INFORMATION FOR THE PATIENT: BREAST IMPLANT SURGERY WITH MOTIVA IMPLANTS®

CAUTION

Only surgeons with qualified training and certified by your country's corresponding national medical board should use this product. The use of this product by unqualified practitioners may result in inferior aesthetic outcomes and serious adverse effects.
Federal (USA) law restricts this device to be used by a certified surgeon.

1. INTENDED USE

Establishment Labs Sterile Silicone Breast Implants Motiva Implants® are intended to be used in female patients for the following procedures:

Breast augmentation (primary and revision): to increase breast size in an initial surgery, and in revision surgery to correct or improve the result of a previous breast augmentation surgery.

- Breast reconstruction (primary and revision): 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 previous breast reconstruction surgery.

2. INDICATIONS

Motiva Implants® are indicated in female patients of at least 18 years old for the following conditions:

- to enhance the aesthetical appearance in patients dissatisfied with the shape or size of their breasts.
- to correct congenital or acquired breast deformities or breast asymmetry, or
- to correct or improve the result of a previous breast implant surgery.

3. INTENDED CONDITIONS FOR USE

Motiva Implants® must be used during breast implant procedures under sterile conditions, in compliance with good aseptic practices.

4. OVERVIEW

- Alternative treatments are available for the conditions above, including external breast prostheses or padding, or the transfer of other body tissues to enlarge breast size. Other synthetic filling materials (such as liquid silicone or other fillers) are not recommended and can provoke serious health problems.

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- The decision to have breast implants is a personal choice. The information provided in this document is intended to raise your awareness about the risks and benefits of surgery using silicone breast implants to help you make a better-informed decision about your breast implant surgery (primary or revision).

- Motiva Implants® are available in SmoothSilk®/SilkSurface®, categorized as a smooth surface, and VelvetSurface®, categorized as a microtextured surface, per ISO 14607:2018 (Non-active surgical implants - Mammary implants - Particular Requirements). Their outer shell is comprised of standard layers and a barrier layer. Both types of layers are made from a medical-grade (silicone tested for biocompatibility and appropriate for medical applications) silicone-based elastomer. The implants are filled with a medical-grade, highly cohesive silicone gel and are surgically implanted above or below your pectoral muscle.

- Breast implants are available in different shapes: round and anatomical, and come in several different sizes and projections. Your surgeon should talk to you about the different possible outcomes based on your physical characteristics and personal expectations.

- When choosing breast implant surgery, you should be aware that you may require additional procedures and further consultations with your surgeon. Silicone breast implants are not lifetime devices and are subject to wear and tear like any other implant device. Breast implantation might not be a one-time surgery. Your implant(s) may have to be removed or replaced, which may imply revision surgery. Many of the changes to your breasts following implantation are irreversible (cannot be undone). If you choose to have your implant(s) removed and not replaced, you may experience unsatisfactory aesthetic results, which can be permanent.

- When you have your implants replaced, your risk of future complications increases compared to that associated with first-time breast implant surgery[1]. For example, the risk of severe capsular contracture is doubled in patients with implant replacement compared to the first-time implantations[2].

[1] Hillard C, Fowler JD, Barta R, Cunningham B. Silicone breast implant rupture: a review. Gland Surg. 2017 Apr;6(2):163-168. doi: 10.21037/gs.2016.09.12. PMID: 28497020; PMCID: PMC5409893

[2] Luvsannyam E, Patel D, Hassan Z, Nukala S, Somagutta MR, Hamid P. Overview of Risk Factors and Prevention of Capsular Contracture Following Implant-Based Breast Reconstruction and Cosmetic Surgery: A Systematic Review. Cureus. 2020 Sep 9;12(9):e10341. doi: 10.7759/cureus.10341. PMID: 33062465; PMCID: PMC7549852.

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5. SILICONE BREAST IMPLANT COMPONENTS

Table 1. Motiva Implants® materials to which the patient can be exposed.
The information on the materials to which the patient can be exposed is detailed in the following table.

Motiva Implants® family	Shell			Patch System		Gel	Microtransponder	
	Silicone standard dispersion (% w/w)	Silicone barrier dispersion (% w/w)	Color masterbatch (% w/w)	Patch (% w/w)	Dip coat (% w/w)	Silicone filling gel (% w/w)	Ferrite microtransponder (Qid®) (% w/w)	Non-ferrite microtransponder (Zen™) (% w/w)
Round SmoothSilk®/SilkSurface® Plus	3.09-7.13	0.63-1.46	0.0003-0.0006	0.159-1.572	0.0002-0.0019	89.77-96.11	0.007-0.066	0.087-0.858
Ergonomix® Round SmoothSilk®/SilkSurface®	2.32-5.37	0.58-1.34	0.0002-0.0005	0.159-1.572	0.0002-0.0019	91.66-96.94		
Round VelvetSurface® Plus	2.92-7.43	0.60-1.52	0.0002-0.0006	0.159-1.572	0.0002-0.0019	89.48-96.32		
Ergonomix® Round VelvetSurface®	2.23-5.25	0.56-1.32	0.0002-0.0005	0.159-1.572	0.0002-0.0019	91.85-97.06		

NOTE: The materials used to manufacture Motiva Implants® pose no risk to patients. They are medical-grade and have been tested per biological safety standards.

Table 2. Device materials

Component No.	Description	Raw Materials	Grade	Type of patient contact
1	Shell, standard dispersion	Addition cure silicone dispersion	Medical	Tissue
2	Shell, barrier dispersion	Addition cure silicone dispersion	Medical	No contact
3	Shell, barrier pigment (BluSeal®)	Color Masterbatch for liquid silicone elastomers	Medical	No contact
4	Patch assembly	Vulcanized sheeting, High Consistency Elastomer and RTV Silicone Adhesive	Medical	Tissue
5	Filling gel	High Purity Silicone Gel	Medical	No contact

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6	Ferrite-Microtransponder	Copper Polystermide Estersol 180 wire, Nickel-Zinc Ferrite core, Photobond 4442 or 4496 Acrylate adhesive, 4305 Application Specific Integrated Circuit (ASIC), and Soda-lime Silicate glass.	Medical	No contact
7	Non-ferrite microtransponder	Copper GIB KSP18 wire, Photobond 4442 Acrylate Adhesive, D4115 Application Specific Integrated Circuit (ASIC), and Borofloat 33 glass	Medical	No contact

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The following tables details the quantitative composition of Motiva Implants®.

- **Motiva Implants Matrix®**

Table 3. The quantitative formula for the raw materials in the Motiva Implants®

Motiva Implants® family	Shell			Patch System		Gel	Microtransponder	
	Silicone standard dispersion (% w/w)	Silicone barrier dispersion (% w/w)	Color masterbatch (% w/w)	Patch (% w/w)	Dip coat (% w/w)	Silicone filling gel (% w/w)	Ferrite microtransponder (Qid®) (% w/w)	Non-ferrite microtransponder (Zen™) (% w/w)
Round SmoothSilk®/Silk Surface® Plus	3.09-7.13	0.63-1.46	0.0003-0.0006	0.159-1.572	0.0002-0.0019	89.77-96.11	0.007-0.066	0.087-0.858
Ergonomix® Round SmoothSilk®/Silk Surface®	2.32-5.37	0.58-1.34	0.0002-0.0005	0.159-1.572	0.0002-0.0019	91.66-96.94		
Round VelvetSurface® Plus	2.92-7.43	0.60-1.52	0.0002-0.0006	0.159-1.572	0.0002-0.0019	89.48-96.32		
Ergonomix® Round VelvetSurface®	2.23-5.25	0.56-1.32	0.0002-0.0005	0.159-1.572	0.0002-0.0019	91.85-97.06		

NOTE: The materials used to manufacture Motiva Implants® pose no risk to patients. They are medical-grade and have been tested per biological safety standards.

The potential toxicity of the chemicals and metals listed in the following tables has been evaluated with toxicity testing and risk assessments to assess the exposure levels compared to the amount determined to be safe likely. Based on the current results and the risk analysis performed, the leachable/extractable from the shell/patch and gel/microtransponder of each family of implants are unlikely to pose a toxicological safety concern.

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Table 4. Quantify leachable elements digested in concentrated nitric acid by Inductively Coupled Plasma/Mass Spectrometry (ICP/MS).

Element	Concentration (µg/unit
Barium	2.626
Calcium	69.96
Copper	0.142
Platinum	1.46
Potassium	56.14
Silicon	203.33
Sodium	124.4
Zinc	3.97

Table 5. Extractable Organics Summary for volatile (VOC), semi-volatile (SVOC), and non-volatile (NVOC) compounds in solvents with different polarity indexes: purified water (PW), Hexane (Hex), Ethanol (EtOH), DMC (dichloromethane), and DMSO (dimethyl sulfoxide).

