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Understanding individual susceptibility to capsular contracture



*Genetic testing to assess individual susceptibility
to fibro-inflammatory responses and capsular contracture after
breast implant surgery*



BREASTIMPLANT

CONTRACTURE



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BREAST IMPLANTS: AN ESTABLISHED PROCEDURE, AN INDIVIDUAL BIOLOGICAL RESPONSE

Silicone breast implants (SBIs) are medical devices widely used in **aesthetic surgery** for breast augmentation and contouring, and in **reconstructive surgery**, particularly following cancer treatment, trauma or congenital breast anomalies.

Advances in implant materials, prosthetic design and surgical techniques have progressively improved biocompatibility, stability and durability. One factor, however, remains intrinsically individual: **the body's biological response to the implant**. Even when the device and procedure are comparable, clinical outcomes may differ substantially between patients.

Among medium- to long-term local complications, **capsular contracture** is one of the most clinically and aesthetically significant and is a leading indication for revision surgery after breast implantation.





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CAPSULAR CONTRACTURE

After a breast implant is placed, the body normally forms a thin capsule of connective tissue around it. This **foreign-body response** is physiological and, in most patients, causes no clinical problems.

In some patients, however, healing and tissue remodelling may become **excessively fibroproliferative**. The periprosthetic capsule thickens, contracts and progressively loses elasticity, producing clinical and aesthetic effects of varying severity.

How it may present

- Progressive increase in breast firmness or hardness
- Pain, tightness or local discomfort
- Changes in breast shape or symmetry
- Implant distortion or malposition
- In more advanced cases, possible need for revision surgery

The Baker grading system

Clinical severity is commonly described using the Baker grading system, which classifies capsular contracture into four grades: from **grade I**, in which the breast is soft and appears natural, to **grade IV**, characterised by marked firmness, pain and visible distortion.



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WHY DO SOME PATIENTS DEVELOP CAPSULAR CONTRACTURE WHILE OTHERS DO NOT?

Capsular contracture is **multifactorial**. Several determinants may contribute and interact:

- ▶ Foreign-body response and persistence of local inflammatory signalling
- ▶ Potential contribution of a subclinical bacterial biofilm on the implant surface
- ▶ Implant characteristics, including material, surface, volume and profile
- ▶ Surgical and peri-operative factors, including implant position and pocket management
- ▶ Extracellular-matrix remodelling and activation of fibrotic pathways

Individual **biological susceptibility** may also contribute. The variability observed among patients undergoing comparable procedures has prompted research into **genetic markers** that may modulate the intensity of inflammatory and fibrotic responses to an implant.

Under comparable clinical and surgical conditions, individual susceptibility may contribute to differences in the evolution of the periprosthetic response.



TGF- β 1: A KEY MEDIATOR OF CAPSULAR FIBROSIS

Among the biological pathways implicated in capsular contracture, **Transforming Growth Factor Beta 1 (TGF- β 1)** is regarded as an important mediator. This cytokine contributes to the regulation of fibro-inflammatory responses through:

- Activation of fibroblasts in periprosthetic tissue
- Differentiation of fibroblasts into contractile myofibroblasts
- Production and deposition of collagen and extracellular matrix
- Remodelling of capsular tissue
- Regulation of immune and fibrotic responses

Selected variants in **TGFB1** have been investigated for their potential influence on the expression or biological activity of TGF- β 1 and may contribute, alongside other determinants, to interindividual variability in fibroproliferative responses. This scientific rationale underpins **BREASTIMPLANT Contracture**.



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A GENETIC TEST FOR INDIVIDUAL SUSCEPTIBILITY ASSESSMENT

BREASTIMPLANT Contracture is a targeted genetic susceptibility test that analyses selected **TGFB1** variants involved in the modulation of fibro-inflammatory responses and investigated in relation to individual predisposition to capsular contracture.

The test may be considered for **patients planning a first breast implant procedure**, as well as for those who already have implants or a **history of periprosthetic complications**.

Test Objective

Its purpose is to provide the clinician with an additional, stable source of genetic information to be integrated with medical history, clinical findings, procedural characteristics and follow-up, supporting a **more personalised overall assessment**.





