For *3i* use only: Incident No._____

Replacement Order No. _____

Warranty Form

To comply with Regulatory requirements for Medical Device Reporting, it is necessary to obtain information regarding this event. Please review and provide, with as much detail as possible, the following information.
For clarity, please **print or type**. **Please place each case on a separate Complaint Form.**

ACCOUNT INFORMATION

Reporter's Name _____

BIOMET *3i* Account No: _____

Customer Name:_____

Address _____ Phone Number: ( ) _____

City _____ Fax Number ( ) _____

State _____ Zip Code_____ E-mail address_____

Patient's Initials or ID No.: _____ Age: _____

DEVICE INFORMATION:

Please provide the following information:

Catalog No.	Lot No.	Quantity	Placement Date	Removal Date	Tooth Site No.	*Replacement request

***If you do not want the exact product as replacement, please specify the product code of choice.**

EVENT INFORMATION:

Did this incident lead to a death or serious injury? [ ] YES [ ] NO
Note: Serious injury is defined as (1) life threatening, (2) results in permanent impairment of a body function or structure or, (3) necessitates medical or surgical intervention by a healthcare professional to preclude permanent impairment of a body function or structure.

What was the cause of the event?

[ ] Trauma or Accident
[ ] Infection
[ ] Device Malfunction
[ ] Biomechanical Overload/Stress
[ ] Other _____
[ ] Non-Integration
[ ] Loss of Integration
[ ] Device Fracture
[ ] Handling-loss of sterility

If this event involved an implant, was the implant: [ ] Not yet restored [ ] Restored

Warranty Form

For *3i* use only: Incident No._____

Replacement Order No. _____

For Implants only:

1) Did the patient present with any relative patient profile? (check all that apply)

□ Smoker □ Osteoporosis □ Diabetes □ Other_____

2) Please describe the density of the bone:

□ High density (Type I) □ Moderate density (Type II) □ Low density (Type III or IV)

3) Was the implant placed in a previously or simultaneously grafted site?

□ No □ Yes: (describe material below)

□ Autogenous □ Allograft □ Xenograft □ Alloplast □ Hybrid

4) Was the implant placed into an immediate extraction site? □ No □ Yes

5) Please describe the implant placement protocol:

□ Single Stage (transgingival) □ Two Stage (submerged)

6) Was the implant loaded (provisional or final) prior to failure?

□ No □ Yes: □ Immediate Loading (within 48 hours)

□ Early Loading (within 8 weeks)

□ Traditional- Delayed (3-4 months mandible, 4-6 months maxilla)

Please record any additional information concerning the event

_____

_____

Remedial actions taken or required to be taken: What additional treatment was taken in response to this incident? Is additional remedial treatment planned? Please Describe.

_____

If required, can copies of pre/post operative radiographs/treatment records be provided? [ ] Yes [ ] No

_____ _____

Doctor's Signature Date

Doctor: Please make a copy of this report for your files and forward the original to ***3i*** with all devices. **To protect you and *3i*, all used devices must be sterilized prior to mailing**. Non-sterile devices may be considered biological hazards based on current United States Postal Regulations. **Please send in padded mailer**.

Send To:
BIOMET *3i*
Regulatory Services/Implant Warranty
4555 Riverside Drive,
Palm Beach Gardens, FL 33410
Phone: (800)443-8166 Fax: (561)514-6316