

**Urgent Field Safety Notice**

**Medtronic Strata II, Delta, and CSF-Flow Control Valves and Shunts**

Variation in Radiopacity

January 2021

Medtronic reference: FA952

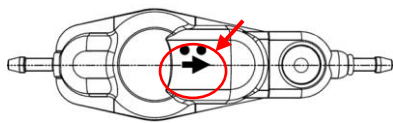
Dear Physician or Healthcare Professional,

The purpose of this letter is to inform you of the potential for variation in radiopaque marking visibility under radiographic imaging for Medtronic adjustable and fixed-pressure valves that are used in the management of hydrocephalus. Reference the attached list for impacted batch information. This issue does not impact the therapeutic pressure performance of these devices, however variation in radiopaque marking visibility post-implant may limit the ability to determine pressure settings and flow direction with radiographic imaging. Alternative methods for determining pressure settings and flow direction are described below.

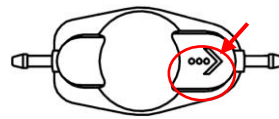
**Background:**

After implanting Medtronic adjustable or fixed-pressure valves for management of hydrocephalus, there may be situations where it is desirable to determine or confirm pressure settings and flow direction. One method for this determination is to utilize radiographic imaging. Medtronic valves contain radiopaque tantalum-impregnated markings that can be viewed under plain radiographic imaging to determine the pressure level and/or current pressure setting of the valve and direction of flow. Until 22 December 2020, Medtronic has received 9 reports regarding inadequate visualization of the radiopaque markers under radiographic imaging. No reports of patient harm have been associated with this issue. Inadequate visualization of the radiopaque markers should not significantly hinder the physician’s ability to manage a patient with an affected product, nor would this impact treatment decisions for symptomatic patients. If the physician is unable to visualize the radiopaque markers, the physician may use other methods (e.g. StrataVarius or Indicator/Locator tool, physical assessment) to obtain the necessary information, or the physician may consider utilizing additional radiographic imaging with contrast to determine the direction of flow.

The below illustrations of Medtronic Strata and fixed-pressure valves depict the location of the radiopaque markings on these devices. The markings will vary based on the type of valve and are described in labeling.

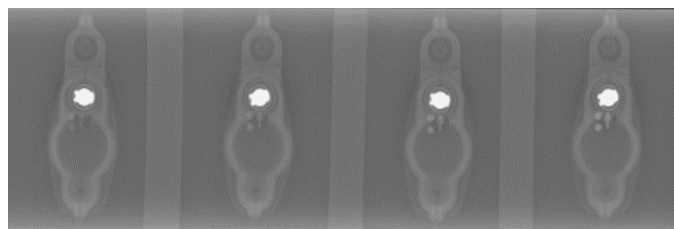


Strata Valve



Fixed – pressure valve

The below images A through D illustrate potential variation in visibility of tantalum-impregnated markings (arrow and dots) under radiographic imaging. Image D shows expected visualization, with reduced visibility in Images A through C.



A

B

C

D

# Medtronic

In response to this issue, Medtronic is working to reduce variation and ensure radiographic visibility of the radiopaque markings. While these efforts are underway, the following information should be considered in the event pressure setting or flow direction markings are not visible under radiographic imaging.

## Determining/Confirming Pressure Settings:

Strata Valves	Medtronic Neurosurgery Strata II valves provide a non-invasive method to address changing patient needs in the management of hydrocephalus. The unique valve design allows the physician to adjust valve pressure or performance level by using the Medtronic Neurosurgery Strata II Adjustment Kit or the StrataVarius Adjustment System.
Delta and CSF-Flow Control Valves	All valves and shunts are accompanied by Patient cards/Wallet cards that are provided to patients to maintain in their records. Refer to these cards as they may provide the surgeon with information regarding pressure level/current pressure setting of the valve, valve type, and manufacturer.

## Determining/Confirming Flow Direction:

Placement that results in incorrect flow direction can present with clinical symptoms within a few hours post-implant of the valve. However, in the unlikely event flow direction is uncertain, radiographic imaging with contrast may be considered, if necessary, for determining flow direction. This imaging procedure may have inherent risks as well, and the decision to proceed is at the physician's clinical discretion.

