Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة 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 52 **dated** 16/3/2023 **Regarding NCMDR recall of InjeTAK Adjustable Tip Needle from (mfr: Laborie Medical Technologies, Corp).**

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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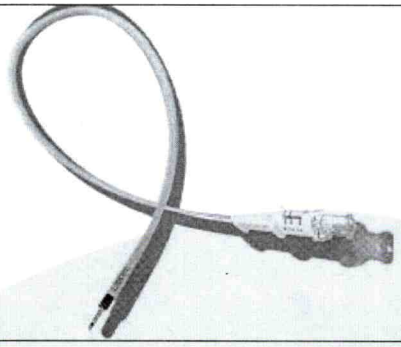
Circular No. 52 **/ 2023**

23 -08-1444 H
16 -02-2023

Recall of injeTAK Adjustable Tip Needle from Laborie Medical Technologies, Corp.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=18466
Product	InjeTAK Adjustable Tip Needle.
Description	Cytoscopy injection needle.
Manufacturer	Laborie Medical Technologies, Corp.
The affected products	Model Numbers: DIS199 and DIS201 Lot Numbers are provided in Table 1 and Table 2 within the attached FSN.
Reason	A potential damaged packaging of the injeTAK needle.
Action	1. Customers are requested to return the product. 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 through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

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URGENT MEDICAL DEVICE RECALL

MEDICAL DEVICE FIELD ACTION -injeTAK Adjustable Tip Needle

(DIS199 and DIS201)

Laborie Medical Technologies Corp.

Lot Numbers are provided in Table 1 and Table 2 within this notification.

February 07, 2023

Re: Customer Notification regarding the potential damaged packaging of the injeTAK needle (DIS199 and DIS201)

Dear Valued Customer,

This is to inform you of a voluntary recall of Laborie Medical Technologies Corp.'s injeTAK Adjustable Tip Needle (DIS199 and DIS201). The purpose of the recall is to address the potential damaged packaging the injeTAK needle is supplied in the lots listed in Table 1 and Table 2. Laborie's records indicate you have received product that is affected by this action.

Laborie became aware of the damaged packaging through the complaint process. A complaint case was issued in response to a customer complaint involving a small hole found in the film of the sterile barrier of the injeTAK needle packaging (DIS201). Further investigation demonstrated that the issue was also present in product inventory (DIS199).

If any adverse effects are experienced with the use of this product, please report it to Laborie Medical Technologies at customercareusa@laborie.com. For Canada, please report it to Laborie Medical Technologies at customercarecanada@laborie.com. It may also be reported to the FDA's MedWatch Adverse Event Reporting program, or your local Regulatory Agency or Competent Authority.

Please provide this information to your facilities. If you have further distributed this product, please identify your customers, and notify them at once of this communication and/or contact Laborie with the contact information so that we can follow-up with the owner of the device.

Laborie Medical Technologies is working diligently to resolve this issue and support our customers to minimize disruption. In the interim, please identify any product in your facilities with the lot numbers listed in Table 1 and Table 2 and complete the response card attached to this Field Notice. The response card contains instructions for return of product to Laborie.

If you have any questions, call Laborie Medical Technologies, at +1-800-522-6743 M-F 8:00 AM- 5:30 PM ET or your Laborie service representative. In accordance with applicable regulation, the FDA has been notified of this Field Action. We regret any inconvenience that this may cause. We do appreciate your patience and understanding as we make efforts to ensure that this product lives up to the high-quality standards expected of all Laborie Medical Technologies products.