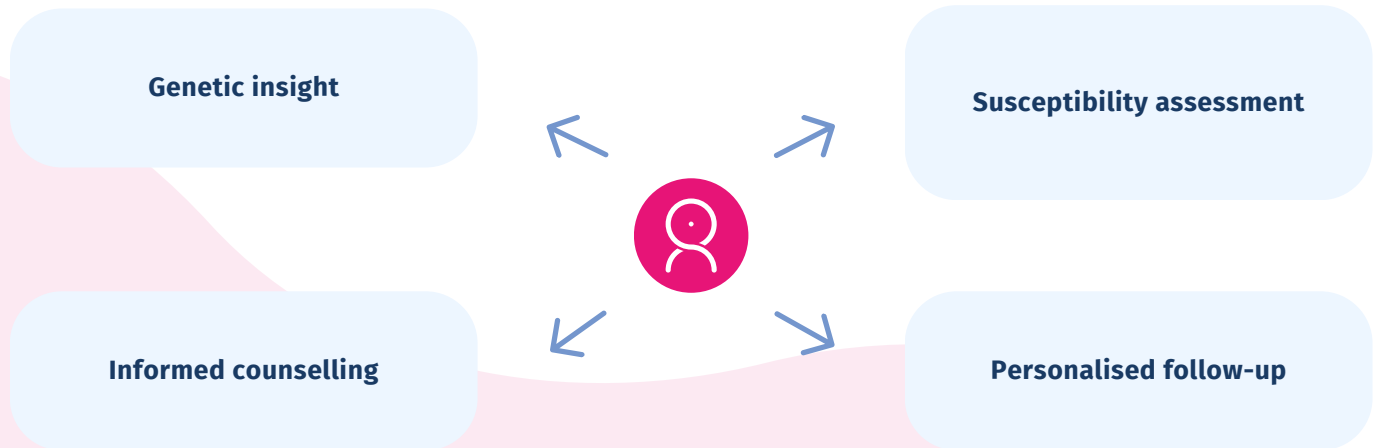
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UNDERSTAND SUSCEPTIBILITY TO PERSONALISE THE CARE PATHWAY

Each patient may respond differently to a breast implant.

BREASTIMPLANT Contracture integrates genetic information into the clinical assessment of susceptibility to capsular contracture. It provides healthcare professionals with a complementary tool for counselling and for planning a more individualised care pathway.





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WHO MAY BENEFIT

BREASTIMPLANT Contracture may be considered at different stages of a patient's clinical pathway.

Before surgery

For patients considering breast implant surgery, the test may complement **pre-operative counselling** with additional information about individual biological susceptibility.

Following previous complications

The test may be particularly relevant when the medical history includes:

- Previous capsular contracture
- Periprosthetic fibrotic reactions
- Recurrent seroma
- Revision or replacement of a previous implant

For patients who already have breast implants

In patients with existing breast implants, the genetic profile may contribute, together with clinical factors, to planning **follow-up** that is proportionate to the overall individual risk profile.

As an aid to medical counselling

The test may support shared decision-making by enabling a balanced discussion of risk based on the integration of clinical and biological information.



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CLINICAL VALUE

BREASTIMPLANT Contracture cannot predict with certainty whether capsular contracture will develop. Its value lies in **identifying a component of genetic susceptibility** to be considered together with established clinical, implant-related and procedural determinants.

The result may support:



