

**Urgent Field Safety Notice**

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

Variation in Radiopacity

January 2021

Medtronic reference: FA952

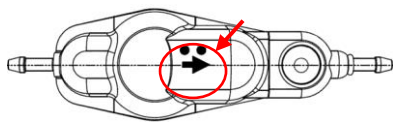
Dear Physician or Healthcare Professional,

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. Please see attached list for impacted Lot numbers. 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.

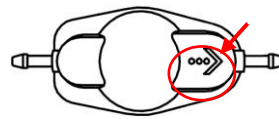
**Background:**

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.

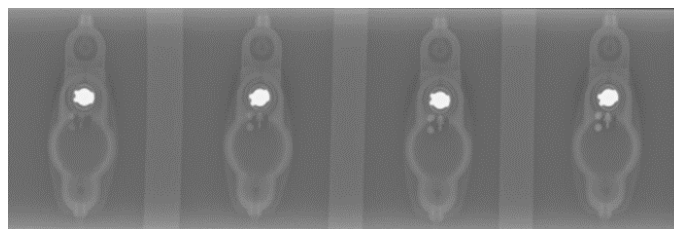


Strata Valve



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



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,

Local / BU Manager

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	SHUNT 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				
42856	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			
46866	ASSY 46866 FP-STRATA 2 SHUNT REG	0219132084	0219132085	0219132126		
92355	VALVE 92355 STRATA NSC SML BIOGLIDE	0220288366				
92856	VALVE 92856 FP STRATA 2 SML BG	0219123889	0219330677			
92866	VALVE 92866 FP STRATA 2 REG BG	0219123853	0219123854			

Model #	Product Description	Delta™		Lot #		
24048	VALVE 24048 DELTA RGL PL 0.5	0218796596				
24053	CHAMBER 24053 DELTA	0220173993	0220631950			
24147	VALVE 24147 DELTA SML PL 0.5	0218806959	0219354642	0220201977		
25121-1	ASSY 25121-1 DELTA SML SNAP PERIT 120	0219404900				
25121-5	ASSY 25121-5 DELTA SML SNAP P-CATH 120	0219404902				
25131-1	DELTA 25131-1 INTL ONLY SHUNT SM 1.0	0219501288	0219501289			
25131-2	SHUNT 25131-2 INTL ONLY DELTA SM 2.0	0219869817				
25131-5	SHUNT 25131-5 INTL ONLY DELTA SM 1.5	0219278742	0219698794	0220112694	0220262088	0219278743
		0219809171	0220180486	0220397742	0219278744	0219948890
		0220217387	0220397744			
25132-2	SHUNT 25132-2 INTL ONLY DELTA REG.2.0	0219272923	0220279501			
25132-5	SHUNT 25132-5 INTL ONLY DELTA REG 1.5	0219278741				
27219-1	VALVE 27219-1 NEONATE DELTA	0219927059	0220149614	0220393237		
27219-2	VALVE 27219-2 NEONATE DELTA	0219281777				
27219-5	VALVE 27219-5 DELTA NEONATE 1.5 IMP	0219948893	0220166870	0220236215	0220720015	
27554-1	VALVE 27554-1 DELTA SM EXTRACTED PL 1.0	0220285334				
27554-2	VALVE 27554-2 DELTA SM EXTRACTED PL 2.0	0220285335				
27554-5	VALVE 27554-5 DELTA SM EXTRACTED PL 1.5	0220285336				
42812	VALVE 42812 DELTA SMALL LEVEL I	0217135294	0218720241	0219621242	0218720240	0218992842
		0220251046				
42813	VALVE 42813 DELTA SMALL LEVEL 1.5	0217135293	0218721467	0218992827	0219289040	0218720605
		0218721468	0219154178	0219312362	0218721466	0218992826
		0219289039	0219761091			
42814	VALVE 42814 DELTA SMALL LEVEL II	0217135298	0219284249	0219761089	0218720604	0219284250
42822	VALVE 42822 DELTA REG PRESS LEVEL I IMP	0217150648	0217244584	0218721470	0217244574	0218721469
		0218986445				
92823	VALVE 92823 BIOGLIDE DELTA REG. 1.5	0219067897				