Sincerely,

Kellie Stefaniak

Kellie Stefaniak
Sr. Director Global Regulatory Affairs

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Table 1: DIS199 Lot Numbers

Lot Number	
D198592	D211823
D19C094	D211825
D197765	D215573
D19B105	D214446
D19C097	D213099
D19C742	D214448
D201666	D213385
D202622	D216690
D203779	D217602
D204597	D21A632
D198638	D21B406
D204100	D219650
D201620	D221275
D207081	D218636
D205443	D21C155
D205441	D221088
D205445	D222083
D207623	D223087
D20A091	D224083
D20C092	D224386
D208579	D225586
D20C094	D225589
D20A092	D227088
D20B085	D226108
D211094	D228087

Table 2: DIS201 Lot Numbers

Lot Number	
D19B109	D214447
D199716	D211094
D19B106	D214449
D19C789	D215574
D19C788	D216689
D19C098	D219083
D19C743	D217081
D201667	D218089
D203778	D21B407
D202623	D21B081
D204598	D21A082
D205444	D221277
D205440	D21C156
D203783	D221089
D205442	D221276
D204101	D222084
D203780	D224084
D207624	D221087
D207082	D222082
D208580	D223088
D205446	D226109
D20B086	D224387
D20A093	D227089
D20C095	D228088
D20C093	D226107
D211824	D228197
D211095	D229088
D211826	D22A099
D213100	D22A719
D213386	D229086

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URGENT MEDICAL DEVICE RECALL

RESPONSE CARD

Device Name: injeTAK Adjustable Tip Needle

Model Numbers: DIS199 and DIS201

Lot Numbers: Reference Table 1 and Table 2

FACILITY INFORMATION	
Name of Facility	
Address of Facility	
Representative Name	
Representative Title	
Representative Email	

Does your facility have any units of DIS199 and /or DIS201 from any of the lots mentioned in **Table 1** and **Table 2**?

If you do **not** have any of the lots listed below, please check the box below to confirm that there are no affected devices at your facility:

☐ I confirm that there are no affected devices from the above lot at the facility.

(If you have confirmed that there are no devices at your facility, please complete signature section on page 3)

If you do have any of the lots listed below, please follow the below instructions.

1. Customers are requested to return the product to the origin of their shipment. **Include this form with the shipment**, and please send it to:

US, Canada, and Australia Only Customers:

Laborie Medical Technologies Corp.
ATTN: Brad Schwarz
180 International Drive
Portsmouth, NH 03801 USA

Rest of World Customers:

Laborie Medical Technologies Corp.
ATTN: Receiving, injeTAK Returns
Colosseum 25, 7521 PV
Enschede The Netherlands

2. Please indicate what you have on hand and the quantity that will be returned in **Table 1** and **Table 2** below.

Table 1: DIS199 Lot Numbers

Lot Number	Quantity on Hand	Quantity Returned	Lot Number	Quantity on Hand	Quantity Returned
D198592			D211823		
D19C094			D211825		
D197765			D215573		
D19B105			D214446		
D19C097			D213099		
D19C742			D214448		
D201666			D213385		
D202622			D216690		
D203779			D217602		
D204597			D21A632		
D198638			D21B406		
D204100			D219650		
D201620			D221275		
D207081			D218636		
D205443			D21C155		
D205441			D221088		
D205445			D222083		
D207623			D223087		
D20A091			D224083		
D20C092			D224386		
D208579			D225586		
D20C094			D225589		
D20A092			D227088		
D20B085			D226108		
D211094			D228087		

See Table 2 on next page.

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Table 2: DIS201 Lot Numbers

Lot Number	Quantity on Hand	Quantity Returned	Lot Number	Quantity on Hand	Quantity Returned
D19B109			D214447		
D199716			D211094		
D19B106			D214449		
D19C789			D215574		
D19C788			D216689		
D19C098			D219083		
D19C743			D217081		
D201667			D218089		
D203778			D21B407		
D202623			D21B081		
D204598			D21A082		
D205444			D221277		
D205440			D21C156		
D203783			D221089		
D205442			D221276		
D204101			D222084		
D203780			D224084		
D207624			D221087		
D207082			D222082		
D208580			D223088		
D205446			D226109		
D20B086			D224387		
D20A093			D227089		
D20C095			D228088		
D20C093			D226107		
D211824			D228197		
D211095			D229088		
D211826			D22A099		
D213100			D22A719		
D213386			D229086		

For the ease of processing, please provide Original P.O./Invoice #:

_____ _____ _____

Representative Print Name *Representative Signature* *Date*

Please send completed and signed response card to LMTrecalls at LMTrecalls@laborie.com.