COLTENE

URGENT: MEDICAL DEVICE RECALL

Affected Devices:

HYGENIC® Dental Dam Forceps p/n H01262

May have been sold as part of the following products:

HYGENIC Simple Dam Kit™, p/n 60019066

HYGENIC Winged Fiesta Kit™, p/n H02778

HYGENIC Wingless Fiesta Kit™, p/n H02790

June 2, 2020

Dear Valued Coltene/Whaledent, Inc. Customer,

The purpose of this letter is to advise you that Coltene/Whaledent, Inc. has identified multiple batches of the **HYGENIC Dental Dam Forceps p/n H01262** that do not meet specification and is voluntarily recalling specific batches of the **HYGENIC Dental Dam Forceps p/n H01262**. This voluntary recall affects only the batches listed below.

Forceps batches (H01262)	Simple Dam Kit (60019066)	Winged (H02778)	Wingless (H02790)
J16743	J73571	J38282	J74546
J16745		J28715	J74184
J29784		J24868	
J31289		J28716	
J33607		J33647	
J44177		J43944	
J44178		J50980	
J44840		J47108	
J47109		J57802	
J47110		J57061	
J49167		J67133	
J67132		J74174	
J73572		J68563	
J73785		J72691	
J74711			

If you received one of the affected batches, please check the laser marked batch number on the forceps. If the laser marked batch number directly on the forceps matches one of the number listed below, you should return the forceps.

1903	1909	1920	1928
1904	1910	1921	1930
1906	1911	1923	1934
1907	1915	1927	1940

Reason for the Voluntary Recall:

Multiple batches of the HYGENIC Dental Dam Forceps were identified to have a pin size larger than acceptable. This larger pin size may make it difficult for the forceps to fit appropriately with the HYGENIC branded or Fiesta branded dental dam clamps.

There are no safety concerns to the patient or user as the larger sized pins on the forceps just render the forceps unusable.

This issue affects the specific batches (see table above) of HYGENIC Dental Dam Forceps p/n H01262 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 HYGENIC Dental Dam Forceps, p/n H01262 or one of the identified kits. If you are located in North America (USA or Canada) please return the product to Coltene/Whaledent, Inc. at the address below. If you are located outside of the North America please return your product to the dealer that sold you the product.

We ask that you 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 HYGENIC Dental Dam Forceps, p/n H01262 is manufactured properly.

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

Product Information:

Forceps batches (H01262)	Simple Dam Kit (60019066)	Winged (H02778)	Wingless (H02790)
J16743	J73571	J38282	J74546
J16745		J28715	J74184
J29784		J24868	
J31289		J28716	
J33607		J33647	
J44177		J43944	
J44178		J50980	
J44840		J47108	
J47109		J57802	
J47110		J57061	
J49167		J67133	
J67132		J74174	
J73572		J68563	
J73785		J72691	
J74711			

Laser marked batch number directly on the forceps:

1903	1909	1920	1928
1904	1910	1921	1930
1906	1911	1923	1934
1907	1915	1927	1940

If you should have additional questions, please contact:

Tricia Cregger, Ph.D., RAC, CBA
Director of Regulatory / R&D
Coltene/Whaledent, Inc.
235 Ascot Parkway
Cuyahoga Falls, OH 44223 USA
Tricia.Cregger@coltene.com
Phone: 330-916-8817
Fax: 330-916-7093

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,

Tricia Cregger

Tricia Cregger, Ph.D.
Director of Regulatory/R&D
Coltene/Whaledent, Inc.

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: _____

- **HYGENIC Dental Dam Forceps, p/n H01262**
- **HYGENIC Simple Dam Kit, p/n 60019066**
- **HYGENIC Winged Fiesta Kit, p/n H02778**
- **HYGENIC Wingless Fiesta Kit, p/n H02790**

I have read and understand the recall instructions provided in the June 2, 2020 letter. Yes ☐ No☐

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

Was this device implanted? (If yes, please specify the implant dates, the quantities implanted, and provide available tracking information).

Affected Product Information: Include information that is applicable for affected product. Ensure laser marked batch number matches one of the 4-digit numbers above before returning.

Affected Product Information Table						
Product Names, Unique Device Identifier	Manufacturer's Product Number/Catalog Number	Lot/Serial Number	Batch number laser marked on forceps	Quantity in inventory	Quantity Used	Quantity returned
HYGENIC Dental Dam Forceps D661H012620	H01262	J16743				
		J16745				
		J29784				
		J31289				
		J36607				
		J44177				
		J44178				
		J44840				
		J47109				
		J47110				
		J49167				

		J67132				
		J73572				
		J73785				
		J74711				
HYGENIC Simple Dam Kit D661600190660	60019066	J73571				
HYGENIC Winged Fiesta Kit D661H027780	H02778	J38282				
		J28715				
		J24868				
		J28716				
		J33647				
		J43944				
		J50980				
		J47108				
		J57802				
		J57061				
		J67133				
		J74174				
		J68563				
		J72691				
HYGENIC Wingless Fiesta Kit D661H027900	H02790	J74546				
		J74184				

Return Response/Comments:

For Distributors:
I have checked my stock and have quarantined inventory consisting of _____ <units, cases, etc.>.

I have identified and notified my customers that were shipped or may have been shipped this product by (***specify date and method of notification***), the number of affected customers are (***specify number of customers who received affected product***);
<or>
Attached is a list of customers who received/may have received this product. Please notify my customers.

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: Tricia Cregger
235 Ascot Parkway
Cuyahoga Falls, OH 44223 USA
Phone: 330-916-8904
www.coltene.com
tricia.cregger@coltene.com

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