# TECHNICAL AND CLINICAL FILE OF STERILE SILICONE BREAST IMPLANTS MOTIVA IMPLANT MATRIX® - CLASS III MEDICAL DEVICE SILKSURFACE™ PLUS, VELVETSURFACE™ PLUS, ERGONOMIX™ SILKSURFACE™ AND ERGONOMIX™ VELVETSURFACE™ FAMILIES

## I: TECHNICAL SPECIFICATIONS

### 1. DEVICE DESCRIPTION

Establishment Labs S.A. Sterile Silicone Breast Implants Motiva Implant Matrix® are mammary augmentation devices with low diffusion barrier shell technology, constructed of successive cross-linked layers of silicone elastomer, which gives the implants its elasticity and integrity. All implants are composed of the above-mentioned shell, a patch, and silicone gel fill. The shell is filled with a platinum-cured siloxane polymer. All raw materials are supplied by a medical grade, long-term implantable silicones vendor with extensive master files registered with the US FDA (Food & Drug Administration).

Establishment Labs S.A. has 2 different surfaces of Sterile Silicone Breast Implants Motiva Implant Matrix® implants:

a. Nanotextured surface: SilkSurface™ PLUS and Ergonomix SilkSurface™)
b. Microtextured surface: VelvetSurface™ PLUS and Ergonomix™ VelvetSurface™

The Sterile Silicone Breast Implants Motiva Implant Matrix® implants are filled by two kinds of filling gels, as described below:

ProgressiveGel ™ PLUS, ProgressiveGel Última™

Sterile Silicone Implants Motiva Implant Matrix® SilkSurface™ PLUS, Sterile Silicone Implants Motiva Implant Matrix® VelvetSurface™ PLUS, are filled with ProgressiveGel™ PLUS.

Sterile Silicone Implants Motiva Implant Matrix® Ergonomix™ SilkSurface™, Sterile Silicone Implants Motiva Implant Matrix® Ergonomix™ VelvetSurface™ are filled with ProgressiveGel™ Ultima™.

## 2. COMPONENTS

All of Establishment Labs S.A. Sterile Silicone Breast Implants Motiva Implant Matrix® are composed by:

### *a) A Shell or envelope*

As shown in Table and Figure 1, the shell is built from unrestricted siloxane polymer elastomers made of two different low viscosity, heat curable silicone dispersions: the Standard Dispersion that forms the base of the layers of the shell, and the Barrier Dispersion that acts as a barrier that prevents or delays the diffusion of the internal gel filler impurities or residues through the shell. The barrier dispersion forms "thicker" links within the dispersion that reduces the diffusion of gel residues through the shell. The shell barrier layer can be colored with pigment, so it can be visually recognized, as a way to easily confirm its existence.

### b) *A Patch or Seal*

The patch is made of a double layer composed by barrier silicone elastomer and an uncatalyzed, vinyl-functional, high consistency silicone elastomer, whose adherent properties are activated when exposed to heat and pressure. Both are unrestricted silicone part numbers from the above-mentioned vendor.

### *c) Filling Gel*

Filling gel is made of a high purity, optically clear silicone gel, two-component system of low viscosity liquids that blend easily in a 1:1 or 3:1 mix ratio, depending of the gel used. The resulting mix after the curing process is a highly cohesive gel with the adequate balance between the desired projection and an excellent mechanical performance of the device inside the body.

The viscoelastic properties control of each gel is achieved by measuring their penetration. The silicone gel has been proved to comply with all the citotoxicity and elemental analysis testing, and its content of impurities or low molecular weight polymer chains (D4 and D5) does not exceed 1%.

### *d) Pigment*

Medical grade, long-term implantable silicone pigments can be used in Sterile Silicone Breast Implants Motiva Implant Matrix® shell. The pigment content represents less than 0.05% of the

barrier layer material and less than 0.008% of all shell layers. This silicone pigment poses no risk on the device performance or the patients health, and is used to visually recognize the implants shell barrier layer, facilitating its inspection by the quality inspectors and allowing the surgeon to confirm its presence, which ultimately enhances the device's safety profile.

***e) Unique Device Identification (UDI microtransponder):***

The implant may or may not contain a unique identification device, which consists of a microtransponder which is used for the silicone implant traceability recognition and post-implantation. The implanted device can be read through a radio frequency reader, providing information for traceability implant and avoiding the need for explantation for such information. Breast implants containing a microtransponder include a miniaturized, implantable, radio frequency identification device (RFID), which is placed in the breast implant filler material. Scanners to scan and read the information in the microtransponders are purchased separately. The microtransponder is a passive device. The microtransponder is used to store an electronic unique device identification number (UDI). The UDI number is used by patient-approved physicians and other health professionals, to access a database that will provide the implanted device specific information and other information provided by the patient.

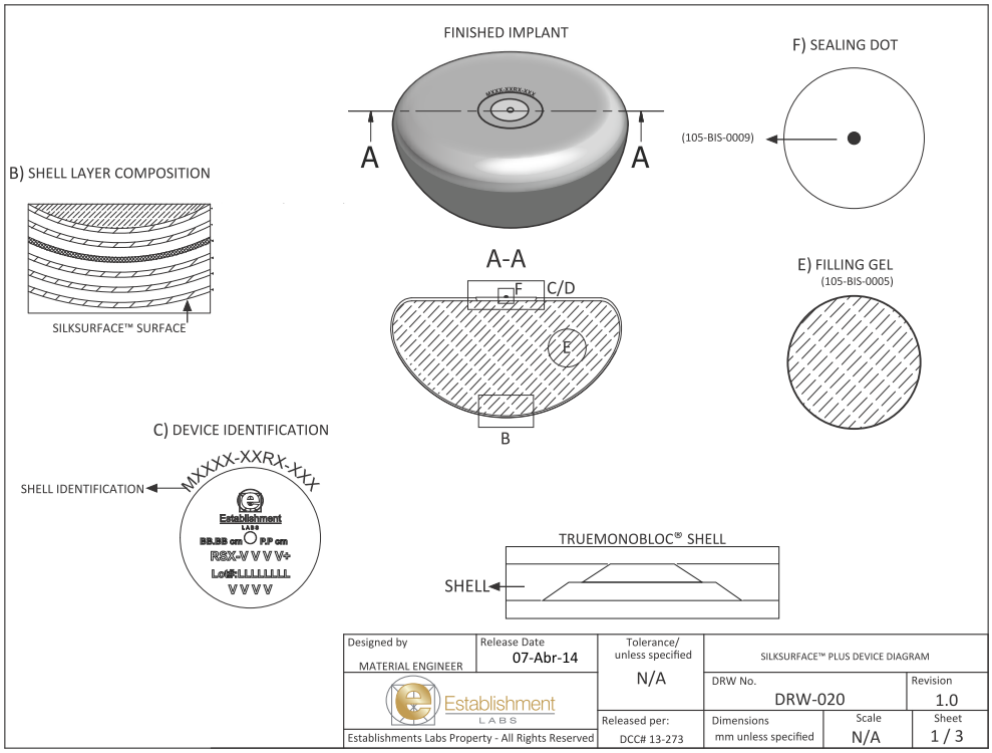
***Table 1: Establishment Labs S.A. Sterile Silicone Breast Implants Motiva Implant Matrix® Components and Materials.***

| ***Component*** | ***Material*** |
|---|---|
| Shell (Envelope): Standard Layers.<br>Shell Thickness 0.013"-0.040" (0.33 mm-1.02 mm) | Standard Silicone Elastomer Dispersion: 95% dimethyl: 5% diphenyl. *MED 6400 (Part A and Part B) Standard Dispersion. |

| | |
|---|---|
| Shell (Envelope): Barrier Layer. | Barrier Silicone Elastomer Dispersion: 85% dimethyl: 15% diphenyl. *MED 6600 (Part A and Part B) Barrier Dispersion. |
| Shell: Pigment | Biocompatible pigment *MED 4800-7<br>dispersed in silicone polymer. |
| Patch Assembly. | Double layer of barrier silicone elastomer plus uncatalyzed, vinyl-functional, high consistency silicone elastomer. *MED7-6600 (Part A and Part B) Barrier Dispersion, *MED 2174 Patch and Filler Unvulcanized Layer. |
| Internal Gel. | Base & crosslinker; platinum-cured siloxane polymer. *MED3-6311 Filling Gel |
| Unique Device Identification<br>Length 8 – 10 mm, Diameter 2,0 – 2,5 mm | Contains a core wire (copper A200) coated with polyurethane, epoxy adhesive Delo Photobond 4442, an RFID chip марки EM 4305 and silica glass grade 8350. |

*This is the part number assigned by the supplier: NuSil Technology.

