A guide to the safety innovations of Motiva Implant Matrix®
Motiva TrueInnovation™

1. **TrueMonobloc®**
   High Performance Shell.

Our TrueMonobloc® configuration links all components of the implant to the same tensile strength. This allows the shell to act as a whole structure, making insertion easier and improving the implant mechanical qualities under stress.\(^1\),\(^2\)

Motiva Implant Matrix® mechanical testing results exceed the specifications of the ASTM F-703: Standard Specification for Implantable Breast Prostheses (Section 9.2) \(^3\), required by the FDA and ISO 14607:2009 (Section 7.0).\(^4\)

2. **BluSeal®**
   Full Safety with our Visual Barrier-Layer Indicator.

Our unique and patented\(^5\) barrier layer indicator provides a safety feature only present in Motiva Implant Matrix®. The presence of a barrier layer minimizes silicone gel diffusion into the body, a feature that has been a standard in the industry for more than 20 years. By keeping gel bleed to the minimum, we can significantly reduce the risk of capsular contracture in all Motiva implants.

With our BluSeal® indicator, surgeons can finally verify the presence of this important safety component surrounding the entire implant. This provides 100% assurance of its presence in every Motiva Implant used. The BluSeal® indicator has complied with the most rigorous quality and safety standards of the American Society of Testing and Materials and ISO.\(^3\),\(^6\)

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**Average Results for Motiva Implant Matrix® After 2 Sterilization Cycles and 5 years of Accelerated Aging**

<table>
<thead>
<tr>
<th>Test Performed</th>
<th>Specification</th>
<th>Average Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elongation at Breaking (%)</td>
<td>ISO: Minimum 450% elongation at failure</td>
<td>715.39%</td>
</tr>
<tr>
<td>Force at Breaking (N)</td>
<td>ASTM: Minimum 11.12 N to break</td>
<td>36.47 N</td>
</tr>
</tbody>
</table>


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**Silicone Release Test (g)**


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150x transverse view of the implant shell including the visual barrier-layer indicator BluSeal®
SAFETY THROUGH INNOVATION

• More than 715.39% Average Shell Elongation at Breaking.
  (ASTM standard: 350% minimum, ISO standard: 450% minimum) \(^{4,5,6}\)
• Average Force at Breaking of more than 36.47 Newtons.
  (ASTM standard: 11.12 Newtons) \(^{1,3}\)
• Post-implantation Rupture and Capsular Contracture Rates less than 1% at 4 years. \(^{10}\)

“Our quality standards for breast implants are the strictest in the industry and our production process is continually inspected by health authorities from high vigilance countries, resulting in more than 60 countries with regulatory approval worldwide.”

- Robert De Mezerville, Global Quality and Clinical Affairs Manager

Motiva 3D Inversion™ Manufacturing Process:
SilkSurface™ & VelvetSurface™

MOLD

Motiva Nanotechnology Imprint™

Standard Layer
BluSeal®
Standard Layer

SALT & SUGAR FREE

www.motivaimplants.com 3
Controlled Surfaces

Motiva Implant Matrix® surfaces are achieved in a single step, with less manipulation of the shell. Controlled surface treatment is accomplished through Motiva 3D Inversion™ Manufacturing Process, with no foreign materials added, resulting in:

SilkSurface™ NanoSurface™
8000 contact points of 16 Microns depth per cm².

VelvetSurface™ MicroSurface™
1800-2200 contact points of 40-100 Microns depth per cm².

Features & Clinical Advantages

- Safest and most uniform shell surface developed without the aggressive cavities caused by crystalline texture treatments. **No residual salt or sugar granules or shapes.**
- Optimized, shell surface for improved implant insertion, enhanced cell interaction and less risk of implant rotation.
- Consistent implant shell, without the traditional “thin spots” that may render the implant more fragile, compromise its durability and affect the barrier layer.
- Controlled surface that enhances implant insertion through smaller incisions and reduces the risk of double capsule and late seroma.

“The need for innovation in the breast implant industry is greater now than ever before. It requires a human-centered, creative, iterative and safe approach in order to find the best ideas and ultimate solutions for surgeons and patients.”

-Salvador Dada-Santos, Global Operations Manager
What is Tribology?

Tribology is the science and technology of interacting surfaces in motion. Biomedical Tribology studies the phenomena of friction and wear in the interaction of surfaces in the human body. It includes the design of medical device surfaces to reduce possible damage to the human body caused by friction and wear. It is widely known from this field that rough surfaces wear more quickly and have a higher friction coefficient. In breast implants with rough surfaces you may have silicone debris detaching from the structure of the silicone elastomer shell and its higher friction coefficient may cause damage to the surrounding tissue, that can be associated with double capsules and late seromas.