Compound	Concentration (µg/unit)
VOC (HS-GC/MS)	
Trimethyl silanol	415
Benzene	1.03
SVOC (GC/MS)	
Benzoic acid	5.81
Caprolactam	53.6
4-Chlorobenzoic acid	189
4-Chlorobenzoic acid, trimethylsilyl ester	32.7
2,4-Dichlorobenzoic acid	328.9
Decamethyl cyclopentasiloxane (D5)	120.3
Dodecamethyl cyclohexasiloxane (D6)	748.1
Tetradecamethyl cycloheptasiloxane (D7)	513.8
Hexadecamethyl cyclooctasiloxane (D8)	165.5
Octadecamethyl Cyclopentasiloxane (D9)	391.5
2,2,4,4,6,8-Hexamethyl-6,8- diphenyl-cyclotetrasiloxane	7,506
Eiscosamethyl cyclodecasiloxane (D10)	1,053

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Compound	Concentration (µg/unit)
2,2,4,4,6,6,8, 10-Octamethyl-8, 10-diphenyl-cyclopentasiloxane	19,485
Cyclic polydimethylsiloxane oligomer (combined values)	113,059
Dimethylsiloxane-methylphenylsiloxane copolymer (combined values)	54,717
Siloxane** (combined values)	11,729.8
1,3,5,7- Tetramethyltetraphenyl cyclotetrasiloxane	19,884
2,4,6,8, 10-Pentamethyl-2,4,6,8, 10-pentaphenyl-1,3,5,7,9,2,4,6,8, 10-pentaoxapentasilecane isomer (combined values)	50,794
Polymethylphenylsiloxane oligomer (combined values)	23,974
Octadecamethyl cyclotetrasiloxane (D4)	79.2
2-Ethyl-hexanol	79.3
Tetraecosamethyl cyclododecasiloxane (D12)	804
Linear polydimethylsiloxane oligomer (combined values)	377
NVOC (LC/UV)	
Palmitic acid	158.5
Stearic acid	168.2
Erucamide	43.79
Irganox 245	23.7
NVOC (LC/UV-Vis)	
Siloxane** (combined values)	250,375
Di(2-ethylhexyl)phthalate	9,439
Unknown*** (n = 9)	576.87-1,308
GC/MS, gas chromatography/mass spectrometry; LC/UV, liquid chromatography/ultraviolet; LC/UV-Vis, l chromatography/ultraviolet visible; NVOC, non-volatile organic compounds; SVOC, semi-volatile organic compounds; VOC organic compound	

NOTE: Values are reported for the solvent that exhibited higher compound concentration.

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- **Anatomical TrueFixation® catalogs**

Table 6. The quantitative formula for the raw materials in Anatomical TrueFixation®

Motiva Implants® family	Shell					Patch System		Gel	Microtransponder	
	Silicone standard dispersion (% w/w)	Silicone barrier dispersion (% w/w)	Color master - batch (% w/w)	Orientation lines (% w/w)	TrueFixation® tabs (% w/w)	Patch (% w/w)	Dip coat (% w/w)	Silicone filling-gel (% w/w)	Ferrite micro-transponder (Qid®) (% w/w)	Non-ferrite microtrans - ponder (Zen®) (% w/w)
Anatomical TrueFixation®	4.11 – 4.85	0.84 – 0.99	0.0003 – 0.0004	0.0107 – 0.0194	0.07 – 0.17	0.39 – 0.91	0.0005 – 0.0012	92.68 – 94.58	0.01 – 0.03	0.15 – 0.37

The potential toxicity of the chemicals and metals listed in the following tables has been evaluated with toxicity testing and risk assessments to assess the exposure levels compared to the reasonable amount determined to be safe. Based on the current results and the risk analysis, the leachable/extractable from the shell/patch and gel/microtransponder of each family of implants are unlikely to pose a toxicological safety concern.

Table 6. Quantify leachable elements digested in concentrated nitric acid by Inductively Coupled Plasma/Mass Spectrometry (ICP/MS).

Element	**Concentration (µg/unit**
Barium	2.626
Calcium	69.96
Copper	0.142
Platinum	1.46
Potassium	56.14
Silicon	203.33
Sodium	124.4
Zinc	3.97

Table 7. Extractable Organics Summary for volatile (VOC), semi-volatile (SVOC), and non-volatile (NVOC) compounds in solvents with different polarity indexes: purified water (PW), Hexane (Hex), Ethanol (EtOH), DMC (dichloromethane) and DMSO (dimethyl sulfoxide) in the Anatomical TrueFixation® device.

Compound	**Concentration (µg/unit)**
VOC (GC/MS)	
Trimethylsilanol	73.848
m&p-xylene	32.9

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Compound	Concentration (µg/unit)
o-xylene	26.1
SVOC (GC/MS)	
Propylene glycol	51.1
Silicone containing compound	1.47
2-Propoxyethanol	2.16
Hexamethyl cyclotrisiloxane	2.50
1,2-propandiol, 1-acetate	1.72
Cyclohexanone	2.41
2-Butoxyethanol	35.9
3-Methoxy-3-methylbutanol	5.16
Hexanoic acid	2.41
1-(2-Methoxy-1-methylethoxy)-2-propanol	31.4
2-(2-Methoxy-1-methylethoxy)-1-propanol	35.3
1-(2-methoxypropoxy)-2-propanol	37.1
2-Ethyl-1-hexanol	89.3
5-Ethyldihydro-2(3H)-furanone	1.90
Acetophenone	2.84
2-Ethyl-hexanoic acid	4.83
Isophorone	15.8
1-(2-Butoxyethoxy)ethanol	120
2-Phenoxyethanol	4.05
Glycerol 1,2-diacetate	24.0
2-oxo-butanoic acid	1.55
2-Hydroxy-iso-butyrophenone	22.7
4-Chlorobenzoic acid	48.5
Triacetin	527
2-(2-butoxyethoxy)ethanol acetate	2.16
4-Chlorobenzoic acid, TMS derivative	2.76
2,4-Dichlorobenzoic acid	422.1
Octamethyl Cyclopentasiloxane (D4)	75.69
Decamethyl cyclopentasiloxane (D5)	162.2
Dodecamethyl cyclohexasiloxane (D6)	772.5
Tetradecamethyl cycloheptasiloxane (D7)	523.7
Hexadecamethyl cyclooctasiloxane (D8)	108.1

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Compound	Concentration (µg/unit)
Octadecamethyl cyclononsiloxane (D9)	99.6
2,2,4,4,6,8-Hexamethyl-6,8-diphenyl-cyclotetrasiloxane (D2P2)	1,339
Eicosamethyl cyclodecasiloxane (D10)	173.7
2,2,4,4,6,6,8,10-Octamethyl-8,10-diphenyl-cyclopentasiloxane (D3P2)	4,165
Cyclic polydimethylsiloxane oligomer (combined values)	112,832.1
Dimethylsiloxane-methylphenylsiloxane copolymer (combined values)	7,273
Siloxane** (combined values)	13,444.5
1,3,5,7-Tetramethyltetraphenyl cyclotetrasiloxane	4,989
2,4,6,8,10-Pentamethyl-2,4,6,8,10-pentaphenyl-1,3,5,7,9,2,4,6,8,10-pentaoxapentasilecane isomer (P5) (combined values)	16,906
Polymethylphenylsiloxane oligomer (combined values)	5818.7
Tetraecosamethyl cyclododecasiloxane (D12)	804
1-Phenoxypropan-2-ol	1.03
1-Butoxy-2-propanol	0.948
Linear polydimethylsiloxane oligomer	909
Chlorinated compound	17.7
2,4-Dichlorobenzamide	1.21
Benzophenone	57.8
1,4-Benenedicrboxylic acid, (bis(2-hydroxyether) ester	4.91
2,2,4-Trimethyl-1,3-pentanediol diisobutyrate	20.3
Dodecanoic acid, 1-methyl ethyl ester	24.4
2,4,6,8-tetramethyl-2,4,6,8-tetraphenylcyclotetrasiloxane (P4)	1930
Adipate ester	38.6
NVOC (LC/UV)	

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Compound	Concentration (µg/unit)
Palmitic acid	119
Stearic acid	173.7
Erucamide	76.76
NVOC (LC/UV-Vis)	
Siloxane (combined values)	57,303.1
Di(2-ethylhexyl)phthalate	1,338
Unknown* (n = 8)	3.53-841
2,4-Dichlorobenzoic acid	2276
DEHP	232
GC/MS, gas chromatography/mass spectrometry; LC/UV, liquid chromatography/ ultraviolet; LC/UV-Vis, liquid chromatography/ultraviolet visible; NVOC, non- vola organic compounds; SVOC, semi-volatile organic compounds; VOC, volatile organi compounds. *The values represent the range in which the amounts of all the unknowns were detected.	

Note: Values are reported for the solvent that exhibited higher compound concentration.

- **Ergonomix2®**

The information on the materials to which the patient can be exposed is detailed in the following table.

Table 8. The qualitative-Quantitative formula for the Ergonomix2® implants.

Material	Component	Product Variety		
		Ergonomix2 (min-max)	**Ergonomix2 with Qid®microtransponder** (min-max)	**Ergonomix2 with Zen®microtransponder** (min-max)
MED-6627	Shell: Super Standard	1.86% - 4.35%	1.86% - 4.35%	1.86% - 4.35%
MED-6629	Shell: Super	0.38% - 0.89%	0.38% - 0.89%	0.38% - 0.89%
MED-4800-7	Shell: Barrier's dispersion pigment	0.0002% - 0.0004%	0.0002% - 0.0004%	0.0002% - 0.0004%
MED-2174	Patch	0.12% - 1.30%	0.12% - 1.30%	0.12% - 1.30%

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Material	Component	Product Variety		
		Ergonomix2 (min-max)	**Ergonomix2 with Qid®microtransponder** (min-max)	**Ergonomix2 with Zen®microtransponder** (min-max)
MED-6600 or MED7-6600 (reported for MED7-6600)	Patch	0.039% - 0.435%	0.039% - 0.435%	0.039% - 0.435%
MED-1511	Patch	0.0002% -	0.0002% - 0.0021%	0.0002% - 0.0021%
MED3-6311	Filling Gel	93.02% - 97.60%	92.94% - 97.59%	92.06% - 97.52%
Copper Polystermide Estersol 180 wire, NickelZinc core, Photobond 4442 Acrylate adhesive, 4305 Application Specific Integrated Circuit (ASIC), and Soda-lime Silicate glass.	Ferrite microtransponder	¾	0.007% - 0.073%	¾
Copper GIB KSP18 wire, Photobond 4442 Acrylate Adhesive, D4115 Application Specific Integrated Circuit (ASIC), and Borofloat 33 glass.	Non-Ferrite microtransponder	¾	¾	0.086% - 0.960%

Table 9. The qualitative-Quantitative formula for the Ergonomix2 Diamond® implants.

