This complaint form is valid for the following product groups (GBU) from Dentsply Sirona:

Implants:	- Ankylos - Astra Tech Implant System - EV Prosthetics - MIS (Seven, Connect,...) - PrimeTaper - OmniTaper - Xive
Digital & custom-made devices	- Atlantis - Simplant - Azento
Regenerative:	- Ossix (Plus, Bone, Volumax) - Symbios

COMPLAINT FORM – IMPLANTOLOGY

CUSTOMER INFORMATION			
Customer ID:		**Country:**	
Name:		**Business/Office name:**	
Street name:		**Contact phone:**	
House number:		**Contact email:**	
Postal/ ZIP code:		**Health professional:**	☐ Yes ☐ No
City:		**Request response:**	☐ Yes ☐ No
State/Province: *(if applicable)*			

Complainant sent report directly to competent authority (e.g. FDA, etc.)	☐ Yes ☐ No
If yes, provide the report number of the competent authority	

PRODUCT INFORMATION			
Brand:	☐ Astra Tech	☐ Ankylos	☐ MIS
	☐ PrimeTaper	☐ OmniTaper	☐ EV Prosthetics
	☐ Symbios	☐ Xive	☐ Atlantis
	☐ Ossix	☐ Other:	
Product name / Product description:		**Patient/Order ref:** *(For custom made products)*	
Lot/Serial number or UDI:		**Catalog/Reference/SKU number:**	
Unique device identifier:		**Expiration date of product:**	/ / *(day / month / year)*
Concomitant product(s):			

WILL PRODUCT BE RETURNED?	
☐ Yes, **Item enclosed**	
☐ **Other attachments:**	
☐ No, **Item won't be returned because:**	

ALLEGED EVENT / ISSUE INFORMATION	
Date of Event:	/ / *(day / month / year)*

For 'Description of Event', describe the event as comprehensive as possible, without giving personal information, e.g. where it occurred, was the package damaged, were there labeling issues, how did the product break, where etc.

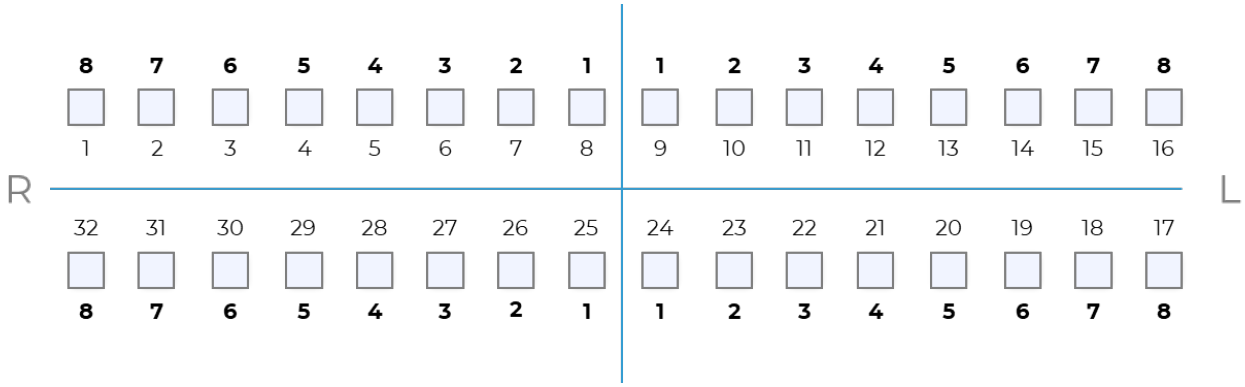
Description of Event:

PATIENT			
Patient Identifier: *NOTE: do not include the name of the patient*			
Age at time of Event:		**Sex:**	☐ Female ☐ Male ☐ Prefer not to say
Oral Hygiene:	☐ excellent ☐ fair ☐ poor		
Medical History/Habits:	☐ Smoker ☐ Diabetic ☐ Bruxer ☐ Alcohol/drug abuse ☐ Periodontitis ☐ Osteoporosis ☐ Blood Coagulation Disorder ☐ Hormonal imbalance ☐ Other, please specify:		
Relevant medications:			
Patient/User [status/event] outcome:	☐ Additional treatment ☐ Recovered ☐ No injury ☐ Hospitalized ☐ Death ☐ Other:		
Provide details of additional required treatment:			
Was there an allergic reaction perceived to be in connection to the treatment or procedure? *(if yes, please fill the additional allergic section)*			☐ Yes ☐ No

NOTE: DATA privacy is applicable per country laws/regulations

Xray, Post-op scan data or other images available?	☐ Yes ☐ No
(Insert Xray, Post-op scan data or other images here)	

Please indicate the position:



Date:	/ / *(day / month / year)*		
First name / Last name:	/	**Signature:**	

NOTE: DATA privacy is applicable per country laws/regulations

Please Complete the details for the appropriate product(s) included in this case in the subsequent pages. *You only need to complete the section applicable to the product(s) included in this case.*

INTERNAL INFORMATION – *to be filled by Dentsply Sirona*			
Selling Location / DI Division:		Internal Reference No.:	
Complaint No. / Complaint system		Date Received at DS *(= Become aware Date)*	/ / *(day / month / year)*

***Specific sections**:*

Please fill in the relevant section below.

