QUESTIONNAIRE ON BREAST IMPLANTS

In IPM the session time is limited to 90 minutes. This means that you should submit your reply within this time. If you exceed it, your reply will be lost. You might consider preparing your comments in a separate document and then importing them into this consultation response form.

This questionnaire should take approximately 7 minutes to complete.

NOTE: *The received individual contributions will be handled in such a way to protect medical confidentiality.*

Privacy statement

Importance of this questionnaire

The questionnaire is intended to cover only patients that undergo an explantation. The aim is to identify whether there are differences between patients that undergo an explantation of PIP breast implants compared with those from other manufacturers on:

i) The nature, frequency and/or severity of adverse effects prior to and at explantation and the correlation between these.
ii) The time to rupture and/or rupture frequency and /or nature and extent of rupture.
iii) The extent of correlation between i) and ii).

We need your help

The findings will be of great value in providing the evidence base for policy formulation, in increasing the safety of future breast implant devices, and in identifying patient symptoms that are most likely to be associated with implant failure. We recognise that to fill in this questionnaire will place demands on your time and we very much appreciate your willingness to participate in this important study. We will keep you informed of the findings both for your interest and to inform your practice.

We will be glad to acknowledge your contribution

The Scientific Committees of the European Commission follow the practice of acknowledging contributions to scientific opinions. Below, at the end of this questionaire, please indicate if you would like to be acknowledged and have your name and/or professional affiliation added to the list of contributors to this study.

The initial data collection phase will end on 31 March 2013. Please submit your data by this deadline. Thank you.

If you have any questions please contact:

Sanco-SCENIHR-Secretariat@ec.europa.eu

Questions marked with an asterisk * require an answer to be given.

1. Background information

1. Patient date of birth *

[Date]

2. Implantation data

2. Is there an implant on the RIGHT side? *

- ( ) Yes
- ( ) No

2.1 Date of implantation *

[Date]

2.2 Please indicate the reason for implantation on the RIGHT side *

- ( ) Aesthetic
- ( ) Mastectomy due to malignant breast tumour
- ( ) Other restorative

2.3 Please indicate the incision used for implantation on the RIGHT side. *

- ( ) Periareolar
- ( ) Inframammary
- ( ) Axillary
- ( ) Other

2.3.1 Please specify the other incision used. *

2.4 History of implantation: *

- ( ) Without complications
- ( ) With complications
- ( ) Unknown

2.4.1 Please specify the complications. *

3. Post implantation data (RIGHT side)

3.1 Were regular checks carried out after the implantation? *

- Yes
- No
- Unknown

3.2 Was there a history of physical trauma prior to the explant? *

- Yes
- No

4. Implant data (RIGHT side)

If you do not have the information please indicate 'Not available'.

4.1 Name of the manufacturer of RIGHT implant. *

4.2 Serial or lot number of RIGHT implant. *

4.3 Size of RIGHT implant. *

4.4 Surface of RIGHT implant: *

- Smooth
- Textured

5. Explantation data and reason for explantation (RIGHT side)

5.1 Was the right implant explanted? *

- Yes
- No

5.2 Date of explantation *

[Date]

5.3 Reason for explantation. Please select all relevant. *

- [ ] Patient developed symptoms
- [ ] Suspicion of rupture of the implant
- [ ] Requested by the patient
- [ ] Routine removal because of time elapsed since implantation
- [ ] Implant displacement or aesthetic reasons
- [ ] Other
- [ ] National policy
- [ ] Outcome of an assessment by the doctor

5.3.1 Please select the symptoms developed by the patient. *

- [ ] Pain
- [ ] Local swelling
- [ ] Change in implant consistency and/or shape
- [ ] Other
- [ ] No symptoms

