



**Customer Complaint**

CC No.	
Name	
Address	
Tel No.	
Email ID	
Mobile No.	
Dealer Name / R.M. Name	
Initial Reply Sent on	/ / By Email / Fax / Letter

Product Discussion :

Item Name	Part No.	Batch No.
Invoice No.	Invoice Date:	

Nature & On site description of complaint (  Tick applicable and, if not, provide description.)

Implant Breakage after Implantation

Implant Rusting after implantation

Instruments related

Implant breakage or bending while insertion

**Description:**

CC: Collected by:  
CC: Collection Date:  
CC: Reached at SHPOPL on:  
CONCLUSION at SHPOPL:

<b>[ I ] Case History Review : Clinical Evaluation:</b>	
<b>[ii] Engineering Examination:</b>	
<b>[iii] Reason for Failure / Complaint:</b>	<b>By:</b>
<b>[iv] Root Cause / Analysis :</b>	<b>By :</b>
<b>[v] Final Conclusion:</b>	<b>By :</b>

**Supporting:**

Incase of broken or rusted implant retrieving, Pre & post operative x rays, surgeons notes during post operative follow up are must. Without this, evaluation will be kept pending. For Metallurgical evaluation Samples are must. Samples must be provided after taking proper receipt from the representative.

**Check List:**

1. Pre-Op X ray: \_\_\_\_\_
2. Post-Op x rays: \_\_\_\_\_
3. X ray when implants was found Broken: \_\_\_\_\_
4. Surgeons note on follow ups: \_\_\_\_\_
5. Microbiological culture by obtaining swab prior to implant removal: \_\_\_\_\_
6. Tissue sample just prior to implant removal or immediately after removal adjacent to implant & Observation of Surgeon in respect of these tissues (see note below): \_\_\_\_\_
7. Samples of Broken implant submitted for evaluation dully sterile: \_\_\_\_\_
8. Annexure A dully filled in: \_\_\_\_\_

**Notes:**

**1. Annexure A is required to be filled in by the orthopedic Surgeon/ Hospital retrieving implant. Annexure B is filled in by SHPOPL through professional metallurgist. Information from both annexure is reviewed to conclude on the subject. Annexure B enclosed is not be filled in by a complainant surgeon/ Hospital.**

2. Examination of tissue (Ref: IS: 11088-1984-clause 5.1.2)

- 2.1 Record the gross characteristics of the tissue immediately adjacent to the implant as to consistency and color, as seen by the naked eye, and with a hand lens or dissecting microscope. Process the excised tissue or histopathological and for such other studies as are appropriate; elective histological, chemical, mechanical, radiological, etc. Cut the sample into appropriate fractions for such studies. Use standard laboratory practice for the histological preparation of the tissue with regard to the trimming of tissue blocks fixation, washing, embedding, and staining. Report the methodology.
- 2.2 Histopathological observations – Classify the amount of tissue reaction in regard to the thickness of the scar, the presence of leucocytes or other tissue cells, the presence of particles detectable by polarized light and such other indications of interaction of tissue and material as might be observed. Note evidence of neoplasia or tissue degeneration. Attach a copy of the histopathological.
- 2.3 Roentgenogram review – Review all pertinent roentgenograms. Attach a copy of the summery and the original radiographic reports. If available. Obtain a reduced photographic copy of any roentgenogram that is judged essential to support the conclusion (see Appendix A).

**APPENDIX- A**  
**To be filled in by Surgeon/hospital**  
**Ref: IS: 11088-1984**

RECOVERY OF IMPLANTS, CASE HISTORY REVIEW

A-1. Date inserted: \_\_\_\_\_

A-2. Date removed: \_\_\_\_\_

A-3. Implant, type: \_\_\_\_\_

A-4 Patient's sex: \_\_\_\_\_

A-5. Patient's date of birth: \_\_\_\_\_

A-6. Patient's weight: \_\_\_\_\_

A-7. Implant location: \_\_\_\_\_

A-8 Patient's activity or occupation: \_\_\_\_\_

A-9. History of foreign body sensitivity: \_\_\_\_\_

A-10. a) Diagnosis at insertion: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

b) Trauma simple or comminuted ;open or closed: \_\_\_\_\_

c) Contributory conditions (for example, alcoholism, senility): \_\_\_\_\_

A-11. Operation at insertion: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

