TRATE

DRILL / INSTRUMENT COMPLAINT & FEEDBACK FORM

Filled by Reporter:

Reporter / Complainant Information

Field	Details
Reporter name	
Clinic name	
Address	
Contact details	
Date of report	

Device identification

Field	Details
Device REF	
Batch No.	
Number of uses	
Sterization status at use	• Sterile • Reprocessed

Event / complaint description

Field	Details
Date of event	
Procedure type	• Single unit • Multiple units
Anatomical location	• Mandible • Maxilla
Event Category	• Breakage • Deformation • Loss of cutting efficiency • Overheating • Corrosion • Connection instability • Irrigation problem • Packaging issue • Other (specify):
Severity of Clinical Impact	• No patient impact • Minor impact • Moderate impact • Serious impact • Device malfunction without harm
Was implant placement completed?	• Yes • No

Initial reported evaluation

Question	Yes / No / N/a	Comments
Was the drill used according to IFU and surgical protocol?		

Any visible defects before use?		
Was irrigation used?		
Was torque within recommended range?		
Any patient-related factors contributing?		

Filled by Manufacturer:

Manufacturer Internal Investigation

Field	Details
Received date	
Information nature	• Complaint • Feedback
Sample returned?	• Yes • No
Visual / Dimensional Inspection Results	
Root Cause	
Corrective / Preventive Action (CAPA No.)	
Risk Assessment Update Required?	• Yes • No
Reportable Incident?	
Closure date	

Feedback to reporter

Action	Date	Responsible
Investigation result communicated		
Acknowledgement sent		

Trend and PMS Integration

Field	Details
Classification of Event	• Drill-related mechanical failure • Performance degradation • Reprocessing issue • Other:
Added to PMS Database?	• Yes • No
Included in PMCF Data Analysis?	• Yes • No
Link to PMS/PMCF Report Section	

Signatures

Role / name	Signature / date
Complaint Handler	
QA/RA Reviewer	

Final Approver	