<table>
<thead>
<tr>
<th>Surface</th>
<th>Roughness parameter (Ra)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SilkSurface™</td>
<td>2488</td>
</tr>
<tr>
<td>VelvetSurface™</td>
<td>7001</td>
</tr>
</tbody>
</table>

Plastic & Reconstructive Surgery Research, Manchester Interdisciplinary Biocentre, The University of Manchester.

YOU CAN TRUST A CONTROLLED SURFACE WITH SCIENTIFICALLY DESIGNED SURFACE ROUGHNESS
Rheological Properties
Mastering Viscoelasticity

At Establishment Labs, we have developed all implants within the matrix with the possibility of three different highly cohesive gels, according to the specific design objectives that correspond to the look desired by the patient. By mastering the rheological properties of our silicone gels, we have been able to control their viscosity and elasticity.

Our silicone gels comply with ASTM F 703-07 Specification for Implantable Breast Prostheses -Section 9.2.1.4 - accepted by the FDA for gel cohesion and Section 10.2- used as a guideline to characterize the firmness of ProgressiveGel™, Progressive Gel PLUSTM and Progressive Gel Ultima™ and required by the FDA for breast implant gel characterization.

What is Rheology?
Rheology is the study of the flow and deformation of materials when experiencing an applied force. Two extremes of rheological behaviour are:

- Elastic behaviour - e.g. perfectly rigid solids, where any deformation reverses spontaneously when an applied force is removed.
- Viscous (or plastic) behaviour - e.g. ideal Newtonian liquids, where any deformation ceases when the applied force is removed.

In between elastic and viscous behaviour lies the real world of most substances, which are viscoelastic materials.

MOVE TO THE NEXT GENERATION OF SILICONE GEL FOR OPTIMUM PERFORMANCE: THE DESIRED SHAPE WITHOUT GEL FRACTURE

Motiva Implant Matrix® Silicone Gel Properties

Viscosity

High Cohesivity

ProgressiveGel™
Maintains the Upper-Pole Fullness

New Generation Gel Technology

ProgressiveGel™ PLUS
A more Natural Look and Feel

ProgressiveGel™ Ultima
The most Natural Look and Feel

Elasticity
Q Inside Safety Technology™

VeriTeQ’s Q Inside Safety Technology™, a passive radio frequency identification (RFID) transponder, is the world’s first FDA cleared micro-transponder for use in humans and the only one with a CE-Mark when used in a breast implant. The inclusion of Q Inside Safety Technology™ allows healthcare providers to securely and accurately identify breast implant information from outside of the body, at the point of care. Q Inside Safety Technology™ consists of a biocompatible micro-transponder, programmed with a unique numeric sequence (15 digits) that is accessed by a proprietary handheld reader when waved over the breast area. The 15-digit number delivered to the reader corresponds with a secure, online database that can be accessed via the internet and by authorized persons only.

By utilizing Q Inside Safety Technology™, physicians and patients have access to secure, non-invasive verification of implant-specific data. Unlike product and warranty cards that are typically provided to a patient undergoing breast augmentation or reconstruction, Q Inside Safety Technology can never be lost or misplaced. Providing your patients the option of breast implants with Q Inside Safety Technology™ can give them increased peace of mind in the event of a safety issue or device recall, thereby helping to ensure their safety and well-being.

“Q inside safety technology is an FDA cleared, first of its kind technology that provides an electronic serial number from within the body for patient control and verification of their implant, for safety, well-being and in the event of a recall or adverse event.”

-Scott Silverman, CEO VeriteQ Corporation

Always Confident Warranty®

Following FDA recommendations, Establishment Labs provides a limited warranty, covering its Motiva Implant Matrix® product range, providing a replacement product in the event of rupture for the lifetime of the implant. Although the FDA has indicated silicone breast implants should be expected to last 10 years on average, new developments in materials and process technology are focused on extending their lifespan. Establishment Labs provides assistance in cases of capsular contracture Baker grades III and IV through its product replacement policy program.

Visit www.motivaimplants.com, regarding Always Confident Warranty®.

In select markets, through Lloyd’s of London, we offer an industry-first, third party insurance backed program to provide financial assistance for revision surgeries in case of implant rupture, implant rotation and capsular contracture Baker grades III or IV, however the warranty must be fully activated for this to be applicable.

In special situations, ask for our industry-first Always Confident Support Program®.
References

2. When compared to non-TrueMonobloc® working prototypes.
7. ISO 14607:2009: Non-active surgical implants: Mammary implants- Particular requirements , Section 7.2.2.8 and Annex A: Test for surface characteristics.