**Pre-operative
counselling**



***Clearer and more
informed clinician-
patient communication***



**A more comprehensive
assessment of
individual susceptibility**



**Personalisation of the
follow-up programme**



**Clinically appropriate follow-
up in patients with an
identified susceptibility profile**

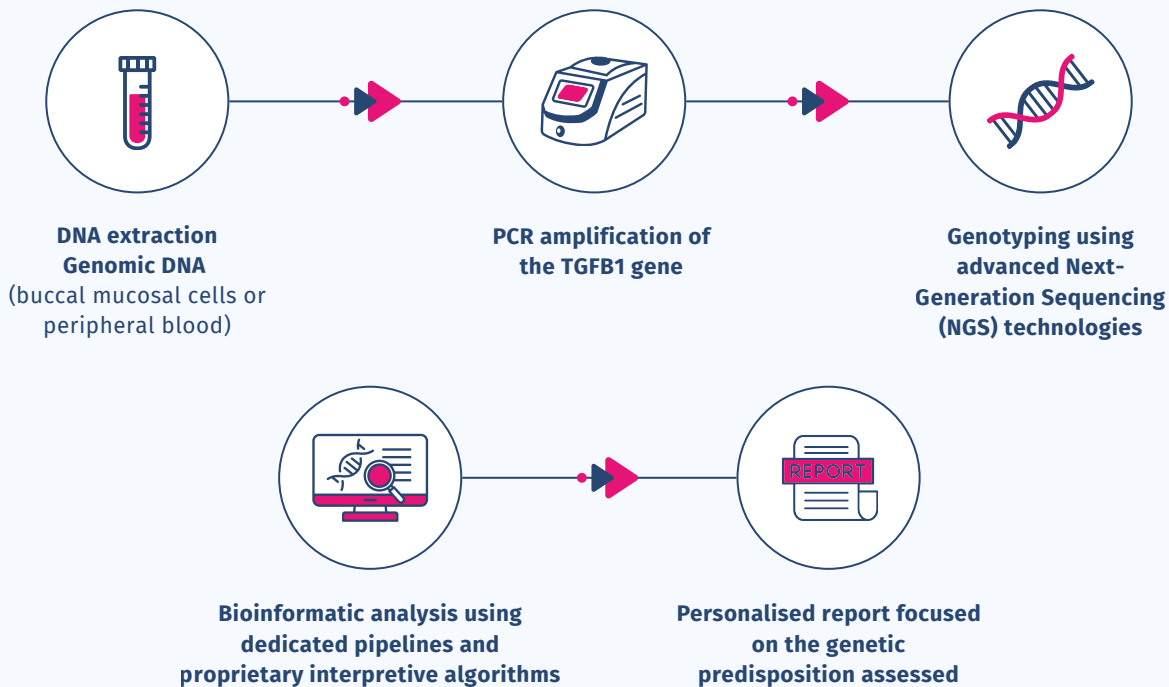
**Genetic insight before surgery for more comprehensive assessment of
individual risk.**



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ANALYTICAL WORKFLOW





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INTERPRETING THE RESULT



POSITIVE RESULT

The genetic profile investigated by the test and associated with **increased susceptibility to capsular contracture was detected**.

*This result indicates **increased individual susceptibility**; it does not mean that capsular contracture will occur. The finding may inform pre-operative assessment, counselling and follow-up planning when considered alongside clinical and surgical factors.*



NEGATIVE RESULT

The genetic profile investigated by the test and associated with increased susceptibility to capsular contracture was not detected.

*This finding indicates **no evidence of marker-associated increased susceptibility** based on the variants analysed. It does not demonstrate a reduction in overall risk and does not exclude capsular contracture, which may also be influenced by clinical, biological, implant-related, surgical and environmental factors not assessed by the test.*

Important interpretation note

BREASTIMPLANT Contracture is a genetic susceptibility test and is not intended for diagnostic use. It cannot predict with certainty either the future occurrence or absence of capsular contracture. The result must be interpreted by a physician or qualified specialist in the context of the patient's overall clinical assessment. It should not be used as the sole basis for deciding whether to perform, defer or modify surgery.



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WHY CHOOSE BREASTIMPLANT CONTRACTURE

Pre-operative assessment

Identifies the test-specific genetic profile associated with increased susceptibility to capsular contracture.

Targeted TGF- β 1 pathway analysis

Analyses selected TGF β 1 variants investigated for their relevance to fibro-inflammatory responses.

Support for counselling

Adds an individual genetic perspective to balanced risk communication.

Potential for personalised follow-up

May help tailor post-operative monitoring to the patient's overall clinical profile.

Simple sample collection

Can be performed using a buccal swab, without a blood draw.

NGS technology

Genotyping by Next Generation Sequencing with dedicated bioinformatic analysis.



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A SIMPLE FIVE-STEP PROCESS



Request
the kit



Complete the
documentation



Collect the
sample



Send the sample
to the laboratory



Receive the
report

Turnaround time



~10 working days

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