May, 2018

Urgent: Medical Device Recall

Model: 66-AC-DS(1.8), MT-DS, MT-DS-01, 70-ZD-MA, 70-ZD-ME, ST-DS-MA, ST-DS-ME, 70-CN-DB, 66-CN-DB, 66-ZD-MD, 66-ZD-MD-01, FC1006, FC8001 and FC8002.

Dear customer:

The purpose of this letter is to advise you that FHC, Inc. is voluntarily recalling our microtargeting™ Depth Stop Adapter, Product Model Number, 66-AC-DS(1.8), UDI numbers 00873263006344, 00873263005149 sold between June 2004 and May 2016.

The product being recalled is also provided as a component of FHC, Inc. system model numbers;

Product Name	Product Number	UDI Number
microTargeting™ Drive System	MT-DS	00873263003527
microTargeting™ Drive System	MT-DS-01	00873263003503
microTargeting™ Drive System	66-ZD-MD	00873263003572
microTargeting™ Drive System	66-ZD-MD-01	00873263003565
microTargeting™ STar™ Drive System (Manual)	ST-DS-MA	00873263004418
microTargeting™ STar™ Drive System (Motorized)	ST-DS-ME	00873263004432
microTargeting™ STar™ Drive System (Manual)	70-ZD-MA	00873263002162
microTargeting™ STar™ Drive System (Motorized)	70-ZD-ME	00873263002155
microTargeting™ Lead Adapter for microTargeting™ Drive	66-CN-DB	00873263004531
microTargeting™ Lead Adapter for STar™ Drive	70-CN-DB	00873263002643
microTargeting™ Drive System Distributed by Medtronic	FC1006	00873263001479
microTargeting™ STar™ Drive System (Manual) Distributed by Medtronic	FC8001	00873263001486, 00873263006351
microTargeting™ STar™ Drive System (Motorized) Distributed by Medtronic	FC8002	00873263006375, 00873263001493

The microTargeting™ Depth Stop is the only component being recalled and **not** the whole system. You are receiving this notification because our records indicate you received the 66-AC-DS(1.8) product or affected system model. Photos of the product are referenced on the follow page.

Reason for the voluntary recall and risk to health: During a DBS lead implant procedure, the FHC Depth Stop Adapter is placed onto the lead to set the desired distance to target. The Depth Stop Adapter then mounts in the Lead

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Measurement Fixture to ensure that the lead is not inserted beyond the targeted depth. The FHC Depth Stop Adapter may cause damage to the lead and stylet when the depth stop screw is over-tightened onto the lead. This damage can manifest as low impedances or a short circuit between one or multiple electrode pairs in the lead, and has resulted in the need to remove and replace the implanted lead intraoperatively or in a follow-up procedure. Recent reports of lead short circuit events have led FHC, Inc. to improve the depth stop design and recall the previous version of this product. There have been no reports of patient death related to this problem.

Actions to be taken: FHC, Inc. Field Representatives will review your inventory and replace effected Depth Stop Adapters you have on hand with an improved design. In the interim, we advise that you do not over-tighten the Depth Stop Adapter screw. If low impedances or a short circuit is found, physicians should replace the lead prior to use and report the issue to FHC, Inc. or your local field rep.

We regret any inconvenience this may have caused you. We are committed to providing you with the highest quality products, services and ongoing support as you care for your patients.

Should you have any further questions regarding this matter you may contact me, by email at kmoeykens@fh-co.com or by telephone at 207-666-5425.

FHC appreciates your cooperation and thanks you for your business.

Sincerely,

Kelly Moeykens
2018.05.10
07:57:40 -04'00'

Kelly Moeykens
Quality System Officer

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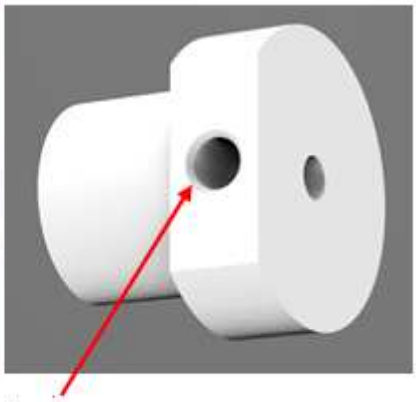
Recalled Depth Stops, 66-AC-DS(1.8):



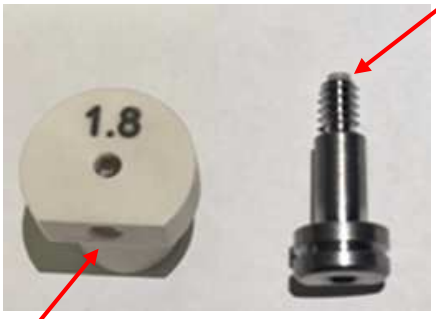
Clear, Nylon Tip

D Shape body with Bevel at thumb screw hole

O Shape body

Replacement Depth Stop, 66-AC-DS(1.8):

Opaque, PEEK Tip



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