Figure 1 is a diagram showing the different parts and materials of Establishment Labs S.A. Sterile Silicone Breast Implants Motiva Implant Matrix®.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(105-BIS-0009)
A
A
B) SHELL LAYER COMPOSITION
SILKSURFACE™ SURFACE
A-A
C/D
F
E
B
E) FILLING GEL
(105-BIS-0005)
C) DEVICE IDENTIFICATION
SHELL IDENTIFICATION
MXXXX-XXRX-XXX
TRUEMONOBLOC® SHELL
SHELL
Designed by
MATERIAL ENGINEER
Release Date
07-Abr-14
Tolerance/ unless specified
N/A
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DRW No.
DRW-020
Revision
1.0
Released per:
DCC# 13-273
Dimensions
mm unless specified
Scale
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Sheet
1 / 3
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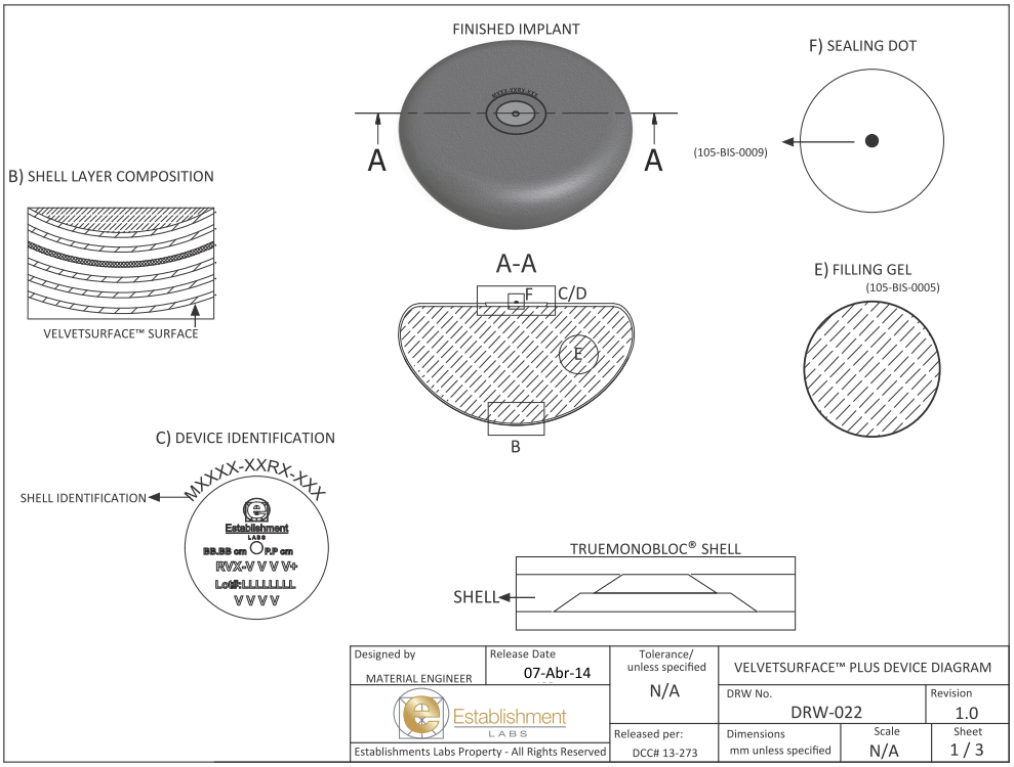
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B) SHELL LAYER COMPOSITION
VELVETSURFACE™ SURFACE
A-A
C/D
F
E
B
E) FILLING GEL
(105-BIS-0005)
C) DEVICE IDENTIFICATION
SHELL IDENTIFICATION
MXXXX-XXRX-XXX
TRUEMONOBLOC® SHELL
SHELL
Designed by
MATERIAL ENGINEER
Release Date
07-Abr-14
Tolerance/ unless specified
N/A
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DRW-022
Revision
1.0
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Dimensions
mm unless specified
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1 / 3
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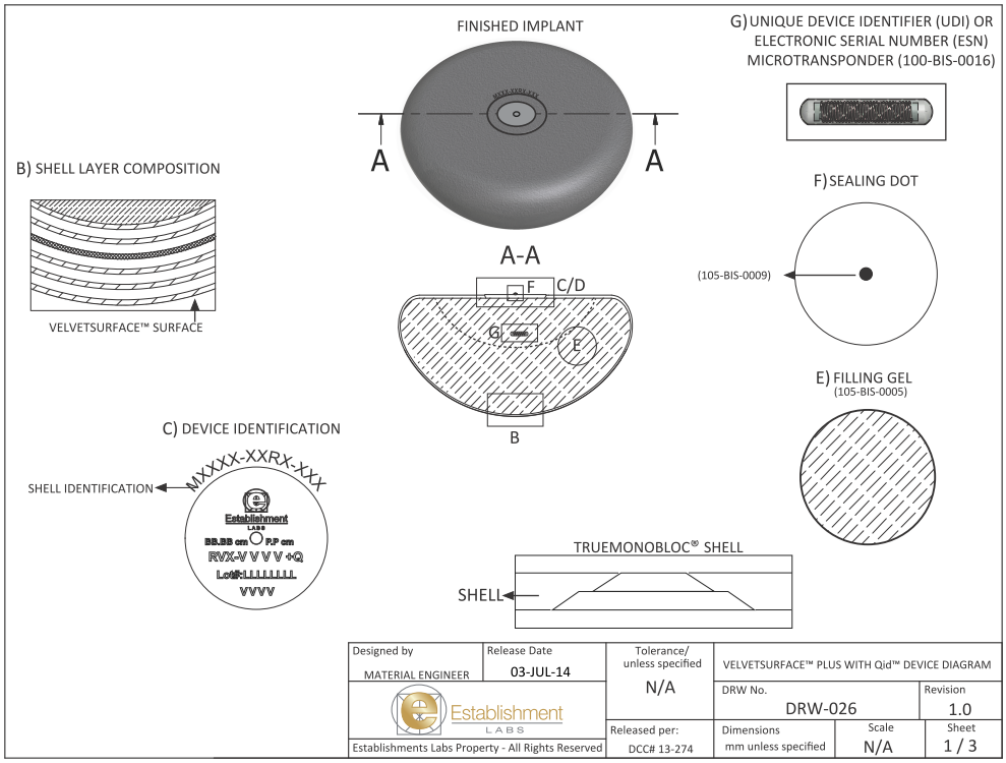
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A
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B) SHELL LAYER COMPOSITION
VELVETSURFACE™ SURFACE
F) SEALING DOT
(105-BIS-0009)
A-A
F
C/D
G
E
B
E) FILLING GEL
(105-BIS-0005)
C) DEVICE IDENTIFICATION
SHELL IDENTIFICATION
MXXXX-XXRX-XXX
TRUEMONOBLOC® SHELL
SHELL
Designed by
MATERIAL ENGINEER
Release Date
03-JUL-14
Tolerance/ unless specified
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DRW No.
DRW-026
Revision
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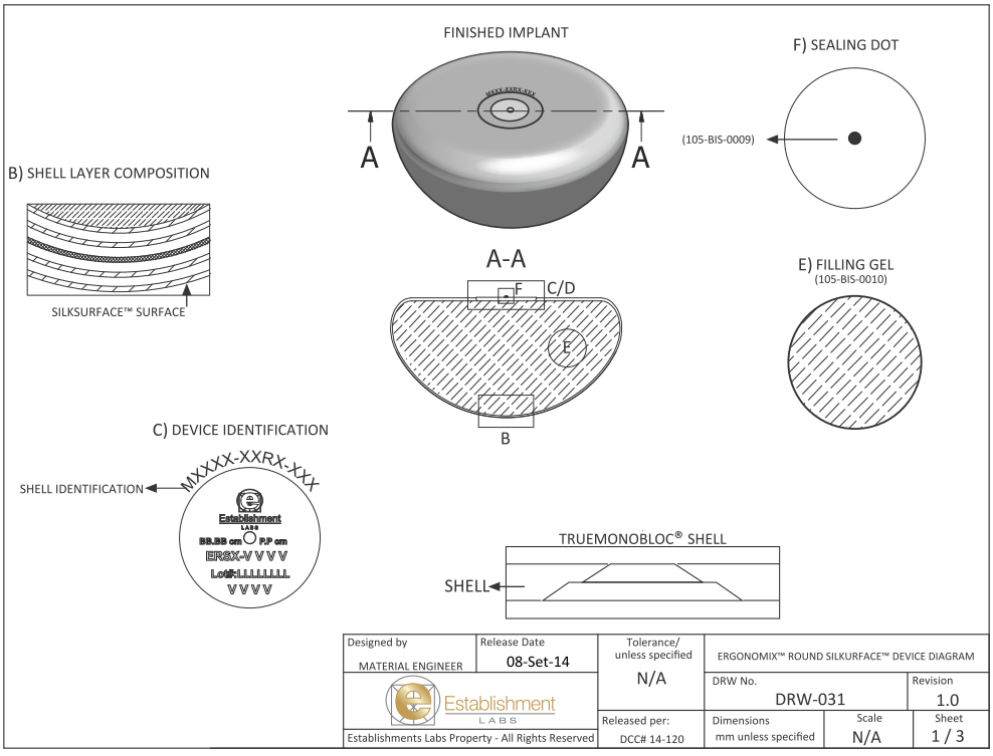
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B) SHELL LAYER COMPOSITION
SILKSURFACE™ SURFACE
A-A
F
C/D
E
B
E) FILLING GEL
(105-BIS-0010)
C) DEVICE IDENTIFICATION
SHELL IDENTIFICATION
MXXXX-XXRX-XXX
TRUEMONOBLOC® SHELL
SHELL
Designed by
MATERIAL ENGINEER
Release Date
08-Set-14
Tolerance/ unless specified
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DRW No.
DRW-031
Revision
1.0
Establishments Labs Property - All Rights Reserved
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Sheet
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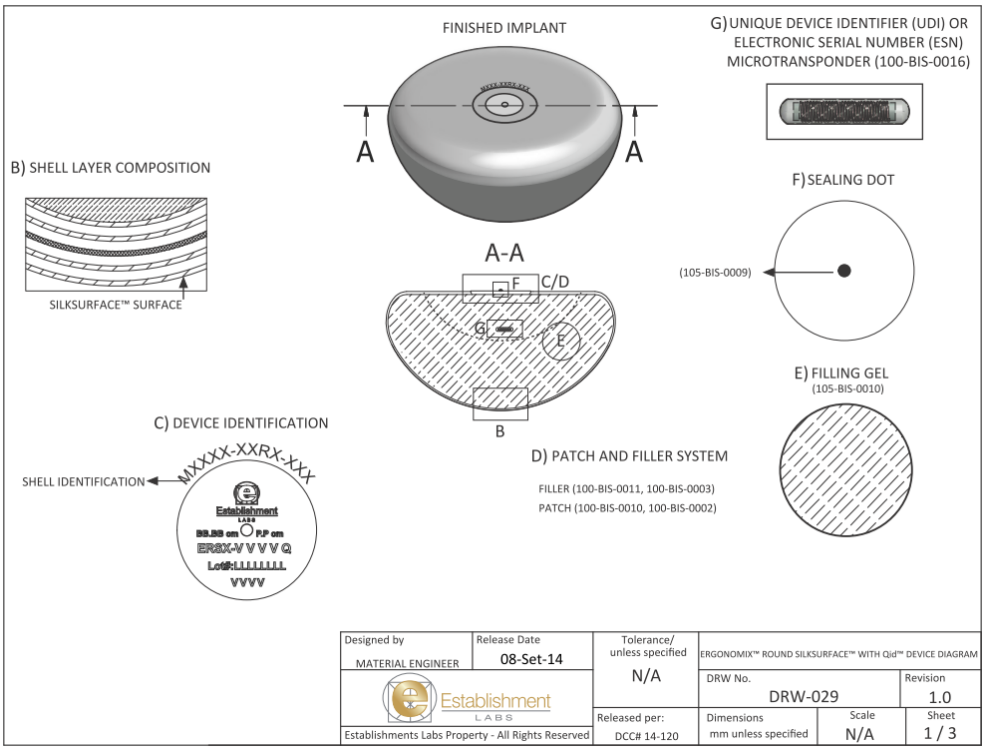
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SILKSURFACE™ SURFACE
A-A
F
C/D
G
E
B
F) SEALING DOT
(105-BIS-0009)
E) FILLING GEL
(105-BIS-0010)
C) DEVICE IDENTIFICATION
SHELL IDENTIFICATION
MXXXX-XXRX-XXX
Establishment
LABS
BB.BB cm P.P cm
ERXX-VVVVQ
Lot#:LLLLLLLLL
VVVV
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FILLER (100-BIS-0011, 100-BIS-0003)
PATCH (100-BIS-0010, 100-BIS-0002)
Designed by
MATERIAL ENGINEER
Release Date
08-Set-14
Tolerance/ unless specified
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DRW No.
DRW-029
Revision
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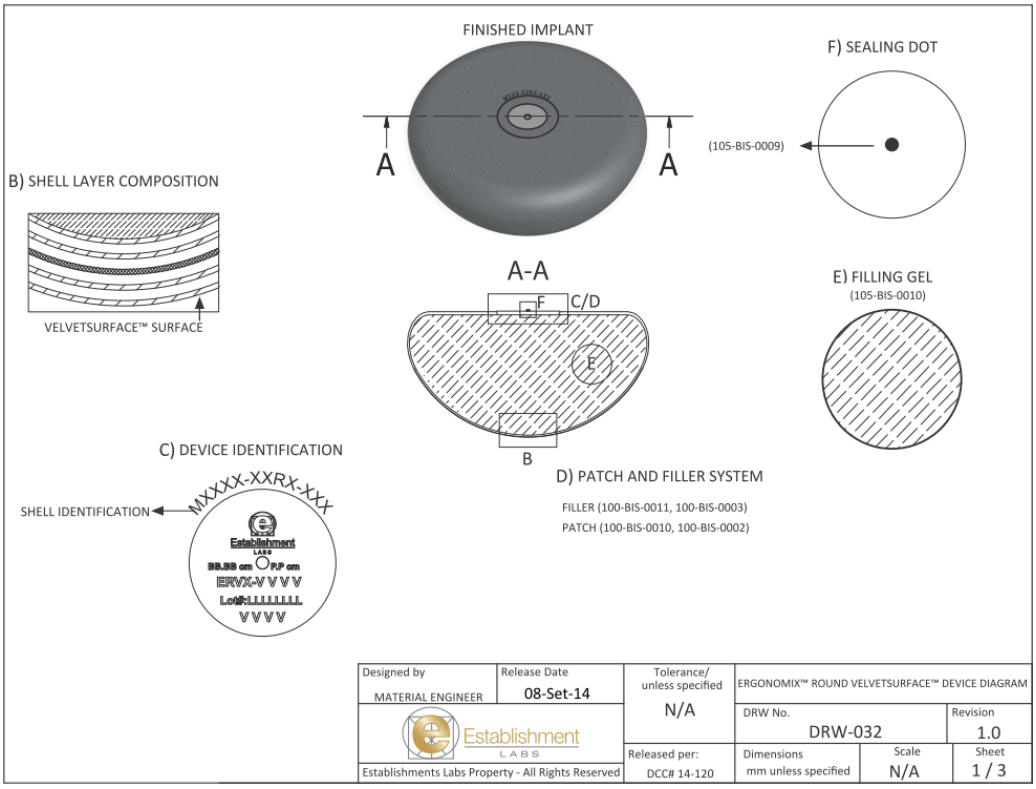
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B) SHELL LAYER COMPOSITION
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A-A
F
C/D
E
B
E) FILLING GEL
(105-BIS-0010)
C) DEVICE IDENTIFICATION
SHELL IDENTIFICATION
MXXXX-XXRX-XXX
Establishment
LABS
BB.BB cm P.P cm
ERVX-VVVV
Lot#:LLLLLLLLL
VVVV
D) PATCH AND FILLER SYSTEM
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PATCH (100-BIS-0010, 100-BIS-0002)
Designed by
MATERIAL ENGINEER
Release Date
08-Set-14
Tolerance/ unless specified
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Revision
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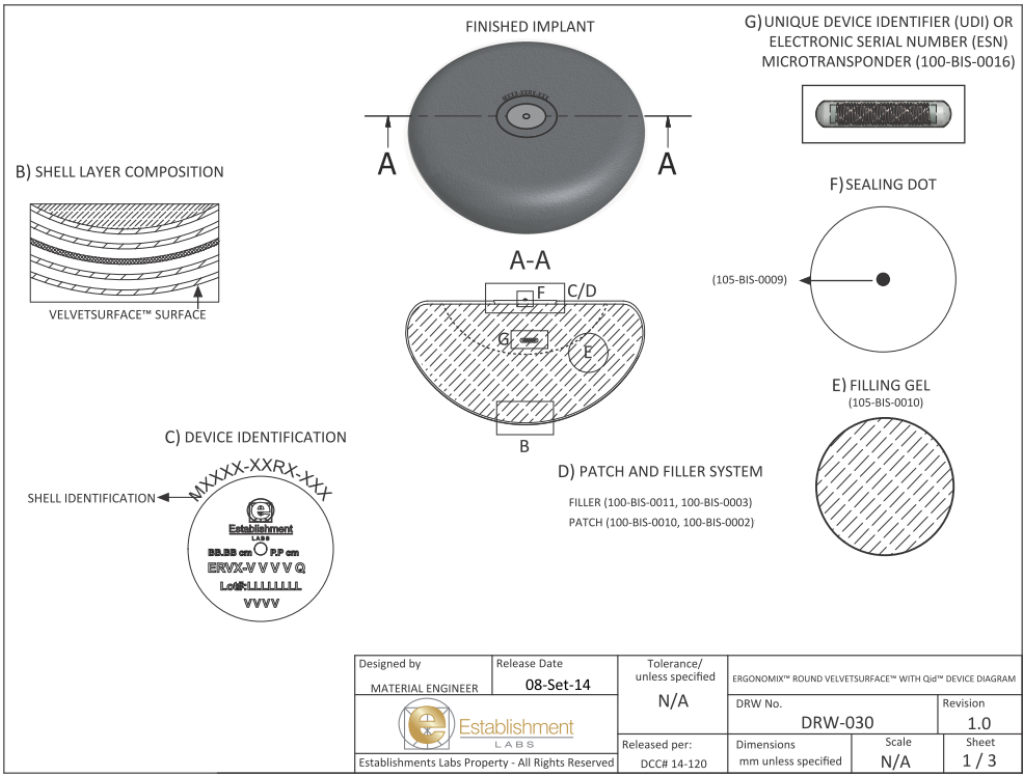
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C/D
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(105-BIS-0009)
E) FILLING GEL
(105-BIS-0010)
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SHELL IDENTIFICATION
MXXXX-XXRX-XXX
D) PATCH AND FILLER SYSTEM
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PATCH (100-BIS-0010, 100-BIS-0002)
Designed by
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Release Date
08-Set-14
Tolerance/ unless specified
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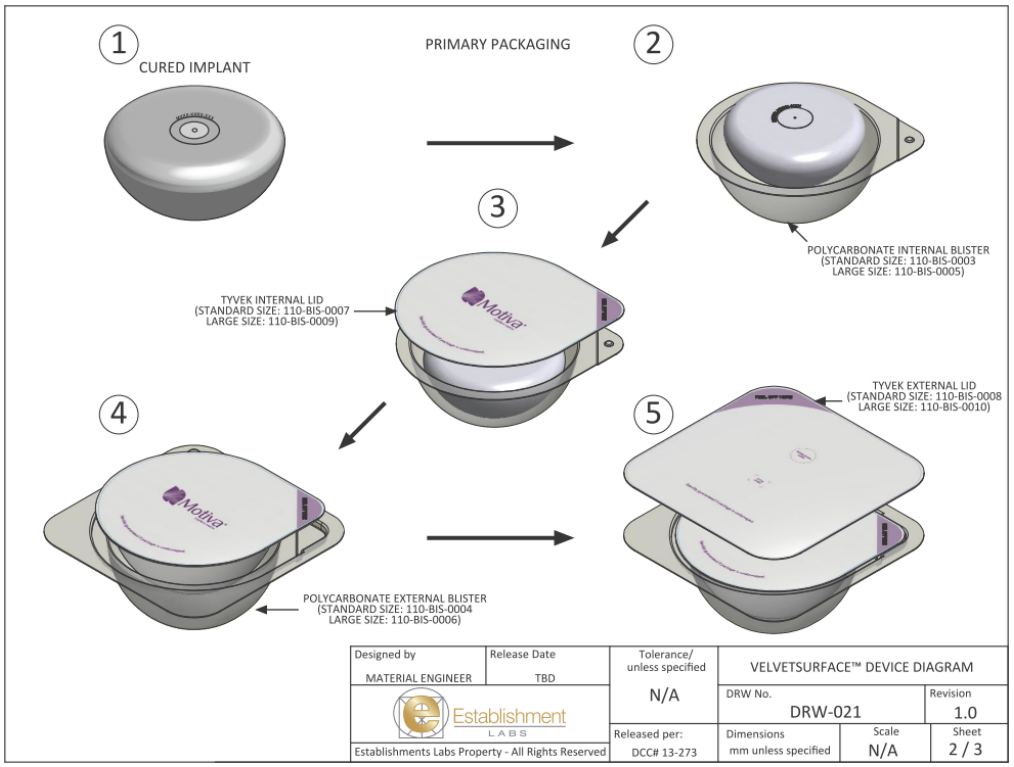
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LARGE SIZE: 110-BIS-0005)
3
TYVEK INTERNAL LID
(STANDARD SIZE: 110-BIS-0007
LARGE SIZE: 110-BIS-0009)
4
5
TYVEK EXTERNAL LID
(STANDARD SIZE: 110-BIS-0008
LARGE SIZE: 110-BIS-0010)
POLYCARBONATE EXTERNAL BLISTER
(STANDARD SIZE: 110-BIS-0004
LARGE SIZE: 110-BIS-0006)
Designed by
MATERIAL ENGINEER
Release Date
TBD
Tolerance/ unless specified
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DRW No.
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Revision
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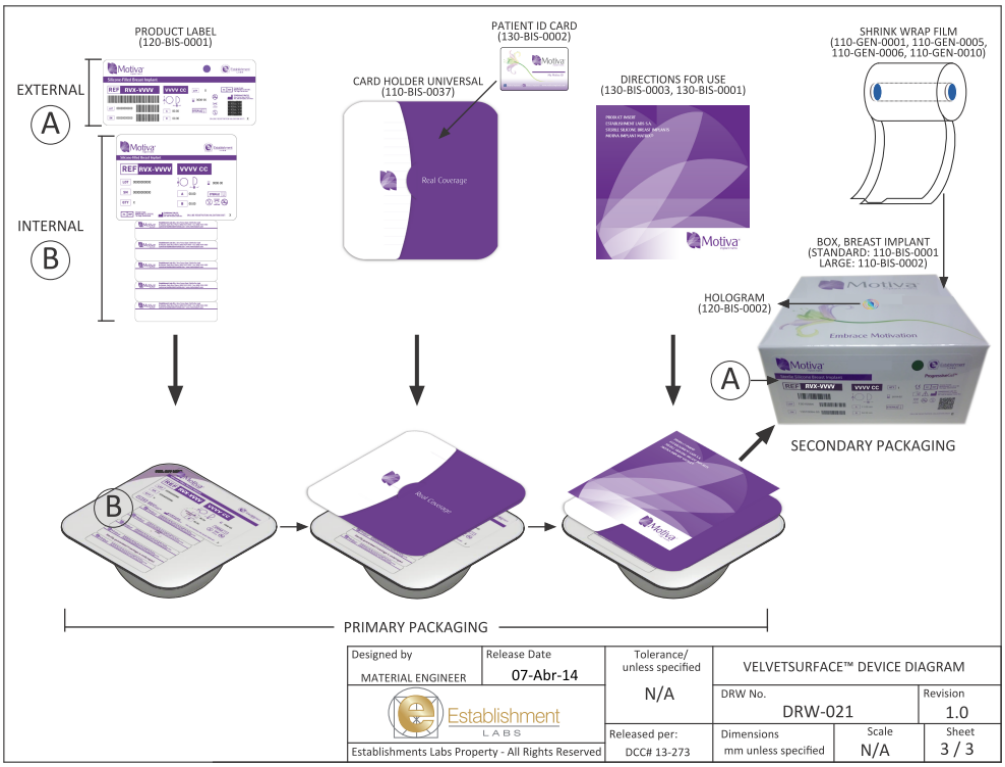