Material	Component	Product Variety		
		Ergonomix2 Diamond® (min-max)	**Ergonomix2 Diamond® with Qid® microtransponder** (min-max)	**Ergonomix2 Diamond® with Zen® microtransponder** (min-max)
MED-6627	Shell: Super Standard	1.81% - 7.38%	1.81% - 7.38%	1.81% - 7.38%

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Material	Component	Product Variety		
		Ergonomix2 Diamond® (min-max)	**Ergonomix2 Diamond® with Qid® microtransponder** (min-max)	**Ergonomix2 Diamond® with Zen® microtransponder** (min-max)
MED-6629	Shell: Super	0.37% - 1.51%	0.37% - 1.51%	0.37% - 1.51%
MED-4800-7	Shell: Barrier's dispersion pigment	0.0001% - 0.0006%	0.0001% - 0.0006%	0.0001% - 0.0006%
MED-2174	Patch	0.06% - 1.04%	0.06% - 1.04%	0.06% - 1.04%
MED-6600 or MED7-6600 (reported for MED7-6600)	Patch	0.019% - 0.346%	0.019% - 0.346%	0.019% - 0.346%
MED-1511	Patch	0.0002% -	0.0002% - 0.0033%	0.0002% - 0.0033%
MED3-6311	Filling Gel	89.72% - 97.74%	89.60% - 97.73%	88.17% - 97.65%
Copper Polystermide Es tersol 180 wire, NickelZinc core, Photobond 4442 Acrylate adhesive, 4305 Application Specific Integrated Circuit (ASIC), and Soda-lime Silicate glass.	Ferrite microtranspon der	¾	0.007% - 0.118%	¾
Copper GIB KSP18 wire, Photobond 4442 Acrylate Adhesive, D4115 Application Specific Integrated Circuit (ASIC), and Borofloat 33 glass.	Non-Ferrite microtranspon der	¾	¾	0.087% - 1.549%

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Table 10. Quantify leachable elements digested in concentrated nitric acid by Inductively Coupled Plasma/Mass Spectrometry (ICP/MS).

Element	Concentration (µg/unit)
Aluminum	<1.02*
Antimony	<1.02*
Arsenic	<1.02*
Barium	0.132
Beryllium	<1.02*
Cadmium	<1.02*
Calcium	3.58
Cerium	<1.02*
Cesium	<1.02*
Chromium	2.94
Cobalt	<1.02*
Copper	1.263
Dysprosium	<1.02*
Erbium	<1.02*
Europium	<1.02*
Gadolinium	<1.02*
Gallium	<1.02*
Hafnium	<1.02*
Iridium	<1.02*
Lanthanum	<1.02*
Lead	<1.02*
Magnesium	<1.02*
Manganese	<1.02*
Molybdenum	<1.02*
Nickel	<1.02*
Niobium	<1.02*
Neodymium	<1.02*
Osmium	<1.02*
Platinum	<1.02*
Praseodymium	<1.02*
Potassium	4.77
Rhenium	<1.02*
Rubidium	<1.02*
Ruthenium	<1.02*
Samarium	<1.02*

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Element	Concentration (µg/unit)
Selenium	<1.02*
Sodium	92.1
Strontium	<1.02*
Tantalum	<1.02*
Tin	<1.02*
Titanium	12.42
Tellurium	<1.02*
Thallium	<1.02*
Thorium	<1.02*
Tungsten	<1.02*
Uranium	<1.02*
Vanadium	<1.02*
Ytterbium	<1.02*
Zinc	4.34
Zirconium	<1.02*
*The reported value corresponds to the quantification limit of 1.02 µg/test article; the compound presence was not found above the quantification limit.	

Table 11. Extractable Organics Summary for semivolatile (SVOC) and non-volatile (NVOC) compounds in solvents with different polarity indexes: purified water (PW), Hexane (Hex), Ethanol (EtOH), DMC (dichloromethane), and DMSO (dimethyl sulfoxide).

Compound	Concentration (µg/unit)
SVOC (HS-GC/MS)	
Hexamethylcyclotrisiloxane (D3)	<30*
Octadecamethyl cyclotetrasiloxane (D4)	<30*
Decamethyl cyclopentasiloxane (D5)	<30*
Dodecamethyl cyclohexasiloxane (D6)	<30*
L3, MDM: octamethyltrisiloxane	<30*
L5, MD3M: dodecamethylpentasiloxane	<30*
SVOC (GC/MS)	
4-Chlorobenzoic acid	30
2,4-Dichlorobenzoic acid	25.9
Hexamethylcyclotrisiloxane (D3)	<20**
Octadecamethyl cyclotetrasiloxane (D4)	99.2
Decamethyl Cyclopentasiloxane (D5)	83.9

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Compound	Concentration (µg/unit)
Dodecamethyl cyclohexasiloxane (D6)	394
Tetradecamethyl cycloheptasiloxane (D7)	503
Hexadecamethyl cyclooctasiloxane (D8)	172.2
Octadecamethyl Cyclopentasiloxane (D9)	381.5
Eicosamethyl cyclodecasiloxane (D10)	1006
2,2,4,4,6,8-Hexamethyl-6,8- diphenyl-cyclotetrasiloxane	2,602
2,2,4,4,6,6,8, 10-Octamethyl-8, 10-diphenyl-cyclopentasiloxane	62,646
Cyclic polydimethylsiloxane oligomer (combined values)***	10,822
Dimethylsiloxane-methylphenylsiloxane copolymer (combined values)***	2,602
Siloxane (combined values)***	11,344
1,3,5,7- Tetramethyltetraphenyl cyclotetrasiloxane	7,950
2,4,6,8, 10-Pentamethyl-2,4,6,8, 10-pentaphenyl-1,3,5,7,9,2,4,6,8, 10-pentaoxapentasilecane isomer (combined values)***	22,798
Polymethylphenylsiloxane oligomer (combined values)***	4,780
2-Ethyl-hexanol	79.3
Linear polydimethylsiloxane oligomer (combined values)***	325
Ester/carboxylic acid-containing unsaturated compound	20
Heptasiloxane, 1,1,3,3,5,5,7,7,9,9,11,11,13,13-tetradecamethyl-	26
Octasiloxane, 1,1,3,3,5,5,7,7,9,9,11,11,13,13,15,15-hexadecamethyl- (combined values)***	3606
Heptasiloxane, hexadecamethyl (combined values)***	3677
Octamethyltrisiloxane (L3)	<20**
Dodecamethylpentasiloxane (L5)	<20**
>L6	5800
Polysiloxane fragment (combined values)***	1883
NVOC (LC/UV)	
Palmitic acid	64.6
Stearic acid	74.2
Erucamide	9.69

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Compound	Concentration (µg/unit)
NVOC (LC/UV-Vis)	
Siloxane (combined values)***	75,035
Di(2-ethylhexyl)phthalate	2,629
Unknown*** (n = 9)	573-994
NVOC (UPLC-MS)	
Chlorine-containing compound (combined values)***	69
Amide containing aliphatic compound with coeluting unknown.	27
Dialkyl benzene carboxylate	47
Polysiloxane fragment (combined values)***	82
Polyoxygenated unsaturated compound (possibly polyester fragment)	38
Polyoxygenated unsaturated compound (possibly polyester fragment) with coeluting unknown	72
Erucamide	62
The nitrogen-containing oxygenated unsaturated compound	94
Alkenoid acid/ester with coeluting polyoxygenated unsaturated compound, polysiloxane fragment, and alkylphenol derivative (possibly Irganox 259)	570
Oxygenated unsaturated compound (possibly contains nitrogen)	200
Alkanoic acid/ester with coeluting polysiloxane fragments	430
Dehydrogenated Irganox 1076 with coeluting Irganox 1076	43
Di-amide containing aliphatic compound with coeluting unknown	190
Unknown**** (n=7)	20-850

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Compound	Concentration (µg/unit)
GC/MS, gas chromatography/mass spectrometry; LC/MS, liquid chromatography/mass spectrometry; LC/UV, liquid chromatography/ultraviolet; LC/UV-Vis, liquid chromatography/ultraviolet-visible; UPLC-MS, Ultra performance liquid chromatography – Mass spectrometry; NVOC, non-volatile organic compounds; SVOC, semi-volatile organic compounds; *The reported value corresponds to the detection limit of 30 µg/test article; the compound presence was not found above the detection limit. **The reported value corresponds to the quantification limit of 20 µg/test article; the compound presence was not found above the quantification limit. ***The concentrations of the same compound were added together, although there were differences in the retention time. ****The values represent the range in which the amounts of all the unknowns were detected.	

Note: Values are reported for the solvent that exhibited higher compound concentration. No volatile compounds were detected.

6. CONTRAINDICATIONS

The use of silicone breast implants is contraindicated in:

- Women with existing carcinoma of the breast, without mastectomy.
- Women with active infections.
- Women who are currently pregnant or nursing.
- Women with uncontrolled diabetes are clinically known to impact the wound-healing ability.
- Women who show tissue characteristics clinically incompatible with mammoplasties, such as tissue damage, compromised vascularity, or ulceration.
- Women with any condition – or treatment – determined by the surgeon to constitute an unjustifiable surgical risk (e.g., unstable cardiovascular disease, coagulopathies, chronic pulmonary problems, etc.).

7. RELEVANT TOPICS

7.1. INFORMED CONSENT

Establishment Labs relies on your surgeon to explain the existing risks and benefits of the implantation. The surgeon is also responsible for obtaining your formal informed consent to perform the surgical procedure.

As a patient, you will be given Establishment Labs' document on "Information for the Patient: Breast Implant

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Surgery with Motiva Implants®" (this document) during your surgical consultation. This document will be available through the website https://motiva.health/patients- motiva-experience/. It would be best if you had enough time to read and fully understand the information provided in the document regarding the risks, benefits, and recommendations associated with silicone gel-filled breast implant surgery.

To document a successful informed decision process, the surgeon must provide their "Informed Consent Document," which must be signed by the surgeon, the patient, and a witness. This document will be part of the patient's medical file. Patients should be advised of all possible side effects and surgery-related complications when considering silicone gel-filled breast implants.