Strata Valves	Ventricular and peritoneal catheters used with shunts are radiopaque and may help determine the direction of flow of Strata valves based on the overall orientation of the valve in relationship to the catheters (Radiopaque valve rotor must be towards the peritoneal catheter; valve dome must be towards ventricular catheter). If necessary, radiographic imaging with contrast may be performed to determine flow direction of a valve.
Delta and CSF-Flow Control Valves	If necessary, radiographic imaging with contrast may be performed to determine flow direction of a valve.

## Actions:

1. Be aware that radiopaque marker visualization with impacted devices under radiographic imaging may be insufficient to determine the pressure level and/or flow direction. In these situations, alternative methods for this determination should be considered, if deemed necessary per clinical discretion.
2. Share this information with all those who need to be aware within your organization.
3. If desired, radiographic imaging of packaged devices may be conducted pre-operatively to determine marker radiopacity. However, marker visibility of packaged devices under radiographic imaging may not be representative of marker visibility post-implant.

## Additional Information:

Please maintain a copy of this letter for your records. The Competent Authority of your country has been notified of this action.

Medtronic will honor standard returned goods policy for products for credit, and if available, replacement. If you have any questions regarding this communication, please contact your Medtronic representative.

Sincerely,

Ayman Doughan,

Business Manager, Cranial Spine, APS

Model #	Product Description	Strata™	Lot #			
27739	SHUNT 27739 STRATA NSC SNAP SML 120CM	0219498492				
27740	SHUNT 27740 STRATA NSC SNAP REG 120CM	0219471229				
27812	VALVE 27812 STRATA II SM EXTRACTED	0218700308				
27814	SHUNT 27814 STRATA II ASSY SML	0219498495	0220423969			
27815	SHUNT 27815 STRATA II ASSY REG	0219378043	0219802947			
27816	SHUNT 27816 SNAP STRATA II SMALL	0219395919	0219395920	0219395921	0219471351	
27817	SHUNT 27817 SNAP STRATA II REG	0219470063	0219470064	0219471352		
27818	SHUNT 27818 STRATA II SML BIO	0219127878	0219127880	0219551126	0219551134	
		0219127879	0219550965	0219551128		
27819	SHUNT 27819 STRATA II REG BIO	0219127871	0219127875	0219480199	0219551138	
		0219127872	0219127876	0219480200	0219551139	
		0219127873	0219480196	0219499010	0219551140	
		0219127874	0219480197	0219551136		
27823	SHUNT 27823 STRATA II ASSY SNP REG BIO	0219471237	0219931727			
27827	VALVE 27827 STRATA II REG EXTRACTED	0218700307	0219267902			
27888	SHNT 27888 STRATA II SNAP ASSY REG PCATH	0219471227	0219931726			
42335	VALVE 42335 STRATA NSC BURR HOLE	0219467660	0219467661	0219467663		
42355	VALVE 42355 FP STRATA NSC SMALL	0217207127	0218605901	0219171583	0219480335	
		0217207128	0218605902	0219171709	0219497185	
		0218226186	0218609097	0219352151	0219497646	
		0218247716	0218609100	0219352152	0219497661	
		0218287189	0218609101	0219480334		
42365	VALVE 42365 FP STRATA NSC REGULAR	0217205762	0218415313	0219081907	0219396254	
		0217205763	0218415314	0219115460	0219396255	
		0217207129	0218415315	0219115461	0219479762	
		0218226204	0218609102	0219307371	0219479763	
		0218226205	0218609103	0219307372	0219497751	
		0218287187	0218609104	0219352155	0219497755	
		0218287188	0218609105	0219352157		
		0218287201	0218609586	0219396250		
		0218396013	0218609587	0219396252		
42836	VALVE 42836 STRATA II BURR HOLE	0218807819	0219815331	0220314447	0220393227	
		0219309515	0220314446	0220393226		
46856	ASSY 46856 FP-STRATA 2 SHUNT SML	0219929565	0220217121	0220278246		

