DIGNITANA

URGENT FIELD SAFETY NOTICE

COMMERCIAL NAME: DigniCap®Delta Scalp Cooling System
FSCA-IDENTIFIER: FSCA 2021-00001
TYPE OF ACTION: Labeling Updates and Customer Communication

April 12, 2022

Attention: Infusion room employees utilizing Scalp cooling and/or Distributors

REASON FOR THIS FIELD SAFETY NOTICE:
The purpose of this Field Safety Notice is to advise you that Dignitana is voluntarily issuing two safety updates to the Instructions for Use (IFUs) for the DigniCap Delta® as a result of adverse events occurring in the US. The use of the headband provided in the DigniCap DeltaKit is now required for all patients and instructions for the application of the headband have been added to all IFUs. Additionally, warnings have been added for risk of condensation build up depending on environmental conditions.

DESCRIPTION OF THE PROBLEM:
Serious injuries have occurred or could occur due to the failure mode associated with this Field Safety Notice. Dignitana has reports of four injuries that have led to this Field Safety Notice.

1. Three users received cryogenic burns from improper placement of the headband and improper use of the device without the headband.
2. One incident was reported where condensation built up on the device in a humid environment causing a nurse to slip and fall, fracturing her ankle.

DETAILS ON AFFECTED DEVICE:
Nomenclature System - GMDN 62231- Scalp Cooling System
Commercial/Brand Name - DigniCap®Delta
Catalogue Number - 900-1001
Lot/Serial numbers: All manufactured units A65860-A73244
Manufacturer Website - https://dignitana.com

RISKS TO HEALTH:
Failure to comply with new instructions could result in the following:

1. Failure to use the headband with the cooling wrap could cause cryogenic burn injury to scalp.
2. Failure to properly remove condensation from the outside of the unit can cause condensation to pool around the floor of the device. This could cause a user to slip and fall, causing injury.

How to recognize that the device may cause the above issues:

1. If the headband is not used, a burning sensation could occur and skin could become discolored.
2. If the device is not wiped down properly in a humid environment, condensation may pool around the device.

ACTIONS TO BE TAKEN BY THE CUSTOMER/USER:

1. Immediately start using updated instructions amended in this letter. This is a long term and permanent change.
2. Retrain staff to ensure that the headband is used correctly for every treatment.

3. Retrain staff that any condensation on the device should be wiped down before, during and after use.
4. Amend the appropriate section of the DigniCap User Manual with the corrections included in this letter. An electronic copy of the updated User Manual will beemailed to you by May 1, 2022.
5. For orders placed after May 1, 2022, labeling on Affected Guides detailed below will include corrected IFUs.

TRANSMISSION OF THIS FIELD SAFETY NOTICE

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

AFFECTED GUIDES:

1. The DigniCap Scalp Cooling System User Manual {PN: 0PIDDCD0IM-EN_C / IFU 20190325-06-EN)
2. DigniCap Delta Scalp Cooling Wrap {LAB 20190221-05-EN)
3. DigniCap Delta Small Cooling Wrap {LAB 20200616-01-EN
4. Quick Reference Guide - DigniCap Delta {IFU-20190327-02-EN)
5. The DigniCap Scalp Cooling System Training Guide- Global (TR-20200104-05-EN)
6. The DigniCap Scalp Cooling System Training Guide TR-2019-0801-05-US
7. DigniCap Delta Procedural Expectations- Global {TR-20191028-03-EN)
8. DigniCap Delta Procedural Expectations TR- 20190721-02-US
9. DigniCap Delta Small Wrap Protocol Global{TR-20200728-02-EN)
10. DigniCap Delta Small Wrap Protocol TR-20200714-01-US
11. DigniCap Delta Training Tips Global {TR-20200420-04-EN)
12. DigniCap Delta Training Tips TR-20191202-05-US

Please read the safety updates below carefully. The affected IFUs have been noted next to the update:

- *Headband Instructions*[1]

  Particular attention should be paid to the top of the ear, the forehead and back of the neck. *Patients should* use a headband to prevent direct skin contact with the inner cooling cap.

  Place the headband over the patient's forehead, lower portion of the ears, and nape of neck {around their hairline). Adjustment may be required.

- *Headband Instructions*[2,3,4,5,6,7,8,9,10,11,12]

  Place the headband over the patient's forehead, lower portion of the ears, and nape of neck (around their hairline). Adjustment may be required. *ALLpatients should wear the headband.

