

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

Your personal data will be processed for product complaint management. For more information on Dentsply Sirona's processing of your personal data, please refer to our Privacy Policy at www.dentsplysirona.com/privacy.

- Endodontics:**
- Root Canal Reciprocating Endo Solution, and
 - Continuous Rotating Solution (e.g files, drills, burs, etc.)
 - Irrigation and activation
 - Obturation instruments and obturators
 - Paper points, Gutta percha points and verifiers
 - Manual files
 - Ultrasonic tips, X-Tips
 - Dental cement
 - Lubricants
 - Hand Instruments
- (e.g. WaveOne Gold, Reciproc Blue, ProTaper Ultimate, TruNatomy, sealer, etc...)

- Orthodontics:**
- Clear Aligners,
 - Interproximal Reduction,
 - Appliance Fabrication,
 - Patient Care & Records
- (e.g. SureSmile, Space File, Essix Plastic, Druformat Scan, retainer Brite, Sonic Cleaner...)

- Restorative:**
- Restorative Materials
 - Matrix Systems,
 - Adhesives,
 - Universal Composites
 - Impression Materials
 - Crown and Bridge material
- (e.g. Palodent, Prime&Bond active, SDR Plus, Esthet-X Flow, Core-X Flow, Ceram.x Spectra ST, SmartLite Pro, Enhance...)

- Pharma:**
- 4% Articadent Dental with adrenaline
 - 4% Astracaine dental with epinephrine
 - Alphacaine N and SP
 - Anestadent 4% and 1:100000
 - 2% Xylocaine Dental with adrenaline
 - 2% Xylocaine Dental with epinephrine
 - Xylocaine 2% with adrenaline
 - Xyloplyin Dental Adrenaline
 - Xylocain Dental Adrenaline
 - 3% Polocaine Dental
 - Carbocain Dental
 - 3% Citanest Dental with Octapressin
 - Citanest Dental Octapressin
 - 4% Citanest Forte Dental with epinephrine 1:200000
 - 4% Citanest Plain Dental
 - Oraqix

FORM NO	9000-CFM-15-006e	REVISION	3	EFFECTIVE DATE	19-Sep-2026
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COMPLAINT FORM – CONSUMABLE / ORTHO / PHARMA

Page 2/5

CUSTOMER INFORMATION			
Customer ID: <i>(If applicable)</i>		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: <i>(if applicable)</i>			

NOTE: DATA privacy is applicable per country laws/regulations

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:		Patient/Order ref: <i>(For custom made products)</i>	
Product name / Product description:		Catalog/Reference/SKU number:	
Lot/Serial number or UDI:		Expiration date of product:	/ / <i>(day / month / year)</i>
Order ID number:			
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:	/ / <i>(day / month / year)</i>

FORM NO	9000-CFM-15-006e	REVISION	3	EFFECTIVE DATE	19-Sep-2026
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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:

For 'Describe any clinical impact, describe e.g., file breakage impact, open bite, TMJ diagnosis etc.. Note: add details in the patient information section.

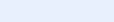
Describe any Clinical impact:

PATIENT			
Patient Identifier: <i>NOTE: <u>do not</u> include the name of the patient</i>		Sex: ☐ Female ☐ Male ☐ Prefer not to say	
Age at time of Event:		Pregnant: <i>If yes, for Pharma, please include additional Pharma pregnancy form</i>	☐ Yes ☐ No
Oral Hygiene:	☐ excellent ☐ fair ☐ poor		
Medical History/Habits:	☐ Smoker ☐ Diabetic ☐ Bruxer ☐ Alcohol/drug abuse ☐ Periodontitis ☐ Osteoporosis ☐ Blood Coagulation Disorder ☐ Hormonal imbalance ☐ Other, please specify:		
Any medications: <i>(both prescription and OTC/herbal supplements)</i>			
Patient/User [status/event] outcome:	☐ Additional treatment ☐ Recovered ☐ No injury ☐ Hospitalized ☐ Death ☐ Other:		

FORM NO	9000-CFM-15-006e	REVISION	3	EFFECTIVE DATE	19-Sep-2026
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Provide details of additional required treatment:	
Was there an allergic reaction perceived to be in connection to the treatment or procedure? <i>(if yes, please thoroughly describe)</i>	☐ Yes ☐ No
Describe allergic reaction (if yes above): 	

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

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

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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.

FORM NO	9000-CFM-15-006e	REVISION	3	EFFECTIVE DATE	19-Sep-2026
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Specific sections:

Please fill in the relevant section if your product belongs to the product group Endodontics or Ortho.

ENDODONTICS

After how many usages did the product break/deteriorate/damage?	☐ 1 ☐ 2 - 10 ☐ More than 10
What motor was used? <i>If other, please specify</i>	☐ VDW.Gold ☐ VDW.Silver ☐ X-Smart ☐ X-Smart Plus ☐ X-Smart Pro ☐ X-Smart Pro+ ☐ Other:
When did the file break?	☐ On the first pass ☐ On the second pass ☐ More than two passes, please specify:
Was the canal filled with or without the broken piece of the file?	☐ With ☐ Without
Are there any plans to remove the broken section, if the broken section is still in the patients' tooth?	☐ Yes ☐ No
If Apex locator faulty:, apex reported by locator:	☐ Before the apex ☐ After the apex (risk of apical overshoot)

ORTHO

Product Treatment start date:	/ / (day / month / year)
Which stage (step number, Lower or Upper part)	
Were there any changes in the patient's mouth between scans and initial treatment? <i>(if yes, please specify)</i> <i>Changes such as interproximal movements for fit porpoises or any other adjustments to the patient's teeth</i>	☐ Yes: ☐ No
Compliance of the wearing time:	

FORM NO	9000-CFM-15-006e	REVISION	3	EFFECTIVE DATE	19-Sep-2026
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