PLEASE SUBMIT to ACE Surgical QA Department

Please include: Autoclaved sealed implant(s), Radiographs and completed forms

Please confirm both pages are filled out completely, correctly and legibly to help expedite your replacement/credit.

IMPLANT COMPLAINT FORM

To comply with FDA's medical device reporting requirements, it is necessary to obtain information regarding this event. Completion of this form is required for warranty replacement.

I. GENERAL PATIENT INFORMATION

Patient Number: ____________________ D.O.B.: ______________ (mm/dd/yy)
SEX: ❒Female ❒Male

Medical History:

❒ Diabetes Mellitus
❒ Radiation Tx – head/neck area
❒ Chemotherapy at time of implant
❒ Allergies ___________________
❒ **Other local or systemic diseases which may be significant:** ____
❒ Psychological Disorder
❒ Xerostomia
❒ Lymphatic Disorder
❒ Drug/Alcohol Abuse
❒ Smoker
❒ Uncontrolled Endocrine Illness
❒ Compromised Immunoresistance
❒ Blood Coagulation Disorder
❒ Illness Requiring Steroids
❒ **No Significant Findings**

II. IMPLANT PLACEMENT SURGICAL INFORMATION (obtain from patients' chart)

ACE Item #: ________________ Lot #: _________________ Note: One implant per form.

Order # from packing slip/invoice: ______________

Item Description: ____

Surgeon's Name: _________________ Dentist Name: __________________

ACE Customer #: _______________

Name on account:: ____

Office address (Includes Street, City/Town, Zip Code: ____

Phone #: _______________Fax #: __________________ E-Mail address: _________________________________

Implants Placed: ______ Site(s) of implant(s) removed: _________________

Site Prep/Graft Date	Implant Placement Date	Implant Removal Date	Prosth. Restoration Date

Bone quality at the time of implant failure: ❒Type I ❒Type II ❒Type III ❒Type IV

Please specify all grafting materials used to prepare the implant site:
____
____

III. INCIDENT DETAIL DESCRIPTION

Same Day Spinners: ❐ Yes ❐ No

Time of loss in relation to the implantation:

❐ Before prosthetic restoration ❐ Up to 1 yr after prosthetic restoration ❐ 1 to 5 yrs after pros. rest.

Was primary stability achieved? ❐ Yes ❐ No

Did implant achieve osseointegration? ❐ Yes ❐ No

Was an augmentation procedure performed at the time of surgery? ❐No ❐Yes, what kind?___________

Were any of the following involved in the implant failure?
❐Trauma/Accident ❐Implant Fracture ❐Inadequate Bone Quality/Bone Quantity
❐Biomech. Overload ❐Poor Oral Hygiene ❐Previous Bone Augmentation (date_________)
❐Overheating of Bone ❐Immediate Extraction Site ❐Adjacent to Endodontic tooth
❐Nerve Encroachment ❐Peri-implantitis ❐Infection ❐Sinus perforation
❐Other: ____

Premature Loading/pressure information (check all that apply):
❐Provisional Prosthesis ❐Tongue ❐Bruxism ❐Final Prosthesis ❐Other: _______________________

Please identify any of the following conditions noted: (check all that apply):
❐Pain ❐Bleeding ❐Swelling ❐Numbness ❐Mobility ❐Fistula ❐Asymptomatic
❐Other: ____

PLEASE SUBMIT to:

ACE Surgical Supply Company, Inc.
Attn: QA Department
1034 Pearl Street
Brockton, MA 02301

Clinician Signature (required): _________________________________ **Date:** ___________