- *Warnings*[1]

  Depending on environmental conditions (e.g., high humidity and/or high ambient temperature) users may experience condensation that could potentially accumulate on certain components of the DigniCap Delta such as the connectors and Therapy Hose.

This condensation may transfer to the area around the device potentially creating a "Wet floor" condition which could lead to injury from slipping and/or falling. Wipe down the DigniCap Delta and any wet components as needed at any point in time to avoid hazardous situations

- *Attention*[1]

  ATTENTION: Inspect the DigniCap Delta device for any signs of moisture and wipe down before use or any point thereafter.

- *Condensation /nstructions* [5,6]

  Depending on operating conditions with ambient temperature and humidity, some hospitals may see condensation on the Therapy Hose connectors during or after treatment. Ifthis happens, please wipe with a towel to dry.
  If your hospital experiences high humidity, prior to initiating treatment please check the Therapy Hose and connector for any condensation that has pooled from the previous treatment. Remove any condensation that has occurred with a towel.

AFFECTED PRODUCT

Product and Distribution Information Table					
Product Name	Manufacturer's Product Number/Catalog Number	Lot/Serial Number	Manufacturing/Distribution Dates	Expiration Date (MM/DD/YYYY)	Quantity
DigniCap Delta• Scalp Cooling System	900-1001	All manufactured units A65860-A73244	2019-YTD	N/A	All

CONTACT INFORMATION

If you have any questions, contact Dignitana Monday - Friday, 9:00 AM to 4:00 PM, CST
Phone: +1877-350-2150
Email info@dignitana.com
Website: www.dignicap.com

INSTRUCTIONS FOR ACKNOWLEDGEMENT

Please return the attached acknowledgement form to Dignitana by **May 31, 2022:**
Email: qualityaffairs@dignitana.com
Postal mail: Dignitana, 10925 Estate Lane W-185, Dallas, TX 75238 USA
Dignitana, Traktorgränden 3, 226 60 Lund, Sweden

The Swedish Competent Authority has been notified of this action. Adverse events or quality problems experienced with use ofthis product may be reported using the following options:

1) Complete and submit a report online at https://dignitana.com/contact-us/
2) Report to the Medical Products Agency,
   Instructions for Reporting: https://www.lakemedelsverket.se/en/reporting-adverse-reactions-events-and-incidents/incidents--medical-devices#hmainbodyl
3) Report to the US FDA MedWatch Adverse Event Reporting Program:
   Online: Complete and submit a report at: www.accessdata.fda.gov/scripts/medwatch/
   Regular mail or Fax: Download the form from www.fda.gov/MedWatch/getforms.htm

or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form or submit by fax to 800-332-0178.

We appreciate your ongoing patience and commitment to Dignitana as we continually strive to ensure that The DigniCap Scalp Cooling System best meet the needs of you and your patients.

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Enclosures: 1. Acknowledgement and Response Form
2. User Manual corrections

DIGNITANA

MEDICAL DEVICE FIELD SAFETY NOTICE ACKNOWLEDGEMENT AND RESPONSE FORM

Response is Required

AFFECTED PRODUCT The DigniCap Delta Scalp Cooling System
Lot/Serial numbers: All manufactured units A65860-A73244

CUSTOMER INFORMATION Customer Name _____
Address _____

_____

1. We have read and understand the changes in the attached Medical Device Field Safety Notification.

YES NO_

If NO, please explain: _____

_____

2. We request more information regarding this Medical Device Field Safety Notification.

YES NO_

3. Any adverse events associated with the product?

YES **NO_**

If YES, please explain: _____

_____

Please provide any additional information, if applicable

_____

_____

For Distributors Only- Select one:

__ I have identified my customers that were shipped this product and notified them_____ _
via (select one): ___ Email Postal Mail on date: ___ _

___ Attached is a list of customers who received this product. Please notify my customers.

Signature of Receipt _____

Name: _____
Title: _____
Phone: _____
Email: _____

Return this completed acknowledgement form to Dignitana by May 31, 2022

Email: qualityaffairs@dignitana.com

Postal mail: Dignitana, 10925 Estate Lane W-185, Dallas, TX 75238 USA
Dignitana, Traktorgränden 3, 226 60 Lund, Sweden