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Office Follow-Up (Years 1, 5 & 9)
Name: _____

Current Medications/Treatments

1. List all medications taken since the participant's last study visit:

Currently Taking	Previously Taken	Medication
☐	☐	1. Oral Birth Control Name: _____ How long taken: _____
☐	☐	2. Other Birth Control (e.g., IUD, Nuvaring, Depo Shot) Name: _____ How long taken: _____
☐	☐	3. Hormones To Treat: ☐ Menopause ☐ Other, *specify*: _____ Name: _____ How long taken: _____
☐	☐	4. Fertility Medication (e.g., Clomid) Name: _____ How long taken: _____
☐	☐	5. Aspirin/NSAIDS To Treat: _____ Name: _____ How long taken: _____
☐	☐	6. Anti-Depression Medication (e.g., Prozac, Zoloft) To Treat: _____ Name: _____ How long taken: _____
☐	☐	7. Anti-Anxiety Medication (e.g., Xanax, Valium) To Treat: _____ Name: _____ How long taken: _____
☐	☐	8. Pain Medication (e.g., Vicodin, Percocet) To Treat: _____ Name: _____ How long taken: _____
☐	☐	9. Other prescription medications (including Breast Cancer Treatment) *Specify:* _____ To Treat: _____ How long taken: _____

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Office Follow-Up (Years 1, 5 & 9)
Name: _____

Family Medical History

1. Since last update, have any of the participant's relatives been diagnosed with any of the medical conditions listed below? Yes ☐ No ☐

   If YES, please select all that apply.

Diagnosis	Child	Parent or Sibling	Grandparent or Grandchild	Other Blood Relative
1. Rheumatoid Arthritis	☐	☐	☐	☐
2. Breast Cancer (Female)	☐	☐	☐	☐
3. Lung Cancer	☐	☐	☐	☐

Medical History

1. Since last update, has the participant been diagnosed with any of the medical conditions listed below? Yes ☐ No ☐

   If YES, please indicate the year of diagnosis.

Diagnosis	YES	Year of Diagnosis
1. Sleep Disorder	☐	__ __ __ __
2. Fibrocystic Disease	☐	__ __ __ __
3. Anxiety Disorder (OCD, Panic, etc.)	☐	__ __ __ __
4. Depression or Other Mood Disorder	☐	__ __ __ __
5. Attention Deficit Disorder	☐	__ __ __ __
6. Breast Cancer	☐	__ __ __ __
a. If YES, at what stage was Breast Cancer diagnosed? ☐ Stage I ☐ Stage II ☐ Stage III ☐ Stage IV		
7. Lung/Bronchus Cancer	☐	__ __ __ __
8. Brain Cancer	☐	__ __ __ __
9. Lymphoma (not including ALCL)	☐	__ __ __ __
10. ALCL-type Lymphoma	☐	__ __ __ __
11. Cervical/Vulvar Cancer	☐	__ __ __ __
12. Rheumatoid Arthritis	☐	__ __ __ __
13. Scleroderma	☐	__ __ __ __
14. Raynaud's Disease	☐	__ __ __ __
15. Lupus/SLE	☐	__ __ __ __
16. Rheumatic Polymyalgia	☐	__ __ __ __
17. Chronic Fatigue Syndrome	☐	__ __ __ __
18. Fibromyalgia	☐	__ __ __ __

Diagnosis	YES	Year of Diagnosis
19. Sjogren's Syndrome	☐	__ __ __ __
20. Multiple Sclerosis	☐	__ __ __ __
21. Myositis (Polymyositis/Dermatomyositis)	☐	__ __ __ __
22. Other, *specify:* _____	☐	__ __ __ __

Breast Related Complications

1. Since the last update, has the participant experienced any complications with her breast implant(s)?
   Yes ☐ No ☐

If YES, please complete a Complication Report for each new complication since last update.