5.3.1.1 Please select the change in implant consistency. *

- ( ) Softer breast
- ( ) Harder breast

5.3.2 Please specify other reasons for explantation. *

6. Findings during explantation (RIGHT side)

6.1 RIGHT SIDE: local findings observed during explantation (please select all relevant) *

- [ ] Free silicone within fibrous capsule
- [ ] Milky fluid around the implant
- [ ] Free silicone outside the fibrous capsule
- [ ] Skin perforation
- [ ] Suspicion of inflammation
- [ ] Thickening or granulation of the capsule
- [ ] Capsular calcification
- [ ] Granuloma within the breast glandular tissue
- [ ] Implant rupture occured during the explantation
- [ ] Suspicion of anaplastic large cell lymphoma
- [ ] Suspicion of malignant breast tumours
- [ ] Other

6.1.1 Please specify other local findings observed.*

6.2 Regional or systemic pathological findings observed during explantation (RIGHT side). Please select all relevant:*

- [ ] Inflammation
- [ ] Infection
- [ ] State of lymph nodes
- [ ] Silicone beyond local area
- [ ] Other malignant tumors
- [ ] No findings

6.2.1 Please select for inflammation.*

- ( ) Regional
- ( ) Systemic

6.2.2 Please select for infection.*

- ( ) Regional
- ( ) Systemic

6.2.3 Please select for state of lymph nodes.*

- ( ) Enlarged axillary lymph nodes
- ( ) Enlarged distant lymph nodes

6.2.4 Please select for silicone beyond local area.*

- ( ) Silicone in axillary lymph nodes
- ( ) Silicone in distant lymph nodes

6.2.5 Please select for other malignant tumors.*

- ( ) Regional
- ( ) Systemic

7. State of explant after explantation (RIGHT side)

7.1.1 RIGHT implant visibly ruptured. *

- Yes
- No

7.1.1.1 Please specify the rupture. *

- Destroyed/melted
- Pinhole
- Tear

7.1.2 RIGHT implant: change in implant consistency? *

- Yes
- No

7.1.2.1 Please specify the change in implant consistency. *

7.1.3 RIGHT implant: Gel bleed? *

- Yes
- No

7.1.3.1 Please specify. (see pictures) Images courtesy of Professor Dr. Dirk W. Schubert, Centre for Silicone Breast Implant Investigation, Friedrich-Alexander Universität Erlangen-Nürnberg *

- Cohesive
- Less cohesive

7.1.4 RIGHT implant: Location of the failure: *

- [ ] Anterior - central
- [ ] Posterior - central
- [ ] Peripheral - equatorial

7.1.4.1 Please estimate size of failure in mm for Anterior - central. *

7.1.4.2 Please estimate size of failure in mm for Posterior - central. *

7.1.4.3 Please estimate size of failure in mm for Peripheral - equatorial. *

7.2 RIGHT implant: additional information about the failure:

7.3 Were laboratory investigations (e.g. anatomopathology, microbiology, etc.) performed for this patient? *

- Yes
- No

7.3.1 Please provide a summary.

7.4 Were laboratory tests (e.g. mechanical, toxicology, chemical testing) performed on the implant? *

- Yes
- No

7.4.1 Please provide a summary.

8. Implantation data (LEFT side)

8. Is there an implant on the LEFT side? *

- Yes
- No

8.1 Date of implantation *

[Date]

8.2 Please indicate the reason for implantation on the LEFT side. *

- Aesthetic
- Mastectomy due to malignant breast tumour
- Other restorative

8.3 Please indicate the incision used for implantation on the LEFT side. *

- Periareolar
- Inframammary
- Axillary
- Other

8.3.1 Please specify the other incision used. *

8.4 History of implantation: *

- Without complications
- With complications

8.4.1 Please specify the complications. *

9. Post implantation data (LEFT side)

9.1 Were regular checks carried out after the implantation? *

- Yes
- No
- Unknown

9.2 Was there a history of physical trauma prior to the explant? *

- Yes
- No

10. Implant data (LEFT side)

If you do not have the information please indicate 'Not available'.

