Prospective Study on Breast Implant Illness

Patient information pack

March 2021 V 5.0

E: info@saferbreastimplants.org

Introduction

The group of symptoms associated in women with breast implants utilised for both cosmetic enhancement and breast reconstruction has been termed Breast Implant Illness (BII). The association of breast implants and systemic symptoms is not new and dates back to the 1990s, when there was a reported association of breast implants with autoimmune disease. We have commenced a prospective, controlled study of women with BII and other implant related adverse events to examine likely contributing factors.

Study Participation

You have enrolled via our online application form or recruited through your treating surgeon/study centre to be part of this study. This pack contains consent forms, evaluation forms and datasheets that will be used to track your progress before, during and after breast implant removal. Your participation in this study is entirely voluntary and you can choose to withdraw at any stage. Your personal and medical data is confidential and protected by privacy laws. All data for study analysis will be stored delinked from your personal information and will be pooled for the purposes of statistical analysis. In some cases, if the study data points to significant disease, we will, with your permission, refer you for medical assessment either with your family GP and/or nominated specialist.

Study design

There are a number of data collection points in this study aimed at evaluating progress after a surgical procedure to remove implants/capsule.

1. Preoperative work up – ideally performed within 3 months of the surgical procedure. These will include patient questionnaires (PROM/PROMIS), blood tests, implant and symptom history snapshot and general medical history
2. Operative and implant details/photographs – obtained with your consent from your treating doctor
3. Implant/tissue examination – obtained with your consent from your treating doctor. For patients presenting to our research clinics, additional toxicology and microbiome analysis will be performed. You will be able to access these results upon request.
4. First follow up 6-12 months following surgery
5. Second follow up 18-24 months following surgery

It is vital that once you have agreed to participate, that we continue to track your progress and collect outcome data. This longitudinal follow up information will allow us to look for patterns in both preoperative and intraoperative data points and will hopefully give us clues as to what might be likely causes of BII. It will also allow us to potentially profile patients at risk of developing BII, with a view to preventing it in high-risk patients.

There are 6 forms in this study pack.
Form 1: consent to participate (human ethics)
Form 2: demographics and implant history
Form 3: symptom tracker
Form 4: medical history and data sheets 1,2 and 3.1/3.2
Form 5: preoperative work up
Form 6: explantation surgery documentation

Questions

We will guide you through filling this information during the study. You can contact the team anytime during the study by email info@saferbreastimplants.org if you have any questions or concerns.

Your treating doctor will also be able to contact our lead clinicians and researchers if he/she has any questions.

We are grateful for your participation. Together, we will work hard to find answers.

STUDY PARTICIPANT NUMBER (SPN)

Your study participant number is:

IMPORTANT Only enter your personal details on Forms 1 and 2. All data forms should not have any personal information to protect your privacy.

FORM 1: Consent to participate

Faculty of Medicine and Health Sciences

MACQUARIE UNIVERSITY NSW 2109

Phone: +61 (0)2 98123899
Email: anand.deva@ mq.edu.au

Chief Investigators:
A/Professor Mark Magnusson, Dr. Mark Lee, Dr. Rod Teixeira and Professor Anand Deva

Patient Information and Consent Form

Name of Project: **Adverse events related to breast implants**

You are invited to participate in a study of the biological and immunological causes of adverse events related to breast implants. The purpose of the study is to better understand the relationship between implants and systemic disease (Breast implant Illness)

The study is being conducted by Professor Anand Deva of the Faculty of Medicine and Health Sciences. Contact Ph 02 98123899, email info@saferbreastimplants.org

We will collect your personal information when you first enrol in the study. Any information or personal details gathered in the course of the study are confidential. No individual will be identified in any publication of the results. All the data will be kept securely. Only study personnel will have access to the data. A study participation number (SPN) will be assigned to you which will be used for the purposes of the study. A summary of the results of the data can be made available to you on request by contacting Professor Anand Deva, Faculty of Medicine and Health Sciences, 2 Technology Pl Macquarie University 2109.

Participation in this study is entirely voluntary: you are not obliged to participate and if you decide to participate, you are free to withdraw at any time without having to give a reason and without consequence. You will not be entitled to any financial benefits that might conceivably accrue as a result of this research.

Study participation number: _____

I, ... [Print full name]

have read and understood the information above and any questions I have asked have been answered to my satisfaction. I agree to participate in this research, knowing that I can withdraw from further participation in the research at any time without consequence. I have been given a copy of this form to keep.

Participant's Name: _____

Participant's Signature: _____ Date:_____

Investigator's Name:_____
(Block letters)

Investigator's Signature: _____ Date:_____

The ethical aspects of this study have been approved by the Macquarie University Human Research Ethics Committee. If you have any complaints or reservations about any ethical aspect of your participation in this research, you may contact the Committee through the Director, Research Ethics (telephone (02) 9850 7854; email ethics@mq.edu.au). Any complaint you make will be treated in confidence and investigated, and you will be informed of the outcome.

