Ref : FCA202105

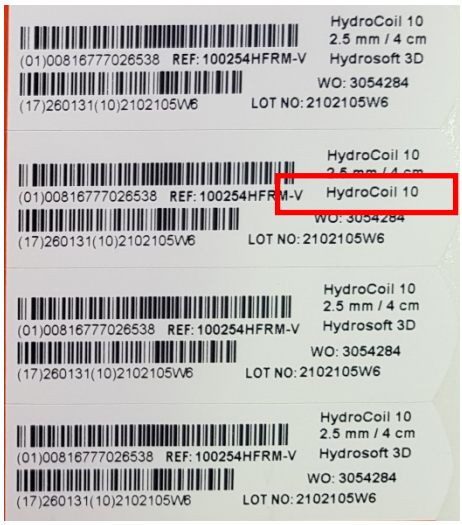
Field Safety Notice

Medical Device Distributor Notification

December 15, 2021

Dear Customer,

MicroVention received notification of a labeling issue concerning the peel-off labels on certain lots of the HydroSoft™ 3D Endovascular Embolization Coil. Specifically, the second of four peel-off labels references the "HydroCoil™ 10" twice, instead of HydroSoft 3D for the second occurence. Since the HydroCoil product group includes HydroSoft 3D, the information on this label is technically correct; however, the typographical error does not specify that the implant is specifically a HydroSoft 3D device. Each device has two sets of four individual peel-off labels, one on the box and one on the pouch. Both sets of the peel-off label has this discrepancy. Please see the image below identifying the printing error:



The second peel-off label repeats the "HydroCoil 10" identification. While this is correct, it is not the level of detail intended. Both sets of peel-off labels have this discrepancy.

MicroVention has determined that there is no patient risk associated with this labeling discrepancy. This typographical error on the printed label does not affect the information displayed when scanning the barcode (the correct HydroSoft 3D information is displayed).
Based on the conclusion that this print error will have no patient impact, no action is required.

Can you please complete and return the **"CUSTOMER ACKNOWLEDGMENT FORM"** form to the attention of Julie Lopez at MVEMEAQARA@microvention.com ?
If your institution has affected inventory and wants to return or exchange it, please contact your Customer Service at xxxxxx .

MicroVention is committed to product improvement through feedback from our customers. We regret any inconvenience that this action may cause, but we appreciate your understanding as we address the label issue and continue to elevate patient safety and customer satisfaction.

Sincerely,

[redacted]

Ref : FCA202105

FIELD SAFETY NOTICE

CUSTOMER ACKNOWLEDGMENT FORM

DISTRIBUTOR NAME: _____

ADDRESS: _____

DISTRIBUTOR CONTACT PHONE #: _____

I have read and understand the recall letter issued by MicroVention Inc. regarding the HydroSoft 3D Endovascular Embolization Coil Products. We have taken the appropriate action to make all personnel aware of this issue and the recommendations provided by the Manufacturer.

Representative Name (Print Name)	Signature	Date

PLEASE EMAIL THE COMPLETED FORM to the attention of Julie Lopez MVEMEAQARA@microvention.com.