42866	VALVE 42866 FP-STRATA 2 REGULAR	0216105046	0216868360	0217971139	0218609596		
		0216105047	0216868581	0218033424	0218609599		
		0216105052	0216868582	0218033629	0218609600		
		0216105053	0216868583	0218033630	0218610066		
		0216259301	0217254779	0218033631	0218639473		
		0216259302	0217254780	0218033632	0218639474		
		0216362463	0217254781	0218033633	0218639475		
		0216362464	0217254782	0218033634	0218639476		
		0216362467	0217254783	0218033635	0218639477		
		0216363865	0217254784	0218033636	0218639478		
		0216418659	0217254785	0218033637	0218964983		
		0216418660	0217255246	0218033638	0219000135		
		0216513862	0217255247	0218033639	0219000143		
		0216513864	0217260220	0218033640	0219081908		
		0216579072	0217260221	0218033641	0219103305		
		0216579074	0217260969	0218034268	0219115462		
		0216666644	0217260970	0218286600	0219115463		
		0216729340	0217778042	0218286601	0219118937		
		0216732201	0217778043	0218286602	0219123053		
		0216732202	0217817034	0218286603	0219128329		
		0216732203	0217817035	0218286604	0219307369		
		0216732204	0217817036	0218286605	0219307370		
		0216732205	0217817037	0218287186	0219395719		
		0216733948	0217817038	0218287199	0219395720		
		0216821015	0217817039	0218287200	0219395721		
		0216821121	0217817040	0218417806	0219395723		
		0216821122	0217923546	0218417807	0219395724		
		0216821123	0217923549	0218417808	0219395725		
		0216821138	0217923550	0218417809	0219480328		
		0216821139	0217923551	0218417810	0219480329		
		0216868349	0217923552	0218417811	0219480330		
		0216868350	0217923555	0218417812	0219480331		
		0216868351	0217971129	0218605895	0219480332		
		0216868352	0217971131	0218605896	0219480333		
		0216868355	0217971134	0218605897	0219497762		
		0216868356	0217971135	0218605899	0219497763		
		0216868357	0217971136	0218605900	0219497764		
		0216868358	0217971137	0218609594	0220440998		
		0216868359	0217971138	0218609595	0220440999		
		44420	SHUNT 44420 STRATA KIT NSC LP	0219467664	0220040131	0220141393	0220355867
				0219467665	0220048557	0220262093	
0219468526	0220075411			0220355866			
44421	KIT 44421 STRATA NSC LP OPEN LUMBAR	0219332742	0220075412	0220141394	0220328424		
		0219332743	0220121098	0220166866			
44430	SHUNT 44430 STRATA KIT NSC LP ASSY	0219498721					
44465	VALVE 44465 STRATA NSC LP	0217268265	0218808947				
46636	SHUNT 46636 STRATA NSC BURR	0220285340					
46655	ASSY 46655 FP SHUNT STRATA NSC SMALL	0219498725					
46665	ASSY 46665 FP SHUNT STRATA NSC REG	0220059296	0220400355				
46837	SHUNT 46837 STRATA II BURR HOLE	0219354861					

<b>42856</b>	VALVE 42856 FP-STRATA 2 SMALL	0216868584	0218033643	0218605894	0218873200		
		0217254777	0218033644	0218609602	0218873201		
		0217254778	0218033645	0218609603	0218873202		
		0217255248	0218034266	0218609604	0218964967		
		0217778039	0218034267	0218639469	0219053149		
		0217778040	0218286596	0218639470	0219071024		
		0217778041	0218286597	0218639471	0219103301		
		0217817029	0218286598	0218639472	0219497757		
		0217817030	0218286599	0218787024	0219497758		
		0217817031	0218416085	0218787025	0219497759		
		0217817032	0218605889	0218787926	0219497760		
		0217817033	0218605890	0218787927	0219497761		
		0217971140	0218605891	0218787928			
		0217971141	0218605892	0218787934			
		0218033642	0218605893	0218873198			
		<b>46866</b>	ASSY 46866 FP-STRATA 2 SHUNT REG	0219132084	0219132085	0219132126	
		<b>92355</b>	VALVE 92355 STRATA NSC SML BIOGLIDE	0220288366			
<b>92856</b>	VALVE 92856 FP STRATA 2 SML BG	0219123889	0219330677				
<b>92866</b>	VALVE 92866 FP STRATA 2 REG BG	0219123853	0219123854				