A-12. Antibiotics at insertion, if yes, answer the following:

a) Reasons for antibiotics:

i) \_\_\_\_\_

ii) \_\_\_\_\_

iii) \_\_\_\_\_

b) Type: \_\_\_\_\_

c) Dosage: \_\_\_\_\_

d) Duration: \_\_\_\_\_

A-13. Functional level of the patient attained between insertion and removal  
 (Ambulatory, ambulatory with aids, no ambulatory). Comment on any unusual physical  
 activity or event for this treatment. \_\_\_\_\_

\_\_\_\_\_

---

A-14. Roentgenogram review (Indication Yes, No, Doubt, Or Not applicable)

- |   |  |
|---|--|
| a) Bony change in relation to implant       | h) Fracture of bone                          |
| b) Absorption or rarefaction                | j) Penetration of implant across joint space |
| c) Increased density (sclerosis-compaction) | k) Penetration of implant through bone       |
| d) Non- union                               | m) Fracture of implant                       |
| e) Bone fragments held apart                | n) Permanent deformation of implant          |
| f) Migration of implants                    | p) Other                                     |
| g) Malalignment                             |  |

A-15. Reason (s) for removal (Indicate Yes or No-mark primary reason with an asterisk)

- |  |  |
|--|--|
| a) Routine                                   | h) Instability                         |
| b) Early infection (< 6 months)              | j) Unsatisfactory position of implant  |
| c) Late infection (> 6 months)               | k) Non-union                           |
| d) Breakage or deformation of implant        | m) Allergic or hypersensitive reaction |
| e) Pain in the vicinity of implant           | n) Reason not known                    |
| f) Stiffness of joint in vicinity of implant | p) Other (specify)                     |
| g) Prominence of bursae                      |  |

A-16. Finding at surgery (Indicate Yes, No, Doubt, or Not applicable)

- |  |                             |
|--|-----------------------------|
| a) Pus                                     | f) Implant easily removed   |
| b) Scar tissue                             | g) Fractured grouting agent |
| c) Granulation tissue                      | f) Caseation                |
| d) Foreign body (debris or stained tissue) | j) Bony reaction            |
| e) Bursal fluid                            | k) Other                    |

A-17. Swab from implant site (Indicate Yes or No)

- a) Swab from implant site
- b) Sterile
- c) If no, indicate type

A-18. Examination of tissue: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Filled in by: \_\_\_\_\_

Position: \_\_\_\_\_

Hospital Name & address: \_\_\_\_\_

Contact Information: Email & mobile \_\_\_\_\_

**APPENDIX-B**  
**To be filled in by SHPOPL**

**RECOVERY OF IMPLANTS, ENGINEERING EXAMINATION**

B-1. Implant Type.....

B-2. Number of components.....

B-3. Macroscopic Examination (Indicate Yes No. Doubt, or Not Applicable)

	Location	Estimate Degree
a) Wear or burnishing	----	-----
b) Gallin	----	-----
c) Scratching	----	-----
d) Change of Shape	----	-----
e) Mechanical Damage	----	-----
f) Macro Porosity	----	-----

B-4. Microscopical Examination (Indicate location and orientation of samples)

- a) Inclusion content (recommended practice)
- b) Grain Size
- c) Grain boundary constituents
- d) Microporosity
- e) Other distinguishing features( for example, cast stainless steel-delta-ferrite)
  - i) -----
  - ii) -----
  - iii) -----

B-5. Type of material (Indicate method of determination)

- a) Chemical composition

B-6. Corrosion ( if Yes, identify )

- a) General corrosion
- b) Pitting corrosion
- c) Crevice corrosion
- d) Galvanic Corrosion
- e) Unable to identify

B-7. Mechanical failure ( if Yes, identify mode)

- a) Fatigue
- b) Torsion
- c) Impact
- d) Stress- corrosion
- e) Static- overstress, causing plastic deformation
- f) Corrosion fatigue
- g) Combination of above (identify)
- h) Other (specify)

- i) Unable to identify

Indicate location of failure and method of identification.

B-8. Mechanical properties: (indicate N.A. if not available). Samples should be taken from areas representative of the original material.

- a) Sample size and orientation
- b) Hardness (indicate type)
- c) 0 2 percent offset yield stress
- d) Ultimate tensile strength
- e) Percent elongation
- f) Reduction in area
- g) Other tests as applicable (for example, transverse bend test )

B-9. Dimension of Implants:

B-10. Conclusion

<p>Conclusion at SHPOPL:</p> <p>Case History review: clinical evaluation:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>By: _____</p> <p>Engineering Examination:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>by: _____</p> <p>Final conclusion:</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>
---

<p>Informed to complainant on: _____</p> <p>Informed by: _____</p>
--