

**Bicon Dental Implants**

Adverse Event Worksheet

Internal Use Only – Report Receipt Date: \_\_\_\_\_

Received By: \_\_\_\_\_ Reference # \_\_\_\_\_

Dear Doctor

To comply with the FDA requirements for Medical Device Reporting and CE Mark regulations, it is necessary to obtain information regarding this event. **Please complete this sheet in its entirety and be as specific as possible.** Attach the failed Implant and any additional sheets or x-rays as necessary.

Did this incident lead to a death or serious Injury\*? Yes \_\_\_\_\_ No \_\_\_\_\_

\*Defined as 1) life threatening 2) results in permanent impairment of a body function or structure 3) necessitates medical intervention by a health care professional to preclude permanent impairment of a body function or structure

**Account Information:**

Doctor Name and Address \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Phone# \_\_\_\_\_ Fax# \_\_\_\_\_

**Product # and Lot# REQUIRED before any replacements will be shipped:**

Product#: \_\_\_\_\_ Lot#: \_\_\_\_\_ Date Implanted \_\_\_\_\_ Date Explanted \_\_\_\_\_

Product#: \_\_\_\_\_ Lot#: \_\_\_\_\_ Date Implanted \_\_\_\_\_ Date Explanted \_\_\_\_\_

Product#: \_\_\_\_\_ Lot#: \_\_\_\_\_ Date Implanted \_\_\_\_\_ Date Explanted \_\_\_\_\_

**Patient Information** (circle one)

Age: \_\_\_\_\_ Male or Female \_\_\_\_\_ Tooth#’s: \_\_\_\_\_ Smoker Yes \_\_\_\_\_ No \_\_\_\_\_

Describe Event \_\_\_\_\_ Was the Implant placed using the one stage procedure Yes \_\_\_\_\_ No \_\_\_\_\_

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**Were any of the following involved in the event? (Please Tick)**

Procedure Complication \_\_\_\_\_ Premature Loading \_\_\_\_\_ Patient Systemic Factors \_\_\_\_\_ Biomechanical Overload \_\_\_\_\_

Trauma or Accident \_\_\_\_\_ Device Fracture \_\_\_\_\_ Bone Fracture \_\_\_\_\_ Poor Hygiene \_\_\_\_\_

Poor Quality Bone \_\_\_\_\_ Sinus Penetration \_\_\_\_\_ Infection \_\_\_\_\_ Non Integration \_\_\_\_\_

**NB:** Any used device must be sterilized, placed in a sterile bag and placed in a padded pouch for return. Non-sterile devices are considered biological hazards. Make a copy of this sheet and return original to Bicon Europe Ltd, Unit 4 Ballycummin Village, Ballycummin, Co.Limerick, Ireland. Contact Number 061 303 494 or UK Freephone 0800 731 4266 Email [Ireland@bicon.com](mailto:Ireland@bicon.com) for queries.

Doctor’s Signature \_\_\_\_\_

Date: \_\_\_\_\_