Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

02 AUG 2021

FDA ADVISORY
No. 2021-1898

TO: **ALL CONCERNED HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

SUBJECT: **Completion of the Voluntary Product Recall of HYGENIC® Dental Dam Forceps p/n H01262**

This is to inform all concerned healthcare professionals and establishments that the Voluntary Recall of affected batches of HYGENIC® Dental Dam Forceps p/n H01262 that may have been sold as part of Hygenic Simple Dam Kit™, p/n 60019066, Hygenic Winged Fiesta Kit™, p/n H02778 and Hygenic Wingless Fiesta Kit™, p/n H02790, manufactured by Coltene/Whaledent, Inc. and imported by Dent1st Corp. as shown in the table below is completed and hereby closed by the Food and Drug Administration (FDA).

Forceps Batches (H01262)	Simple Dam Kit (60019066)	Winged (H02778)	Wingless (H02790)
J16743	J73571	J38382	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			

As stated in the FDA Advisory No. 2020-1808 dated 05 October 2020, Dent1st Corp. has conducted the voluntary recall of the aforementioned product due to identified multiple batches of the said products have a pin size larger than acceptable size. 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.

After due and thorough evaluation of the submitted documents by Dent1st Corp., FDA has determined that reasonable efforts have been made to recall and properly returned to the source country the affected product batches in accordance with FDA Circular No. 2016-012, known as the Guidelines on Product Recall.

The issuance of this advisory shall not in any manner preclude this Office from issuing subsequent orders it may deem necessary and appropriate, should there be subsequent findings of any violation of existing FDA laws, rules and regulations.

All FDA Regional Field Offices and Regulatory Enforcement Units in coordination with law enforcement agencies and Local Government Units are requested to monitor and seize the cited product lots if still found available in the market.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health and Research through e-mail at cdrrhr-prsdd@fda.gov.ph, or call (02) 8857-1900 local 8301.

Dissemination of this advisory to all concerned is hereby requested

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Director General

DTN: 20200610074911 / 20200616123352