Please return item(s) **sterilized** 

Simplant Complaint registry form



## To be filled in by selling location

Selling location: Contact person in Location/ DSD TrackWise Complaint no.: Date of filing complaint:

## Customer/user

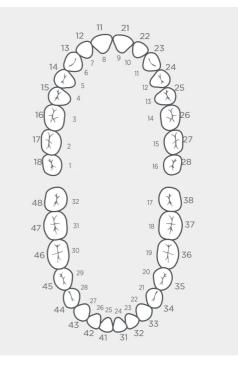
Customer ID:

Name: Address line 1: Address line 2: E-mail: Contact/Phone:

## Failed product

Order ID/ Serial:			
Patient reference:			
Guide type:			
Immediate Smile:			
Wafer:			
Reduction Guide: $\Box$			
Other involved products:			

## Failed implant position(s)



## Patient harm due to failing product

- $\hfill\square$  A neighboring tooth has been damaged or hit by an implant
- □ The implant fenestrated the cortical wall
- $\square$  A nerve was hit



## Classify the problem

🗆 Imp	lant transfer for implant(s) position	on:		
	🗆 Too deep	$\Box$ Too shallow	🗆 Too mesial	
	□ Too distal	□ Too buccal	Too lingual	
🗆 Gui	de broke			
	□ During shipment			
		□ Before surgery	During surgery	
□ Bad	fit			
	$\Box$ Only in patient's mouth			
	$\Box$ Both on model and in patient's mouth			
Bra	Brand and type of the (CB)CT scanner:			
Bra	Brand and type of the optical scanner:			
□ Oth	er			
	Drill protocol issue	□ Tooth extraction	□ Wrong supporting surface	
	□ Missing/incorrect tube(s)	$\Box$ Communication issue	$\Box$ Special design not followed	
Post-op scan data or other images available?				

### Event

#### Date of event:

The sterilization was performed according to the Instructions For Use:

□ Yes □ No

The surgery was performed in accordance to the surgical guidelines (drilling protocol):

Describe product failure and patient's current situation. Please describe the issue as detailed and thorough 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.



## Additional pictures in order to explain product failure:

## Remake request

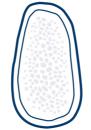
If the patient is scheduled for a new treatment which requires a new Simplant Guide, please fill out the questionnaire below.

#### Surgery type:



Tooth supported guide





Mucosa supported guide

) ) (

Other, Please specify below

Guide type: Simplant Pilot Guide

Simplant Universal Guide



Bone supported guide

Other, Please specify below

Specific remarks regarding the remake:

# Versandetikett

Absender	Bitte	
	ausreichend	
	frankieren	
	Dentsply Sirona Deutschland GmbH	
	Rücksendung Reklamation	
	Fabrikstr. 39	
	64625 Bensheim	

Dentsply Sirona