Dartmouth Biomedical Engineering Center
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DBEC #: _____
(Lab Use Only)

IMPLANT RETRIEVAL FORM

See reverse for shipping procedure.

SURGEON INFORMATION: Retrieval Surgeon:

Address

Telephone: Fax #: Email:

Did you implant the retrieved prosthesis? ◯ yes ◯ no If not, who did?

PATIENT INFORMATION: Unique Patient ID*: ◯ M ◯ F Age: Wt: lbs. Ht. in

Patient activity level prior to onset of symptoms: ◯ very active ◯ active ◯ ambulatory w/ aids ◯ nonambulatory

Patient activity level immediately prior to surgery: ◯ very active ◯ active ◯ ambulatory w/ aids ◯ nonambulatory

Description of pain (prior to surgery): severity: ◯ none ◯ mild ◯ moderate ◯ severe

location: ☐ buttock ☐ groin ☐ knee ☐ thigh other:

duration: months

What was the primary diagnosis for which this prosthesis was implanted?

Please describe any additional significant diagnoses prior to surgery:

Patient smoking status: ◯ nonsmoker ◯ chewing tobacco/snuff ◯ former smoker ◯ smoker

IMPLANT INFORMATION: ◯ Left ◯ Right Manufacturer: Model:

Implant lot #s (HIGH PRIORITY for poly components):

(If possible, please enclose copies of the *retrieved* implants' ID stickers from the patient file.)

Date of implantation: / / Date of retrieval: / /

Was this implanted as a primary or revision implant? ◯ primary ◯ revision ◯ unknown

In vivo dislocation? ◯ yes ◯ no If yes: ◯ many ◯ few ◯ one # of dislocations during retrieval:

Why was this implant removed? ☐ dislocation ☐ instability ☐ loose ☐ lysis ☐ painful ☐ position ☐ postmortem ☐ sepsis

☐ subsidence wear of: ☐ poly ☐ metal fracture of: ☐ bone ☐ implant ☐ poly other:

Which component?

Pertinent History:

Poly insert disassociation in vivo? ◯ yes ◯ no ◯ loosely attached Was this implant hydroxapatite (HA) coated? ◯ yes ◯ no

What was the quality of bone at the time of revision? ◯ poor ◯ fair ◯ good ◯ excellent

Was there evidence of significant debris? ☐ no ☐ cement ☐ metal ☐ poly other:

lytic activity at revision? ◯ none ◯ mild ◯ moderate ◯ severe

loosening? ◯ none ◯ mild ◯ moderate ◯ severe

stress shielding? ◯ none ◯ mild ◯ moderate ◯ severe

osteoporosis? ◯ yes ◯ no If yes, was it: ☐ clinical ☐ radiographic

What was the removal difficulty? ◯ none ◯ mild ◯ moderate ◯ severe

What surgical instruments were used?

What surgical approach was used?

MoM DETAILS: Anteversion: Inclination: Direction of dislocation at retrieval:

Metal ion levels:

CLINICAL DETAILS: If you implanted this retrieved prosthesis,

Were you initially satisfied with its size? ◯ yes ◯ no its orientation? ◯ yes ◯ no

Were there any complications?

Additional comments:

***Unique Patient ID** assigned by the surgeon. Please do not send patient names or MRNs without appropriate IRB review and patient consent.

Please sign the data use acknowledgement on the following page, and please enclose all retrieved items including metal shells, stems, heads, screws, pegs, clips, etc.

IMPLANT SHIPPING PROCEDURE

1. **Soak the device(s) in a 70% ethanol solution for 48hrs (except metal-on-metal hips -- use 10% formalin)**
2. **Blot to removed excess ethanol or formalin.**
3. **Wrap in towels (paper or cloth).**
4. **Double wrap in ziploc plastic bags.**
5. **Wrap double-bagged device with paper towels, then place into a final third ziploc bag.**
6. **Ship in a box via a tracked shipping service. Mail to:**

Thayer School of Engineering
Dartmouth Biomedical Engineering Center
14 Engineering Drive, Room 15
Hanover, NH 03755

Thank you!

NOTIFICATION OF RIGHTS AND RESPONSIBILITIES

The Dartmouth Biomedical Engineering Center (herein DBEC) strives to return device evaluation reports to contributing surgeons on a quarterly basis. This data is released back to the surgeon under the Health Insurance Portability and Accountability Act of 1996 (herein HIPAA), 45 CFR 164.506 permitted use of "Treatment, Payment, and Health Care Operations" (herein TPO). The DBEC retains all data as part of a research database limited data set as defined by 45 CFR 164.514(e), with internal procedures and database security reviewed by the Dartmouth Committee for the Protection of Human Subjects. Data returned to surgeons may not be used for research purposes unless reviewed by the appropriate institutional review board (herein IRB). If you plan to use the data for research, you must inform DBEC of the change in status and provide DBEC with a copy of the IRB approval.

RELEASE OF LIABILITY / INDEMNIFICATION

I, the undersigned, do hereby certify that I will only use the results provided to me by the DBEC for TPO, or other HIPAA defined non-research activities. I agree that any use beyond these permitted purposes is outside of this agreement with DBEC and is forbidden without an appropriate IRB approval and timely notification of the change of status to DBEC.

I, the undersigned, do hereby RELEASE, INDEMNIFY, and HOLD HARMLESS DBEC and Dartmouth College from any liability arising out of misuse of the provided data in a manner not consistent with the above statements.

Signature: _____ Date: _____