

Excellence as standard for you and your patients

Nothing is more important to us than your patients' long-term health and safety. That's why breast implants from the Natrelle™ Collection undergo a unique battery of tests to ensure their innovative design meets all relevant national and international quality control standards and Current Good Manufacturing Practice (CGMP) standards.

From start to finish it can take **up to 12 days** to manufacture an Allergan implant which undergoes almost **100 quality control tests**, including materials inspection, product inspection and testing. This is why The Natrelle™ Collection is your **assurance of quality** for every one of the **more than ¾ million implants** and tissue expanders we manufacture and supply annually from our state of the art facility.



Natrelle™ INSPIRA™ Natrelle™ 410 Natrelle™ 510



Gel-filled sizers supporting
The Natrelle™ Collection Natrelle™ 133 Natrelle™ 150

References:

1. Bengtson B P, et al (2007). Style 410 Highly Cohesive Silicone Breast Implant Core Study Results at 3 Years. *Plast. Reconstr. Surg.* **120**(1), 40-485
2. Brown M H, et al (2005). Cohesive Silicone Gel Breast Implants in Aesthetic and Reconstructive Breast Surgery. *Plast. Reconstr. Surg.* **116**(3) 768-779
3. Data on file.
4. Hedén P, et al (2006). Style 410 Cohesive Silicone Breast Implants: Safety and Effectiveness at 5 to 9 Years after Implantation. *Plast. Reconstr. Surg.* **118**(6), 1281-1287
5. Hedén P, et al (2009). Long-Term Safety and Effectiveness of Style 410 Highly Cohesive Silicone Breast Implants. *Aesth Plast Surg.* **33**, 430-436



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COLLECTION

Quality Experience



Individual Women Individual Choices

A trusted leader in safety and aesthetic innovations

Allergan is a multi-specialty healthcare company established 60 years ago with a commitment to uncover the best of science and develop and deliver innovative and meaningful treatments to help people reach their life's potential. Today, we have more than 8,000 employees with a presence in more than 100 countries. Our focus is on several medical specialties including ophthalmology, neurosciences, breast aesthetics and reconstruction, obesity intervention and medical aesthetics.

The Natrelle™ Collection is the pinnacle of over 30 years experience in manufacturing breast implants and tissue expanders which include the latest technologically advanced generation of breast implants. With continued investment in Research & Development we have amassed more clinical data to support the safety of our products than any other breast implant manufacturer.



COMPONENT TESTING

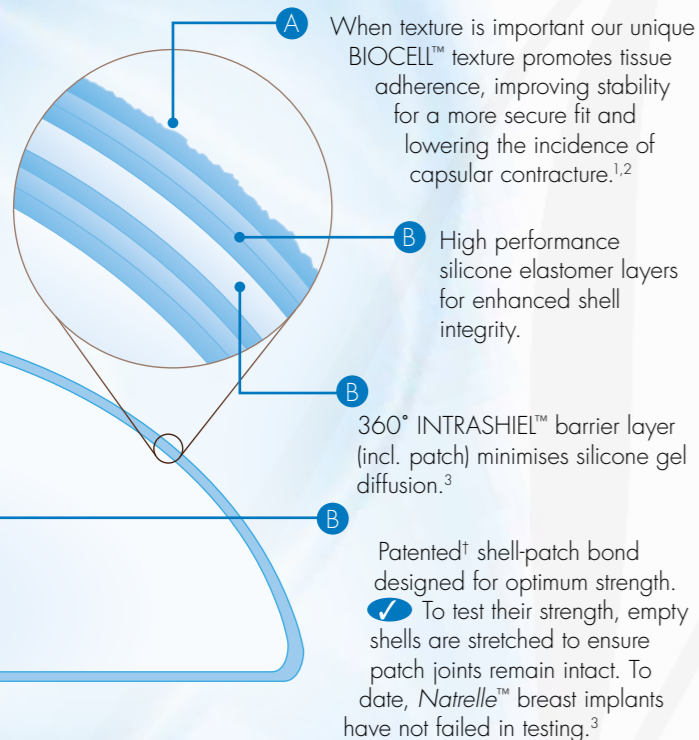
IMPLANT TESTING

PACKAGING & DISTRIBUTION

GLOBALLY RECOGNISED QUALITY STANDARDS

High Quality components

Allergan internal Quality Assurance processes, constantly monitor all aspects of design, raw materials purchasing and manufacture.