Section 8.2 identifies potential side effects associated with breast implant surgery with silicone breast implants. Please review them all in detail. Additional relevant topics you need to be aware of when considering the use of silicone gel-filled breast implants include:

Topical Medications: You should consult a physician or a pharmacist before using topical medicines (e.g., steroids) in the breast area.

Smoking: Smoking may interfere with the healing process.

Radiation to the Breast: Establishment Labs has not tested the in-vivo effects of radiation therapy in patients who have breast implants. Scientific literature suggests that radiation therapy may increase the likelihood of breast implant complications, such as capsular contracture, necrosis, and implant extrusion.

Insurance Coverage: Before surgery, you should check with your insurance company regarding coverage terms.

Breast Examination Techniques: You should perform breast self-examinations monthly and be shown how to distinguish the implant from breast tissue. Therefore, it is important to take into consideration the following recommendations:

- Never manipulate or squeeze the implant excessively. The presence of lumps, persistent pain, swelling, hardening, or change in the implant shape could suggest symptomatic implant rupture. If you have any of these signs, report it to your surgeon and, if possible, receive an evaluation through MR or High-Resolution Ultrasound.

Mental Health and Elective Surgery: It is up to the surgeon to consider whether you are mentally ready for breast implant surgery. Be sure to let your surgeon know if you have a history of and/or current depression or other mental health issues.

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Summary of Safety and Clinical Performance (SSCP) - for the European Community, UK, and Switzerland:
The SSCP document could be consulted for additional and updated information on the Sterile Silicone Breast Implant Motiva Implants®, which will be available through the website https://motiva.health/patients-motiva-experience/ and EUDAMED using the Basic UDI-DI.

8. RISK AND BENEFIT ANALYSIS

8.1. CLINICAL BENEFITS

The following benefits are expected from Sterile Silicone-Gel Breast Implants Motiva Implant Matrix®:

- Increase the breast size and/or
- Reconstruct the breast 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 abnormality, or
- Revision procedure to correct or improve the results of a previous breast implant surgery.

Motiva Implants® and other breast implants currently on the market provide the same primary clinical benefit to facilitate breast implant surgical procedures. Motiva Implants® are intended for long-term breast implantation to improve shape and size.

The main benefit of Motiva Implants® (SmoothSilk®/SilkSurface®, categorized as a smooth surface, and VelvetSurface®, categorized as a microtextured surface) compared with other surface competitors is the surface topography, which was designed to improve compatibility between implants and tissues, minimizing inflammation and possibly inflammation-related complications such as capsular contracture, double capsules, and late seromas.

Smooth breast implants can move with the breast implant pocket, giving a more natural movement. Textured breast implants develop scar tissue, allowing the tissue to integrate with the implant, preventing it from moving around inside the breast when you move.

8.2. RISKS OF BREAST SURGERY WITH SILICONE IMPLANTS

Motiva Implants® share the same intended use and mechanism of action to achieve the intended clinical functionality as other similar breast implants available in the market.

Motiva Implants® are not lifetime devices, and there is a possibility that patients will undergo implant removal(s), with or without replacement, throughout their lifetime. The longer you have your implants, the more likely it will be for you to have them removed or replaced, and the more likely you are to experience local complications and adverse outcomes. The most common local complications and adverse outcomes are capsular contractures, reoperation, and rupture. Other complications include wrinkling, asymmetry, scarring, pain, and infection. You should assume that you will need to have additional surgeries (reoperations). Many of the changes to your breast(s) following implantation may be cosmetically

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undesirable and irreversible. For example, suppose you have your implants removed but not replaced. In that case, you may experience changes to your natural breasts such as dimpling, puckering, wrinkling, breast tissue loss, or other undesirable cosmetic changes. If you have breast implants, you will need to monitor your breasts for the rest of your life. If you notice any abnormal changes in your breasts, you must see a doctor promptly. If you have silicone gel-filled breast implants, you will need to undergo periodic MR examinations to detect implant ruptures that do not cause symptoms ("silent ruptures").

8.2.1. BREAST IMPLANT SURGERY SIDE EFFECTS

After breast implant surgery, patients might experience swelling, hardness, discomfort, itching, bruising, twinges, and pain over the first few weeks. The undesirable side effects identified are detailed below.

8.2.1.1. Related to general anesthesia

General anesthesia is commonly used, and local anesthesia with sedation is also an option. You should be sure to check with your surgeon and the facility where the surgery will occur to become aware of the tests, pre-surgical examinations, and length of time you need to be without food or your routine medications before the surgical procedure.

8.2.1.2. General adverse events related to a surgical procedure

- **Redness/Bruising-** Bleeding during surgery can cause the skin to change color. It is an expected symptom from the surgery and is likely temporary.

- **Pain-** Most women are undergoing breast implant surgery experience post-operatory breast and/or chest pain. While this pain usually recedes in most women as they heal after surgery, it can become a chronic problem in other women. Hematoma, migration, infection, implants that are too large, or capsular contracture can cause chronic pain. Sudden, severe pain may be associated with implant rupture. The surgeon should instruct you to immediately report if there is significant pain or if pain persists.

- **Swelling-** Normal post-operative swelling, which peaks about three to five days after surgery, will amplify chest pressure feelings. It is your body's natural response to the trauma of surgery.

- **Hypertrophic Scarring-** Scarring is a natural healing process and can take time to see improvements. Hypertrophic scars may happen when there is excessive tissue production, which forms the scar. Scars may also be caused because the wound takes too long to heal. Some people are biologically more susceptible to hypertrophic scars due to their genetic make-up[3].

[3] Berman B, Maderal A, Raphael B. Keloids and Hypertrophic Scars: Pathophysiology, Classification, and Treatment. Dermatol Surg. 2017 Jan;43 Suppl 1:S3-S18. doi: 10.1097/DSS.0000000000000819. PMID: 27347634.

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- **Skin Rash/Silicone Reaction/Allergy-** In general, cutaneous risks with breast implants seem low. However, despite the biological compatibility and presumed inertness of their compounds, several reports have documented the presence of cutaneous hypersensitivity-like reactions to breast implants. Topical and systemic medications may relieve the symptoms and lead to a successful resolution. In some cases, implant removal is required for complete symptom relief.

- **Seroma-** Seroma is an accumulation of fluid that results from tissue inflammation[4]. The cause of seroma is known in breast surgery and is connected to a hypovascular milieu or trauma following the surgery or later.

The body often reabsorbs seromas over several weeks, but needle drainage is sometimes needed to remove the fluid[5]. While seromas do not increase breast cancer risk, they sometimes heal with scar tissue or calcifications that can raise a concern about mammograms in the future. Seroma symptoms most often appear a week to 10 days after surgery; the area may feel tender and swollen, with a discrete lump and redness arising within a day or two.

In addition to causing pain, a seroma increases the risk of developing an infection in the breast. Depending on the location, it may also increase pressure over the surgical site and sometimes cause wound dehiscence.

- **Hematoma-** A hematoma is a collection of blood within the breast tissue. Symptoms of hematomas generally include swelling, bruising, and pain around the incision area[6]. Most hematomas will either resolve on their own or will only require draining. Drains are small surgical tubes that lead out of the breast, with a small bulb attached to collect blood and other fluids.

- **Lymphadenopathy-** Silicone-induced lymphadenopathy is a well-known rare complication of implant insertion. It is a disease of the lymph nodes (small, round structures that operate as part of the body's immune system). They become abnormal in size or consistency (most commonly producing swollen or enlarged lymph nodes)[7]

After implant insertion, axillary lymphadenopathy causes are multifactorial, with possible factors including granulomatous reaction, inflammation, and/or malignancy. Literature reports associate lymphadenopathy with intact and ruptured silicone breast implants since microscopic silicone droplets can migrate to body tissues even when the implant surface remains intact. Breast implant rupture and/or leakage through an intake surface can cause fibrosis and granulomatous reactions, which in turn can result in a contracture or regional lymphadenopathy that sometimes mimics malignancy. Various patterns of lymphadenopathy and

[4] Sood A, Kotamarti VS, Therattil PJ, Lee ES. Sclerotherapy for the Management of Seromas: A Systematic Review. Eplasty. 2017 Aug 28;17:e25. PMID: 28890747; PMCID: PMC5575675.

[5] Gioacchini M, Bottoni M, Grassetti L, Scalise A, Di Benedetto G. A simple, reliable, and inexpensive method for seroma drainage. Arch Plast Surg. 2015 May;42(3):361-2. doi: 10.5999/aps.2015.42.3.361. Epub 2015 May 14. PMID: 26015895; PMCID: PMC4439599

[6] https://www.fda.gov/medical-devices/breast-implants/risks-and-complications-breast-implants

[7] Lee Y, Song SE, Yoon ES, Bae JW, Jung SP. Extensive silicone lymphadenopathy after breast implant insertion mimicking malignant lymphadenopathy. Ann Surg Treat Res. 2017 Dec;93(6):331-335. doi: 10.4174/astr.2017.93.6.331. Epub 2017 Dec 1. PMID: 29250513; PMCID: PMC5729128.

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even extranodal pathology may be observed.

Tissue examination is essential to identify the cause of lymphadenopathy. When in doubt, spectrometry analysis can confirm a diagnosis of silicone-induced lymphadenopathy.

- **Surgical Wound Dehiscence-** Surgical wound dehiscence (SWD) is the separation of the margins of a closed surgical incision that has been made in the skin, with or without exposure or protrusion of underlying tissue, organs, or implants. Separation may occur at single or multiple regions, involve the incision's entire length, and affect one or more tissue layers. A dehisced incision may or may not display clinical signs and symptoms of infection.

8.2.1.3. Related to the surgical technique

- **Unsatisfactory Results/Cosmetic Defects-** Unsatisfactory results such as stretch marks, visibility, and dissatisfaction with the implant volume may occur. Some of these results may cause discomfort. Pre-existing asymmetry may not be entirely correctable by implant surgery. Revision surgery could be indicated to increase patient satisfaction, but this involves additional considerations and risks. Careful pre-operative planning and surgical technique can minimize, but not always prevent, unsatisfactory results.