FORM 2: Study Proforma: Demographics and implant history

SPN: _____

First name	
Surname	
Address	
Suburb	
Postcode	
State	
Country	
Date of Birth	
Contact number (optional)	
Email	
Treating Explant Doctor	
Treating Explant Doctor address	
State	
Country	
Explant completed	☐ Y ☐ N
Date explant	
Hospital	

SPN: _____

Reason for implant	
Cosmetic enhancement	☐ Y ☐ N
Revision surgery (cosmetic)	☐ Y ☐ N
Revision surgery (reconstruction)	☐ Y ☐ N
Asymmetry (size difference)	☐ Y ☐ N
Lift and enhancement	☐ Y ☐ N
Breast cancer reconstruction	☐ Y ☐ N
Gender reassignment	☐ Y ☐ N
BIA-ALCL	☐ Y ☐ N
Other	
Implant history (single/most recent)	
Implant type	☐ Textured ☐ Smooth ☑ Not sure
Implant shape	☐ Tear drop (anatomic) ☐ Round ☐ Not sure
Implant fill	☐ Silicone ☐ Saline ☐ Other _____ ☐ Unknown
Implant manufacturer	☐ Mentor (Johnson & Johnson) ☐ Allergan/McGhan/Inamed ☐ Silimed/Sientra ☐ Motiva ☐ PIP ☐ Dow Corning ☐ Other: _____ ☐ Unkown
Do you have an implant card	☐ Y ☐ N If Y – please scan and send to info@saferbreastimplants.org
Date current implants placed	
Name of implanting doctor	
Country of implantation	
Tissue expander	☐ Y ☐ N ☐ Not sure
Mesh/Dermal matrix	☐ Y ☐ N ☐ Not sure
Implant history (multiple)	
Number of previous implants	
Year of previous implantation(s)	
Reason for explant	
BII	☐ Y ☐ N
Rupture	☐ Y ☐ N
Capsular contracture	☐ Y ☐ N
Implant malposition	☐ Y ☐ N
Seroma	☐ Y ☐ N
BIA-ALCL	☐ Y ☐ N

FORM 3: BII Symptom tracker
SPN: _____

Please list your symptoms and date of onset
For severity score – please use the following scale
1 – Mild, intermittent, little or no impact on lifestyle/work
2 – Mild, persistent, slight impact on lifestyle/work
3 – Moderate, persistent, some impact on lifestyle/work
4 – Moderate, persistent, significant impact on lifestyle/work
5 – Severe, persistent, debilitating impact on lifestyle/work

Symptom	Date of onset	Severity score 1-5	Symptom	Date of onset	Severity score 1-5
Nervous system			**Musculoskeletal**		
☐ Headaches			☐ Muscle pain		
☐ Brain fog			☐ Joint pain		
☐ Memory loss			☐ Numbness/tingling		
☐ Vertigo			☐ Fibromyalgia		
☐ Migraine			☐ Nerve pain (pins/needles)		
☐ Tinnitus (ringing ears)			☐ Discoloration of hands/feet		
☐ Visual disturbance (blurriness, irritation)			☐ Stiffness		
☐ Poor concentration			☐ Joint swelling/redness		
Immune/Inflammatory			**GI/Urogenital**		
☐ Recurrent infections			☐ Frequent urination		
☐ Night sweats			☐ Reduced libido		
☐ Chronic fatigue			☐ UTIs		
☐ Easy bruising			☐ Reflux/gastritix		
☐ Sudden food intolerance/allergies			☐ Weight loss/gain		
☐ Swollen and/or tender lymph glands			☐ Irritable bowel		
Skin/hair			☐ Taste alteration		
☐ Hair loss			☐ Swallowing difficulties		
☐ Dry fragile hair			**Psychological**		
☐ Skin rashes			☐ Anxiety		
Cardiorespiratory			☐ Depression		
☐ Shortness of breath			☐ Panic attacks		
☐ Heart palpitations					
☐ Chronic cough					

Additional symptoms

Symptom(s)	Date of onset	Severity score (1-5)

FORM 4: Medical history

SPN: _____

Have you been diagnosed with any of the following conditions?

Condition	Date of diagnosis
☐ Fibromyalgia	
☐ Systemic Lupus Erythematosus	
☐ Hashimoto's thyroiditis	
☐ Inflammatory bowel disease	
☐ Rheumatoid arthritis	
☐ Sjogren's syndrome	
☐ Graves' disease	
☐ Lyme disease	
☐ Atopic disease (asthma/rhinitis/eczema)	
☐ Hypothyroidism	
☐ Vitamin D deficiency	
☐ Iron deficiency	
☐ Diabetes Mellitus	
☐ Psoriasis	
☐ Mixed connective tissue disease	
☐ Breast cancer	
☐ Lymphoma	

Please list any other medical conditions that you have

Condition	Date of diagnosis

Do you have a family history of autoimmune disease/connective tissue disease?

