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21st December 2017

Reference: MHRA ref: 2017/007/029/601/001

Urgent Field Safety Notice
Motiva Implants® - Change of Directions of Use

Specifically, this FSN applies to all codes of the following products:

Round, Ergonomix®, SilkSurface®, ProgressiveGel™ Ultima™ with Qid™ and without Qid™
Round, SilkSurface®, ProgressiveGel™ Ultima™ with Qid™ and without Qid™
Round, VelvetSurface®, ProgressiveGel™ Ultima™ with Qid™ and without Qid™
Round, SilkSurface® or SmoothSilk®, Progressive Gel™ with Qid™ and without Qid™
Round, SilkSurface®, ProgressiveGel™ Plus with Qid™ and without Qid™
Round, VelvetSurface®, ProgressiveGel™ Plus with Qid™ and without Qid™
Round, VelvetSurface®, ProgressiveGel™ with Qid™ and without Qid™

Dear Customer,

Establishment Labs is initiating this voluntary Field Safety Notice (FSN) to inform of a change in the Directions for Use of the aforementioned products. Establishment Labs recently identified an involuntary error in the Directions for Use (DFU) document that is included in each package of product (Motiva Implants®).

Description of the problem:
This error is associated with an incorrect indication about the maximum magnetic field the patient can undergo when scanned under an MRI. It was wrongly indicated that the patient could undergo a maximum of 7 Tesla when **the correct indication is a maximum of 3 Tesla.** Establishment Labs products have been tested to be MR Conditional to 1.5 and 3 Tesla MRIs, which are the magnetic fields commonly available for MRIs in Radiological centers around the world.

The 7 Tesla MRIs availability is very limited, mostly to investigation centers; and even if they are available in Radiological Centers they are designed for scanning head and extremities and not the torso since they lack a body coil. Thus, is it highly unlikely -if not impossible- that a patient implanted with Motiva Implants® can undergo a scan **over** 3 Tesla, or in this case, a 7 Tesla scan. There is no significant risk to patients.

Establishment Labs is proceeding to update the DFU in all of its products. Independently of the correction of the aforementioned error, Establishment Labs is committed to the

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efforts for providing this information to users that have already implanted these products and to request them to inform their patients about this matter. **There is no device deficiency or malfunction associated with this Field Safety Notice**.

The scanning conditions as they will appear in the revised DFU are as follows:

Motiva Implants® are MRI conditional. The patient implanted with Motiva Implants® can undergo MRI scan 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.*
- *Under the scan defined conditions, the Motiva Implants® with Qid™ is expected to produce a maximum temperature rise of 1.5 °C after 15 minutes of continuous scanning (i.e., per pulse sequence).*

In non-clinical testing, the magnetically induced displacement force and magnetically induced torque were tested and no clinically significant displacement or torque was detected. Motiva Implants with Q Inside Safety Technology™ (Qid™) contains a microtransponder that provides electronic serial number data through an external reader. This microtransponder creates an imaging void during breast implant MRI (known as artifact effect) that can block visualization of a small area around the transponder. In non-clinical testing, the image artifact caused by Motiva Implants® with Qid™ extends approximately 15 mm radially from the RFID when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

In selected cases, additional imaging techniques such as ultrasound, tomosynthesis, digital compression mammogram, subtraction contrast mammography and scintimammography are recommend to be used to complement the visualization of the region affected by the artifact and improve the overall diagnosis.

Studies conducted by the manufacturer indicate that the use of a "combined" or "dual" modality, using additional imaging technologies (i.e. MRI with: Ultrasound (US), Mammography, Tomosynthesis, etc.), may considerably increase the diagnostic accuracy of procedures involving Motiva Implants® with Qid. The addition of other imaging modalities, using standard practices, allows for the complete radiological survey of the breasts.

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Advise on action to be taken by the user:

1. Establishment Labs requests that users of Motiva Implants® to whom this notice is ultimately directed, inform their patients at the shortest possible time about this change and insure their awareness. To assist users in providing this information Establishment Labs has also set up a Q&A document for patients. This Q&A can be found at http://www.motivaimagine.com/support/breast/screening/

2. It is requested that a representative of the Distributor provides a confirmation note that this Field Safety Notice has been effectively communicated to all users in their territory (Clinic, Medical Center, etc.). This note should be signed and stamped and can be scanned and sent via e-mail to regulatoryaffairs@establishmentlabs.com.

3. Users can continue to implant the products they have in their hands. As stated, **there is no device deficiency or malfunction associated with this Field Safety Notice**.

Contact reference person:
In case you need further information in relation with this Safety Notice you can communicate at regulatoryaffairs@establishmentlabs.com

The undersign confirms that this Field Safety Notice has been evaluated by the Medicines and Healthcare Products Regulatory Agency (MHRA) from the United Kingdom, and that it is also being distributed among all Competent Authorities from the Europe Union where this product has been placed in the market.

Alvaro Sanabria Fernández
Quality Manager
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Acknowledgement Letter

Field Safety Notice
Motiva Implants® - Change of Directions of Use

By this mean, the undersigned confirms that the above reference Field Safety Notice regarding Change of Directions of Use in the Motiva Implants® has been distributed to users of this product in the territory.

____ A list of users to which the Field Safety Notice was distributed to is attached.

____ A list of users cannot be provided per local legislation.

Note:
Please fill out the information below, **scan and send to:**

regulatoryaffairs@establishmentlabs.com

Receipt date: _____

Name: _____

Title: _____

Company: _____

Company Stamp