***Figure 1: Establishment Labs S.A. Sterile Silicone Breast Implants Motiva Implant Matrix® Device Diagram.***

## 3. PRESENTATIONS, MODELS, DIMENSIONS

Sterile Silicone Breast Implants Motiva Implant Matrix® are available in a range of bases or diameters (8.5cm to 15cm), profiles or projections: (low, moderate, high and super high) and volumes (105cc to 1050cc), as well as in nanotextured shell surface (SilkSurface™ PLUS and Ergonomix SilkSurface™) and microtextured shell surface (VelvetSurface™ PLUS and Ergonomix™ VelvetSurface™). The following chart includes all catalog references of Establishment Labs S.A. Sterile Silicone Breast Implants Motiva Implant Matrix® SilkSurface™ PLUS, VelvetSurface™ PLUS and Ergonomix™:

**Sterile Silicone Breast Implants Motiva Implant Matrix® - Round SilkSurface™ PLUS Corsé**

| Catalogue Number | Base (cm) | Projection (cm) | Catalogue Number | Base (cm) | Projection (cm) |
|---|---|---|---|---|---|
| RSC-180 | 8.50 | 4.0 | RSC-440 | 11.50 | 5.7 |
| RSC-210 | 9.00 | 4.2 | RSC-475 | 11.75 | 5.8 |
| RSC-240 | 9.50 | 4.5 | RSC-510 | 12.00 | 6.0 |
| RSC-260 | 9.75 | 4.6 | RSC-550 | 12.25 | 6.1 |
| RSC-280 | 10.00 | 4.8 | RSC-590 | 12.50 | 6.3 |
| RSC-300 | 10.25 | 4.9 | RSC-650 | 13.00 | 6.6 |
| RSC-325 | 10.50 | 5.1 | RSC-725 | 13.50 | 6.9 |
| RSC-350 | 10.75 | 5.2 | RSC-825 | 14.00 | 7.2 |
| RSC-380 | 11.00 | 5.4 | RSC-925 | 14.50 | 7.5 |
| RSC-410 | 11.25 | 5.5 | RSC-1050 | 15.00 | 7.8 |

