

Dartmouth Biomedical Engineering Center 14 Engineering Drive, Hanover, NH 03755 Tel. 603-646-3489 Fax. 603-646-3856

DBEC #:

(Lab Use Only)

Email: Dartmouth. Biomedical. Engineering. Center@Dartmouth.edu

IMPLANT RETRIEVAL FORM

See reverse for shipping procedure.

| SURGEON INFORMATION Retrieval Surgeon: | | | | |
|--|--|--|--|--|
| Address | | | | |
| Telephone: Fax #: Email: | | | | |
| Did you implant the retrieved prosthesis? | | | | |
| PATIENT INFORMATION Unique Patient ID*: OM F Age: | | | | |
| IMPLANT INFORMATION Left Right Manufacturer: Model: | | | | |
| Implant lot #s (HIGH PRIORITY for poly components): | | | | |
| Was this a revision of a hemiarthroplasty, TSA, or RSA? | | | | |
| Humerus cemented? OY ON Glenoid cemented? OY ON ON/A | | | | |
| Date of implantation: / / Date of retrieval: / / / | | | | |
| Was this implanted as a primary or revision prosthesis? Oprimary revision Ounknown | | | | |
| Original diagnosis for implantation (check all that apply): osteoarthritis rheumatoid arthritis avascular necrosis | | | | |
| post-traumatic arthritis proximal humerus malunion chronic instability acute proximal humerus fracture | | | | |
| cuff tear arthropathy irreparable rotator cuff tear other: | | | | |
| Reasons for retrieval (check all that apply): fracture of: poly implant bone implant disassociation infection | | | | |
| instability: posterior anterior loosening malposition nonunion of tuberosity notching osteolysis | | | | |
| pain poly wear postmortem other: | | | | |
| Which component/s? | | | | |
| Revision procedure: Conversion to hemiarthroplasty Conversion to conventional TSA Conversion to RSA | | | | |
| resection arthroplasty spacer implantation arthrodesis | | | | |
| INTRA-OPERATIVE INFORMATION | | | | |
| Intra-operative humeral version: | | | | |
| Intra-operative or radiographic glenoid version: | | | | |
| Intra-operative glenoid baseplate position: | | | | |
| Intra-operative stability of the shoulder: | | | | |

Please sign the data use agreement on the following page, and please enclose all retrieved items including screws.

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

IMPLANT SHIPPING PROCEDURE

- 1. Soak the device(s) in either a 70% ethanol solution, or a 10% neutral buffered formalin solution, for 48hrs
- 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: | |
|------------|-------|--|
| | | |