- **Lactation Difficulties-** . Women who undergo mastectomies and then have breast implant reconstruction surgeries may not breastfeed on the affected side due to loss of breast tissue and the glands that produce milk.

- **Bottoming Out**- Refers to the inferior displacement of a breast implant that increases the distance between the nipple-areolar complex and the inframammary fold (IMF) after breast implant surgery. Risk factors reported in the literature are, but not limited to, the lack of quality of pre-existing breast tissue (thin subcutaneous tissue, defective dermal elements, breast tuberosity), characteristics of the selected breast implant (such as being overly large), IMF dissection, and the type of implant placement during surgery (submuscular and subglandular planes)[8].

The clinical symptoms resulting from a bottomed-out implant include asymmetry, upward- pointing nipples, sagging, palpability, etc.

- **Delayed Wound Healing-** Some patients may experience a prolonged wound healing time. Smoking causes a decrease in the blood's oxygen levels, directly affecting surgical wounds' healing process. Delayed wound healing may increase the risk of infection, extrusion, and necrosis and may vary depending on the type of surgery or incision.

[8] Mañero, Ivan M.D.; Montull, Patricia M.PD.; Guisantes, Eva M.D. Bottoming Out: A Simple Technique for Correcting Breast Implant Displacement. Plastic and Reconstructive Surgery: December 2009 - Volume 124 - Issue 6 - p 452e-453e

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- **Infection-** Infection can occur with any surgery or implant. Most infections resulting from surgery appear within a few days to weeks after the operation[9]. However, infection is possible at any time after surgery. In addition, breast and nipple piercing procedures may increase the possibility of infection. If an infection does not respond to antibiotics, the implant may have to be removed, with replacement occurring only after the infection is resolved.

As with other surgical procedures, Toxic Shock Syndrome (TSS), a life-threatening condition, has been reported in rare instances following breast implant surgery. TSS symptoms occur suddenly and can include high fever (102° F/38.8° C or higher), vomiting, diarrhea, fainting, dizziness, and/or sunburn-like rash. Patients should contact their doctor immediately for diagnosis and treatment if they experience these symptoms[10].

- **Visibility/Palpability-** Visibility and palpability of the implant can occur because the envelope is thin due to several causes, including excessive volume, the implant's content is not cohesive, or previous surgery and cutaneous aging. If the implant is fitted in a subglandular pocket, a change to a submuscular pocket is needed. The implant volume should be reduced, and it should be ensured that the content is a cohesive gel.

- **Changes in Nipple and Breast Sensation-** Breast surgery can increase or decrease breast and/or nipple sensitivity. Typically, the sensation is lost after complete mastectomy, where the nipple itself is removed and can be severely lessened by partial mastectomy. The range of changes varies from intense sensitivity to no feeling in the nipple or breast following surgery. While some of these changes can be temporary, they can also be permanent and may affect the patient's sexual response or breastfeeding ability[11].

For some patients, additional sensitivity in the nipple area may be noticed days or weeks after breast implant surgery. This is normal and is due to the stretching of the area near your nerves during the surgery. Fortunately, this extra sensitivity will go away as the tissues continue healing. The risk of extra sensitivity is small, and it is typically not permanent.

[9] Song JH, Kim YS, Jung BK, Lee DW, Song SY, Roh TS, Lew DH. Salvage of Infected Breast Implants. Arch Plast Surg. 2017 Nov;44(6):516- 522. doi: 10.5999/aps.2017.01025. Epub 2017 Oct 27. PMID: 29076316; PMCID: PMC5801791.

[10] Franchelli S, Pesce M, Baldelli I, Marchese A, Santi P, De Maria A. Analysis of clinical management of infected breast implants and of factors associated to successful breast pocket salvage in infections occurring after breast reconstruction. Int J Infect Dis. 2018 Jun;71:67-72. doi: 10.1016/j.ijid.2018.03.019. Epub 2018 Apr 13. PMID: 29660396.

[11] Araco A, Araco F, Sorge R, Gravante G. Sensitivity of the nipple-areola complex and areolar pain following aesthetic breast augmentation in a retrospective series of 1200 patients: Periareolar versus submammary incision. *Plast Reconstr Surg*. 2011;128(4):984- 989. doi:10.1097/PRS.0b013e3182268d73

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- **Ptosis-** The 'waterfall effect' is a descriptive term to indicate sagging of breast tissue over a fixed or encapsulated implant. It occurs more frequently than surgeons anticipate, especially over the long term after breast implant surgery. Certain breast implants are more prone to contribute to this problem, as are implants placed in submuscular pockets that ride high, especially in women with anatomical musculoskeletal variance or asymmetry[12].

- **Rotation-** Anterior and posterior rotation, also called flipping, has been observed more frequently with cohesive gel implants. The flat base of the implant is positioned anteriorly, deforming the breast of the patient. Proper placement and pocket dissection reduce the risk of occurrence[13].

Flipping can be treated with bimanual manipulation in the office and can be done repeatedly in recurrent cases. However, revision surgery may be necessary to reduce pocket dimensions in some cases.

Regarding implant characteristics, flipping has been associated with the presence or absence of texturing, implant shape or profile, and the gel filling ratio (i.e., to what degree the implant has been filled). Other factors such as infection, hematoma, seroma, capsular contracture, dissection, surgeon's experience, physical activity, and external manipulation of the implant could potentially contribute to the development of this complication.

- **Malposition-** Malposition of a breast implant is defined as an incorrect placement during surgery or shifting from its original position. It is also called displacement or lateralization. Malposition has been reported frequently due to its multifactorial causes, which can be expected during the device's lifetime.

The implants' shifting can be produced by trauma, capsular contracture, gravity, or initial wrong placement[14]. The surgeon must plan the operation carefully and conduct the surgery with a technique that minimizes but does not wholly evade malposition risk. The risk associated with this event is dissatisfaction with aesthetic outcomes.

[12] Frame J. The waterfall effect in breast augmentation. Gland Surg. 2017 Apr;6(2):193-202. doi: 10.21037/gs.2016.10.01. PMID: 28497023; PMCID: PMC5409900

[13] Jong, Justin MD[*]; Gabriel, Allen MD, FACS[†]; Trekell, Melissa MD[‡]; Lawser, Amy S. MSN, RN[§]; Heidel, Eric PhD[¶]; Buchanan, Dallas MD, FACS[‖]; Chun, Joseph T. MD, FACS[**] Cohesive Round Implants and the Risk of Implant, Plastic, and Reconstructive Surgery - Global Open: December 2020 - Volume 8 - Issue 12 - p e3321 doi: 10.1097/GOX.0000000000003321

[14] Karan Chopra, MD, Arvind U. Gowda, MD, Edwin Kwon, MD, Michelle Eagan, MD, W. Grant Stevens, MD, Techniques to Repair Implant Malposition after Breast Augmentation: A Review, *Aesthetic Surgery Journal*, Volume 36, Issue 6, June 2016, Pages 660– 671, https://doi.org/10.1093/asj/sjv261

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- **Symmastia**- Is a relatively rare implant displacement problem that occurs when the skin and muscle between the breasts over the sternum (breastbone) detaches and the two pockets of tissue that hold the breast implants come together to form one pocket. This allows the implants to come together in the middle, creating the appearance of a "uniboob" and sometimes causing discomfort or pain. It's often difficult to correct symmastia and it may require more than one surgery. Surgery will often involve removing the implants and replacing them with new (usually smaller) implants.

8.2.1.4. Related to breast implants

If any of the following or other adverse events occur, contact your surgeon as soon as possible:

- **Inflammation/Irritation-** Breast implants are no different from any foreign material implanted into the human body and can trigger a host's protective immune reaction. It is a foreign body response demonstrated by redness, swelling, warmth, pain, and/or loss of function. This foreign body response is universal and ideally removes or otherwise surrounds the "irritant material" with fibrous tissue to prevent unwanted immune consequences.

- **Gel Fracture-** Gel fracture is a fissure or cracks in the implant's gel when excessive intrinsic forces forcibly separate the silicone gel filling. As a result, the implant's shape is irrevocably lost, leading to the need for implant replacement. It can occur with cohesive silicone gel and most frequently due to exposing the implant to excessive compression forces applied to a small shell area during implant insertion. Gel fracture can also occur due to the development of capsular contracture and may result in device distortion.

The incision should be of appropriate length to accommodate the implant's volume and profile with its highly cohesive gel, which will reduce the potential excessive stress that may damage the implant's gel and possibly implant rupture or gel fracture.

Gel fracture can be detected by ultrasound or magnetic resonance imaging (MRI). Most gel fractures are undetectable by physical examination.

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- **Gel Diffusion-** Small quantities of silicone may diffuse or bleed through the elastomer envelope of silicone gel-filled implants. The detection of small quantities of silicone in the periprosthetic capsule, axillary lymph nodes, and other distal regions in patients with apparently intact gel-filled implants has been reported in the literature. Some studies on long-term implants have suggested that gel bleed may contribute to capsular contracture and lymphadenopathy development. On the other hand, there is evidence against gel bleed being a significant contributing factor to capsular contracture. Other local complications are provided because there are similar or lower complication rates for silicone gel-filled breast implants than for saline-filled breast implants[15].

- **Heat Sensation-** Sterile Silicone Breast Implants Motiva Implants® with microtransponder, under MRI scan defined conditions, can produce a minimal heat sensation.

- **Capsular Contracture-** A capsular contracture pertains to hypertrophic scar tissue investing in a foreign body or surgically implanted device, compromising the aesthetic outcome, resulting in pain, breast deformity, and often necessitating further operations[16]. Detection of breast cancer by mammography may also be challenging. Capsular contracture may be more common following infection, hematoma, and seroma, and the chance of it happening may increase over time. Capsular contracture occurs more commonly in patients undergoing revision surgery than in patients undergoing primary surgery. Capsular contracture is the most common complication following implant-based breast surgery and is one of the most common reasons for reoperation.