☐ Y ☐ N

FORM 4: Medical history (cont'd)
SPN: _____

Do you have any allergies?
☐ Y ☐ N
If Yes – please list: _____

Please list any medical specialists you have seen in the last 12 months

Specialty	Name of doctor	Address

Are you: ☐ Premenopausal ☐ Perimenopausal ☐ Post-menopausal

Do you smoke currently?
☐ Y ☐ N

Are you an Ex-smoker?
☐ Y ☐ N

If Yes – what year did you quit smoking? _____

Level of education (highest completed)

☐ Did not complete high school
☐ High school
☐ Associate degree
☐ Bachelor's degree
☐ Post-graduate degree

FORM 4: Medical history (cont'd)
SPN: _____

Please list any medications that you are taking

Medication name	Dosage

Would you be interested in speaking any further about your experiences of having breast implant removal and/or breast implant illness as part of the research

☐ Y ☐ N

If yes, would you be happy for your email contact details to be passed onto the researchers at Leeds Beckett University (leanne.j.staniford@leedsbeckett.ac.uk and G.L.Jones@leedsbeckett.ac.uk) who will be running the research interviews about your experiences of explantation and/or BII. The researchers will be in touch via email to provide further information on what the this would involve and help you decide if you would like to take part.

DATASHEET 1
Karolinska Institute Breast implant patient reported outcome measure

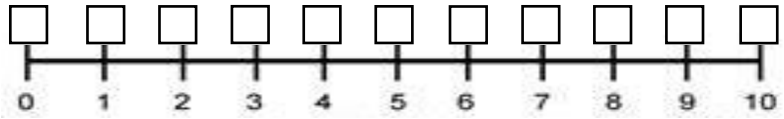
SPN: _____ Date of Response: _____

What do you think about the shape of your breasts?

Left breast				
Very dis-satisfied ☐	Dis-satisfied ☐	Neither or ☐	Satisfied ☐	Very satisfied ☐

Right breast				
Very dis-satisfied ☐	Dis-satisfied ☐	Neither or ☐	Satisfied ☐	Very satisfied ☐

How similar are the breasts in shape?



Very different Very similar

What do you think about the size of your breasts?

Left breast				
Very dis-satisfied ☐	Dis-satisfied ☐	Neither or ☐	Satisfied ☐	Very satisfied ☐

Right breast				
Very dis-satisfied ☐	Dis-satisfied ☐	Neither or ☐	Satisfied ☐	Very satisfied ☐

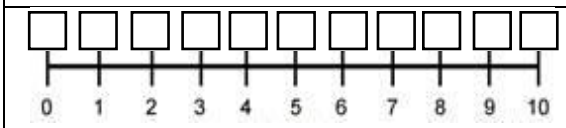
If you are dissatisfied or very dissatisfied with the size, is that because the breast is

Left breast	
Too large ☐	Too small ☐

Right breast	
Too large ☐	Too small ☐

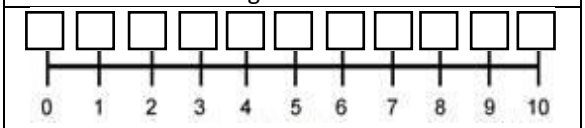
How is your ability to feel touch of the nipples (sensibility)

Left breast



Normal sensibility — Very reduced

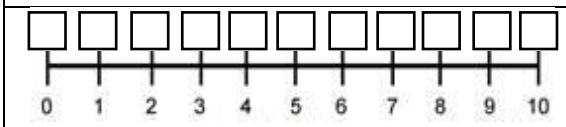
Right breast



Normal sensibility — Very reduced

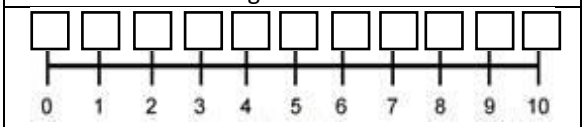
Do you have discomfort / pain in the breasts?

Left breast



No pain — Much pain

Right breast



No pain — Much pain

How often have you experienced discomfort / pain in the breasts during the past 3 months?

Never ☐ Seldom ☐ Sometimes ☐ Often ☐ Always ☐

What do you think about your result of the surgery?

Very dissatisfied ☐ Dissatisfied ☐ Neither or ☐ Satisfied ☐ Very satisfied ☐

Have you given birth after your breast surgery? Yes ☐ No ☐

Please enter your weight: _____kg **Height:_____cm**

DATASHEET 2
PROMIS Distress-Anxiety

SPN : _____ Date of Response: _____

Emotional Distress-Anxiety

Please respond to each item by marking one box per row.