C Our unique range of TruForm™ gels offer enduring shape control and include the latest generation of Form Stable gels. Every lot of TruForm™ gel undergoes penetrometer testing prior to use to ensure the cross linking density conforms to strict predetermined specifications.

COMPONENT TESTING

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High Quality implants

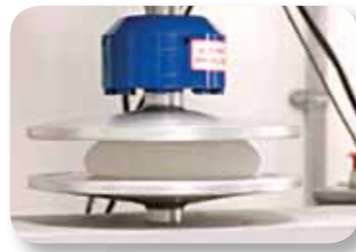
In addition to the quality control tests on our implant components we also subject the implants to more stringent testing to ensure we not only meet, but also exceed, all regulatory requirements.

Fatigue testing

Our Natrelle™ silicone gel-filled breast implants are tested for durability and strength by compressing them to 80% of their size 2 million times (this is 3 times a second, 24 hours a day, for over a week).³

Rupture resistance

Our Natrelle™ silicone gel-filled breast implants are also tested for rupture by compressing them under extreme force. They can withstand in excess of 250kg which is more than 10 times the recommended maximum force of a routine mammogram.³



Long-term durability

Low long-term rupture rates

To help track the long-term safety of our breast implants, we have conducted extensive clinical studies, both in Europe and the U.S. These studies show that Allergan's Natrelle™ silicone-filled breast implants have low long-term rupture rates.

- 1% rupture rate at 3 years using serial MRI screening at year 1 and 3 (n=941 all cohorts)¹
- 0.3% MRI assessed rupture rate at 5-9 years (n=144)⁴

Ongoing research

Not only have we amassed more clinical data supporting the safety of our products than any other breast implant manufacturer, but our commitment to excellence is reflected in our ongoing research programme in which we use robust clinical study designs to put our products through even longer-term testing. This is why The Natrelle™ Collection gives you peace of mind as implants of the highest quality supported by unequalled long-term patient satisfaction.^{1,4,5}

COMPONENT TESTING

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GLOBALLY RECOGNISED QUALITY STANDARDS

Secure distribution

We put a great deal of passion and effort into the production of our implants and it is equally as important to us to ensure that our premium implants reach you in the same impeccable condition in which they leave our factory.

In addition to the exacting standards to which we manufacture our implants, we also strive to exceed quality standards for the labelling, packaging, shipping and traceability of all of our products.

These security measures include:

- The use of tamper-evident seals
- The use of stringent safeguards to prevent damage or interference with the implants
- Delivery tracking systems

These controls are put in place to preserve the breast implant integrity from the final packaging activities to the moment the customer receives the product.



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GLOBALLY RECOGNISED QUALITY STANDARDS

Globally recognised Quality standard approvals

Allergan are one of only two manufacturers that have a **CE mark** for all of their products as well as **FDA approval** for selected ranges that are also available in the United States.

What does it take to get FDA approval?

FDA approval is usually a two-step process:

1. A core clinical study (which is study that runs for 10 years) is used to evaluate the safety and effectiveness of the implants in humans as part of a Pre-Market Approval (PMA) application.
2. The FDA convenes a panel of experts to examine the data and information provided in the PMA. These data include the results of chemical, toxicological, mechanical, and clinical testing. The FDA then issues a decision after reviewing the panel's recommendation.

In addition to the above 2 steps, Allergan is conducting a large post-approval study to further assess the devices long-term safety.

This is why Natrelle™ silicone gel-filled breast implants are one of the most studied FDA approved medical devices in existence.

Standards of approval – production process

- MDD 93/42/EEC: Medical Device Directive
- ISO 14607:2009: Non-active surgical implants – mammary implants – particular requirements for mammary implants
- ISO 13485:2003: Quality managements systems – requirements for regulatory purposes
- FDA 21 CFR Part 820 : Quality System Regulation
- EN ISO 14644 & 14698: Clean Room ISO Class 7 certification (10k)

Quality guaranteed from start to finish