

What Can We Learn from Retrieved Implants?

or

Learning from Failure

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When is a Removed Device a Failed Device?

- *Any removed total joint replacement has failed.
- *Any device with evidence of frank failure has failed.
- *Any device removed in the presence of clinical failure has failed.

Classification of Removed Implants

- Class I - Devices removed for cause and/or displaying probable evidence of frank failure
- Class II - Devices removed for probable cause but without evidence of frank failure
- Class III - Devices removed for other than cause (routine removal, secondary procedures, etc.)

When is a Removed Device a Failed Device?

Class I - Devices removed for cause and/or displaying probable evidence of frank failure.

*Class I devices have probably failed.

Class II - Devices removed for probable cause but without evidence of frank failure.

*Class II devices have possibly failed.

Class III - Devices removed for other than cause.

*Class III devices have probably not failed

The Removed Implant = The Retrieved Implant

Study of Retrieved Implants

Class III - Routine Removal

- *Clean and identify

- *Visual examination and description

- *Medical history review

- *Store

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Class II - Removal for Cause without Frank Failure

All of steps for Class III and (as applicable)

- *Examine intraoperative photographs
- *Evaluate culture reports
- *Evaluate histological sections
- *Evaluate metallographic sections
- *Perform mechanical analysis
- *Other special tests

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Class I - Removal for Cause and/or Frank Failure

All of steps for Class III, applicable steps for Class II and (as applicable)

- *Perform mechanical testing (portions)
- *Obtain chemistry, hardness, etc.
- *Obtain special histological studies

Study of Retrieved Implants

In all Cases, whether initial classification was I, II or III:

*Prepare summary so that:

Initial classification is either upheld or altered.

Probable mechanisms and causes of failure are identified.

Responsibility for Retrieving Implants

Retrieval and analysis of implants is an integral part of the medical management of the patient. Thus, the responsibility for DR & A lies with the treating physician.

Who Benefits from Study of Removed Implants?

- *The patient -- better diagnosis and treatment.
- *The surgeon -- identification and limitation of liability.
- *The manufacturer -- improvement of product.
- *The Federal Government -- basis for regulatory decisions.
- *The academic -- material for research and teaching.