Model #	Product Description	Delta™		Lot #	
<b>24048</b>	VALVE 24048 DELTA RGL PL 0.5	0218796596			
<b>24053</b>	CHAMBER 24053 DELTA	0220173993	0220631950		
<b>24147</b>	VALVE 24147 DELTA SML PL 0.5	0218806959	0219354642	0220201977	
<b>25121-1</b>	ASSY 25121-1 DELTA SML SNAP PERIT 120	0219404900			
<b>25121-5</b>	ASSY 25121-5 DELTA SML SNAP P-CATH 120	0219404902			
<b>25131-1</b>	DELTA 25131-1 INTL ONLY SHUNT SM 1.0	0219501288	0219501289		
<b>25131-2</b>	SHUNT 25131-2 INTL ONLY DELTA SM 2.0	0219869817			
<b>25131-5</b>	SHUNT 25131-5 INTL ONLY DELTA SM 1.5	0219278742	0219698794	0220112694	0220262088
		0219278743	0219809171	0220180486	0220397742
		0219278744	0219948890	0220217387	0220397744
<b>25132-2</b>	SHUNT 25132-2 INTL ONLY DELTA REG 2.0	0219272923	0220279501		
<b>25132-5</b>	SHUNT 25132-5 INTL ONLY DELTA REG 1.5	0219278741			
<b>27219-1</b>	VALVE 27219-1 NEONATE DELTA	0219927059	0220149614	0220393237	
<b>27219-2</b>	VALVE 27219-2 NEONATE DELTA	0219281777			
<b>27219-5</b>	VALVE 27219-5 DELTA NEONATE 1.5 IMP	0219948893	0220166870	0220236215	0220720015
<b>27554-1</b>	VALVE 27554-1 DELTA SM EXTRACTED PL 1.0	0220285334			
<b>27554-2</b>	VALVE 27554-2 DELTA SM EXTRACTED PL 2.0	0220285335			

<b>27554-5</b>	VALVE 27554-5 DELTA SM EXTRACTED PL 1.5	0220285336			
<b>42812</b>	VALVE 42812 DELTA SMALL LEVEL I	0217135294 0218720240	0218720241 0218992842	0219621242 0220251046	
<b>42813</b>	VALVE 42813 DELTA SMALL LEVEL 1.5	0217135293 0218720605 0218721466	0218721467 0218721468 0218992826	0218992827 0219154178 0219289039	0219289040 0219312362 0219761091
<b>42814</b>	VALVE 42814 DELTA SMALL LEVEL II	0217135298 0218720604	0219284249 0219284250	0219761089	
<b>42822</b>	VALVE 42822 DELTA REG PRESS LEVEL I IMP	0217150648 0217244574	0217244584 0218721469	0218721470 0218986445	
<b>92823</b>	VALVE 92823 BIOGLIDE DELTA REG. 1.5	0219067897			
<b>42824</b>	VALVE 42824 DELTA REG PRESS LEVEL II IMP	0217135295	0217135302	0219423220	0219761099
<b>46812</b>	ASSY 46812 DELTA SHUNT SMALL PL 1	0219279163			
<b>46813</b>	ASSY 46813 DELTA SHUNT SM LEV 1.5	0219278857	0219278858	0220352837	0220398089
<b>46822</b>	ASSY 46822 DELTA SHUNT REG P/L 1	0219279162	0220400352	0220602457	
<b>42823</b>	VALVE 42823 DELTA REG LEVEL 1.5	0217135290 0217286224 0217344860	0217344861 0218720187 0218753744	0218753745 0219312363 0219800605	0219802486
<b>46824</b>	ASSY 46824 DELTA SHUNT REG P/L 2	0220088041	0220602458		
<b>46832</b>	SHUNT 46832 NEONATAL DELTA SNAP L 1	0220285342			
<b>46833</b>	SHUNT 46833 NEONATAL DELTA SNAP 1.5	0219894798	0220398845		
<b>46834</b>	SHUNT 46834 NEONATAL DELTA SNAP L 2	0220285343			
<b>92822</b>	VALVE 92822 BIOGLIDE DELTA REG. 1.0	0219067896			
<b>46823</b>	ASSY 46823 DELTA SHUNT REG LEV 1.5	0219279147	0220352830		

Model #	Product Description	CSF-Flow Control™		Lot #			
9003 A	KIT 9003 A INTL ONLY SHUNT CONT SM LO	0219354851	0219354853	0220114768			
		0219354852	0219354854	0220398628			
9003 B	KIT 9003 B INTL ONLY SHUNT CONT SM ME	0219278737	0219851769	0220085757	0220173989		
		0219278738	0219851770	0220099077	0220285673		
		0219278739	0219981926	0220099078	0220352833		
		0219278740	0220053812	0220134024	0220398644		
		0219708098	0220053813	0220134025			
		0219708099	0220081704	0220156462			
		0219851768	0220085756	0220156463			
9003 C	KIT 9003 C INTL ONLY SHUNT CONT SM HI	0219278736	0220393229				
9003 D	KIT 9003 D SHUNT INTL ONLY CONT REG L	0219278734	0219278735	0220011262			
9003 E	KIT 9003 E SHUNT INTL ONLY CONT REG M	0219278731	0219769316	0219851773	0220680023		
		0219278733	0219851771	0220305451			
		0219769315	0219851772	0220622330			
9003 F	KIT 9003 F SHUNT INTL ONLY CONT REG H	0219354855	0219927060	0220546836			
9040 A	KIT 9040 A SHUNT INTL ONLY BH 12MM LOW	0219278730	0220011259	0220397733			
9040 B	KIT 9040 B SHUNT INTL ONLY BH 12MM MED	0219127889	0219128120	0220099076	0220397688		
		0219128109	0219128121	0220102737	0220397689		
		0219128111	0219917405	0220118172	0220397691		
		0219128112	0220009922	0220156744	0220397699		
		0219128113	0220009923	0220156745	0220397703		
		0219128115	0220040136	0220201972	0220400359		
		0219128117	0220059298	0220201979	0220702309		
		0219128118	0220059299	0220217393			
		0219128119	0220099075	0220249127			
9040 C	KIT 9040 C SHUNT INTL ONLY BH 12MM HIGH	0219969972					
9040 D	KIT 9040 DSHUNT INTL ONLY BH 16MM LOW	0219272921	0219950183				
9040 E	KIT 9040 E SHUNT INTL ONLY BH 16MM MED	0219127462	0219127895	0219917404	0220262090		
		0219127463	0219127896	0219988521	0220285669		
		0219127464	0219127897	0220075419	0220285670		
		0219127465	0219127898	0220141390	0220285672		
		0219127886	0219698790	0220141391	0220301203		
		0219127887	0219698792	0220141405	0220324602		
		0219127890	0219721377	0220141706	0220330904		
		0219127891	0219721378	0220156743	0220360618		
		0219127892	0219721379	0220173988	0220637047		
		0219127893	0219721380	0220249134			
		0219127894	0219721381	0220255058			
		9040 F	SHUNT 9040 F KIT INTL BH 16MM HIGH	0219278729	0219698786		
		22011 L	SHUNT 22011 L INTL ONLY ULTRA SM LOW	0219278853	0219278854		
22011 LL	SHUNT 22011 LL INTL ONLY ULTRA SM L-L	0220099072					