10.1 Name of the manufacturer of LEFT implant. *

10.2 Serial or lot number of LEFT implant. *

10.3 Size of LEFT implant. *

10.4 Surface of the LEFT implant: *

- Smooth
- Textured

11. Explantation data and reason for explantation (LEFT side)

11.1 Was the left implant explanted? *

- Yes
- No

11.2 Date of explantation *

[Date]

11.3 Reason for explantation. Please select all relevant. *

- Patient developed symptoms
- Routine removal because of time elapsed since implantation
- National policy
- Suspicion of rupture of the implant
- Implant displacement or aesthetic reasons
- Outcome of an assessment by the doctor
- Requested by patient
- Other

11.3.1 Please select the symptoms developed by the patient. *

- Pain
- Local swelling
- Change in implant consistency and/or shape
- Other

11.3.1.1 Please select the change in implant consistency. *

- Softer breast
- Harder breast

11.3.2 Please specify other reasons for explantation. *

12. Findings during explantation (LEFT side)

12.1 LEFT SIDE: local findings observed during explantation (please select all relevant) *

- [ ] Free silicone within fibrous capsule
- [ ] Milky fluid around the implant
- [ ] Free silicone outside the fibrous capsule
- [ ] Skin perforation
- [ ] Suspicion of inflammation
- [ ] Thickening or granulation of the capsule
- [ ] Capsular calcification
- [ ] Granuloma within the breast glandular tissue
- [ ] Implant rupture occured during the explantation
- [ ] Suspicion of anaplastic large cell lymphoma
- [ ] Suspicion of malignant breast tumours
- [ ] Other

12.1.1 Please specify other local findings observed. *

12.2 Regional or systemic pathological findings observed during explantation(LEFT side). Please select all relevant: *

- [ ] Inflammation
- [ ] Infection
- [ ] State of lymph nodes
- [ ] Silicone beyond local area
- [ ] Other malignant tumours
- [ ] No findings

12.2.1 Please select for inflammation. *

- ( ) Regional
- ( ) Systemic

12.2.2 Please select for infection. *

- ( ) Regional
- ( ) Systemic

12.2.3 Please select for state of lymph nodes. *

- ( ) Enlarged axillary lymph nodes
- ( ) Enlarged distant lymph nodes

12.2.4 Please select for silicone beyond local area. *

- Regional
- Systemic

12.2.5 Please select for malignant tumours. *

- Regional
- Systemic

13. State of explant (LEFT side)

13.1.1 LEFT implant visibly ruptured. *

- Yes
- No

13.1.1.1 Please specify the rupture. *

- Destroyed/melted
- Pinhole
- Tear

13.1.2 LEFT implant: change in implant consistency? *

- Yes
- No

13.1.2.1 Please specify change in implant consistency. *

13.1.3 LEFT implant: Gel bleed? *

- Yes
- No

13.1.3.1 Please specify. (see pictures) Images courtesy of Professor Dr. Dirk W. Schubert, Centre for Silicone Breast Implant Investigation, Friedrich-Alexander Universität Erlangen-Nürnberg *

- ( ) Cohesive
- ( ) Less cohesive

13.1.4 LEFT implant: Location of the failure: *

- [ ] Peripheral - equatorial
- [ ] Anterior - central
- [ ] Posterior - central

13.1.4.1 Please estimate size of failure in mm for Peripheral - equatorial. *

13.1.4.2 Please estimate size of failure in mm for Anterior - central. *

13.1.4.3 Please estimate size of failure in mm for Posterior - central. *

13.2 LEFT implant: additional information about the failure:

13.3 Were laboratory investigations (e.g. anatomopathology, microbiology, etc.) performed for this patient? *

- Yes
- No

13.3.1 Please provide a summary.

13.4 Were laboratory tests (e.g. mechanical, toxicology, chemical testing) performed on the implant? *

- Yes
- No

13.4.1 Please provide a summary.

14. Information on the respondent

14.1 Name of respondent *

14.2 Job position *

14.3 Contact details respondent (e-mail and/or phone number). *

14.4 Clinic/hospital address. *

15. Additional comments

15.1 Additional comments (If your comments are relevant to a specific topic listed above, please indicate the number of the question.)

15.2 The Scientific Committees of the European Commission follow the practice of acknowledging contributions to scientific opinions. Do you wish to be acknowledged? *

- Yes
- No

15.3 How would you like to be acknowledged? By name, name and professional affiliation, professional affiliation, etc. *