HUNTLEIGH
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Field Safety Notice

FSN01-22

Disposable Intraoperative Probe

Medical Device Recall

Product to be recalled;

Order Codes: **DIPP10, DISP10***

Product Code: **DIOP8**

Product Lot Numbers: **(10)7842006001**

DIOP8 Probe (Pouch) Label

DIPP10 Box Label

Distribution Date: **30th Sept 2021 to 31st January 2022**

Date Initiated: **31st January 2022**

Dear Customer,

Our sales records indicate that you have purchased and received Huntleigh Dopplex Disposable Intraoperative Probe lot number: **(10)7842006001**.

We are contacting you to provide information regarding a Field Safety Notice resulting in a recall notification released by our company to proactively address an issue reported to Huntleigh in a recently received customer complaint.

We have isolated the issue to one specific lot number **(10)7842006001** where there is a possibility of the probe head becoming loose. Our risk assessments have shown there is a potential hazard

Huntleigh Healthcare Limited
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United Kingdom

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Email: sales@huntleigh-diagnostics.co.uk
www.huntleigh-diagnostics.com

VAT Reg: GB 382 474 630
Registered No: 942245 England & Wales.
Registered Office: ArjoHuntleigh House,
Houghton Hall Business Park, Houghton Regis,
Bedfordshire, LU5 5XF

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related to the problem and as a precaution we are recalling lot **(10)7842006001**. This has resulted from one isolated complaint concerning this device. Please be assured there have been no injuries reported.

Note: This notice applies to the Huntleigh Dopplex Disposable Intraoperative Probe (manufactured lot number (10)7842006001. No other lot numbers are affected by this issue. *The PA8 supplied with the DISP10 is also not affected by this recall, and should be retained.

What to do (distributor/end user);

1. Check current stock of Dopplex Single Use Intraoperative Probe, quarantine any from the affected lot: **(10)7842006001**.
2. Label and bag as DO NOT USE and arrange for safe disposal.
3. Complete the attached declaration and return to Huntleigh, email **steve.monks@arjo.com**
4. Huntleigh will arrange replacement of all disposed product upon receipt of the completed declaration form, as a gesture of goodwill we will also provide additional box of probes (DIPP10).

Huntleigh is taking this issue seriously as customer satisfaction and safety are of primary importance to us. We regret any inconvenience that this Recall may cause, however we greatly appreciate your understanding as we take actions to ensure the safety of our caregivers and patients.

Contact

If you have any further questions or require any further assistance, please contact your regional sales manager or email Huntleigh at **sales@huntleigh-diagnostics.co.uk**

Sincerely,

Simon Larsen
Managing Director

Steve Monks
QRE Director

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Declaration Form

FSN01-22

Disposable Intraoperative Probe

(To be submitted to Huntleigh, email **steve.monks@arjo.com**)

Name:	
Position/Job Title:	
Address:	
Email:	
Tel:	
# of probes placed in quarantine and safely disposed from the affected lot **(10)7842006001**	
# of probes already used from the affected lot **(10)7842006001**	

I declare that:

- I have checked **all** locations for the Dopplex Single Use Intraoperative Probe (DIPP10), and placed in quarantine any from the affected lot **(10)7842006001.**
- Labelled and bagged as DO NOT USE and arranged for their safe disposal.

Name (PRINT):_____

Signature: _____

Date: _____

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