**Sterile Silicone Breast Implants Motiva Implant Matrix® - Round SilkSurface™ PLUS Mini**

| Catalogue Number | Base (cm) | Projection (cm) | Catalogue Number | Base (cm) | Projection (cm) |
|---|---|---|---|---|---|
| RSM-105+ | 08.50 | 2.20 | RSM-245+ | 11.50 | 2.80 |
| RSM-125+ | 09.00 | 2.30 | RSM-260+ | 11.75 | 2.80 |
| RSM-140+ | 09.50 | 2.40 | RSM-275+ | 12.00 | 2.90 |
| RSM-150+ | 09.75 | 2.40 | RSM-290+ | 12.25 | 2.90 |
| RSM-160+ | 10.00 | 2.50 | RSM-310+ | 12.50 | 3.00 |
| RSM-170+ | 10.25 | 2.50 | RSM-360+ | 13.00 | 3.10 |
| RSM-185+ | 10.50 | 2.60 | RSM-400+ | 13.50 | 3.20 |
| RSM-205+ | 10.75 | 2.60 | RSM-430+ | 14.00 | 3.30 |
| RSM-220+ | 11.00 | 2.70 | RSM-475+ | 14.50 | 3.40 |
| RSM-230+ | 11.25 | 2.70 | RSM-525+ | 15.00 | 3.50 |

**Sterile Silicone Breast Implants Motiva Implant Matrix® - Round SilkSurface™ PLUS Demi**

| Catalogue Number | Base (cm) | Projection (cm) | Catalogue Number | Base (cm) | Projection (cm) |
|---|---|---|---|---|---|
| RSD-135+ | 8.50 | 3.1 | RSD-300+ | 11.50 | 3.9 |
| RSD-155+ | 9.00 | 3.3 | RSD-320+ | 11.75 | 3.9 |
| RSD-180+ | 9.50 | 3.4 | RSD-340+ | 12.00 | 4.0 |
| RSD-190+ | 9.75 | 3.4 | RSD-360+ | 12.25 | 4.0 |
| RSD-205+ | 10.00 | 3.5 | RSD-380+ | 12.50 | 4.1 |
| RSD-215+ | 10.25 | 3.5 | RSD-425+ | 13.00 | 4.3 |
| RSD-230+ | 10.50 | 3.6 | RSD-475+ | 13.50 | 4.4 |
| RSD-245+ | 10.75 | 3.7 | RSD-525+ | 14.00 | 4.5 |
| RSD-265+ | 11.00 | 3.8 | RSD-575+ | 14.50 | 4.6 |
| RSD-285+ | 11.25 | 3.8 | RSD-625+ | 15.00 | 4.8 |

**Sterile Silicone Breast Implants Motiva Implant Matrix® - Round SilkSurface™ PLUS Full**

| Catalogue Number | Base (cm) | Projection (cm) | Catalogue Number | Base (cm) | Projection (cm) |
|---|---|---|---|---|---|
| RSF-145+ | 8.50 | 3.5 | RSF-355+ | 11.50 | 4.7 |
| RSF-175+ | 9.00 | 3.7 | RSF-375+ | 11.75 | 4.8 |
| RSF-205+ | 9.50 | 3.9 | RSF-400+ | 12.00 | 4.9 |
| RSF-220+ | 9.75 | 4.0 | RSF-425+ | 12.25 | 5.0 |
| RSF-235+ | 10.00 | 4.1 | RSF-450+ | 12.50 | 5.1 |
| RSF-255+ | 10.25 | 4.2 | RSF-500+ | 13.00 | 5.3 |
| RSF-275+ | 10.50 | 4.3 | RSF-550+ | 13.50 | 5.5 |
| RSF-295+ | 10.75 | 4.4 | RSF-625+ | 14.00 | 5.7 |
| RSF-315+ | 11.00 | 4.5 | RSF-700+ | 14.50 | 5.9 |
| RSF-335+ | 11.25 | 4.6 | RSF-775+ | 15.00 | 6.1 |

**Sterile Silicone Breast Implants Motiva Implant Matrix® - Round SilkSurface™ PLUS Corsé**

| Catalogue Number | Base (cm) | Projection (cm) | Catalogue Number | Base (cm) | Projection (cm) |
|---|---|---|---|---|---|
| RSC-180+ | 8.50 | 4.0 | RSC-440+ | 11.50 | 5.7 |
| RSC-210+ | 9.00 | 4.2 | RSC-475+ | 11.75 | 5.8 |
| RSC-240+ | 9.50 | 4.5 | RSC-510+ | 12.00 | 6.0 |
| RSC-260+ | 9.75 | 4.6 | RSC-550+ | 12.25 | 6.1 |
| RSC-280+ | 10.00 | 4.8 | RSC-590+ | 12.50 | 6.3 |
| RSC-300+ | 10.25 | 4.9 | RSC-650+ | 13.00 | 6.6 |
| RSC-325+ | 10.50 | 5.1 | RSC-725+ | 13.50 | 6.9 |
| RSC-350+ | 10.75 | 5.2 | RSC-825+ | 14.00 | 7.2 |
| RSC-380+ | 11.00 | 5.4 | RSC-925+ | 14.50 | 7.5 |
| RSC-410+ | 11.25 | 5.5 | RSC-1050+ | 15.00 | 7.8 |

**Sterile Silicone Breast Implants Motiva Implant Matrix® - Round VelvetSurface™ PLUS Mini**

| Catalogue Number | Base (cm) | Projection (cm) | Catalogue Number | Base (cm) | Projection (cm) |
|---|---|---|---|---|---|
| RVM-105+ | 08.50 | 2.20 | RVM-245+ | 11.50 | 2.80 |
| RVM-125+ | 09.00 | 2.30 | RVM-260+ | 11.75 | 2.80 |
| RVM-140+ | 09.50 | 2.40 | RVM-275+ | 12.00 | 2.90 |
| RVM-150+ | 09.75 | 2.40 | RVM-290+ | 12.25 | 2.90 |
| RVM-160+ | 10.00 | 2.50 | RVM-310+ | 12.50 | 3.00 |
| RVM-170+ | 10.25 | 2.50 | RVM-360+ | 13.00 | 3.10 |
| RVM-185+ | 10.50 | 2.60 | RVM-400+ | 13.50 | 3.20 |
| RVM-205+ | 10.75 | 2.60 | RVM-430+ | 14.00 | 3.30 |
| RVM-220+ | 11.00 | 2.70 | RVM-475+ | 14.50 | 3.40 |
| RVM-230+ | 11.25 | 2.70 | RVM-525+ | 15.00 | 3.50 |

**Sterile Silicone Breast Implants Motiva Implant Matrix® - Round VelvetSurface™ PLUS Demi**

| Catalogue Number | Base (cm) | Projection (cm) | Catalogue Number | Base (cm) | Projection (cm) |
|---|---|---|---|---|---|
| RVD-135+ | 8.50 | 3.1 | RVD-300+ | 11.50 | 3.9 |
| RVD-155+ | 9.00 | 3.3 | RVD-320+ | 11.75 | 3.9 |
| RVD-180+ | 9.50 | 3.4 | RVD-340+ | 12.00 | 4.0 |
| RVD-190+ | 9.75 | 3.4 | RVD-360+ | 12.25 | 4.0 |
| RVD-205+ | 10.00 | 3.5 | RVD-380+ | 12.50 | 4.1 |
| RVD-215+ | 10.25 | 3.5 | RVD-425+ | 13.00 | 4.3 |
| RVD-230+ | 10.50 | 3.6 | RVD-475+ | 13.50 | 4.4 |
| RVD-245+ | 10.75 | 3.7 | RVD-525+ | 14.00 | 4.5 |
| RVD-265+ | 11.00 | 3.8 | RVD-575+ | 14.50 | 4.6 |
| RVD-285+ | 11.25 | 3.8 | RVD-625+ | 15.00 | 4.8 |

**Sterile Silicone Breast Implants Motiva Implant Matrix® - Round VelvetSurface™ PLUS Full**

| Catalogue Number | Base (cm) | Projection (cm) | Catalogue Number | Base (cm) | Projection (cm) |
|---|---|---|---|---|---|
| RVF-145+ | 8.50 | 3.5 | RVF-355+ | 11.50 | 4.7 |
| RVF-175+ | 9.00 | 3.7 | RVF-375+ | 11.75 | 4.8 |
| RVF-205+ | 9.50 | 3.9 | RVF-400+ | 12.00 | 4.9 |
| RVF-220+ | 9.75 | 4.0 | RVF-425+ | 12.25 | 5.0 |
| RVF-235+ | 10.00 | 4.1 | RVF-450+ | 12.50 | 5.1 |
| RVF-255+ | 10.25 | 4.2 | RVF-500+ | 13.00 | 5.3 |
| RVF-275+ | 10.50 | 4.3 | RVF-550+ | 13.50 | 5.5 |
| RVF-295+ | 10.75 | 4.4 | RVF-625+ | 14.00 | 5.7 |
| RVF-315+ | 11.00 | 4.5 | RVF-700+ | 14.50 | 5.9 |
| RVF-335+ | 11.25 | 4.6 | RVF-775+ | 15.00 | 6.1 |

**Sterile Silicone Breast Implants Motiva Implant Matrix® - Round VelvetSurface™ PLUS Corsé**

| Catalogue Number | Base (cm) | Projection (cm) | Catalogue Number | Base (cm) | Projection (cm) |
|---|---|---|---|---|---|
| RVC-180+ | 8.50 | 4.0 | RVC-440+ | 11.50 | 5.7 |
| RVC-210+ | 9.00 | 4.2 | RVC-475+ | 11.75 | 5.8 |
| RVC-240+ | 9.50 | 4.5 | RVC-510+ | 12.00 | 6.0 |
| RVC-260+ | 9.75 | 4.6 | RVC-550+ | 12.25 | 6.1 |
| RVC-280+ | 10.00 | 4.8 | RVC-590+ | 12.50 | 6.3 |
| RVC-300+ | 10.25 | 4.9 | RVC-650+ | 13.00 | 6.6 |
| RVC-325+ | 10.50 | 5.1 | RVC-725+ | 13.50 | 6.9 |
| RVC-350+ | 10.75 | 5.2 | RVC-825+ | 14.00 | 7.2 |
| RVC-380+ | 11.00 | 5.4 | RVC-925+ | 14.50 | 7.5 |
| RVC-410+ | 11.25 | 5.5 | RVC-1050+ | 15.00 | 7.8 |

**Sterile Silicone Breast Implants Motiva Implant Matrix® SilkSurface™ PLUS Mini with $Q_{id}$™**

| Catalogue Number | Base (cm) | Projection (cm) | Catalogue Number | Base (cm) | Projection (cm) |
|---|---|---|---|---|---|
| RSM-105+Q | 08.50 | 2.20 | RSM-245+Q | 11.50 | 2.80 |
| RSM-125+Q | 09.00 | 2.30 | RSM-260+Q | 11.75 | 2.80 |
| RSM-140+Q | 09.50 | 2.40 | RSM-275+Q | 12.00 | 2.90 |
| RSM-150+Q | 09.75 | 2.40 | RSM-290+Q | 12.25 | 2.90 |
| RSM-160+Q | 10.00 | 2.50 | RSM-310+Q | 12.50 | 3.00 |
| RSM-170+Q | 10.25 | 2.50 | RSM-360+Q | 13.00 | 3.10 |
| RSM-185+Q | 10.50 | 2.60 | RSM-400+Q | 13.50 | 3.20 |
| RSM-205+Q | 10.75 | 2.60 | RSM-430+Q | 14.00 | 3.30 |
| RSM-220+Q | 11.00 | 2.70 | RSM-475+Q | 14.50 | 3.40 |
| RSM-230+Q | 11.25 | 2.70 | RSM-525+Q | 15.00 | 3.50 |

