification is zero and puts the patient at no risk of an invasive procedure.

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

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

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 & 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[a], 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[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

# SCREENING PATIENTS WITH MOTIVA IMPLANTS WITH Q INSIDE SAFETY TECHNOLOGY

### SCREENING FOR REVISION SURGERY

When planning a breast augmentation or breast reconstruction revision surgery the information on 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 activate the reader, find the start button located on the back of the reader. To power the unit on, simply push the button and then release.
The display screen will show Motiva Q Inside Reader "Reading" and the reader will emit a single beep.

Place the reader next to the skin. 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 and varying the angle of the reader on the area to be read.


Fig.3. Image showing how the scan should be performed and the MotivaImagine™ reader.

### SCREENING FOR IMPLANT RUPTURE

Implant rupture is a well-known complication after surgery and is the main cause of implant removal[3].
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 rupturing insilicone 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[4].
When using MRI, a small image void (sometime referenced as an "artifact") is created by the presence of the Q Inside Safety Technology™ microtransponder. 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), that is recommended to complement the visualization of the artifact affected region.
Imaging voids or artifacts are commonplace when implanted medical devices are present. The RFID used in the Q Inside Safety Technology™ feature has been determined not to cause any imaging voids or artifacts with X-rays or ultrasound based imaging.
The MRI study consists of an ordered combination of RF and gradient pulses used to acquire multiple image series correlated to variable parameters settings. These are also known as sequences. A "selective silicone" sequence present in many of the vendors MR software is commonly used to evaluate breast implants integrity because of its specific capacity to enhance the silicone signal

but will also produce a larger void imaging 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.

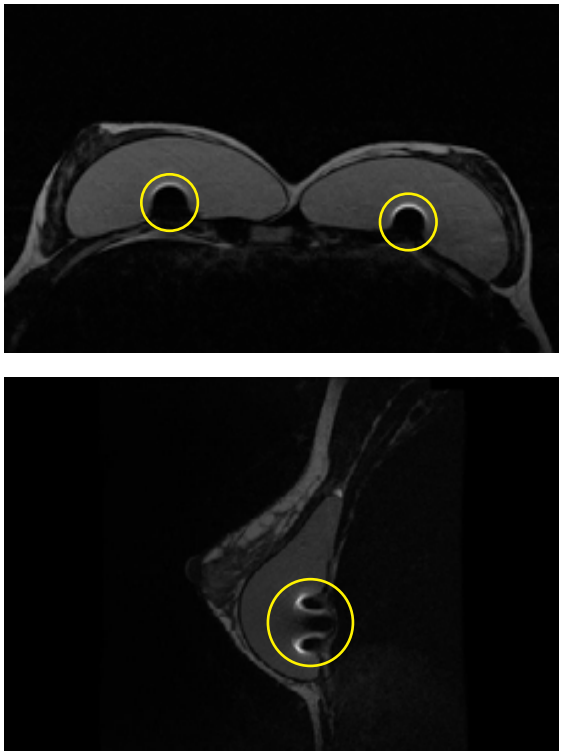

Fig.4. Images of an axial and sagittal view of MR images depicting the microtransponder's artifact.

## 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[5].
Guidelines for who should undergo breast cancer screening vary within and among countries[6].
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[7].

Studies have shown that ultrasound can and does detect mammographically occult breast cancer in women with dense breast tissue[7]. In these cases, the combination of ultrasound and mammography may still identify the vast majority of cancers when they are node negative[8].
The microtransponder is visible inside the implant mass, due to its good echogenicity. Aside from making its presence evident inside the implant, the Qid microtransponder will not interfere in any way during the exam, its results, or a consequent diagnosis.

In either its 2-D or 3-D variants (Tomosynthesis) silicone gel breast implants are visible in the resulting images. Radiologists perform additional pictures of the breasts by means of an implant displacement technique to better evaluate the breast tissue.

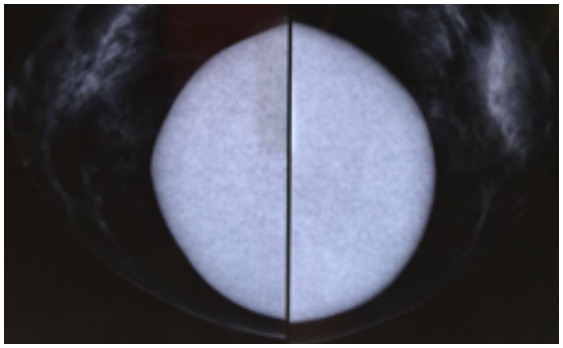

Fig.5 Right and left breast mammography showing Motiva Implants® breast implants.

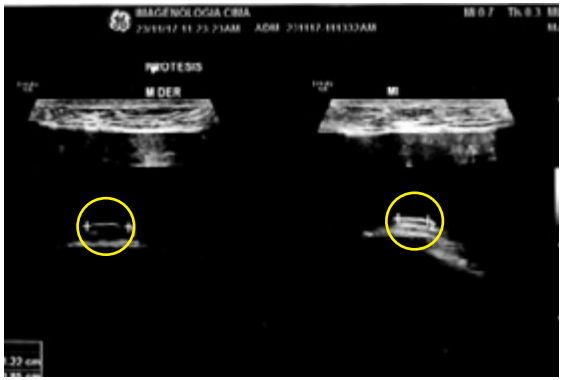

Fig.6 Breast ultrasound showing the RFID in both right and left implants.

Women who have been treated for breast cancer are at risk for a second breast cancer, such as tumor recurrence in the ipsilateral breast or a newly developed cancer in the contralateral breast[5]. 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[5].
Annual screening mammography (non-implanted patients) and magnetic resonance imaging (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[9].

### Q INSIDE SAFETY TECHNOLOGY™ RFID TECHNICAL SPECIFICATIONS

Weight 0.06 grams
Length: 9 mm
Diameter: 2.1 mm
Frequency: 134.2 ±4 KHz Read Range: >10 cms
Operating Temperature Tolerance: -20°C to +70°C


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

### Q INSIDE SAFETY TECHNOLOGY™ HANDHELD READER TECHNICAL SPECIFICATIONS

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

## REFERENCES


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