Capsular contracture is graded into four (4) levels depending on its severity:

- Baker Grade I: The breast is normally soft and looks natural;
- Baker Grade II: The breast is a little firm but looks normal;
- Baker Grade III: The breast is firm and looks abnormal;
- Baker Grade IV: The breast is hard, painful, and looks abnormal.

[15] Loureno FR, Kikuchi IS, Andreoli Pinto T de J. Silicone Gel Bleed on Breast Implants. *Open Biomater J*. 2011;3(October):14-17. doi:10.2174/1876502501103010014

[16] Headon H, Kasem A, Mokbel K. Capsular Contracture after Breast Augmentation: An Update for Clinical Practice. Arch Plast Surg. 2015 Sep;42(5):532-43. doi: 10.5999/aps.2015.42.5.532. Epub 2015 Sep 15. PMID: 26430623; PMCID: PMC4579163

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Patients should also be advised that additional surgery might be needed in cases where pain and/or firmness are severe (Baker Grades III or IV) and that capsular contracture may happen again after additional surgeries.

A closed capsulotomy (external manipulation of the capsule to "pop" the tissue capsule and open it up) is a standard procedure for treating capsular contracture; however, most manufacturers, including Establishment Labs, contraindicate it because it can cause implant rupture.

- **Rupture-** Breast implants rupture when the shell develops a tear or hole. Rupture can occur any time after implantation but is more likely to occur the more prolonged the implant. The following may cause implants to rupture: damage by surgical instruments, implant stress and weakening during implantation, implant age, implant design, submuscular rather than subglandular location, the occurrence of post-operatory hematomas or seromas, folding or wrinkling of the implant shell, excessive force to the chest, trauma, compression during mammographic imaging, and severe capsular contracture[17].

Silicone gel-filled implant ruptures are most often silent; this means that most of the time, neither doctor nor the patient can determine with the physical examination if the implant has a tear or hole in the shell. The integrity of breast implants (and detection of gel fractures and/or silent ruptures) can be evaluated through several techniques. High-resolution ultrasound (HRUS) is widely accepted by health providers and patients for rupture diagnosis. Additionally, the US FDA recommends MRI surveillance, with the first MRI performed three years post-operatively, and subsequent MRIs performed every two years after that[18]. These recommendations may vary from country to country, so you should be provided additional guidance based on your country's current care standards. Establishment Labs does not recommend closed capsulotomy for treating capsular contracture because it can cause implant rupture.

Symptoms include lumps surrounding the implant or in the axilla, change or loss of size or shape of the breast or implant, pain, tingling, swelling, numbness, burning, or hardening of the breast. These symptoms are not specific to rupture and may also be experienced by patients with capsular contracture.
Some reported cases suggest that silicone implant leakage should be considered in the differential diagnosis of eosinophilia (increased numbers of eosinophils in the peripheral blood)[19].

[17] Hillard C, Fowler JD, Barta R, Cunningham B. Silicone breast implant rupture: a review. Gland Surg. 2017 Apr;6(2):163-168. doi: 10.21037/gs.2016.09.12. PMID: 28497020; PMCID: PMC5409893
[18] Update on the Safety of Silicone Gel-Filled Breast Implants (2011) - Executive Summary (2011). Accessed March 26, 2021. https://www.fda.gov/medical-devices/breast-implants/update-safety-silicone-gel-filled-breast-implants-2011-executive-summary
[19] Levenson, Toby; Greenberger, Paul A; Murphy, Robert (1996). Peripheral Blood Eosinophilia, Hyperimmunoglobulinemia A and Fatigue: Possible Complications Following Rupture of Silicone Breast Implants. 77(2), 119‑122. doi:10.1016/S1081-1206(10)63497-7

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- **Extrusion-** Breast implant extrusion or exposure occurs when the breast skin and tissues are holding the implant fail, causing the implant to protrude through the skin and become exposed. It happens in less than 2 percent of patients.. Breast implant extrusion can occur for various reasons: improper wound healing due to an infection, trauma, too little soft tissue coverage, oversized implant coupled with too little tissue coverage, or lack of blood supply. Breast implant extrusion calls for surgery and removal of the implant[20].

- **Double Capsule-** The double capsule refers to the finding of two distinct capsular layers, separated by an inter-capsular space (ICS), around a breast implant. Although rare, double capsules can occur after breast implant surgery. This condition's etiopathology is still undefined, but two main hypotheses could explain this complication's development. Clinical signs may vary from asymptomatic to firmness of the implant, discomfort, change in shape or position of the implant, and pain.

- **Asymmetry-** Pre-operative asymmetries include areolas in different positions medially or regarding height, different breast shapes (e.g., one round and the other tuberous), or different breast sizes. These asymmetry types should be differentiated from a post- operative aesthetic difference in the two breasts produced by factors described previously, such as a fall of the fold, a high implant, or a rotation of the implant. They can be prevented using adequate pre-operative planning, correct dissection of the pockets, and comparing the two breasts after fitting the implants. It is possible that after a breast implant surgery, minor deformities in the wall of the thorax or a morphologic mammary disorder may become much more evident. For this reason, the predicted correction of these anomalies should be discussed before the operation[21].

- **Rippling/Wrinkling-** Rippling is the cutaneous manifestation, visible or palpable, of the implant ripples and edge that are typically most apparent when the patient bends forward. In situations where the implant's soft tissue coverage is insufficient, these unfavorable effects become more apparent. Adequate coverage over the implant ripples is a mandatory element in preventing rippling or implant edge visibility.

- **Necrosis-** Necrosis is the formation of dead tissue around the implant. This may prevent wound healing and require surgical correction and/or implant removal. Permanent scar deformity may occur following necrosis. Factors associated with necrosis include infection, steroids in the surgical pocket, smoking, chemotherapy/radiation, and excessive heat or cold therapy.

[20] Breast Cancer. Breast Implant Extrusion. Published 2020.
https://www.breastcancer.org/treatment/surgery/reconstruction/corrective/implant-extrusion#:~:text=In relatively rare cases after,This is called "extrusion."
[21] Breast Asymmetry (2019). Accessed on March 26, 2021.
https://www.breastcancer.org/treatment/surgery/reconstruction/corrective/asymmetry

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- **Calcification/Calcium Deposits-** Calcium deposits can form in the scar tissue surrounding the implant and cause pain and firmness. Calcium deposits are visible on mammography. As these deposits must be differentiated from calcium deposits that are a sign of breast cancer, additional surgery may be necessary to remove and examine calcifications. Calcium deposits also occur in women who undergo breast reduction procedures, in patients who have experienced hematoma(s) and/or seroma(s), and even in the breasts of women who have not undergone any breast surgery. The occurrence of calcium deposits significantly increases with age.

- **Reoperation (Explantation)-** Rupture, unacceptable cosmetic outcomes (dimpling, wrinkling, and other potentially permanent cosmetic changes of the breast), and other complications may require additional surgeries to the patient´s breasts.

Implants are not lifetime devices, and there is a possibility that patients will undergo implant removal(s), with or without replacement, throughout their life. When implants are explanted without replacement, changes to the patient's breasts may be irreversible.

You should be advised that future complications increase with revision surgery compared to primary breast implant surgery. For example, the risk of severe capsular contracture doubles for breast implant surgery with implant replacement compared to first time implantation due to an accidental compromise of implant shell integrity during reoperation, potentially leading to product failure.

Irradiation may cause premature removal because of extrusion, capsular contracture, and recurrent seroma/hematoma.

- **Interference with Mammography-** Establishment Labs emphasizes the importance of mammography. You should inform your examiners in an accredited mammography center about your implants' presence, type, and placement and request diagnostic mammography rather than screening mammography[22]. Breast implants may complicate the interpretation of mammographic images by obscuring underlying breast tissue and/or compressing overlying tissue. Pre- and post-surgical mammography may be performed to determine a baseline for routine future studies in breast implant surgery.

- **Interference with Magnetic Resonance Imaging (MRI)-** Motiva Implants® with microtransponder are considered MRI conditional. During the MRI study, the

[22] Sá Dos Reis C, Gremion I, Richli Meystre N. Study of breast implants mammography examinations for identification of suitable image quality criteria. Insights Imaging. 2020 Jan 3;11(1):3. doi: 10.1186/s13244-019-0816-5. PMID: 31900684; PMCID: PMC6942083.

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microtransponder can create an MRI artifact immediately around the microtransponder (known as an artifact) that can prevent radiologists from seeing parts of the implant's footprint and parts of the patient's tissue.

Therefore, there are potential added MRI risks associated with this artifact, including, but not limited to, an inadequate evaluation of the implant shell for the detection of rupture or missing a diagnosis of cancer should its obscure cancer in the artifact area.

8.3. OTHER REPORTED CONDITIONS

There have been reports in the literature of other conditions in women with silicone gel-filled breast implants. Many of these conditions have been studied to evaluate their potential association with breast implants. No cause-and-effect relationship has been established between breast implants and the conditions listed below. Furthermore, it is possible that other risks, yet unknown, could be determined to be associated with breast implants in the future.

- **Neurological Signs and Symptoms-** Some women with breast implants have experienced neurological disturbances (e.g., visual symptoms or alterations in sensation, muscle strength, walking, balance, thinking, or memory) or diseases (e.g., multiple sclerosis), and they believe those symptoms are related to their implants. However, there is no evidence in the published literature of a causal relationship between breast implants and neurological disease.

- **Cancer-** Breast cancer reports in the medical literature reveal that patients with breast implants are not at a greater risk of developing breast cancer than those without breast implants. Reports in the medical literature indicate that breast implants do not significantly delay breast cancer detection or adversely affect cancer survival prognosis in implanted women. Some studies even suggest lower rates of breast cancer in women with breast implants.