**Sterile Silicone Breast Implants Motiva Implant Matrix® SilkSurface™ PLUS Demi with $Q_{id}$™**

| Catalogue Number | Base (cm) | Projection (cm) | Catalogue Number | Base (cm) | Projection (cm) |
|---|---|---|---|---|---|
| RSD-135+Q | 8.50 | 3.1 | RSD-300+Q | 11.50 | 3.9 |
| RSD-155+Q | 9.00 | 3.3 | RSD-320+Q | 11.75 | 3.9 |
| RSD-180+Q | 9.50 | 3.4 | RSD-340+Q | 12.00 | 4.0 |
| RSD-190+Q | 9.75 | 3.4 | RSD-360+Q | 12.25 | 4.0 |
| RSD-205+Q | 10.00 | 3.5 | RSD-380+Q | 12.50 | 4.1 |
| RSD-215+Q | 10.25 | 3.5 | RSD-425+Q | 13.00 | 4.3 |
| RSD-230+Q | 10.50 | 3.6 | RSD-475+Q | 13.50 | 4.4 |
| RSD-245+Q | 10.75 | 3.7 | RSD-525+Q | 14.00 | 4.5 |
| RSD-265+Q | 11.00 | 3.8 | RSD-575+Q | 14.50 | 4.6 |
| RSD-285+Q | 11.25 | 3.8 | RSD-625+Q | 15.00 | 4.8 |

**Sterile Silicone Breast Implants Motiva Implant Matrix® SilkSurface™ PLUS Full with $Q_{id}$™**

| Catalogue Number | Base (cm) | Projection (cm) | Catalogue Number | Base (cm) | Projection (cm) |
|---|---|---|---|---|---|
| RSF-145+Q | 8.50 | 3.5 | RSF-355+Q | 11.50 | 4.7 |
| RSF-175+Q | 9.00 | 3.7 | RSF-375+Q | 11.75 | 4.8 |
| RSF-205+Q | 9.50 | 3.9 | RSF-400+Q | 12.00 | 4.9 |
| RSF-220+Q | 9.75 | 4.0 | RSF-425+Q | 12.25 | 5.0 |
| RSF-235+Q | 10.00 | 4.1 | RSF-450+Q | 12.50 | 5.1 |
| RSF-255+Q | 10.25 | 4.2 | RSF-500+Q | 13.00 | 5.3 |
| RSF-275+Q | 10.50 | 4.3 | RSF-550+Q | 13.50 | 5.5 |
| RSF-295+Q | 10.75 | 4.4 | RSF-625+Q | 14.00 | 5.7 |
| RSF-315+Q | 11.00 | 4.5 | RSF-700+Q | 14.50 | 5.9 |
| RSF-335+Q | 11.25 | 4.6 | RSF-775+Q | 15.00 | 6.1 |

**Sterile Silicone Breast Implants Motiva Implant Matrix® SilkSurface™ PLUS Corsé with $Q_{id}$™**

| Catalogue Number | Base (cm) | Projection (cm) | Catalogue Number | Base (cm) | Projection (cm) |
|---|---|---|---|---|---|
| RSC-180+Q | 8.50 | 4.0 | RSC-440+Q | 11.50 | 5.7 |
| RSC-210+Q | 9.00 | 4.2 | RSC-475+Q | 11.75 | 5.8 |
| RSC-240+Q | 9.50 | 4.5 | RSC-510+Q | 12.00 | 6.0 |
| RSC-260+Q | 9.75 | 4.6 | RSC-550+Q | 12.25 | 6.1 |
| RSC-280+Q | 10.00 | 4.8 | RSC-590+Q | 12.50 | 6.3 |
| RSC-300+Q | 10.25 | 4.9 | RSC-650+Q | 13.00 | 6.6 |
| RSC-325+Q | 10.50 | 5.1 | RSC-725+Q | 13.50 | 6.9 |
| RSC-350+Q | 10.75 | 5.2 | RSC-825+Q | 14.00 | 7.2 |
| RSC-380+Q | 11.00 | 5.4 | RSC-925+Q | 14.50 | 7.5 |
| RSC-410+Q | 11.25 | 5.5 | RSC-1050+Q | 15.00 | 7.8 |

**Sterile Silicone Breast Implants Motiva Implant Matrix® VelvetSurface™ PLUS Mini with $Q_{id}$™**

| Catalogue Number | Base (cm) | Projection (cm) | Catalogue Number | Base (cm) | Projection (cm) |
|---|---|---|---|---|---|
| RVM-105+Q | 08.50 | 2.20 | RVM-245+Q | 11.50 | 2.80 |
| RVM-125+Q | 09.00 | 2.30 | RVM-260+Q | 11.75 | 2.80 |
| RVM-140+Q | 09.50 | 2.40 | RVM-275+Q | 12.00 | 2.90 |
| RVM-150+Q | 09.75 | 2.40 | RVM-290+Q | 12.25 | 2.90 |
| RVM-160+Q | 10.00 | 2.50 | RVM-310+Q | 12.50 | 3.00 |
| RVM-170+Q | 10.25 | 2.50 | RVM-360+Q | 13.00 | 3.10 |
| RVM-185+Q | 10.50 | 2.60 | RVM-400+Q | 13.50 | 3.20 |
| RVM-205+Q | 10.75 | 2.60 | RVM-430+Q | 14.00 | 3.30 |
| RVM-220+Q | 11.00 | 2.70 | RVM-475+Q | 14.50 | 3.40 |
| RVM-230+Q | 11.25 | 2.70 | RVM-525+Q | 15.00 | 3.50 |

**Sterile Silicone Breast Implants Motiva Implant Matrix® VelvetSurface™ PLUS Demi with $Q_{id}$™**

| Catalogue Number | Base (cm) | Projection (cm) | Catalogue Number | Base (cm) | Projection (cm) |
|---|---|---|---|---|---|
| RVD-135+Q | 8.50 | 3.1 | RVD-300+Q | 11.50 | 3.9 |
| RVD-155+Q | 9.00 | 3.3 | RVD-320+Q | 11.75 | 3.9 |
| RVD-180+Q | 9.50 | 3.4 | RVD-340+Q | 12.00 | 4.0 |
| RVD-190+Q | 9.75 | 3.4 | RVD-360+Q | 12.25 | 4.0 |
| RVD-205+Q | 10.00 | 3.5 | RVD-380+Q | 12.50 | 4.1 |
| RVD-215+Q | 10.25 | 3.5 | RVD-425+Q | 13.00 | 4.3 |
| RVD-230+Q | 10.50 | 3.6 | RVD-475+Q | 13.50 | 4.4 |
| RVD-245+Q | 10.75 | 3.7 | RVD-525+Q | 14.00 | 4.5 |
| RVD-265+Q | 11.00 | 3.8 | RVD-575+Q | 14.50 | 4.6 |
| RVD-285+Q | 11.25 | 3.8 | RVD-625+Q | 15.00 | 4.8 |

**Sterile Silicone Breast Implants Motiva Implant Matrix® VelvetSurface™ PLUS Full with $Q_{id}$™**

| Catalogue Number | Base (cm) | Projection (cm) | Catalogue Number | Base (cm) | Projection (cm) |
|---|---|---|---|---|---|
| RVF-145+Q | 8.50 | 3.5 | RVF-355+Q | 11.50 | 4.7 |
| RVF-175+Q | 9.00 | 3.7 | RVF-375+Q | 11.75 | 4.8 |
| RVF-205+Q | 9.50 | 3.9 | RVF-400+Q | 12.00 | 4.9 |
| RVF-220+Q | 9.75 | 4.0 | RVF-425+Q | 12.25 | 5.0 |
| RVF-235+Q | 10.00 | 4.1 | RVF-450+Q | 12.50 | 5.1 |
| RVF-255+Q | 10.25 | 4.2 | RVF-500+Q | 13.00 | 5.3 |
| RVF-275+Q | 10.50 | 4.3 | RVF-550+Q | 13.50 | 5.5 |
| RVF-295+Q | 10.75 | 4.4 | RVF-625+Q | 14.00 | 5.7 |
| RVF-315+Q | 11.00 | 4.5 | RVF-700+Q | 14.50 | 5.9 |
| RVF-335+Q | 11.25 | 4.6 | RVF-775+Q | 15.00 | 6.1 |

**Sterile Silicone Breast Implants Motiva Implant Matrix® VelvetSurface™ PLUS Corsé with $Q_{id}$™**

| Catalogue Number | Base (cm) | Projection (cm) | Catalogue Number | Base (cm) | Projection (cm) |
|---|---|---|---|---|---|
| RVC-180+Q | 8.50 | 4.0 | RVC-440+Q | 11.50 | 5.7 |
| RVC-210+Q | 9.00 | 4.2 | RVC-475+Q | 11.75 | 5.8 |
| RVC-240+Q | 9.50 | 4.5 | RVC-510+Q | 12.00 | 6.0 |
| RVC-260+Q | 9.75 | 4.6 | RVC-550+Q | 12.25 | 6.1 |
| RVC-280+Q | 10.00 | 4.8 | RVC-590+Q | 12.50 | 6.3 |
| RVC-300+Q | 10.25 | 4.9 | RVC-650+Q | 13.00 | 6.6 |
| RVC-325+Q | 10.50 | 5.1 | RVC-725+Q | 13.50 | 6.9 |
| RVC-350+Q | 10.75 | 5.2 | RVC-825+Q | 14.00 | 7.2 |
| RVC-380+Q | 11.00 | 5.4 | RVC-925+Q | 14.50 | 7.5 |
| RVC-410+Q | 11.25 | 5.5 | RVC-1050+Q | 15.00 | 7.8 |

**Sterile Silicone Breast Implants Motiva Implant Matrix® Ergonomix™ Round SilkSurface™ Mini**

| Catalogue Number | Style | Height (cm) | Width (cm) | Projection (mm) |
|---|---|---|---|---|
| ERSM-105 | Mini | 8.5 | 8.5 | 22 |
| ERSM-125 | Mini | 9 | 9 | 23 |
| ERSM-140 | Mini | 9.5 | 9.5 | 24 |
| ERSM-150 | Mini | 9.75 | 9.75 | 24 |
| ERSM-160 | Mini | 10 | 10 | 25 |
| ERSM-170 | Mini | 10.25 | 10.25 | 25 |
| ERSM-185 | Mini | 10.5 | 10.5 | 26 |
| ERSM-205 | Mini | 10.75 | 10.75 | 26 |
| ERSM-220 | Mini | 11 | 11 | 27 |
| ERSM-230 | Mini | 11.25 | 11.25 | 27 |
| ERSM-245 | Mini | 11.5 | 11.5 | 28 |
| ERSM-260 | Mini | 11.75 | 11.75 | 28 |

| Catalogue Number | Style | Height (cm) | Width (cm) | Projection (mm) |
|---|---|---|---|---|
| ERSM-275 | Mini | 12 | 12 | 29 |
| ERSM-290 | Mini | 12.25 | 12.25 | 29 |
| ERSM-310 | Mini | 12.5 | 12.5 | 30 |
| ERSM-360 | Mini | 13 | 13 | 31 |
| ERSM-400 | Mini | 13.5 | 13.5 | 32 |
| ERSM-430 | Mini | 14 | 14 | 33 |
| ERSM-475 | Mini | 14.5 | 14.5 | 34 |
| ERSM-525 | Mini | 15 | 15 | 35 |

