Feedback Form

This form is used for an evaluation of customer feedback.
The following table shall be used to document the customer feedback. The section 1) – 4) describes topics concerned which are categorized as customer complaint. Section 5) shall be used to describe a feedback that does not address a topic which is mentioned under 1) until 4).
The definition of a customer complaint is stated within SOP Complaint handling.

Please mark only one of the following topics which describe your feedback.
If you choose one of the (1-4), please complete the complaint form (beginning at page 2)

The feedback describes		
1) ☐ Product failure	➡	**SOP Complaint handling**
2) ☐ Handling issue/User error		
3) ☐ Packaging problem		
4) ☐ Labelling issue		
If you have another feedback that does not match with one of the above mentioned topics, please complete only the following section as appropriate and leave the following pages blank:		
5) ☐ Others: **Description of feedback:** Please include reference number and/or product details (Item no., lot no., expiry date etc.) if your feedback is related to a particular product	➡	**SOP PMS**

Customer feedback will be forwarded to person/department concerned.

If your feedback describes a customer complaint, please complete the following sheet accordingly.

Complaint Form for COLTENE Products (Details of complaint: section (C))–

Including information for Medical Device Incident Reports in case of an adverse events (or potential ones) – Details of an adverse event: section (B) An adverse event is any undesirable experience associated with the use of a medical product in a patient/user. The event is serious and should be reported to authorities when the patient outcome is: death, life-threatening, serious injury, hospitalization (initial or prolonged), disability or permanent damage, required intervention to prevent permanent impairment or damage Or the adverse event is/could be hazardous for public health	☐ YES ☐ NO
Complaint file No.: *(Filled in by COLTENE Customer Center)*	
Date of receiving complaint: *(when COLTENE got aware o the complaint; filled in by COLTENE Customer Center)*	

(A) The following three questions must be answered for each complaint. **1st assumption of risk evaluation in case of a potential risk for patient/user or third party or an adverse event**		
Does the complaint state (or imply that) the event resulted in death, serious injury or serious deterioration in the health of patient/user or third party?	☐ YES	☐ NO
Does the complaint state (or imply that) there was or could have been a risk of death, serious injury or serious deterioration in the health of patient/user or third party?	☐ YES	☐ NO
Does the complaint state (or imply that) the product failed to perform in accordance with its intended instruction for use, leading to a delay in treatment which could describe a risk of death, serious injury or serious deterioration in the health of patient/user or third party?	☐ YES	☐ NO

If one of these questions is answered with yes the complaint is potentially reportable and therefore the report must be filled out and forwarded immediately to one of the corresponding COLTENE Customer Center!
If all questions answered with “no”, please go further to section (C)

(B) Following questions must be answered only in case of an adverse event (not potential one):	
What kind of person is injured?	☐ patient ☐ dentist ☐ technician ☐ dentist’s assistant ☐ others :
Which kind of injury?	☐ minor injury ☐ serious injury ☐ others:
Please state details to medical treatment, name of doctor, medication:	

Please complete and return this sheet (incl. a photo of complained product) to the corresponding COLTENE Customer Center!

(C) 1) Complaint reported					**When?**
By:	☐ dentist	☐ technician	☐ dealer	☐ others	**Date of complaint:** *(when issue occurred)*
	Describe others:				
Via:	☐ phone call	☐ fax	☐ e-mail	☐ visit on site	
	☐ Others:	Describe others:			
Data of complainant					

2) Dentist / Technician concerned	**3) Dealer concerned**
Name and Address:	**Name and Address:**
Phone No.:	**Phone No.:**
Fax No.:	**Fax No.:**
E-mail	**E-mail**

4) Product details			
Article no.:		**Product name:**	
Expiry date:		**Quantity:**	
LOT/serial no.:		**Others:**	

5) Can the product be returned to Coltène/Whaledent AG for evaluation?	
☐ YES	If yes, please wait for further instructions of COLTENE customer center.
☐ NO	Reason:

6) Replacement?					
☐ YES	☐ Sent to: ☐ dentist	☐ technician	☐ dealer	☐ Others:	
☐ NO	Reason:				

7) Further details of complaint
Background information to the application:
Possible reasons for malfunctions?
Precise description of application / treatment:
Application of further products / pharmaceuticals during treatment? ☐ YES ☐ NO If yes: product name, manufacturer
Is the user experienced with this particular Coltène product, or was this a first time user? Is the user experienced with similar products? Which brands and products?
Others/Comments:
Date & Name, signature: