

Urgent Field Safety Notice

StimLoc™ Burr Hole Cover

Part Numbers 3387S-40, 3389S-40, 3391S-40, 3550S-01, 924256, DB-5000

Excess Nylon Flash on Specific Lots

Recall

June 2021

Medtronic Reference: FA980

Dear Healthcare Professional,

Medtronic is voluntarily recalling specific lots of the StimLoc™ Burr Hole Cover due to a manufacturing issue resulting in excess nylon flash on the clip. Please review the information contained in this letter, quarantine any affected product (see Attachment A for list of affected lot numbers) in your inventory for return to Medtronic.

Issue Description:

Medtronic has identified that specific lots of the StimLoc clips may have excess nylon molding flash. This issue can prevent the clip from snapping into the StimLoc base, which could allow for lead movement or lead damage. This could potentially result in delivery of therapy to the wrong location, inadequate delivery of therapy, or intracranial hemorrhage. As of May 19, 2021, Medtronic has received 26 complaints related to this issue, two of which reported surgical replacement or revision of the lead or Burr Hole Cover. There have been no reports of intracranial hemorrhage.



Excess flash (red circle)

Patient Management Recommendations:

Previous lead placements with the affected lots where there was successful assembly and fixation with the StimLoc base, clip, and cap do not require additional patient follow-up. If you were able to complete placement, position the lead in the base exit slot, and snap the cap onto the base; the lead will be properly secured as described in the instructions for use (IFU).

As described in the IFU, during any lead placement procedure, avoid significant contact between the lead body and the support clip to prevent changing the position of the lead. As also described in the IFU, ensure the lead body is positioned in the base exit slot before installing the cap to prevent damage to lead. At any time during an implant procedure, if

there is any difficulty with anchoring the lead with kit components, do not use those items, and use a new lead and StimLoc Burr Hole Cover assembly.

Required Actions:

1. Please inform your materials department to identify, segregate, and quarantine unused affected units within their inventory. The list of affected lot numbers is included as Attachment A with this letter.
2. Contact Medtronic to return affected units and schedule replacement(s).

Additional Information:

Medtronic is communicating this information to the appropriate regulatory agencies.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions, please contact your Medtronic Representative at <XXXX>.

Sincerely,

Local / BU Manager

Attachment A:
Affected Lot Numbers

3387S-40 DBS Lead with StimLoc®							
VA21YUS	VA24RVV	VA25SDK	VA26Q2S	VA27X8H	VA2980G	VA29Z9A	VA2DA2Z
VA21ZJU	VA24S65	VA25WK1	VA26XP2	VA27ZRF	VA29814	VA2A5MJ	VA2DA5Y
VA21ZYP	VA24S66	VA2613V	VA26ZFU	VA281L5	VA2985H	VA2AK84	VA2DA9E
VA222L5	VA24SRF	VA261EL	VA275SC	VA2820Y	VA29BSM	VA2APV8	VA2DEKH
VA227E2	VA24UVS	VA263GC	VA275SD	VA282CS	VA29E09	VA2B3PB	VA2DVM9
VA22LDZ	VA24ZFG	VA26460	VA276GS	VA283SF	VA29LP7	VA2B3PN	VA2DVME
VA236DC	VA254MA	VA2696J	VA277EB	VA28C1Z	VA29LPC	VA2B3PQ	VA2DVNX
VA23BWB	VA254MC	VA2696L	VA27JJV	VA28C36	VA29PPY	VA2BFSP	
VA23BXM	VA254MD	VA269LV	VA27MQ3	VA28DVB	VA29S0E	VA2BHV6	
VA23J1U	VA2562G	VA26AGU	VA27RMG	VA28LVR	VA29S0F	VA2CEVY	
VA23J4X	VA257LH	VA26E5P	VA27SW9	VA28NFL	VA29SB3	VA2CPP0	
VA23L21	VA25QDQ	VA26E5R	VA27V4Y	VA28NG1	VA29UNG	VA2CXDR	
VA23S64	VA25RHC	VA26K1N	VA27WDK	VA28SC8	VA29UPA	VA2D9X8	
VA24R3X	VA25S3A	VA26K1R	VA27WDP	VA28XL0	VA29Z98	VA2DA0S	

3389S-40 DBS Lead with StimLoc®							
VA21X0Y	VA24WXJ	VA260NN	VA27QE4	VA28NFM	VA29ZU0	VA2BE8A	VA2CQET
VA21ZJV	VA25101	VA26233	VA27RET	VA28SCE	VA2A3HK	VA2BEXC	VA2CQFM
VA21ZL1	VA259WX	VA2670U	VA27REU	VA28URD	VA2A6K7	VA2BF1G	VA2CQH2
VA227NQ	VA25B79	VA2672S	VA27SWB	VA28URE	VA2ACW4	VA2BFG0	VA2CRKW
VA228PU	VA25HSZ	VA26GGZ	VA27V8S	VA28XHX	VA2ACW5	VA2BHHW	VA2D6WD
VA22C6L	VA25N4Y	VA26GPA	VA27WDE	VA28ZQ0	VA2AD57	VA2BJEH	VA2D71G
VA22KF4	VA25N50	VA26KJ3	VA27ZA2	VA28ZQ2	VA2AD5G	VA2C8BG	VA2D730
VA22MXM	VA25N6D	VA26NWX	VA27ZRE	VA291YL	VA2AH9C	VA2CABX	VA2D739
VA22TDL	VA25RSZ	VA26Q16	VA280V2	VA291YM	VA2AHHR	VA2CBQ0	VA2D73E
VA22V9R	VA25TBA	VA26Q6E	VA283SH	VA2924E	VA2AHNG	VA2CFBH	VA2DAZA
VA22VZB	VA25UBK	VA26R4H	VA2865T	VA2924F	VA2AHNM	VA2CJ4Z	VA2DAZT
VA22Y79	VA25UG1	VA26TK5	VA2893X	VA29LPD	VA2AHT7	VA2CK66	VA2DB2C
VA237AP	VA25VKR	VA26XGF	VA289WG	VA29LUC	VA2AR36	VA2CK8L	VA2DB2L
VA2382J	VA25VQD	VA26ZJV	VA289WH	VA29MUW	VA2B3SB	VA2CLRF	VA2DB2V
VA2382Y	VA25XC7	VA272ZP	VA28DN6	VA29PLU	VA2B3SC	VA2CN0F	VA2DBAU
VA2384E	VA25YHU	VA275D6	VA28E06	VA29PM8	VA2B7G5	VA2CN0H	VA2DUR8
VA239JK	VA25YHW	VA276MJ	VA28KWJ	VA29UB3	VA2BDS1	VA2CN7Z	VA2DUR9
VA23P6D	VA25YR5	VA27E9P	VA28LHR	VA29UPD	VA2BDSE	VA2CN86	VA2DURH
VA23S5Z	VA25ZJ3	VA27JJS	VA28LHU	VA29UPH	VA2BDSX	VA2CN8A	
VA24PD4	VA25ZJ6	VA27K8D	VA28M21	VA29ZES	VA2BE44	VA2CNX0	
VA24RVR	VA25ZUB	VA27NE2	VA28M22	VA29ZM2	VA2BE7W	VA2CNXG	

VA24WXH	VA25ZWB	VA27PDB	VA28M9B	VA29ZSC	VA2BE86	VA2CPPV	
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924256					
StimLoc® Burr Hole Cover					
082202020A	082203820A	082211120A	082228819A	082234520A	082202121A
082207920A	082214120A	082232319A	082235019A		

3350S-01						
Spare Parts Kit for StimLoc® Burr Hole Cover						
082300620	082307020	082307620	082329819	082332919	082335119	082335320

3391S-40					
DBS Lead with StimLoc®					
VA2391V	VA25B91	VA2AD6N	VA2BJWK	VA2DN50	VA2DR23

3389S-28	
DBS Lead with StimLoc®	
VA25K4W	

DB5000	
StimLoc® Support Clips	
082104420	