- **Breast Mass/Cyst-** A breast cyst is a fluid-filled sac that develops within the breast tissue. These sacs form when normal fluid-producing glands in the breast enlarge or become blocked[23]. Depending on the type of breast implant and the implant placement, the mass may be due to an implant valve or, as sometimes occurs in women with thin breast tissue, the implant itself. Breast cysts are usually found on a self-breast exam. When they are small, they often go unnoticed or may instead be seen on a mammogram.

- **Breast Tissue Atrophy-** Breast tissue atrophy may result from aging or the pressure exerted by a usually large breast implant about the patient's breast and chest wall size.

[23] The NSW Breast Cancer Institute (2006) Breast cysts - An information guide for patients

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- **Chest Wall Deformity-** The breast implant's pressure may cause the breast tissue to thin and shrink (with increased implant visibility and palpability), potentially leading to chest wall deformity. It can occur while implants are still in place or following implant removal without replacement.

- **Breast Implant Illness (BII)-** Over the past several years, the FDA has received new information about systemic symptoms, commonly referred to as breast implant illness (BII), that some patients attribute to their implants. Some people with BII also get diagnosed with a specific autoimmune or connective tissue disorder[24], but many do not.

Researchers are investigating the symptoms to understand their origins better. These symptoms and what causes them are poorly understood. In some cases, removing breast implants without replacement is reported to reverse breast implant illness symptoms.

Symptoms can include central nervous system disorders (brain fog, memory loss, tinnitus, vertigo, headaches, blurred vision, migraines), musculoskeletal disorders (fibromyalgia, muscle pain, hand discoloration, numbness, headaches, migraines), psychological disorders (anxiety, panic attacks, feeling of imminent death), immune/inflammatory disorders (Raynaud Syndrome, scleroderma, Hashimoto thyroiditis, Sjogren syndrome, autoimmune disease, recurrent infections, rheumatoid arthritis, night sweats, toxic shock, chronic fatigue, dry eye, sudden food intolerance, systemic lupus erythematosus, multiple sclerosis), as well as anemia and symptoms related to the cardiorespiratory and genitourinary systems.

- **Connective Tissue Disease (CTD)-** Since the early 1990s, nearly a dozen comprehensive systemic reviews have been commissioned by government health ministries in several countries to examine the alleged links between silicone gel breast implants and systemic diseases[25]. No hard evidence has been found to support an association between silicone breast implants and CTDs.

Case reports of women with silicone breast implants and connective tissue disease (CTD) include the following symptoms: nervous system alterations (brain fog, memory loss, blurred vision, migraines, tinnitus), musculoskeletal disease (muscle/joint pain, fibromyalgia, numbness/tingling in upper and lower limbs, slow muscle recovery after

[24] FDA. Risks and Complications of Breast Implants. Published 2020. https://www.fda.gov/medical-devices/breast-implants/risks-and-complications-breast-implants

[25] Balk EM, Earley A, Avendano EA, Raman G. Long-Term Health Outcomes in Women with Silicone Gel Breast Implants: A Systematic Review. Ann Intern Med. 2016 Feb 2;164(3):164-75. doi: 10.7326/M15-1169. Epub 2015 Nov 10. PMID: 26550776.

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activity), immune/inflammatory (Raynaud syndrome, Sjogren syndrome, Hashimoto thyroiditis, scleroderma, recurrent/persistent infections, rheumatoid arthritis), GI/genitourinary (reduced libido, pancreatitis, urinary tract infection, metallic taste, chocking, sudden disease, reflux, gastritis, weight loss/gain), cardiorespiratory and psychological symptoms.

Recent studies still suggest that this association is possible, given that silicone in breast implants can act as a foreign body that can elicit an inflammatory response. Microscopic particles of silicone from the original surgical site have been found far away from it (e.g., in the liver), suggesting a small number of silicone particles detach from the implants and migrate through the lymphatic or circulatory system to other organs. In theory, they could act as adjuvants and start an inflammatory process in joints or activate the immune system and stimulate autoantibodies production. Nevertheless, no conclusive data is available in this regard[26].

- **Breast Implant Associated-Anaplastic Large Cell Lymphoma (BIA-ALCL)[27]-** BIA-ALCL is a rare type of T-cell lymphoma involving cells of the immune system[28]. The World Health Organization in year 2016 recognized it as a breast implant-associated disease. The exact number of cases remains difficult to determine due to significant limitations in world-wide reporting and lack of global implant sales data. It has been reported that most data suggest that BIA-ALCL occurs more frequently following the implantation of breast implants with textured surfaces rather than those with smooth surfaces. Establishment Labs has complied with the French National Agency for Medicines and Health Products Safety (ANSM) request to the manufacturers of textured breast implants to perform biocompatibility testing. There is a significant body of medical literature relating to breast implants and the risk of developing ALCL. According to the FDA, all the information reviewed as of the date of FDA's March 2017 notice suggests that "women with breast implants have a shallow but increased risk of developing ALCL compared to women who do not have breast implants." Most cases of breast implant-associated ALCL are treated by removing the implant and the capsule surrounding the implant, and some cases have been treated by chemotherapy and radiation.

Diagnostic evaluation should include cytological evaluation of seroma fluid with Wright Giemsa-stained smears and cell block immunohistochemistry testing for a cluster of differentiation (CD) and Anaplastic Lymphoma Kinase (ALK) markers. The sour surgeon will

[26] Hölmich LR, Lipworth L, McLaughlin JK, Friis S. Breast implant rupture and connective tissue disease: A review of the literature. *Plast Reconstr Surg*. 2007;120(7 SUPPL. 1):62-69. doi:10.1097/01.prs.0000286664.50274.f2

[27] Piubelli MLM, Ferrufino-Schmidt MC, Miranda RN. Gluteal Implant-Associated Anaplastic Large Cell Lymphoma (ALCL) is Distinct from Systemic ALCL ALK Negative in a Patient with Gluteal Implants. *Aesthetic Surg J*. 2019;39(10):NP441-NP442. doi:10.1093/asj/sjz197

[28] Clemens MW, Nava MB, Rocco N, Miranda RN. Understanding rare adverse sequelae of breast implants: anaplastic large-cell lymphoma, late seromas, and double capsules. Gland Surg. 2017 Apr;6(2):169-184. doi: 10.21037/gs.2016.11.03. PMID: 28497021; PMCID: PMC5409903

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develop an individualized treatment plan in coordination with your multi-disciplinary care team. Current clinical practice guidelines must be followed, such as those from the Plastic Surgery Foundation or the National Comprehensive Cancer Network (NCCN), when choosing your treatment approach.

For the latest statistical data on reported cases, refer to: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm

9. POST-OPERATIVE CARE

The recovery process depends on your profile and other variables. Below, we have detailed some general instructions and possibilities to expect:

- You might have an elevated body temperature.
- Your breasts may remain swollen and sensitive to physical contact for a month or longer.
- You are likely to feel tired and sore for several days following the operation.
- You could experience a feeling of tightness in the breast area as your skin adjusts to your new breast size.
- Avoid any strenuous activities for at least a couple of weeks, though you may be able to return to work within a few days.
- Breast massage may also be recommended as appropriate.
- Sleep or rest with your head slightly elevated, avoiding lateral positions.
- Keep your arms close to your body and avoid lifting weights until allowed by your surgeon.
- Do not drive for at least two days after your surgery, and not exercise until approved by your surgeon.
- Do not expose your breasts directly to sunlight until approved by your surgeon.
- Your surgeon may recommend a topical cream.
- Immediately after surgery, your breasts will be swollen and tender, so you will likely need to wear a medical compression bra, also called a surgical bra, *without underwires.* Your surgeon will provide or recommend the best bra after breast implant surgery, along with instructions on how long you must wear it. Most patients wear their medical compression garments day and night for one to two weeks, after which they can transition to a supportive sports bra.
- Pregnancy and nursing after breast implant surgery may cause breast tissue and muscle changes that could lead to ptosis (drooping) and flipping.

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10. STERILE PRODUCT

Motiva Implants® are sterilized during manufacturing by using a dry heat sterilization method. An implant is intended to be used only in one patient for a single procedure and supplied in a sealed, double sterile barrier primary package.

11. SURGICAL PROCEDURE

11.1. SURGICAL TECHNIQUE

Breast implants may be positioned in several different tissue planes, described as the pocket location. The selection of this pocket is often an essential process in obtaining the desired outcome. Surgeons should consider using published principles for implant selection that minimize the risks of both short- and long-term complications.

In some cases, the surgeon may include intra-operative, single-use, sterile, silicone breast sizers from the Motiva Implants®; these are single-use devices designed for temporary intra-operative placement to assist in determining the appropriate breast implant volume and shape for each patient before implantation of Motiva Implants®.

11.2. IMPLANT SELECTION

Motiva Implants® come in various widths, heights, projections, and volumes to offer you the most appropriate device for your specific needs. The implant size should be consistent with your chest wall dimensions, including base width measurements, tissue characteristics, and implant projection. Therefore, this decision should be made in conjunction with your surgeon to avoid choosing an implant that is too large for your tissue to tolerate and avoid post-operative implant visibility and palpability.

The following conditions may cause implants to be more palpable: textured implants, larger implants, sub-glandular placement, and insufficient tissue available to cover the implant. Enormous implants may speed up the effects of gravity on the breasts. They can result in drooping or sagging, the risk of developing clinical complications, or aesthetically undesirable results, which sometimes require surgical intervention for correction.

11.3. INCISION

The incision should be of sufficient length to place the implant inside the breast without risking damage to the implant. Table 5 details the differences between incision types for the placement of breast implants.

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Table 5. Types of incisions for breast implant surgery with silicone implants.

Incision type	Characteristics
Periareolar	Better concealed. May reduce the possibility of future breastfeeding. Associated with a higher risk of changes in nipple sensation.
Inframammary	Less concealed than the periareolar incision. Associated with fewer breastfeeding difficulties.
Axillary	Least concealed of all incision sites (when the arm is lifted).