Complication Report

1. Please select One Complication:
   - ☐ 1. Asymmetry
   - ☐ 2. Breast Mass/Cyst/Lump
   - ☐ 3. Excessive Breast Pain
   - ☐ 4. Capsular Contracture (Baker III or IV)
   - ☐ 5. Capsule Calcification
   - ☐ 6. Delayed Wound Healing
   - ☐ 7. Hematoma
   - ☐ 8. Hypertrophic or Other Abnormal Scarring
   - ☐ 9. Implant Extrusion
   - ☐ 10. Implant Malposition
   - ☐ 11. Implant Palpability
   - ☐ 12. Implant Visibility
   - ☐ 13. Infection
   - ☐ 14. Irritation/Inflammation
   - ☐ 15. Lymphadenopathy
   - ☐ 16. Abnormal nipple sensation (e.g., hyper, hypo)
   - ☐ 17. Ptosis
   - ☐ 18. Rupture or Suspected Rupture
     a. Initial reason for suspecting rupture:
        - ☐ Silent (no symptoms, suspected via MRI)
        - ☐ Silent (no symptoms, found at explant or intraoperatively)
        - ☐ Silent (no symptoms, found via other source)
        - ☐ Symptomatic (rupture symptoms are present)
   - ☐ 19. Seroma
   - ☐ 20. Skin Paresthesia/Hypersensitivity
   - ☐ 21. Tissue or Skin Necrosis
   - ☐ 22. Wrinkling/Rippling
   - ☐ 23. Other, *specify:*_____

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Office Follow-Up (Years 1, 5 & 9)
Name: _____

2. Onset Date: __ __ __ __ __ __ __ __

3. Is the complication related to the breast implant itself or to the implantation surgery?
   - ☐ 1. Device related
   - ☐ 2. Procedure related
   - ☐ 3. Other, *specify:*_____
   - ☐ 4. Unknown

4. Side:
   - ☐ 1. Right
   - ☐ 2. Left
   - ☐ 3. Both
   - ☐ 4. N/A

5. Initial Severity:
   - ☐ 1. Very Mild
   - ☐ 2. Mild
   - ☐ 3. Moderate
   - ☐ 4. Severe
   - ☐ 5. Very Severe

6. Treatment (select all that apply):
   - ☐ 1. Nothing at this time
   - ☐ 2. Secondary Procedure
   - ☐ 3. Massage
   - ☐ 4. Medication
   - ☐ 5. Other, *specify:*_____

7. Resolution:
   a. Resolution Status:
   - ☐ 1. Resolved with treatment
     - ☐ a. Secondary Procedure
     - ☐ b. Other Treatment
   - ☐ 2. Resolved without treatment
   - ☐ 3. No treatment possible
   - ☐ 4. Not yet resolved

   b. Resolution Date: __ __ __ __ __ __ __ __

If the participant has experienced more than one complication since last visit, please complete another Complication Report after completing this Office Visit Form.

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Office Follow-Up (Years 1, 5 & 9)
Name: _____

Secondary Procedures

1. Since the last update, has the participant had any breast related secondary procedures?
   Yes ☐ No ☐

If YES, please complete a Secondary Procedure Report for each new secondary procedure since last update.

Secondary Procedure Report

1. Procedure Date: __ __ __ __ __ __ __ __

2. Side:
   ☐ 1. Right
   ☐ 2. Left
   ☐ 3. Both

2. Primary Reason for Procedure:

   ☐ 1. Asymmetry
   ☐ 2. Breast Pain (Excessive)
   ☐ 3. Capsular Contracture
   ☐ 4. Delayed Wound Healing
   ☐ 5. Extrusion
   ☐ 6. Hematoma
   ☐ 7. Hypertrophic or Other Abnormal Scarring
   ☐ 8. Infection
   ☐ 9. Irritation/Inflammation
   ☐ 10. Implant Malposition
   ☐ 11. Tissue or Skin Necrosis
   ☐ 12. Ptosis
   ☐ 13. Rupture or Suspected Rupture
   ☐ 14. Seroma
   ☐ 15. Size Change
   ☐ 16. Nipple Reconstruction
   ☐ 17. Wrinkling/Rippling
   ☐ 18. Other, *specify:* _____

3. Surgical Procedure(s) Performed *(select all that apply):*

Right Side	Left Side	Procedure
☐	☐	1. Biopsy

Right Side	Left Side	Procedure
☐	☐	2. Capsule Procedure (Capsul-ectomy/-otomy/-orrhaphy)
☐	☐	3. Implant Removal (Without Replacement)
☐	☐	4. Implant Removal (With Replacement)
☐	☐	5. Incision and Drainage
☐	☐	6. Mastopexy
☐	☐	7. Nipple Tattoo
☐	☐	8. Position Change
☐	☐	9. Scar Revision
☐	☐	10. Skin Adjustment
☐	☐	11. Other, *specify:* _____

If more than one secondary procedure has been performed since last visit, please complete another Secondary Procedure Report after completing this Office Visit Form.

