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ALLERGAN

ALLERGAN

About Allergan Breast Implants

- **Over 35 years manufacturing experience**
- **Registered in 76 countries worldwide**
- **There are 19 Allergan clinical trials involving approximately 160,000 patients[1]**
- **Allergan is committed to scientific excellence and has four long-term follow-up studies ongoing[1]**
- **Total R&D investment 2006–2011: $226m**

Natrelle™ 410 by Allergan is one of the few FDA licensed Anatomical implant* marketed in Europe, Africa and The Middle East.

The CORE studies, which have been developed to obtain FDA approval have prospectively followed over 1800 patients for 10 years.[2,3]

Level 2 evidence is currently the highest level of evidence available to support breast implants. Only 3 manufacturers including Allergan possess level 2 evidence.

High Quality Implants

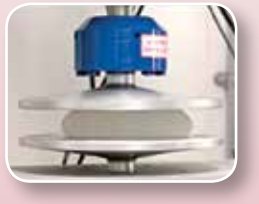
In addition to the quality control tests on our implant components we also subject them to more stringent testing to ensure we not only meet, but also exceed, all regulatory requirements.

Fatigue testing

For durability and strength our implants are compressed to 80% of their size, 2 million times (this is 3 times a second, 24 hours a day, for over a week).[1]

Rupture resistance

Implants are compressed under an extreme force of 250kg, which is more than 10 times the recommended maximum force of a routine mammogram.[1]

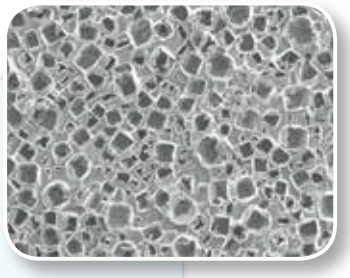


Long-term durability

Low long-term rupture rates

Extensive EU and US studies demonstrate 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)[2]
- 0.3% MRI assessed rupture rate at 5-9 years (n=144)[3]



About BIOCELL™

Our unique BIOCELL™ texture promotes tissue adherence, improving stability for a more secure fit and lowering the incidence of capsular contracture [4,5]

- Level 2 evidence demonstrates that at 6 years the *Natrelle*™ 410 implant has a capsular contracture rate of 4.6% and a wrinkling rate of 0.7% in primary breast augmentation [3]
- Evidence is also available demonstrating that comparatively BIOCELL™ textured implants promote capsular adherence through optimal pore sizes in reducing the risks of capsular contracture [4,5]
- Other single centre and multicentre studies (below level 2) support a similar rate of complications. These include capsular contracture rate of 5.3% baker 3 and 0% baker 4.[6]

All this data represents the safety and efficacy of BIOCELL™ textured implants. Additionally textured implants have consistently demonstrated high levels of patient satisfaction with 95.1% of patients being satisfied with their primary augmentation at 6 years.[3]

Given the recent FDA approval of *Natrelle*™ 410 implants and the ongoing commitment by Allergan, as required by the FDA, to seek approval for other implant ranges, this is a clear demonstration of the safety and efficacy of these implants and the associated BIOCELL™ texture.

Over 600,000 of the current Natrelle™ 410 design have been produced and sold outside the United States in 24 countries since 1993.

*Different ranges are approved and available in different regions/countries