Laborie
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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