<b>22011 M</b>	SHUNT 22011 M INTL ONLY ULTRA SM MED	0219278855 0219278856 0219768090	0219768091 0219798970 0219798971	0219798972 0220010048 0220112693	0220141392
<b>22017 B-L</b>	SHUNT 22017 B-L ASSY US PER 90CM SM LOW	0219802495			
<b>22017 B-M</b>	SHUNT 22017 B-M ASSY US PER 90CM SM MED	0219802494			
<b>22017B-LL</b>	SHUNT 22017B-LL ASSY US PER 90CM SM LL	0219583129	0220286100		
<b>23093</b>	VALVE 23093 CONT. REG. LOW-LOW	0218796592	0219952709		
<b>27102</b>	VALVE 27102 CONTOURED SML LOW LOW	0218806424	0219316930	0220280248	
<b>27553 M</b>	VALVE 27553 M CSF-FLOW CNTRL SM EXTR MP	0220286709			
<b>27643M</b>	SHUNT 27643M ASSY SM PCATH130CM MED	0219480202			
<b>27683M</b>	SHUNT 27683M RG SNP PCATH90 PLI STD OE	0219802492			
<b>42312</b>	VALVE 42312 SM CONTOURED LOW PRES IMP	0218045303 0218045304 0218045527 0218408997	0218408998 0218408999 0218590082 0218721471	0218721472 0219234579 0219497114 0219648109	0219978722 0220100564 0220444728
<b>42314</b>	VALVE 42314 SM CONTOURED MED PRESS IMP	0217286212 0217286213 0217286214 0217706616 0217706621 0217706622 0217706623 0217962420 0217962421	0217971628 0217971633 0218409003 0218409004 0218409005 0218590077 0218590078 0218590079 0218590080	0218590081 0218720196 0218720202 0218972089 0218972090 0219234580 0219312365 0219375930 0219761087	0220122285 0220124886 0220124887 0220124888 0220272309 0220444084 0220444085 0220444726
<b>42316</b>	VALVE 42316 SM CONTOURED HIGH PRESS	0217286211 0217706612	0217962419 0217971634	0217971635 0218424703	0218424704 0218590071
<b>42322</b>	VALVE 42322 CONTOURED REG LOW PRESS IMP	0217286216 0217962409	0217962418 0217971637	0217971638 0218424701	0218424702
<b>42324</b>	VALVE 42324 CONTOURED REG MED PRESS IMP	0217962422 0217962423 0217962424 0217962425 0218402220 0218408987 0218408988 0218408989 0218408990	0218408991 0218408992 0218408993 0218408994 0218408996 0218590073 0218590074 0218590075 0218590076	0218720244 0218720287 0218720289 0219234581 0219234582 0219320159 0219320160 0219320162 0219320163	0219574223 0219761097 0219910255 0219910256 0220324658 0220530229
<b>42326</b>	VALVE 42326 CONT HIGH PRESS IMP	0218590084 0218590085	0219312364 0219978742	0220444083	
<b>42410</b>	VALVE 42410 ULTRA SMALL LOW-LOW	0219277363	0219278519	0219278520	
<b>42414</b>	VALVE 42414 ULTRA SMALL MEDIUM PRESS IMP	0219278516 0219278517	0219374313 0219374314	0219733266 0219733267	
<b>42532</b>	VALVE 42532 BURR HOLE 12MM LOW PRESS IMP	0218605545	0218605686		



<b>42534</b>	VALVE 42534 BURR HOLE 12MM MED PRESS IMP	0218605539	0218605543	0219375927	0219761086
		0218605540	0218605544	0219375928	0219910252
		0218605541	0219375125	0219375929	0219910253
		0218605542	0219375926	0219438310	0220444735
<b>42536</b>	VALVE 42536 BURR HOLE 12MM HI PRESS IMP	0218605538			
<b>42542</b>	VALVE 42542 BURR HOLE 16 MM LOW IMP	0218605536	0218605537	0220280189	
<b>42544</b>	VALVE 42544 BURR HOLE 16MM MED PRESS IMP	0218605688	0218979002	0219123586	0219465703
		0218605689	0218979003	0219123588	0219761093
		0218605690	0218979005	0219123589	0219761094
		0218605691	0218979086	0219422860	0219761095
		0218978999	0218979087	0219422861	0219761096
		0218979001	0219123064	0219465702	0220272311
<b>42546</b>	VALVE 42546 BURR HOLE 16MM HI PRESS IMP	0218605687	0219579789		
<b>46564</b>	SHUNT 46564 CSF SNAP ASSY US MEDIUM	0219894795			
<b>46622</b>	SHUNT 46622 CSF ASSY SMALL LOW CONT C/P	0219279151	0220288369		
<b>46624</b>	SHUNT 46624 CSF ASSY SMALL MED CONT C/P	0219278874	0219894797	0220201981	0220602456
<b>46626</b>	SHUNT 46626 CSF ASSY SMALL HIGH CONT C/P	0220285339			
<b>46642</b>	SHUNT 46642 ASSY REG LOW C/P-90CM	0219279160			
<b>46644</b>	SHUNT 46644 ASSY REG MED C/P-90CM	0219278877	0219278878	0219278879	0219278880
<b>46646</b>	SHUNT 46646 ASSY REG HIGH C/P-90CM	0219694364	0220075413	0220075414	
<b>92322</b>	VALVE 92322 CSF CONT REG LOW BIO	0220522999			
<b>92324</b>	VALVE 92324 CSF CONT REG MED BIO	0219067893	0219067894	0220400350	