For a better understanding of the anatomical position where different incisions are made, refer to the image below:

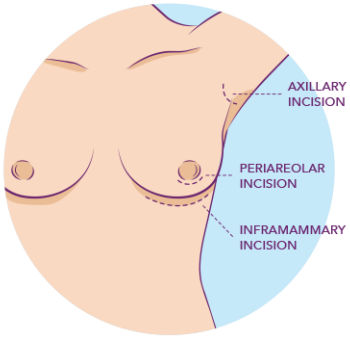

Figure 1. Anatomical location of possible incision sites for breast implant surgery with silicone implants.

11.4. PLACEMENT

One of the most relevant factors in a successful breast implant surgery is the proper placement of the implant. Table 6 details the differences between placement pockets for silicone breast implants.

Table 6. Placement for breast implant surgery with silicone implants.

Placement	Characteristics
Submuscular/Subpectoral (under the chest muscle)	Less palpable implants. Lower likelihood of capsular contracture. Easier mammographies. Associated with a longer surgical procedure, more extended recovery period, and more pain. It can influence the degree of difficulty in performing some reoperation procedures.

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Subglandular (under your mammary/glandular tissue but over the fascia* layer)	May reduce surgery and recovery duration. Less painful. Easier access for reoperation than submuscular placement. May result in increased implant palpability. Greater risk of capsular contracture and ptosis (sagging). Increased difficulty in performing mammographies.
Subfascial (under both the mammary tissue and the fascia* layer)	Natural-looking shape. Associated with a more extended procedure and more challenging dissection. Less painful than submuscular/dual plane. Better lower-pole coverage but less upper-pole coverage. Minimal muscular distortion with arm movement. More predictable results.
Dual plane	Benefits of these techniques have been reported, but not limited to, improved soft tissue coverage, less interference with mammography, better lower pole fullness with improved upper and medial pole contour. This technique's reported risks are not limited to implant visibility, palpability, capsular contracture, and some animation deformities.

**Fascia* refers to a thin layer of connective tissue that lies on top of the chest muscle.*

For a better understanding of the anatomical place where the implants could be placed according to the surgeon's criteria, observe the image below:

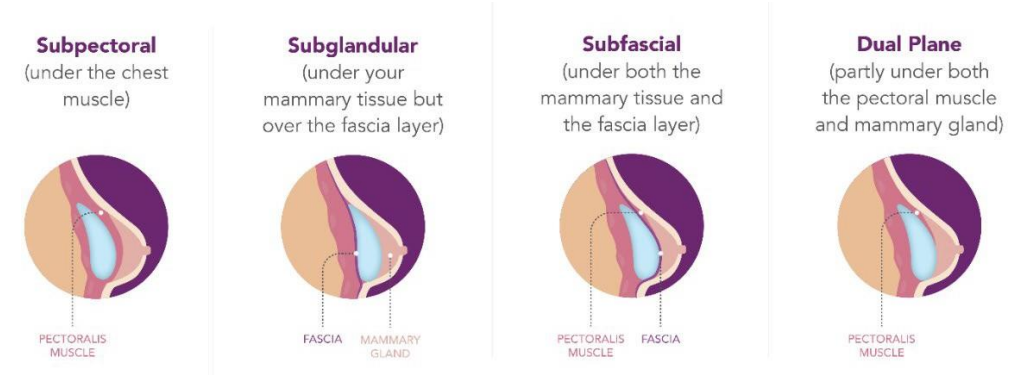

Figure 2. Anatomical locations of the placement pockets of breast implants.

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12. SPECIFIC BREAST IMPLANT CHARACTERISTICS

12.1. BLUSEAL® TECHNOLOGY

Motiva Implants® are the only breast implants in the world that come with a lightly tinted blue barrier layer, made with biocompatible dyes to allow for pre-surgical visual inspection by your surgeon to ensure the integrity of the entire implant shell. Thus, the BluSeal® barrier layer prevents the use of defective products and prevents silicone gel leakage into the body after implantation.

12.2. MICROTRANSPONDER

Motiva Implants® are available with an optional microtransponder, a long-term implantable, radio frequency identification device (RFID), safely embedded in the breast implant filler material. Scanners to read the information in the microtransponders are sold separately. The microtransponder is a passive radiofrequency identification device (RFID) that uses radio waves to provide an Electronic Serial Number (ESN) that assures full traceability to implant specific data.

The microtransponder in the breast implant provides the patient an electronic serial number used to access a database containing the breast implant information (serial and lot numbers, the reference number, volume, size, and projection, model, surface type, manufacturing date, etc.).

Unlike product and warranty cards typically provided to a patient undergoing breast implant surgery, a microtransponder can never be lost or misplaced. This authentication system does not include any personal patient information and is compliant will all governmental regulations.

13. FOLLOW-UP EXAMINATIONS

13.1. SYMPTOMATIC RUPTURE

Symptoms associated with rupture may include hard knots or lumps surrounding the implant, loss of size, pain, tingling, swelling, numbness, burning, or hardening of the breast area. If you notice any of these changes, consult your plastic surgeon so that she/he can examine your implant(s) for rupture and determine whether you need to have an MR examination to find out if your symptoms are due to implant rupture. If rupture has occurred, you should have your implant removed and/or replaced.

13.2. INSTRUCTIONS FOR PATIENTS UNDERGOING MAGNETIC RESONANCE (MR)

You should be monitored continuously throughout the lifetime of your breast implant(s). It is essential to have regular MRs over the devices´ lifetime to screen for silent rupture, even if there appear to be no problems with them (as mentioned earlier in this document).

Motiva Implants® with microtransponders create an imaging void during breast implant MR (known as artifact effect) that can block visualization of a small area around the microtransponder. In non- clinical

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testing, the image artifact caused extends approximately 15 mm radially from the microtransponder when imaged using a gradient echo (GRE) pulse sequence and a 3-Tesla MR system.

Motiva Implants® microtransponder is MR conditional. The patient implanted can undergo an MR scan under the following conditions:

- The static magnetic field of 1.5-Tesla and 3 -Tesla only.
- Maximum spatial gradient magnetic field of 4.000-gauss/cm (40-T/m).
- Maximum MR system reported whole-body average specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the First Control Operating Mode.
- Under the scan's defined conditions, Motiva Implants® with microtransponder are expected to produce a maximum temperature rise of 1.5° C after 15 minutes of continuous scanning (i.e., per pulse sequence).

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

Studies conducted by Establishment Labs indicate that the use of "combined" or "dual" modality imaging techniques (i.e., MR with another imaging method such as ultrasound, mammography, tomosynthesis, etc.) may considerably increase diagnostic accuracy when Motiva Implants® with microtransponder are present. The addition of other imaging modalities, using standard practices, allows for the complete radiological survey of the breasts.

14. ADDITIONAL INFORMATION

14.1. LIFE EXPECTANCY

Motiva Implants® are not lifetime devices. Based on the chemical characteristics of the materials used in Motiva® devices, the accelerated aging testing for five years shelf-life, post-market surveillance information, and a vast literature review from clinical data obtained from equivalent devices, a survival rate at ten years of 80% has been established as acceptance criteria for the Motiva Implants® lifespan.

15. DEVICE TRACEABILITY

Motiva Implants® are subject to device tracking via the MotivaImagine® registration system. You can register your implants at https://motiva.health/motivaImagine/. If you have difficulty registering your implants, you can contact Establishment Labs to receive assistance.

Implant registration will help ensure that Establishment Labs has a record of each device's related information (such as ID, lot, and serial numbers), surgery date, and patient and surgeon contact information so that they can be contacted in the event of a field action or other situations related to the

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device that patients should be made aware of.

16. PRODUCT EVALUATION

Establishment Labs requires that any complications resulting from the use of Motiva Implants® be reported immediately to your doctor. Your doctor must fill out all the necessary information using the Motiva Implants® Complaint Form available at the following webpage: www.motiva.health/support.

17. PATIENT IMPLANT CARD

You must have a record of your surgical procedure in case of future consultations or additional surgeries. Each implant comes with a Patient Implant Card, which must be given to you by your surgeon for personal reference. Besides the information stated on the Patient Record Label (which should come affixed to the back of the card), the Patient Implant Card also includes your name (patient identification), the position of the implant, date of implantation (surgery date), and the name of the treating surgeon (healthcare center or doctor). This implant card is for patients' permanent records and should always be kept safely.

Below, you can find symbols for your reference.

Non-harmonized symbols in product labeling					
	Patient Identification		Imaging Studies Conditional	VOL	Implant volume
	Healthcare center or doctor		Manufacturer		Unique Device Identifier
	Date		MR conditional, the device can be imaged safely under the tested specifications described in Directions for Use.	MD	Medical device
	Position of the implant	REF	Catalogue number		Serial Number

18. REPORTING AND ADDITIONAL INFORMATION

If you need additional information related to Motiva Implants®, do not hesitate to contact us. If any serious incident occurs, go immediately to your surgeon and report the event to the closest Establishment Labs office:

LEGAL MANUFACTURER
Establishment Labs S.A.:
Coyol Free Zone & Business Park Building 4th Street, Building B-15,Alajuela, Costa Rica. Zip code: 20113
Phone: +506 2434-2400

www.motiva.health/support
www.motiva.health

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MANUFACTURING SITES

Coyol Free Zone & Business Park Building 4th Street, Building B-15,
Alajuela, Costa Rica.

Coyol Free Zone & Business Park Building 0 Street, Building B-25,
Alajuela, Costa Rica.

EUROPEAN REPRESENTATIVE

Emergo Europe: Prinsessegracht 20, 2514 AP
The Hague, The Netherlands.

EUROPEAN IMPORTER

EDC Motiva BVBA Nijverheidsstraat 96, Wommelgem
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USA

Motiva USA LLC
1187 Coast Village Road
Suite 1-402
Santa Barbara, CA 93108

Applicable to patients in EU Members States, UK and Switzerland::

Any serious incident related to Motiva Implants® devices should be reported to Establishment Labs and the corresponding competent authority in which the patient is established, if applicable according to local regulations.

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