IMPLANTS			
Description of Failure:	☐ Implant Loss ☐ Fracture of Implant ☐ Non Primary Stability – only on the day of surgery ☐ Other Surgical or Insertion Issues please describe: ☐ Abutment Fracture ☐ Abutment Screw Fracture ☐ Bridge Screw Fracture ☐ Abutment Loosening ☐ Tool malfunction – please, describe: ☐ Other – please, describe:		
Implant Placement Date:	/ / *(day / month / year)*	**Immediate Implant Placement:**	☐ Yes ☐ No
Loss / Explantation Date:	/ / *(day / month / year)*	**Immediate Loading:**	☐ Yes ☐ No
Time of Implant Loss / Explantation:	☐ Healing Period ☐ Re-entry ☐ Prior to Functional Loading ☐ After Functional Loading		
Sinus Elevation / Augmentation:	☐ Pre-operative ☐ At Time of Implant Placement ☐ None		
Grafting Procedure:	☐ Yes ☐ No		
Oral Hygiene:	☐ Excellent ☐ Fair ☐ Poor		
Bone Quality:	☐ I ☐ II ☐ III ☐ IV		

Prosthetics	
Prosthetic Restoration Date:	/ / *(day / month / year)*
Prosthetic Treatment:	☐ Complete Denture ☐ Only Implant Supported ☐ Bridge ☐ Partial Denture ☐ Single Tooth
When did the Event Occur?	☐ Laboratory Handling ☐ Clinical Installation ☐ Clinical Function

ATLANTIS

☐ **Fracture:**	☐ At Extension ☐ Between Implants ☐ At the Internal Connection
☐ **Fit:**	☐ On the Plaster Model ☐ In the Mouth of the Patient
☐ **Failure with a Combination Product:**	☐ Screw ☐ Attachment ☐ Ceramic ☐ Rider
☐ **Material:**	☐ Wrong Material ☐ Porosity Problem ☐ Esthetics
Failure Type:	☐ Design ☐ Cleanliness ☐ Documentation related ☐ Labelling ☐ Other:
Date of Rebasing of Prosthesis:	/ / *(day / month / year)*

INSTRUMENTS

How long has the tool been used?	year(s) or uses				
If applicable, Torque control device used:	☐ Yes. If yes, please specify Torque applied: Ncm ☐ No ☐ N/A				
Disinfectant / Detergent used:					
Cleaning used:	☐ Automated Washer Disinfector ☐ Manual Cleaning				
Sterilization Method:					
Temperature:	°C °F	**Exposure Time:**	min	**Dry time:**	min

SIMPLANT GUIDE AND MGUIDE

Patient Harm due to Failing Product:	☐ A neighboring tooth has been damaged or hit by an implant ☐ The implant fenestrated the cortical wall ☐ A nerve was hit		
Implant transfer for implant(s) position:	☐ Too deep	☐ Too shallow	☐ Too mesial
	☐ Too distal	☐ Too buccal	☐ Too lingual
Guide broke:	☐ During shipment	☐ Before surgery	☐ During surgery
Bad fit:	☐ Only in patient's mouth	☐ Both on model and in patient's mouth	
Other:	☐ Drill protocol issue	☐ Tooth extraction	☐ Wrong supporting surface
	☐ Missing/incorrect tube(s)		☐ Communication issue
	☐ Special design not followed		
Sterilization Method:			

Temperature:	°C °F	**Exposure Time:**	min	**Dry time:**	min

The surgery was performed in accordance with the surgical guidelines (drilling protocol)?	☐ Yes	☐ No
Were there any changes in the patient's mouth between the time of ordering the guide up until surgery was performed?	☐ Yes	☐ No

Note: Describe product failure and patient's current situation.

Please describe the issue as detailed as possible. We need to know if the surgery was performed with or without the guide, was the issue discovered before, during or after the surgery.

Mention specifically which implants (if any) are part of the issue. What is the current situation of the patient? In order to investigate the issue, we need you to be as specific and detailed as possible.

DATUM

Were antibiotics used prior to procedure?	☐ Yes ☐ No:
Was debridement performed prior to the procedure?	☐ Yes ☐ No:
Was pre-surgical rinse or disinfection performed?	☐ Yes ☐ No:
Was an infection present at the time of treatment?	☐ Yes ☐ No:
Did patient follow recommended post-op instructions?	☐ Yes ☐ No:

Procedure performed? Mark the relevant boxes below.

Socket Graft:	☐ Loss of material ☐ Infection ☐ Incomplete fill ☐ Socket cleaned ☐ Socket disinfected ☐ Decortication ☐ Flap created ☐ Membrane used ☐ Sutures placed
Ridge Augmentation:	☐ Loss of material ☐ Flap opening ☐ Infection ☐ Primary coverage ☐ Flap relaxed ☐ Releasing incisions ☐ Material moistened ☐ Material expanded pre-closure ☐ Suture type used
Immediate Implant:	☐ Loss of material ☐ Flap opening ☐ Infection ☐ Site contaminated ☐ Exposed implant ☐ Exposed membrane ☐ Implant stable in native bone ☐ Method to fixate membrane
Sinus Elevation / Augmentation:	☐ Loss of material ☐ Flap opening ☐ Infection ☐ Sinus perforation ☐ Particulate graft ☐ Exposed membrane ☐ Healing period: months
Perio/regeneration procedure:	☐ Loss of material ☐ Flap opening ☐ Infection ☐ Roof surface scale EDTA applied ☐ Particulate graft ☐ Level of post-op ☐ Plaque control

IMPORTANT: **FORM SHALL BE RETURNED WITHIN 1 MONTH OF PRODUCT FAILURE**

- Customer complaints should be reported as close as possible to the incident's occurrence date.
- Please attach all the devices involved.
- Product must be sterilized and disinfected prior to shipping.
- We are interested in comprehensive investigation of received complaints therefore, submission of completely fulfilled form is kindly appreciated.