Device Tracking Form USA

I. COMPLETE UPON IMPLANT

DEVICE AND SURGERY INFORMATION

Date of implantation *(mm/dd/yy)*

Afflix LEFT breast implant label here. If label is not available, record Catalogue Number (REF) and Serial Number (SN) below

Left

Place device sticker here

REF (Left)

SN (Left)

☐ Reconstruction ☐ Augmentation ☐ Revision

Afflix RIGHT breast implant label here. If label is not available, record Catalogue Number (REF) and Serial Number (SN) below

Right

Place device sticker here

REF (Right)

SN (Right)

☐ Reconstruction ☐ Augmentation ☐ Revision

IMPLANTING/EXPLANTING PHYSICIAN INFORMATION

Last Name | First Name

Address | City/State/Province | Zip/Postal Code

Email | Telephone | Fax

☐ The surgeon who implanted this device complied with FDA requirements pertaining to use of the Patient Decision Checklist for this device, including pre-operative review and appropriate initials and signatures. (To be completed by implanting physician)

ATTENDING/FOLLOWING PHYSICIAN INFORMATION (if different from above)

Last Name | First Name

Address | City/State/Province | Zip/Postal Code

Email | Telephone | Fax

PATIENT INFORMATION

Last Name | First Name

Address | City/State/Province | Zip/Postal Code

Email | Telephone | Fax

☐ Patient declines the release of their patient specific information*

II. COMPLETE ONLY FOR NEW DEVICES OPENED AND DISCARDED/DESTROYED

SN

REF

Disposal Date *(mm/dd/yy)*

Reasons/Comments

III. COMPLETE ONLY IF MOTIVA IMPLANTS WERE REMOVED

EXPLANTED DEVICE INFORMATION

Date of explant *(mm/dd/yy)*

Device to be returned? Reconstruction Augmentation

LEFT

SN (Left) Unknown

REF (Left) Unknown

Reason for left removal

Did the device cause or contribute to the reason for removal? Yes No

If no, please provide the cause

Original implant date *(mm/dd/yy)* Unknown

Original implanting physician Unknown

RIGHT

SN (Right) Unknown

REF (Right) Unknown

Reason for left removal

Did the device cause or contribute to the reason for removal? Yes No

If no, please provide the cause

Original implant date *(mm/dd/yy)* Unknown

Original implanting physician Unknown

For questions regarding device tracking, please contact us at 1 (800) 924-5072

Device Tracking Forms can be submitted to www.motivausa.com electronically using the QR code