



Establishment
LABS

Product Replacement Policy

Capsular Contracture

ESTABLISHMENT LABS S.A. may offer free replacement of its breast implants that experience capsular contracture of Baker grades III or IV, for a period of 10 years after implantation, upon request. The plastic surgeons shall make the request for the replacement of the product to the local Distributor. Such request must be accompanied by an MRI scan of the patient and the doctor's report on the case. Any replacement request shall be made prior to the explantation of the devices. The replacement shall only cover the implant suffering of the contracture.

All requests shall be considered by ESTABLISHMENT LABS S.A.'s Replacement Committee, which will make a final decision on the replacement. When/If approved by the Committee, ESTABLISHMENT LABS S.A. will provide a replacement product free of charge. All breast implants replaced under this program shall be returned to ESTABLISHMENT LABS S.A. as soon as they are explanted.

ESTABLISHMENT LABS S.A. is under no obligation of approving any replacement, and assumes no responsibility for the occurrence of any of the complications that may accompany any surgical procedure. The replacement is limited to ESTABLISHMENT LABS S.A. breast implants. ESTABLISHMENT LABS S.A. shall not be responsible for any incidental or consequential damages of any kind, directly or indirectly, arising from the use of this product, including without limitation, medical, surgical and hospital costs or any reimbursement thereof.

This policy is not a warranty or guarantee and no replacement of products is warranted. The only purpose of this policy is to provide assistance in cases where ESTABLISHMENT LABS S.A. considers deserved.

The only warranties covering ESTABLISHMENT LABS S.A. products are the Always Confident Warranty® and the 5Y and 2Y Programs (where applicable). Any additional coverage is expressly excluded.