Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2020-1808

05 OCT 2020

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

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

The Food and Drug Administration (FDA) warns all healthcare professionals and establishments on 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. The following batches are affected by this recall:

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			

Table 1. Affected batches of HYGENIC® Dental Dam Forceps p/n H01262

All concerned healthcare professionals and establishments are advised to check the laser marked batch number on the forceps. If the laser marked batch number on the forceps matches one of the number listed below, the said forceps must be returned to Dent1st Corp.

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

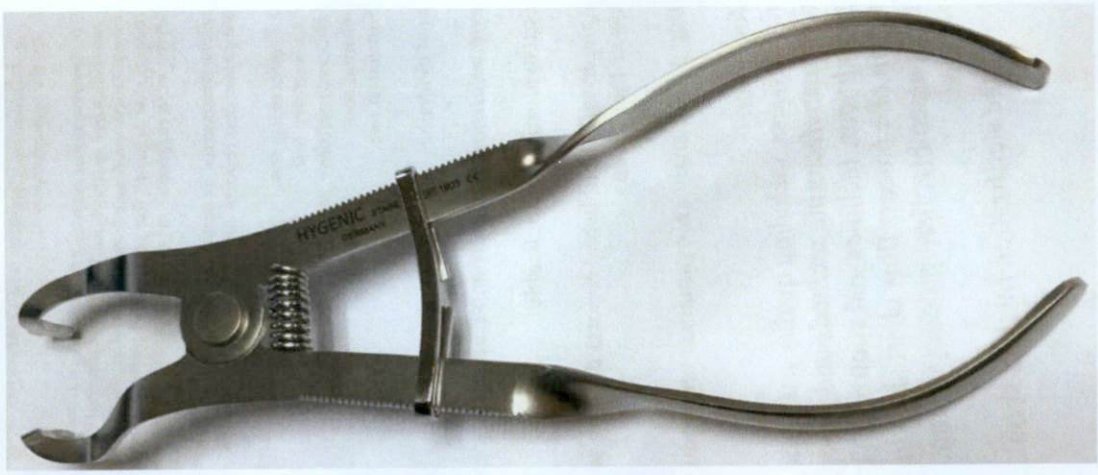

Figure 1. Photo of the Affected HYGENIC® Dental Dam Forceps p/n H01262

Multiple batches of the abovementioned medical device were identified to have a pin size larger than the 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 render the forceps unusable.

In light of the foregoing, all concerned healthcare professional, establishment, and the general public is warned to discontinue further use, sale, and distribution of the above mentioned medical device.

All FDA Regional Field Offices and Regulatory Enforcement Units, in coordination with law enforcement agencies and Local Government Units, are requested to ensure that product is not sold or made available in the market or areas of jurisdiction.

To report any sale or distribution of unregistered medical device, the online reporting facility, **eReport** can be accessed at **www.fda.gov.ph/ereport**.

Any suspected adverse reaction experienced from the use of the medical device but not limited to the lot numbers stated above should be reported immediately to FDA.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through e-mail at **cdrrhr@fda.gov.ph**, or call **(02) 857-1900 loc. 8301.**

Dissemination of this advisory to all concerned is hereby requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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