42824	VALVE 42824 DELTA REG PRESS LEVEL II IMP	0217135295	0217135302	0219423220	0219761099	
46812	ASSY 46812 DELTA SHUNT SMALL PL 1	0219279163				
46813	ASSY 46813 DELTA SHUNT SM LEV 1.5	0219278857	0219278858	0220352837	0220398089	
46822	ASSY 46822 DELTA SHUNT REG P/L 1	0219279162	0220400352	0220602457		
42823	VALVE 42823 DELTA REG LEVEL 1.5	0217135290	0217344861	0218753745	0219802486	0217286224
		0218720187	0219312363	0217344860	0218753744	0219800605
46824	ASSY 46824 DELTA SHUNT REG P/L 2	0220088041	0220602458			
46832	SHUNT 46832 NEONATAL DELTA SNAP L 1	0220285342				
46833	SHUNT 46833 NEONATAL DELTA SNAP 1.5	0219894798	0220398845			
46834	SHUNT 46834 NEONATAL DELTA SNAP L 2	0220285343				
92822	VALVE 92822 BIOGLIDE DELTA REG. 1.0	0219067896				
46823	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				
22011 M	SHUNT 22011 M INTL ONLY ULTRA SM MED	0219278855	0219768091	0219798972	0220141392	0219278856
		0219798970	0220010048	0219768090	0219798971	0220112693
22017 B-L	SHUNT 22017 B-L ASSY US PER 90CM SM LOW	0219802495				
22017 B-M	SHUNT 22017 B-M ASSY US PER 90CM SM MED	0219802494				
22017B-LL	SHUNT 22017B-LL ASSY US PER 90CM SM LL	0219583129	0220286100			
23093	VALVE 23093 CONT. REG. LOW-LOW	0218796592	0219952709			
27102	VALVE 27102 CONTOURED SML LOW LOW	0218806424	0219316930	0220280248		
27553 M	VALVE 27553 M CSF-FLOW CNTRL SM EXTR MP	0220286709				
27643M	SHUNT 27643M ASSY SM PCATH130CM MED	0219480202				
27683M	SHUNT 27683M RG SNP PCATH90 PLI STD OE	0219802492				

42312	VALVE 42312 SM CONTOURED LOW PRES IMP	0218045303	0218408998	0218721472	0219978722	0218045304
		0218408999	0219234579	0220100564	0218045527	0218590082
		0219497114	0220444728	0218408997	0218721471	0219648109
42314	VALVE 42314 SM CONTOURED MED PRESS IMP	0217286212	0217971628	0218590081	0220122285	0217286213
		0217971633	0218720196	0220124886	0217286214	0218409003
		0218720202	0220124887	0217706616	0218409004	0218972089
		0220124888	0217706621	0218409005	0218972090	0220272309
		0217706622	0218590077	0219234580	0220444084	0217706623
		0218590078	0219312365	0220444085	0217962420	0218590079
42316	VALVE 42316 SM CONTOURED HIGH PRESS	0217286211	0217962419	0217971635	0218424704	0217706612
		0217971634	0218424703	0218590071		
42322	VALVE 42322 CONTOURED REG LOW PRESS IMP	0217286216	0217962418	0217971638	0218424702	0217962409
		0217971637	0218424701			
42324	VALVE 42324 CONTOURED REG MED PRESS IMP	0217962422	0218408991	0218720244	0219574223	0217962423
		0218408992	0218720287	0219761097	0217962424	0218408993
		0218720289	0219910255	0217962425	0218408994	0219234581
		0219910256	0218402220	0218408996	0219234582	0220324658
		0218408987	0218590073	0219320159	0220530229	0218408988
		0218590074	0219320160	0218408989	0218590075	0219320162
42326	VALVE 42326 CONT HIGH PRESS IMP	0218408990	0218590076	0219320163		
		0218590084	0219312364	0220444083	0218590085	0219978742
42410	VALVE 42410 ULTRA SMALL LOW-LOW	0219277363	0219278519	0219278520		
42414	VALVE 42414 ULTRA SMALL MEDIUM PRESS IMP	0219278516	0219374313	0219733266	0219278517	0219374314
		0219733267				
42532	VALVE 42532 BURR HOLE 12MM LOW PRESS IMP	0218605545	0218605686			
42534	VALVE 42534 BURR HOLE 12MM MED PRESS IMP	0218605539	0218605543	0219375927	0219761086	0218605540
		0218605544	0219375928	0219910252	0218605541	0219375125
		0219375929	0219910253	0218605542	0219375926	0219438310
		0220444735				
42536	VALVE 42536 BURR HOLE 12MM HI PRESS IMP	0218605538				
42542	VALVE 42542 BURR HOLE 16 MM LOW IMP	0218605536	0218605537	0220280189		
42544	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	
42546	VALVE 42546 BURR HOLE 16MM HI PRESS IMP	0218605687	0219579789			
46564	SHUNT 46564 CSF SNAP ASSY US MEDIUM	0219894795				
46622	SHUNT 46622 CSF ASSY SMALL LOW CONT C/P	0219279151	0220288369			
46624	SHUNT 46624 CSF ASSY SMALL MED CONT C/P	0219278874	0219894797	0220201981	0220602456	
46626	SHUNT 46626 CSF ASSY SMALL HIGH CONT C/P	0220285339				
46642	SHUNT 46642 ASSY REG LOW C/P-90CM	0219279160				
46644	SHUNT 46644 ASSY REG MED C/P-90CM	0219278877	0219278878	0219278879	0219278880	
46646	SHUNT 46646 ASSY REG HIGH C/P-90CM	0219694364	0220075413	0220075414		
92322	VALVE 92322 CSF CONT REG LOW BIO	0220522999				
92324	VALVE 92324 CSF CONT REG MED BIO	0219067893	0219067894	0220400350		