COLTENE

URGENT: MEDICAL DEVICE RECALL

Affected Device:

TENAX FIBER TRANS Translucent Esthetic Post System p/n TFT1

September 18, 2026

Dear Valued Coltene/Whaledent, Inc. Customer,

The purpose of this letter is to advise you that Coltene/Whaledent, Inc. has identified three batches of the **TENAX FIBER TRANS Translucent Esthetic Post System p/n TFT1** that have been sold to markets without appropriate marketing authorization. There are no concerns related to safety or effectiveness as this product has marketing authorization in other markets. Coltene/Whaledent, Inc. is voluntarily recalling specific batches of the **TENAX FIBER TRANS Translucent Esthetic Post System p/n TFT1**. This voluntary recall affects only the batches listed below.

- Batch P77755
- Batch N81918
- Batch N73767

Reason for the Voluntary Recall:

Three batches of the **TENAX FIBER TRANS Translucent Esthetic Post System** were identified to have inadvertently shipped to markets for which they were not intended.

There are no safety concerns to the patient or user as this product is actively being sold into other markets.

This issue affects the specific batches (see above) of **TENAX FIBER TRANS Translucent Esthetic Post System p/n TFT1** only.

Risk to Health and Safety:

There is no risk to health and safety related to this voluntary recall.

Actions to be taken by the Customer / User:

We have sent this notification letter to you as our records indicate that you are a customer that has received at least one of the affected batches of the **TENAX FIBER TRANS Translucent Esthetic Post System**, **p/n TFT1**.

You may return any unused product and we will replace your product at no cost. If you have already used the product, please inform us of such.

Corrective actions have already been implemented to ensure further supply of **TENAX FIBER TRANS Translucent Esthetic Post System**, **p/n TFT1** are shipped to the appropriate markets.

Please acknowledge the receipt of this notification by completing the return response form. Please return the completed form by either of the following means:

- Email: Liza Bruk@coltene.com
- Mail: Coltène/Whaledent, Inc.
  235 Ascot Parkway
  Cuyahoga Falls, OH 44223 USA

If you should have additional questions, please contact:

Liza Bruk
Lead Regulatory Affairs Specialist
Coltene/Whaledent, Inc.
235 Ascot Parkway
Cuyahoga Falls, OH 44223 USA
Liza.Bruk@coltene.com

We appreciate your cooperation and we recognize the inconvenience this may have caused you and your colleagues, Thank you for your support in this important matter.

Sincerely,



MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form
Response is Required

Customer Information:
Contact name: _____
Company: _____
Address Line 1: _____
Address Line 2: _____
Phone number: _____

- **TENAX FIBER TRANS Translucent Esthetic Post System, p/n TFT1**

I have read and understand the recall instructions provided in the September 18, 2026 letter. Yes ☐ No☐

Any adverse events associated with recalled product? Yes ☐ No ☐
If yes, please explain:
_____
_____
_____

Affected Product Information: Include information that is applicable for affected product.

Product Names, Unique Device Identifier	Manufacturer's Product Number / Catalog Number	Lot/Serial Number	Quantity in inventory	Quantity Used	Quantity returned
TENAX FIBER TRANS Translucent Esthetic Post System 00840016201660	TFT1	P77755			
		N81918			
		N73767			

Return Response/Comments:

I have identified and notified my customers that were shipped or may have been shipped this product by:

(specify date and method of notification)

Questions: (when applicable)

☐ Please have Customer Service contact me.

Signature of Receipt _____ __

Date_____

Name/Title	
Telephone	
Email address	

PLEASE MAIL, FAX, OR EMAIL COMPLETED RESPONSE FORM and RETURNED PRODUCT TO:

Coltène/Whaledent, Inc.
Attn: Liza Bruk
235 Ascot Parkway
Cuyahoga Falls, OH 44223 USA
Phone: 330-916-8904
www.coltene.com
Liza.Bruk@coltene.com

If you are located outside of North America, contact the above email for instructions on where to send returned product.