**Sterile Silicone Breast Implants Motiva Implant Matrix® Ergonomix™ Round SilkSurface™ Demi**

| Catalogue Number | Style | Height (cm) | Width (cm) | Projection (mm) |
|---|---|---|---|---|
| ERSD-135 | Demi | 8.5 | 8.5 | 31 |
| ERSD-155 | Demi | 9 | 9 | 33 |
| ERSD-180 | Demi | 9.5 | 9.5 | 34 |
| ERSD-190 | Demi | 9.75 | 9.75 | 34 |
| ERSD-205 | Demi | 10 | 10 | 35 |
| ERSD-215 | Demi | 10.25 | 10.25 | 35 |
| ERSD-230 | Demi | 10.5 | 10.5 | 36 |
| ERSD-245 | Demi | 10.75 | 10.75 | 37 |
| ERSD-265 | Demi | 11 | 11 | 38 |
| ERSD-285 | Demi | 11.25 | 11.25 | 38 |
| ERSD-300 | Demi | 11.5 | 11.5 | 39 |
| ERSD-320 | Demi | 11.75 | 11.75 | 39 |
| ERSD-340 | Demi | 12 | 12 | 40 |
| ERSD-360 | Demi | 12.25 | 12.25 | 40 |
| ERSD-380 | Demi | 12.5 | 12.5 | 41 |
| ERSD-425 | Demi | 13 | 13 | 43 |
| ERSD-475 | Demi | 13.5 | 13.5 | 44 |
| ERSD-525 | Demi | 14 | 14 | 45 |
| ERSD-575 | Demi | 14.5 | 14.5 | 46 |
| ERSD-625 | Demi | 15 | 15 | 48 |

**Sterile Silicone Breast Implants Motiva Implant Matrix® Ergonomix™ Round SilkSurface™ Full**

| Catalogue Number | Style | Height (cm) | Width (cm) | Projection (mm) |
|---|---|---|---|---|
| ERSF-145 | Full | 8.5 | 8.5 | 35 |
| ERSF-175 | Full | 9 | 9 | 37 |
| ERSF-205 | Full | 9.5 | 9.5 | 39 |
| ERSF-220 | Full | 9.75 | 9.75 | 40 |
| ERSF-235 | Full | 10 | 10 | 41 |
| ERSF-255 | Full | 10.25 | 10.25 | 42 |
| ERSF-275 | Full | 10.5 | 10.5 | 43 |
| ERSF-295 | Full | 10.75 | 10.75 | 44 |
| ERSF-315 | Full | 11 | 11 | 45 |
| ERSF-335 | Full | 11.25 | 11.25 | 46 |
| ERSF-355 | Full | 11.5 | 11.5 | 47 |
| ERSF-375 | Full | 11.75 | 11.75 | 48 |

| Catalogue Number | Style | Height (cm) | Width (cm) | Projection (mm) |
|---|---|---|---|---|
| ERSF-400 | Full | 12 | 12 | 49 |
| ERSF-425 | Full | 12.25 | 12.25 | 50 |
| ERSF-450 | Full | 12.5 | 12.5 | 51 |
| ERSF-500 | Full | 13 | 13 | 53 |
| ERSF-550 | Full | 13.5 | 13.5 | 55 |
| ERSF-625 | Full | 14 | 14 | 57 |
| ERSF-700 | Full | 14.5 | 14.5 | 59 |
| ERSF-775 | Full | 15 | 15 | 61 |

**Sterile Silicone Breast Implants Motiva Implant Matrix® Ergonomix™ Round SilkSurface™ Corsé**

| Catalogue Number | Style | Height (cm) | Width (cm) | Projection (mm) |
|---|---|---|---|---|
| ERSC-180 | Corsé | 8.5 | 8.5 | 40 |
| ERSC-210 | Corsé | 9 | 9 | 42 |
| ERSC-240 | Corsé | 9.5 | 9.5 | 45 |
| ERSC-260 | Corsé | 9.75 | 9.75 | 46 |
| ERSC-280 | Corsé | 10 | 10 | 48 |
| ERSC-300 | Corsé | 10.25 | 10.25 | 49 |
| ERSC-325 | Corsé | 10.5 | 10.5 | 51 |
| ERSC-350 | Corsé | 10.75 | 10.75 | 52 |
| ERSC-380 | Corsé | 11 | 11 | 54 |
| ERSC-410 | Corsé | 11.25 | 11.25 | 55 |
| ERSC-440 | Corsé | 11.5 | 11.5 | 57 |
| ERSC-475 | Corsé | 11.75 | 11.75 | 58 |
| ERSC-510 | Corsé | 12 | 12 | 60 |
| ERSC-550 | Corsé | 12.25 | 12.25 | 61 |
| ERSC-590 | Corsé | 12.5 | 12.5 | 63 |
| ERSC-650 | Corsé | 13 | 13 | 66 |
| ERSC-725 | Corsé | 13.5 | 13.5 | 69 |
| ERSC-825 | Corsé | 14 | 14 | 72 |
| ERSC-925 | Corsé | 14.5 | 14.5 | 75 |
| ERSC-1050 | Corsé | 15 | 15 | 78 |

**Sterile Silicone Breast Implants Motiva Implant Matrix® Ergonomix™ Round SilkSurface™ Mini with $Q_{id}$™**

| Catalogue Number | Style | Height (cm) | Width (cm) | Projection (mm) |
|---|---|---|---|---|
| ERSM-105Q | Mini | 8.5 | 8.5 | 22 |
| ERSM-125Q | Mini | 9 | 9 | 23 |
| ERSM-140Q | Mini | 9.5 | 9.5 | 24 |
| ERSM-150Q | Mini | 9.75 | 9.75 | 24 |
| ERSM-160Q | Mini | 10 | 10 | 25 |
| ERSM-170Q | Mini | 10.25 | 10.25 | 25 |
| ERSM-185Q | Mini | 10.5 | 10.5 | 26 |
| ERSM-205Q | Mini | 10.75 | 10.75 | 26 |
| ERSM-220Q | Mini | 11 | 11 | 27 |
| ERSM-230Q | Mini | 11.25 | 11.25 | 27 |

| Catalogue Number | Style | Height (cm) | Width (cm) | Projection (mm) |
|---|---|---|---|---|
| ERSM-245Q | Mini | 11.5 | 11.5 | 28 |
| ERSM-260Q | Mini | 11.75 | 11.75 | 28 |
| ERSM-275Q | Mini | 12 | 12 | 29 |
| ERSM-290Q | Mini | 12.25 | 12.25 | 29 |
| ERSM-310Q | Mini | 12.5 | 12.5 | 30 |
| ERSM-360Q | Mini | 13 | 13 | 31 |
| ERSM-400Q | Mini | 13.5 | 13.5 | 32 |
| ERSM-430Q | Mini | 14 | 14 | 33 |
| ERSM-475Q | Mini | 14.5 | 14.5 | 34 |
| ERSM-525Q | Mini | 15 | 15 | 35 |

**Sterile Silicone Breast Implants Motiva Implant Matrix® Ergonomix™ Round SilkSurface™ Demi with Q$_{id}$™**

| Catalogue Number | Style | Height (cm) | Width (cm) | Projection (mm) |
|---|---|---|---|---|
| ERSD-135Q | Demi | 8.5 | 8.5 | 31 |
| ERSD-155Q | Demi | 9 | 9 | 33 |
| ERSD-180Q | Demi | 9.5 | 9.5 | 34 |
| ERSD-190Q | Demi | 9.75 | 9.75 | 34 |
| ERSD-205Q | Demi | 10 | 10 | 35 |
| ERSD-215Q | Demi | 10.25 | 10.25 | 35 |
| ERSD-230Q | Demi | 10.5 | 10.5 | 36 |
| ERSD-245Q | Demi | 10.75 | 10.75 | 37 |
| ERSD-265Q | Demi | 11 | 11 | 38 |
| ERSD-285Q | Demi | 11.25 | 11.25 | 38 |
| ERSD-300Q | Demi | 11.5 | 11.5 | 39 |
| ERSD-320Q | Demi | 11.75 | 11.75 | 39 |
| ERSD-340Q | Demi | 12 | 12 | 40 |
| ERSD-360Q | Demi | 12.25 | 12.25 | 40 |
| ERSD-380Q | Demi | 12.5 | 12.5 | 41 |
| ERSD-425Q | Demi | 13 | 13 | 43 |
| ERSD-475Q | Demi | 13.5 | 13.5 | 44 |
| ERSD-525Q | Demi | 14 | 14 | 45 |
| ERSD-575Q | Demi | 14.5 | 14.5 | 46 |
| ERSD-625Q | Demi | 15 | 15 | 48 |

**Sterile Silicone Breast Implants Motiva Implant Matrix® Ergonomix™ Round SilkSurface™ Full with Q$_{id}$™**

| Catalogue Number | Style | Height (cm) | Width (cm) | Projection (mm) |
|---|---|---|---|---|
| ERSF-145Q | Full | 8.5 | 8.5 | 35 |
| ERSF-175Q | Full | 9 | 9 | 37 |
| ERSF-205Q | Full | 9.5 | 9.5 | 39 |
| ERSF-220Q | Full | 9.75 | 9.75 | 40 |
| ERSF-235Q | Full | 10 | 10 | 41 |
| ERSF-255Q | Full | 10.25 | 10.25 | 42 |
| ERSF-275Q | Full | 10.5 | 10.5 | 43 |
| ERSF-295Q | Full | 10.75 | 10.75 | 44 |
| ERSF-315Q | Full | 11 | 11 | 45 |
| ERSF-335Q | Full | 11.25 | 11.25 | 46 |

| Catalogue Number | Style | Height (cm) | Width (cm) | Projection (mm) |
|---|---|---|---|---|
| ERSF-355Q | Full | 11.5 | 11.5 | 47 |
| ERSF-375Q | Full | 11.75 | 11.75 | 48 |
| ERSF-400Q | Full | 12 | 12 | 49 |
| ERSF-425Q | Full | 12.25 | 12.25 | 50 |
| ERSF-450Q | Full | 12.5 | 12.5 | 51 |
| ERSF-500Q | Full | 13 | 13 | 53 |
| ERSF-550Q | Full | 13.5 | 13.5 | 55 |
| ERSF-625Q | Full | 14 | 14 | 57 |
| ERSF-700Q | Full | 14.5 | 14.5 | 59 |
| ERSF-775Q | Full | 15 | 15 | 61 |

**Sterile Silicone Breast Implants Motiva Implant Matrix® Ergonomix™ Round SilkSurface™ Corsé with $Q_{id}$™**

| Catalogue Number | Style | Height (cm) | Width (cm) | Projection (mm) |
|---|---|---|---|---|
| ERSC-180Q | Corsé | 8.5 | 8.5 | 40 |
| ERSC-210Q | Corsé | 9 | 9 | 42 |
| ERSC-240Q | Corsé | 9.5 | 9.5 | 45 |
| ERSC-260Q | Corsé | 9.75 | 9.75 | 46 |
| ERSC-280Q | Corsé | 10 | 10 | 48 |
| ERSC-300Q | Corsé | 10.25 | 10.25 | 49 |
| ERSC-325Q | Corsé | 10.5 | 10.5 | 51 |
| ERSC-350Q | Corsé | 10.75 | 10.75 | 52 |
| ERSC-380Q | Corsé | 11 | 11 | 54 |
| ERSC-410Q | Corsé | 11.25 | 11.25 | 55 |
| ERSC-440Q | Corsé | 11.5 | 11.5 | 57 |
| ERSC-475Q | Corsé | 11.75 | 11.75 | 58 |
| ERSC-510Q | Corsé | 12 | 12 | 60 |
| ERSC-550Q | Corsé | 12.25 | 12.25 | 61 |
| ERSC-590Q | Corsé | 12.5 | 12.5 | 63 |
| ERSC-650Q | Corsé | 13 | 13 | 66 |
| ERSC-725Q | Corsé | 13.5 | 13.5 | 69 |
| ERSC-825Q | Corsé | 14 | 14 | 72 |
| ERSC-925Q | Corsé | 14.5 | 14.5 | 75 |
| ERSC-1050Q | Corsé | 15 | 15 | 78 |

**SURFACE VARIANTS**

***Table IV-A: Sterile Silicone Breast Implants Motiva Implant Matrix® Shell Surfaces***

| Nanotextured Surface | Microtextured Surface |
|---|---|
| SilkSurface™ PLUS Mini, SilkSurface™ PLUS | VelvetSurface™ PLUS Mini |
| SilkSurface™ PLUS - Demi | VelvetSurface™ PLUS Demi |

| | |
|---|---|
| SilkSurface™ PLUS Full | VelvetSurface™ PLUS Full |
| SilkSurface™ PLUS Corsé | VelvetSurface™ PLUS Corsé |

***Table IV-B: Sterile Silicone Breast Implants Motiva Implant Matrix® Ergonomix™ Shell Surfaces.***

| **Nanotextured Surface Ergonomix™ Round with Qid™** |
|---|
| Round SilkSurface™ - Mini with $Q_{id™}$ |
| Round SilkSurface™ - Demi with $Q_{id™}$ |
| Round SilkSurface™ - Full with $Q_{id™}$ |
| Round SilkSurface™ - Corsé with $Q_{id™}$ |

## 4. SUMMARY OF THE MANUFACTURING PROCESS

Sterile Silicone Breast Implants Motiva Implant Matrix® are manufactured by dipping a mandrel into a silicone dispersion. The shell or envelope is built in multiple dipping steps, which produces several layers. The middle layer is intended to act as a barrier for the diffusion of low molecular weight silicones from the implant to the tissues, and is referred to as the barrier layer. This layer can be pigmented and, together with the standard dispersion layers, form the barrier system shell that is common to both nanotextured and microtextured silicone gel-filled breast implants manufactured by Establishment Labs.

Once the shell has been cured, it is sealed by vulcanizing it to a patch material and the resulting configuration is then cured.

The device is subsequently filled with the internal filling silicone gel and enters the last curing process. Once the shell has been filled with the gel, the filling puncture is sealed with a special, medical grade, long-term implantable adhesive. After the implant has been cured and inspected, the unit is then placed in a double sterile barrier, sterilized and finally packed in its ultimate protection barrier.

## 5. PACKAGING SPECIFICATIONS

Establishment Labs S.A. Sterile Silicone Breast Implants Motiva Implant Matrix® are packaged in a double sterile barrier system, made of two polycarbonate trays, both covered with highly consistent and permeable polyethylene Tyvek® lid covers. The Polycarbonate material used in the trays allows the use of high temperatures during the dry heat sterilization process, and the Tyvek® material allows the system to breathe while maintaining the desired sterile conditions. This sterile barrier system is commonly used by the medical industry and is regulated by AAMI and ISO Quality Standards.

### 5.1 LABEL SPECIFICACTIONS

#### 5.1.1 Box Specifications

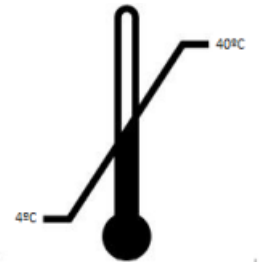
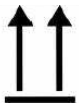
Establishment Labs S.A. Sterile Silicone Breast Implants Motiva Implant Matrix® carton box has two sizes, depending on the volume of the implant:

The Standard box includes the Establishment Labs S.A. Sterile Silicone Breast Implants Motiva Implant Matrix® boxes bases from 8.5 cm to 11.75 cm, the Dimensions are: 189 ±1 mm x 186 ±1 mm x 89 ±1 mm.

The large box is used to package Establishment Labs S.A. Sterile Silicone Breast Implants Motiva Implant Matrix® bases from 12 cm to 15 cm, the dimensions are: 213 ±1 mm x 221 ±1 mm x 105 ± 1 mm.

The box used by the sterile silicone breast implants Motiva Implant matrix® contains the next symbols:

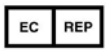
| **BOX SYMBOLS** | |
|---|---|
| **INTERNATIONAL SYMBOLS** | **MEANING** |
| CE 0086 | CE Mark/0086, code of the regulator entity who issue the certification |

| | |
|---|---|
|  | The Product must not be re-sterilized |
|  | Do not reuse |
|   | Storage Limits temperature |
|  | Do not expose to the sun |
|  | Store in a dry |
|  | Do not use if package is damaged |
|  | Keep up during storage |
|  | Fragile product |
|  | Recyclable materials |
|  | Reading information contained within the box |
|  | See manual inside the package |
| **OTHER SYMBOLS** | **MEANING** |

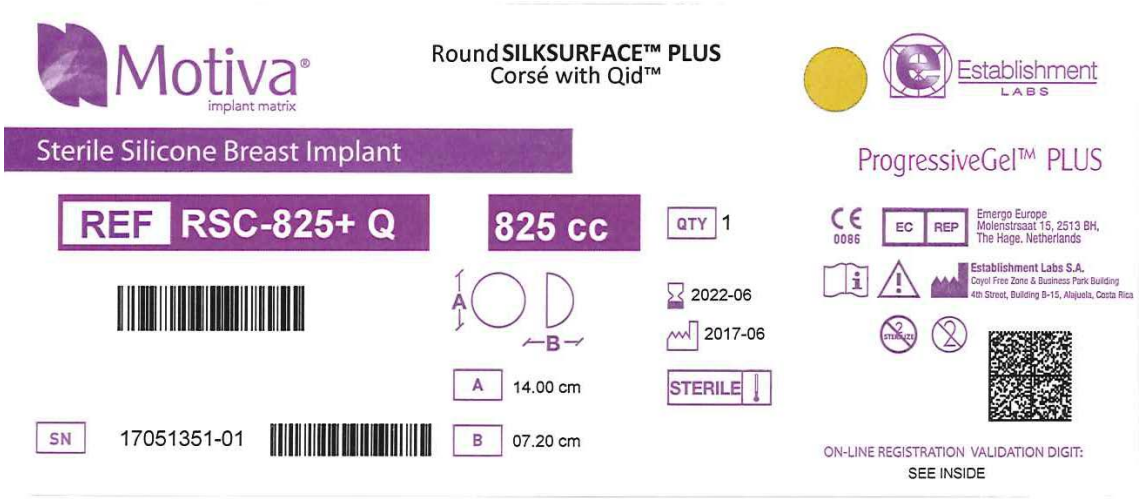
| | |
|---|---|
|   | Packaging materials from responsible resources |
|   | No use of salt and sugar in the texturing process |
|   | No use of water during the texturing process |
|   | Printed materials with vegetable-based inks |
|   | Using less material for less waste |

Additionally, the box contains a ¨Finished Product Label¨ with all the traceability information of the implant and international symbols to comply with national and international regulations.
The Finished Product Label used by the sterile silicone breast implants Motiva Implant matrix® implants contains the next symbols:

| INTERNATIONAL SYMBOLS | MEANING |
|---|---|
| REF | Reference of the Commercial Product Catalogue |
| SN | Serial Number |
| QTY | Quantity |
|   | B: Base<br>A: Height |

| | |
|---|---|
|  | Product Expiration Date |
| CE 0086 | CE Mark/0086, code of the regulator entity who issue the certification |
|  | Sterile Product, Dry Heat |
|  | See manual inside the package |
|  | EMERGO EUROPE, legal representative to the European Union for the company |
|  | Manufacturer Name and Physical Address |
|  | The Product must not be re-sterilized |
|  | Do not reuse |
|  | Right |
|  | Left |
|  | Implant Base |
|  | Projection |
|  | Volume |
|  | Implant Type |
|  | Reading information contained within the box |

In addition, the ¨Finished Product Label¨ has an internal indicator located in the "Finished Product Label" used by the Warehouse Department as described in the next graphic.




Graphic. Finished product label.

### 5.1.2 Labelling of Polycarbonate Inner Container (Internal Blister)

Sterile Silicone Breast Implants Motiva Implant Matrix® has the Motiva logo and the following warning label:

“Sterility is guaranteed if the packaging is not broken”

The Inner container (Internal Blister) has two sizes, depending on the volume of the implant:

The Standard Blister: is used to package Sterile Silicone Breast Implants Motiva Implant Matrix® base from 8.5 to 11.75 cm, the diameter is 152 mm, depth is 65 mm.

The Large Blister: is used to package Sterile Silicone Breast Implants Motiva Implant Matrix® base Equal to 12 cm or more, the diameters of large blíster are: diameter 182 mm, depth 80,50 mm.

### 5.1.3 Labelling of the External Polycarbonate Container (External Blister)

Establishment Labs S.A. Sterile Silicone Breast Implants Motiva Implant Matrix® has two dimensions:

The Standard Blister: is used to package Sterile Silicone Breast Implants Motiva Implant Matrix® base from 8.5 to 11.75 cm, the diameters of the standard blister are: 159 mm, depth 75 mm.

The Large Blister: is used to package Sterile Silicone Breast Implants Motiva Implant Matrix® base Equal to 12 cm or more, the diameters of large blíster are: diameter 187 mm, depth 90 mm.

**5.2 INFORMATION LOCATED IN THE IMPLANT PATCH SYSTEM:**

The patch system of the Sterile Silicone Breast Implants Motiva Implant Matrix® implants contains the following information:

- Logo of the manufacturer Establishment Labs
- Base size (cm)
- Projection (cm)
- Commercial Catalog (Reference number)
- Lot number
- Volume

**5.3 TRANSPORTATION AND STORAGE CONDITIONS:**

- Storage temperature: Store between: -29°C ± 2°C and 60°C ± 2°C
- relative humidity: Between 30% ± 5 % - 85% % ± 5.
- Atmosphere pressure: Not Applicable, because transportation/store testing per ASTM D4169 DC13, Low Pressure/High Altitude testing is only required for non-porous packaging. The Establishment Labs S.A. Sterile Silicone Breast Implants Motiva Implant Matrix® internal packaging it´s porous

**6.4. SHELF LIFE**

- Shelf Life: 5 years.

**6. STERILIZATION**

Establishment Labs S.A. Sterile Silicone Breast Implants Motiva Implant Matrix® are sterilized using the double-killing, dry heat sterilization method.

The Dry Heat Sterilization process is dependent of two main variables: temperature and exposure time. These variables determine the sterilization cycle that is based on the overkill method, which requires a 12-log reduction of a biological indicator with a higher resistance to dry heat than the bioburden population during the manufacturing process.

The Dry Heat Sterilization validation is based on AAMI and ISO standards. The test conditions are designed to demonstrate that the sterilization process can deliver a minimum sterility assurance level (SAL) of $10^{-6}$.

This validation addresses the critical operating variables for Dry Heat Sterilization: time, temperature, and sterilization load. Replicate biological challenge (half cycle) tests are conducted under worst-case conditions to measure physical and microbiological parameters throughout the load and assure process efficacy at or below minimum cycle conditions while using the maximum sterilization load. Heat penetration tests are conducted without process adjustments to measure physical parameters under maximum load conditions.

The overkill method of sterilization requires confirmation that the challenge system used for validation is suitable. The biological indicator population and resistance are verified. Product bioburden is identified from routine sampling. Reference literature is used to confirm that the overall resistance of the bioburden population is less than that of the biological indicators.

