Product Complaint Form

For internal use only	Notification n°. __ /__

JDentalCare medical devices have been designed only to be used in conjunction with the associate JDentalCare components according to the Instruction for use and the Surgical Manual. JDentalCare components and or surgical instruments is recommended. JDentalCare disclaims any liability and shall have no responsibility for any damage resulting from any use other than that specified in the informative material.

ATTENTION! HOW TO COMPILE AND RETURN PRODUCTS

- Fill in the module for one product at a time with all information
- Disinfect and sterilized the product before return in a properly pack label as STERILE
- Pack and ship the product(s) with the complaint form and supporting documents if available (X-rays/photos)
- Ship it at the following Shipping Address:

JDentalCare Srl, Italy
Via Dino Campana, 2
41123, Modena, Italy
Phone: + 39 059 454255
Email: amministrazione@jdentalcare.com

CUSTOMER INFORMATION

Name		Practice stamp
Organization / Dental Clinic		
Street		
City / Country / Zip Code		
E-mail / Telephone		
Contact Name		

PRODUCT INFORMATION

Product Type: ☐ Dental Implant ☐ Abutment ☐ Instrument / Tool
Product Available for return? ☐ Yes ☐ No

CODE	LOT	Quantity	Expiration date

Attention! In case of dental implant reports, please enter the data on the prosthetic components used. (Mandatory information)

CODE	LOT	Quantity	Expiration date

EVENT

Date ___ /___ /___

☐ Broken / fractured implant	☐ Primary stability couldn't be achieved	☐ External trauma	☐ Labelling
☐ Broken / fractured component	☐ Failure to osseointegrate	☐ Compatibility issue	☐ Packaging
☐ Fractured prosthetic screw	☐ Loss of osseointegration	☐ Functional issue	☐ Loosening
☐ Dropped from the implant driver	☐ Damage (deformation, surface defect)	☐ Side effects / allergies	☐ Other: ____

OCCURRENCE OF THE EVENT

☐ Before Clinical Procedure (ex. Any procedures where there was no patient involved)
☐ During Clinical procedure (ex. During placement of implant/ prosthetics)
☐ After Clinical procedure (ex. After placement of implant/ prosthetics)

Describe the event / incident:

PATIENT INFORMATION

ID Patient: Age:___ Sex: ☐ M / ☐ F
Bone Quality: ☐ I ☐ II ☐ III ☐ IV
Oral hygiene: ☐ excellent ☐ fair ☐ poor
Patient profile: ☐ bruxer ☐ diabetic ☐ smoker ☐ none ☐ Other: _____

IMPLANT INFORMATION

Position: _____				
Date of Implant Placement: _____				
Post extraction: ☐ yes ☐ no	Immediate loading: ☐ yes ☐ no		Delayed loading: ☐ yes ☐ no	
Implant placement and torque:	☐ manual placement ☐ torque wrench ☐ handpiece Torque: ___ Ncm			
Augmentation:	☐ no ☐ preoperative ☐ at the time of Implant Placement ☐ none If yes, Grafting Materials: _____			
Healing:	☐ non-submerged healing		☐ submerged healing	
Date of Loss / explanation: _____				
Time of Implant Loss / explanation:	☐ Healing period	☐ Re-Entry	☐ Prior to Functional Loading	☐ After Functional Loading

PROSTHESIS INFORMATION (to be filled in only in case of complaints about prothesis)

Prosthetic Restoration (temporary): _____		Prosthetic restoration (definitive): _____	
Prosthetic screw placement and torque:	☐ manual placemen ☐ torque wrench ☐ handpiece		Torque: ____ Ncm
Prosthetic treatment:	☐ cemented	☐ fixed partial denture	☐ overdenture on ball / emi abutment
	☐ screw retained	☐ complete denture	☐ other:

WERE ANY OF THE FOLLOWING INVOLVED IN THE EVENT?

☐ Trauma / Accident	☐ Bone resorption	☐ Undersized implant bed
☐ Inadequate bone quality / quantity	☐ Overheating of bone	☐ Abutment / implant fracture
☐ Inadequate gum quality / quantity	☐ Peri-implantitis	☐ Immediate implantation
☐ Sinus perforation	☐ Nerve encroachment	☐ Preceding / simultaneous bone augmentation
☐ Biomechanical Overload	☐ Infection	☐ Bruxism
☐ Other: _____		

AT THE TIME OF IMPLANT FAILURE THERE WAS:

☐ Pain	☐ Asymptomatic	☐ Bleeding	☐ Numbness	☐ Allergy	☐ Inflammation
☐ Swelling	☐ Abscess	☐ Other: _____			

SURGICAL INSTRUMENTS INFORMATION (to be filled in only in case of complaints about surgical instruments)

Approximate numbers of uses:	☐ Initial use ☐ 2-10 ☐ 11-20 ☐ 21-30 ☐ more than 30
Cleaning methods:	☐ Manual ☐ Ultrasonic ☐ Other: _____
Sterilization method :	☐ Autoclave ☐ Dry heat ☐ Other:

STERILIZATION DECLARATION

I, _____ declare that the products described above were properly sterilized within the ideal standards.

Responsible for sterilization: _____ Signature: _____

Note: Products which are not cleaned and sterilized and with the respective sterilization confirmation will not be received and accepted for analyze and the replacement request will be rejected.

COMMITMENT AGREEMENT

I confirm that information provided in this product complaint form is correct and consistent with patient-s file.

Compilation date: _____

Name: _____ Signature: _____