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
EDANX27	I felt something awful would happen	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX53	I felt uneasy	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX05	I felt anxious	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX12	I felt upset	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX55	I had difficulty calming down	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX01	I felt fearful.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX02	I felt frightened.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX33	I felt terrified.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX08	I was concerned about my mental health	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX47	I felt indecisive	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX18	I had sudden feelings of panic	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX26	I felt fidgety	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANX07	I felt like I needed help for my anxiety	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

DATASHEET 3.1
PROMIS Distress-Depression

SPN : _____ Date of Response: _____

Please respond to each item by marking one box per row.

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
EDDEP06	I felt helpless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP19	I felt that I wanted to give up on everything	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP35	I found that things in my life were overwhelming	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP05	I felt that I had nothing to look forward to	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP41	I felt hopeless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP28	I felt lonely	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP09	I felt that nothing could cheer me up	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP31	I felt discouraged about the future	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP46	I felt pessimistic	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP17	I felt sad	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP29	I felt depressed	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP36	I felt unhappy	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP54	I felt emotionally exhausted	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

DATASHEET 3.2
PROMIS Distress-Depression

SPN : _____ Date of Response: _____

	In the past 7 days…	Never	Rarely	Sometimes	Often	Always
EDDEP21	I felt that I was to blame for things.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP26	I felt disappointed in myself	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP39	I felt I had no reason for living	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP48	I felt that my life was empty	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP04	I felt worthless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP14	I felt that I was not as good as other people.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP22	I felt like a failure.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP27	I felt that I was not needed.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP23	I had trouble feeling close to people.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP07	I withdrew from other people	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP02	I felt lonely even when I was with other people.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP12	I had mood swings	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP16	I felt like crying.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG09	I felt angry.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDANG29	I felt irritable	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP38	I felt unloved.....	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDEP55	I felt like I needed help for my depression	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Form 5: Preoperative blood workup
SPN: _____

The following blood screening tests should be performed by your treating doctor prior to explantation surgery.

For patients in Australia, please ensure that a copy of your results are sent to Professor Anand Deva
Suite 301, 2 Technology Place, Macquarie Park NSW 2109, Australia

For patients outside Australia, a copy of these de-identified tests can be sent with your SPN to info@saferbreastimplants.org

LIST OF TESTS TO ORDER

Full blood count
Urea, electrolytes, Creatinine, Glucose (not fasting)
Cholesterol/Lipids
Liver function tests
Coagulation screen
Thyroid function tests
C reactive protein, ESR
Serum IgG, Ig M
Autoimmune disease markers (Rheumatoid factor, ANA, Double stranded DNA)
Iron, Ferritin
Vitamin D
B12, Folate

We are aware of additional assays that are being offered by some laboratories to look at environmental factors. These test results can be included in any information that you would like to send in. Please scan and email with your SPN to info@saferbreastimplants.org

Preoperative imaging
Any ultrasound, MRI or CT, CTPET scan reports can be scanned, deidentified and marked with your SPN and sent to info@saferbreastimplants.org

Form 6: Explantation surgery documentation

SPN: _____

Please ensure that your treating doctor fills out this form and returns it to you for submission. Completed forms are to be emailed to info@saferbreastimplants.org

Procedure details			
Date		Address of facility	
State		Country	
Treating doctor			

Explant details			
Implant type confirmed	☐ Y ☐ N If no Please list Manufacturer Shell Fill	Implant status	☐ Intact ☐ Intracapsular rupture ☐ Extracapsular rupture
Capsulectomy	☐ En bloc ☐ Total precise capsulectomy ☐ Subtotal capsulectomy ☐ Partial capsulectomy ☐ Capsule sampling only ☐ No capsulectomy performed		
Implant Serial numbers (if available			
Right		Left	
Photographs taken? ☐ Y ☐ N If Yes – please send copies via email to info@saferbreastimplants.org. Remember to quote your SPN.			
Other findings			

Testing	
Histology	☐ **Y** ☐ **N**
Bacteriology	☐ Y ☐ N
Fungal culture/PCR	☐ Y ☐ N
Mycobacterial culture/PCR	☐ Y ☐ N
Cytology	☐ Y ☐ N

For patients in Australia, please ensure that a copy of your results are sent to Professor Anand Deva Suite 301, 2 Technology Place, Macquarie Park NSW 2109, Australia. For patients outside Australia, a copy of these de-identified tests can be sent with your SPN to info@saferbreastimplants.org.

Follow up progress

SPN: _____

Time point	Date of assessment	Assessor initials	PROMS /PROMIS	BII Symptom tracker	Repeat bloods (if indicated)
6 -12 months			☐	☐	☐
18-24 months			☐	☐	☐