

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سِیَاطِنَا حَمَانَا
وَزَارَةُ الصِّحَّةِ
وَالرَّيَاةِ الْعَامَّةِ لِلصِّدْقِ
وَالرَّقَابَةِ الدَّوَلِيَّةِ
مَسْقَط

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)

Director General of Engineering Affairs, MOH

Director General of Royal Hospital

Director General of Khoula Hospital

Director General of Medical Supplies (MOH)

Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)

Hospital Director (Al Nahda Hospital)

Hospital Director (Al Massara Hospital)

The Head of Medical Services in SQU Hospital

The Head of Medical Services in Royal Oman Police

The Head of Medical Services in Ministry of Defence

The Head of Medical Services in The Diwan

The Head of Medical Services in The Sultan's Special Force

The Head of Medical Services in Internal Security Services

The Head of Medical Services in Petroleum Development of Oman

The Head of Medical Services in LNG Oman

ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No. 150... dated 24/08/20... Regarding NCMDR Recall of Hygenic® Dental Dam Forceps p/n H01262. from (mfr: from Coltene Whaledent Inc).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information

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Circular No. 150/2020

04 -1-1442 H

24 -08-2020

Recall of Hygenic® Dental Dam Forceps from Coltene Whaledent Inc.

Source	NCMDR- National Centre Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=8&rid=15299
Product	Hygenic® Dental Dam Forceps.
Description	Dental dressing forceps, reusable.
Manufacturer	Coltene Whaledent Inc.
The affected products	See attached FSN
Reason	Multiple batches of the Hygenic Dental Dam Forceps were identified to have a pin size larger than acceptable.
Action	1. Return the affected product and any unused product. A replacement will be provided at no cost. 2. Contact the local agent for remedial action.
Product image	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control contact E-mail: Med-device@moh.gov.om



Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL


- Home
- Published FSNs/Recalls
- About NCMDR
- Contact Us
- FAQ
- Login

Swissmedic Recall

Reference Number: mdprc 011 08 20 000

[Back](#)

Date submitted: 8/10/2020

Manufacturer:	Coltene Whaledent Inc.
Device Type:	HYGENIC® Dental Dam Forceps p/n H01262
Description:	Dental dressing forceps, reusable
Medical Device Identifier:	See attached FSN
Reason of Field Safety Corrective Action:	Multiple batches of the HYGENIC Dental Dam Forceps were identified to have a pin size larger than acceptable.
Remedy Action:	Return The affected product and any unused product. A replacement will be provided at no cost.
Athorized Representative/Importer/Distributor:	Asnan Medical Services
Report Source:	Swissmedic
Source Ref. Number:	Vk_20200609_01
SFDA Comments:	SFDA urges all hospitals that have devices subjected to recall, to contact the company.
Attachments:	 Vk_20200609_01-EN-1 (Coltene-Whaledent Inc).pdf

[View History](#)

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			