## 7. MECHANICAL STANDARDS

***Table V: Silicone Breast Implants Motiva Implant Matrix®: Results for Mechanical Testing and Specifications according to NF EN ISO14607: 2009 Standard.***

| ISO 14607 Section | Test | Specification | Result |
|---|---|---|---|
| 7.2.2.2.2 and Annex B1 | Shell Elongation. | Minimum 450% elongation at failure. | Pass. Average elongation 665.74% |
| (*) | Shell Break force. | Minimum 11.12 N<br>According to ASTM F-703.<br>(*) Internal Specification. | Pass. Average break force 25.76N |
| 7.2.2.2.2 and Annex B1 | Shell Tensile set: The sample shall be elongated to 300 %, maintained at this elongation for 3 min, and then relaxed to the starting position. | After this, the tensile set shall be a maximum of 10 %. | Pass. Average 1.74% |
| (*) | Shell Tear resistance. | Minimum 3.5 N to break.<br>(*) Internal Specification. | Pass. Average 19.78N |
| 7.2.2.2.4 and Annex B2 | Shell Strength of joints, seams or seals Continue test to joint failure. | No failure of joint when extended to 300% elongation for 10 seconds. | Pass. No joint failure |
| 7.2.2.4.2 and Annex D | Filling material.<br>Test for silicone gel cohesion. | The specimen shall meet the requirements of the test if there is no separation and the projecting length of the gel is less than or equal to 30 mm. | Pass. No gel separation |

| ISO 14607 Section | Test | Specification | Result |
|---|---|---|---|
| 7.2.2.5.2 and Annex E1 | Implant Fatigue resistance test. The test shall proceed for $2\times10^6$ cycles. | Following this test, no tears, cracks, or cuts shall be present on the mammary implant when observed visually at a X10 magnification. | Pass. No tears, cracks, or cuts |
| 7.2.2.5.3 and Annex E2 | Implant Impact resistance test: The test is based on the vertical drop of a specified mass on the implant. | The implant shall not rupture. | Pass. No rupture |
| 7.2.2.5.4 and Annex E3 | Implant Static rupture resistance test: This test determines the static rupture resistance of mammary implants in compression device machine with a horizontal fixed plate and a mobile plate. | Inspect the implant for damage and note the place of the rupture and the force and projection height at the moment of rupture. Reference only test. Standard NF EN ISO14607:2009 contains no specific requirements regarding the results of this test. | Pass. Reference only test |

***Table V: Silicone Breast Implants Motiva Implant Matrix®: Results for Mechanical Testing and Specifications according to NF EN ISO14607: 2009 Standard. Continued***

| ISO 14607 Section | Test | Specification | Result |
|---|---|---|---|
| 7.2.2.8 and Annex A | Implant Surface: The characteristics of the surface shall be examined by scanning electron microscopy (SEM) and documented in order to present the average surface characteristics (standard deviation). | The surface characteristics (e.g. pore size, peaks and valleys) shall be measured over an area of approximately 4 mm2. Reference only test. Standard NF EN ISO14607:2009 contains no specific requirements regarding the results of this test. | Pass. Reference only test |
| 7.2.3.4 and Annex H | Implant Release test: The test consists of submerging of the implants (37 °C ± 2°C) while stirring in a simulated body fluid (SBF). | Reference only test. Standard NF EN ISO14607:2009 contains no specific requirements regarding the results of this test. | Pass. Reference only test |

**Source**: Establishment Labs S.A. VAL-001.R Motiva Product Performance Qualification Report (LNE Report- *Laboratoire National de Métrologie et d'Eessais, Trappes*. France: Motiva Implant Matrix® Silicone Breast Implants Mechanical characterization test Report – Document L050836- 28-May-10).

## II: CLINICAL SPECIFICATIONS

### 1. CLINICAL EFFECT

The expected clinical effect of Sterile Silicone Breast Implants Motiva Implant Matrix® is to increase the size of a woman's breasts through a surgical procedure known as augmentation mammoplasty, by a volumetric filling effect, for cosmetic or reconstructive purposes.

### 2. INDICATIONS

**Breast augmentation for women at least 18 years old**. Breast augmentation, including primary augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery.

**Breast Reconstruction**. Breast reconstruction, including primary reconstruction to replace breast tissue that has been removed due to cancer or trauma, or that has failed to develop properly due to a severe breast anomaly, as well as revision surgery to correct or improve the results of a primary breast reconstruction surgery.

### 3. INCISION SITES AND ANATOMICAL PLACEMENT

Possible Incision sites for the insertion of Sterile Silicone Breast Implants Motiva Implant Matrix® are axillary, inframammary and periareolar. Potential placements for the devices are subglandular, and submuscular (including its variants such as dual plane and subfascial).

### 4. CONTRAINDICATIONS, WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS

Contraindications, warnings, precautions and potential adverse effects can be found in the Directions for Use, Establishment Labs S.A. Sterile Silicone Breast Implants Motiva Implant Matrix®, (please refer to Appendix I).

### 5. INSTRUCTIONS FOR USE

Motiva Implant Matrix® Sterile Silicone Breast Implants Instructions for Use can be found in the Product Insert, Establishment Labs S.A.

### 6. DISPOSAL

Implants cannot be re-sterilized or reused, as are products for single use. Dispose of used or

contaminated implants and implants that have expired must be performed in accordance with standard practice in the medical institution, and in the manner prescribed by local, federal and state rules and regulations. Disposal of packaging materials should also be in accordance with the standard practice of the medical establishment, and in the manner prescribed by local, federal and state rules and regulations.

## 7. APPLICABLE QUALITY STANDARDS

1. Directive 93/42/EEC, “Medical Devices Directive”, of 14 June 1993, concerning medical devices

2. Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007.

3. ISO 14971:2007, Medical Devices - Application of Risk Management to Medical Devices

4. ISO 14607:2009, Non-Active Surgical Implants - Mammary Implants – Particular Requirements.

5. ASTM F703-07, Standard Specification for Implantable Breast Prostheses.

6. ISO 11737-1:2006, Sterilization of medical devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products

7. ISO 11737-2:2009, Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.

8. Ph. Eur. 7th ed, Bioburden.

9. Ph. Eur. 7th ed. and USP 31st rev., Endotoxine LAL.

10. Method 8260B, Volatile Organic Compounds by gas Chromatography/Mass Spectrometry (GC/MS).

11. AAMI/ISO 11607-1:2006, Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems.

12. ASTM F 1980-07(2011), Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

13. ANSI/AAMI/ISO 20857:2010, Sterilization of health care products - Dry Heat - Requirements for the development, validation, and routine control of an industrial sterilization

process for medical devices.

14. ASTM D4169-09, Standard Practice for Performance Testing of Shipping Containers and Systems.

15. BS EN ISO 15223-1:2012, Medical Devices. Symbols to be used with medical device labels, labeling and information to be supplied. General requirements

16. Directive 2007/47/EC, Annex X: Clinical Evaluation Section 1

17. EN ISO 13485:2003, Medical devices - Quality management systems - Requirements for regulatory purposes.

18. EN ISO 14630:2008, Non-active surgical implants -- General requirements.

19. EN ISO 15225:2010, Medical devices -- Quality management -- Medical device nomenclature data structure.

20. EN ISO 10993-1:2009, Biological Evaluation of Medical Devices -- Part 1. Evaluation and Testing within a Risk Management Process.

21. EN ISO 10993-2:2006, Biological Evaluation of Medical Devices -- Part 2: Animal welfare requirements.

22. EN ISO 10993-3:2003, Biological Evaluation of Medical Devices -- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.

23. EN ISO 10993-4:2002, Biological Evaluation of Medical Devices -- Part 4: Selection of tests for interactions with blood.

24. EN ISO 10993-5:2009, Biological Evaluation of Medical Devices -- Part 5: Tests for in vitro cytotoxicity.

25. EN ISO 10993-6:2007, Biological Evaluation of Medical Devices -- Part 6: Tests for local effects after implantation.

26. EN ISO 10993-9:2009, Biological Evaluation of Medical Devices -- Part 9: Framework for identification and quantification of potential degradation products.

27. EN ISO 10993-10:2010, Biological Evaluation of Medical Devices -- Part 10: Tests for irritation and skin sensitization.

28. EN ISO 10993-11:2006, Biological Evaluation of Medical Devices -- Part 11: Tests for systemic toxicity.

29. EN ISO 10993-13:2010, Biological Evaluation of Medical Devices -- Part 13: Identification and quantification of degradation products from polymeric medical devices.

30. EN ISO 10993-18: 2005, Biological Evaluation of Medical Devices -- Part 18: Chemical characterization of materials.

31. EN ISO/TS 10993-20:2006, Biological Evaluation of Medical Devices -- Part 20: Principles and methods for immunotoxicology testing of medical devices.

32. EN ISO 11607-1:2006, Packaging for Terminally Sterilized Medical Devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems.

33. EN ISO 11607-2:2006, Packaging for Terminally Sterilized Medical Devices -- Part 2: Validation requirements for forming, sealing and assembly processes.

34. ISO 14698-1:2003: Cleanrooms and Associated Controlled Environments -- Biocontamination Control -- Part 1: General principles and methods

35. ISO 14698-2:2003: Cleanrooms and Associated Controlled Environments -- Biocontamination Control -- Part 2: Evaluation and interpretation of biocontamination data

36. EN ISO 11737-1:2006, Sterilization of Medical Devices -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products.

37. EN ISO 14937:2009, Sterilization of Health Care Products -- General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices.

38. EN ISO 11737-2:2009, Sterilization of Medical Devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.

39. EN ISO 14155:2011, Clinical Investigation of Medical Devices for Human Subjects -- Good clinical practice.

## 8. APPENDIXES

Appendix I: Directions for Use, Establishment Labs S.A. Sterile Silicone Breast Implants Motiva Implant Matrix®.

Appendix II: Summary of Technical and Clinical Characteristics of Motiva Implant Matrix® Sterile Silicone Breast Implants.

# APPENDIX I

# DIRECTIONS FOR USE

# ESTABLISHMENT LABS S.A.

***STERILE SILICONE BREAST IMPLANTS MOTIVA IMPLANT MATRIX®***

# APPENDIX II

# SUMMARY OF THE TECHNICAL AND CLINICAL CHARACTERISTICS OF MOTIVA IMPLANT MATRIX®

# STERILE SILICONE BREAST IMPLANTS

**Summary of Technical and Clinical Characteristics of Motiva Implant Matrix® Sterile Silicone Breast Implants**

| PARAMETER | CHARACTERISTICS |
|---|---|
| **Technical Specifications** | Multilayer silicone shell: Dimethyl- diphenyl silicone elastomer dispersion (standard layers) Dimethyl- diphenyl elastomer dispersion (barrier layer) mixed with vinyl-dimethyl pigment. |
| | Patch assembly: Double layer of uncatalyzed, vinyl-functional, high consistency silicone elastomer, with dimethyl- diphenyl layer. |
| | Internal Gel: Base & crosslinker of platinum-cured siloxane polymer. ProgressiveGel™. |
| | Range of Diameters (width, base): 8.5 cm - 15 cm. |
| | Projections (profiles): Mini (low), Demi (medium), Full (high), Corsé (ultrahigh). |
| | Size (volume): 105cc - 1050cc. |
| | Shell surfaces: nanotextured (SilkSurface™ PLUS and Ergonomix™ SilkSurface™), microtextured (VelvetSurface™ PLUS and Ergonomix™ VelvetSurface™). |
| | Manufacturing Process:<br>1. Shell built in multiple dipping steps; 2. Curing; 3. Patching; 4. Curing; 5. Gel filling; 6. Sealing; 7. Curing. |
| | Packaging: double sterile barrier system: Two Polycarbonate trays covered with high-density polyethylene lids. |
| | Sterilization: Dry heat. |
| **Clinical Specifications** | Clinical Effect: To increase the size of a woman's breasts by a volumetric filling effect. |
| | Indications: Breast augmentation and reconstruction. |
| | Incision sites: Axillary, inframammary, periareolar. |
| | Anatomical placement: Subglandular, submuscular. |
| | Contraindications, warnings, precautions and adverse effects: Refer to Appendix I- Motiva Implant Matrix® Sterile Silicone Breast Implants Product Insert, Establishment Labs S.A. |
| | Efficacy and Safety: Implants are safe and effective for use in breast augmentation and reconstruction. |