FILLABLE MEDICAL COMPLAINT INFORMATION – To be filled-out by complainant
Return address – Datum-complaints@dentsplysirona.com

PART 1:

Contact Information	Complaint reference number (if applicable):	
Name of clinic and or Clinician:	Complaint country origin:	
Phone:	Address:	
e-mail address:	Date of Event:	
Product Information Description: **OSSIX Plus** ☐ **, OSSIX Volumax** ☐ **, OSSIX Bone** ☐ **, OSSIX Agile** ☐ **, OSSIX Graft** ☐		
Number of units:	Lot No.	Expiration Date:
Number of units:	Lot No.	Expiration Date:
Number of units:	Lot No.	Expiration Date:

PART 2:

Event Description					
Procedure date		Device placement date		Remedial action taken	
Patient's age		Patient's gender	Male ☐ / Female ☐		
Patient's health history	Diabetes ☐, smoker ☐, compromised health ☐		Other		
Patient's contributory habits and health conditions	Tobacco use ☐ Alcohol & Drug abuse ☐ Bruxism ☐ Parafunctional habits (pencil etc.) ☐ Hormonal imbalance ☐ Diabetes ☐ Periodontal disease ☐		Other Relevant Medications		
Oral hygiene	very good ☐ Good ☐ Fair ☐ Bad ☐	Weeks after extraction:	immediate ☐ 1-4 ☐ 4-14 ☐ 4-25 ☐ over 25 ☐		

PART 3:

General Procedural Information		Additional information:
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? *Fill in relevant information bellow*

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