If any complications occurred during this procedure, please complete a Complication Report after completing this Office Visit Form.

Explant Report

1. Since the last update, has the participant's Sientra breast implant(s) been explanted?
   Yes ☐ No ☐

If YES, please complete an Explant Report:

Explant Report

	Right Side	Left Side
1. At explantation, was the implant observed to be ruptured?	☐ Yes ☐ No	☐ Yes ☐ No
2. Was the implant replaced?	☐ Yes ☐ No	☐ Yes ☐ No
a. If replaced, what type of replacement implant was used?	☐ Sientra Gel Implant ☐ Gel (Other manufacturer) ☐ Saline (Other manufacturer) ☐ Other, *specify:* _____	☐ Sientra Gel Implant ☐ Gel (Other manufacturer) ☐ Saline (Other manufacturer) ☐ Other, *specify:* _____
b. Catalog Number/Size for Replacement Implant	☐ 10521 - __ __ __ ☐ 10512 - __ __ __ ☐ 20621 - __ __ __ ☐ 20610 - __ __ __ ☐ 20646 - __ __ __	☐ 10521 - __ __ __ ☐ 10512 - __ __ __ ☐ 20621 - __ __ __ ☐ 20610 - __ __ __ ☐ 20646 - __ __ __

	☐ 20644 - __ __ __ ☐ 20645 - __ __ __ ☐ 20676 - __ __ __	☐ 20644 - __ __ __ ☐ 20645 - __ __ __ ☐ 20676 - __ __ __
c. Serial Number for Replacement Implant	__ __ __ __ __ __ __	__ __ __ __ __ __ __

If any complications occurred during this procedure, please complete a Complication Report after completing this Office Visit Form.

MRI Data

1. Since the last update, has the participant had an MRI performed to evaluate her breast implants?
   Yes ☐ No ☐

   If YES, please complete the following:

   a. Date of MRI: __ __ __ __ __ __ __ __

   b. Results of MRI (*select one for each side*):

Right Side	Left Side	Results
☐	☐	No evidence of rupture
☐	☐	Indeterminate evidence of rupture
☐	☐	Definitive rupture
☐	☐	Results for this side not included in the report (e.g., Unreadable or not implanted)

If participant has had multiple MRIs since the last visit, please complete another MRI Report after completing this Office Visit Form.

Mammography Data

1. Since last update, has the participant had a Mammogram performed?
   Yes ☐ No ☐

   If YES, please complete the following:

   a. Date of Most Recent Mammogram: __ __ __ __ __ __ __ __

   b. Please indicate the type of mammogram:
      ☐ 1. Screening Mammogram
      ☐ 2. Diagnostic Mammogram (e.g., follow-up for suspicion of cancer or other symptoms)

   c. Was the Eklund Technique used?
      ☐ 1. Yes
      ☐ 2. No

☐ 3. Unknown

d. Results:
☐ 1. Normal
☐ 2. Abnormal
☐ 3. Unknown

e. Please specify BI-RADS (Breast Imaging-Reporting and Data System):

Right Side	Left Side	Results	
		☐ Unknown	
☐	☐	BI-RADS 0	Incomplete Assessment
☐	☐	BI-RADS 1	Negative Findings
☐	☐	BI-RADS 2	Benign Findings
☐	☐	BI-RADS 3	Probably Benign
☐	☐	BI-RADS 4	Suspicious Abnormality (Biopsy recommended)
☐	☐	BI-RADS 5	Highly Suggestive of Malignancy
☐	☐	BI-RADS 6	Known Biopsy – Proven Malignancy

If participant has had multiple mammograms since last visit, please complete another Mammogram Report after completing this Office Visit Form.

Office Visit Performed By:

☐ Investigator
☐ Non-Study Investigator Name:_____

Specialty: _____

City/ST: _____

Phone Number: _____

Signature: _____