

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سلطنة عمان
وزارة الصحة
الديرة العامة للصحة
والرعاية الدوائية
مسقط

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. 203 dated 28/10/20 Regarding NCMDR Recall of Sterile hypodermic / blunt fill needle – MEDOJECT from (mfr: Chirana T. Injecta, a.s).

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. 203 / 2020

11 -03-1442 H

28 -10-2020

Recall of Sterile hypodermic / blunt fill needle – MEDOJECT from Chirana T. Injecta, a.s

Source	NCMDR- National Centre Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=15395
Product	Sterile hypodermic / blunt fill needle – MEDOJECT.
Description	Injections / Infusions / Transfusions / Dialysis - syringes and cannulas.
Manufacturer	Chirana T. Injecta, a.s.
The affected products	Attached.
Reason	Appearance of black spots after puncture or wiping needles by white paper towel.
Action	1. Identify Device. 2. Quarantine Device. 3. Return Device. 4. 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

Urgent Field Safety Notice (FSN)
Sterile hypodermic needle – MEDOJECT
Sterile blunt fill needle - MEDOJECT

The observation that the needle surface gives black color when touched by white tissue may potentially rise some concerns about safety of medical device by users and patients. In order to eliminate any such concerns, we decided to make a voluntary recall of all 5 affected batches.

1. Information on Affected Devices*	
1	1. Device Type(s)*
.	Sterile hypodermic needle – MEDOJECT, Sterile blunt fill needle - MEDOJECT
1	2. Commercial name(s)
.	Sterile hypodermic needle – MEDOJECT, Sterile blunt fill needle - MEDOJECT
1	3. Unique Device Identifier(s) (UDI-DI)
.	-
1	4. Primary clinical purpose of device(s)*
.	Sterile hypodermic needle MEDOJECT – injection and taking off a blood and other liquids at patients Sterile blunt fill needle MEDOJECT - to be attached to a syringe in order to aspiration fluids from vials or ampules during the preparation of medications
1	5. Device Model/Catalogue/part number(s)*
.	CH21112, CH18112SB, CH18112F, CH15112
1	6. Software version
.	N/A
1	7. Affected serial or lot number range
.	CH21112 (0,8(21G) x40mm) - LOT 180608, 180705 CH18112SB (1,2(18G) x40mm) - LOT 190920 CH18112F (1,2(18G) x40mm) - LOT 200110 CH15112 (1,8(15G) x40mm) - LOT 190920
1	8. Associated devices
.	Within context of the FSCA

2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem*
.	Appearance of black spots after puncture or wiping needles by white paper towel. The observation that the needle surface gives black color when touched by white tissue may potentially rise some concerns about safety of medical device by users and patients. In order to eliminate any such concerns, we decided to make a voluntary recall of all 5 affected batches.
2	2. Hazard giving rise to the FSCA*
.	Based on all gathered information there is no fact that the sterile needles MEDOJECT create any risk to patient and user. Test of In vitro toxicity proved that the surface of the needle is non- toxic and there are no particles of surface black deposit formed in terms of embolism. These needles fully comply to standards EN ISO 7864:2016, EN ISO 9626:2016 and ISO 15510:2014 and are in fact safe for use.
2	3. Probability of problem arising
.	More than 350 million needles sold in the last 5 years. This is the first reported problem of this type for needles.