MHRA Device Safety Information

MDSI (SC) 2102 07 April 2021

Medoject sterile hypodermic and blunt fill needles manufactured by Chirana T. Injecta – discontinue use

This is a copy of web content published by the Medicines & Healthcare products Regulatory Agency on 29 March 2021. The original webpage can be accessed here.

Summary

There is the potential for a black residue to be present on all Medoject hypodermic and blunt fill needles

Background

Some users of these needles have seen a black residue on the surface. The manufacturer issued a Field Safety Notice (FSN) recalling the 5 batches reported.

Further investigation by the MHRA has since revealed that the specific root cause of this issue is unknown, and it may affect all batches of the Medoject hypodermic and blunt fill needles.

Since the FSN was released, the black residue has been identified as amorphous carbon. The information currently available to the manufacturer suggests that the risk of harm to patients is low. There is a large number of alternative devices available on the UK market. Therefore, because the specific root cause of the problem is undetermined, the MHRA is advising the following actions:

Action

Advice for healthcare professionals

1. Identify all Medoject hypodermic and blunt fill needles in your organisation
2. Stop using these needles and dispose of them
3. Share this information with all those who may also have affected products
4. Report any suspected or actual adverse incidents involving these devices through your healthcare institution's local incident reporting system and your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales.
5. If you have any queries about this information, please contact:

   Manufacturer: Chirana T.Injecta Rastislav.Broska@t-injecta.sk +421 910 955 937

Enquiries and further information

Enquiries (and adverse incident reports) in Scotland should be addressed to:

Incident Reporting & Investigation Centre (IRIC)
NHS National Services Scotland
Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB
Tel: 0131 275 7575 Email: nss.iric@nhs.scot

Reporting options are available on the HFS website: How to report an Adverse Incident

Further information about reporting incidents can be found in CEL 43 (2009) or by contacting IRIC at the above address.

Information about medical device safety information produced by the MHRA can be found on the MHRA website here: https://www.gov.uk/drug-device-alerts/medical-device-safety-information-produced-by-the-mhra

Date: 11.09.2020

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

For Attention of*: Distributors and users in the countries where these batches were sold.

Rev 1: September 2018
FSN Ref: 2020-CH-09 FSCA Ref: 2020-CH-09

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)
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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.

2.	4. Predicted risk to patient/users
	Based on all gathered information there is no fact that these 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.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	We received information about incident from customer in Slovenia with following description: “When the puncture site on the sachet of infusion solution is punctured with a needle, a black spot is formed on the puncture site. When the needle is taken out of the plastic tube and the needle is wiped with a paper towel (white), a black mark/trace remains on the tissue.” We declare that Sterile needles Medoject are made, tested and comply with listed standards: EN ISO 7864:2016 - Sterile hypodermic needles for single use, EN ISO 9626:2016 - Stainless steel needle tubing for the manufacture of medical devices and ISO 15510:2014 - Stainless steels - Chemical composition. Cannulas are made of stainless-steel SUS304. The harmless of used materials has been confirmed by complex biocompatibility testing according to EN ISO 10993 standards. During in vitro cytotoxicity testing has been used for extraction medications-containing medium, in addition during most of biocompatibility tests performed acc. to EN ISO 10993 standards was used for sample extraction 0,9% sodium chloride solution (NaCl saline solution) and no interaction with the needle occurred, all tests are compliant. In theory based on literature review the black spots after puncture or wiping by white paper towel could be the: • Iron oxide (Fe3O4) or some other oxides created as a reaction between metal elements in steel and oxygen or aqueous solution like electrolyte (Fe3O4 is harmless to patient, it is used also as intravenous compound for anemia treatment). • Carbon from stainless steel. Higher electrochemical “dissolution” of elements from steel making higher concentration of carbon on the surface. • Other factors not known. We assume that black color can be result of presence of some ferric oxides as the results of the processing of the stainless-steel tubes. The effect may vary, and it is not perfectly controlled. Additionally, to that the following cleaning process efficiency may cause that some deposit remains on the surface as powder or substance layer which may be wiped off mechanically. We selected the worst-case of returned samples of needles in term of the occurrence of black trace on white paper towel after needles wiping - needle 1,2x40mm (CH18112SB), LOT: 190920. These samples were tested on: • In vitro cytotoxicity test in the independent external accredited laboratory according to EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (Test report No. 3/20/129 from 20th July 2020) • particulate contamination: sub-visible particles in accordance with EuPh 2.9.19 (Test protocol No. 561/2020 from 20th August 2020). The tests were showing that such needles are not toxic, and they do not contain the particles of size more than 125µm and contain only small amount of particles of smaller size (2-25µm).
2.	7. Other information relevant to FSCA
	N/A

	3. Type of Action to mitigate the risk*
3.	**1. Action To Be Taken by the User*** ☒ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified.
3.	2. By when should the action be completed? — 31st October 2020
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return) — No
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None - Start with voluntary recall of listed 5 LOTs of needles (from 16th September 2020) - Implementation of batch release quality control test for cleanliness with the procedure of wiping the surface by white tissue. (LOTs produced from 11th September 2020) - Further investigation of manufacturing process to identify the cause of the problem and implement necessary measures to eliminate the cause. (long-term action, starting from 11th September 2020)
3	6. By when should the action be completed? — Specify where critical to patient/end user safety
3.	7. Is the FSN required to be communicated to the patient /lay user? — No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? Choose an item. Choose an item.

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	
4.	3. For Updated FSN, key new information as follows:	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
4	6. Anticipated timescale for follow-up FSN	
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	CHIRANA T.Injecta, a.s.
	b. Address	Nám. Dr. A. Schweitzera 194 Stará Turá, 916 01 Slovakia
	c. Website address	www.t-injecta.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * State Institute for Drug Control, Bratislava, Slovakia	
4.	9. List of attachments/appendices:	
4.	10. Name/Signature	PaedDr. Zdenka Klbečková Regulatory Affairs Manager

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.