

IMPORTANT MEDICAL DEVICE INFORMATION

Eon Mini™ (Model 65-3788) and Brio™ (Model 65-6788)
Implantable Pulse Generators for Neurostimulation

May 24, 2011

Dear Doctor,

This letter provides you with important information about Eon Mini Model 65-3788 and Brio Model 65-6788, Implantable Pulse Generators (IPGs). Our records indicate that you may have implanted potentially affected device(s) or have a potentially affected device(s) in your product inventory.

As part of our systematic tracking and product monitoring, St. Jude Medical's analysis of complaint data revealed reports of 78 Eon Mini IPGs and 1 Brio IPG that lost the ability to communicate or recharge. Spinal Cord Stimulation patients may experience a loss of pain relief. Deep Brain Stimulation patients may experience recurrence of symptoms, possibly in greater intensity than prior to use of the neurostimulation system. Either instance may result in a subsequent explant. Explant surgery, as with any surgery, presents a risk to patient health. Adverse events associated with an unplanned surgery may be comparable to adverse events associated with planned reoperations, and may include pain, scarring, and infection, as well as complications from anesthesia. We are therefore taking action to notify you of this potential issue and to pass on patient management recommendations from our medical advisory board.

This action relates only to defects of the internal battery component that is fully contained within the outer hermetically sealed IPG titanium can. The potentially affected battery is not used in any other Neuromodulation products. A list of device serial numbers potentially affected is enclosed in Attachment A. St. Jude Medical is recalling all unused Eon Mini and Brio IPGs identified in Attachment A.

Issue Summary:

St. Jude Medical has received reports of inability to communicate or recharge 78 Eon Mini IPGs and 1 Brio IPG. In the cases reported, the duration between recharges became progressively shorter until the IPG failed to charge or there was a sudden loss of power which resulted in device replacement. After thorough analysis we determined that weld failures within the internal battery of the IPG caused these reports. The weld failures caused the batteries to leak electrolyte and prevented them from holding a charge. The inner battery is fully contained within the hermetically sealed outer titanium case of the IPG, so patients cannot be exposed to the electrolyte material.

Extensive review of our battery supplier's manufacturing methods identified a need to improve controls relating to the battery weld process. We have comprehensively addressed this and no reports of this battery failure mode have been received for batteries manufactured with the improved process controls.

Rate of occurrence:

The battery failures caused by this defect represent 0.46% of the total IPG devices potentially affected by this recall. This rate is based on failures reported to date, a greater percentage may actually be defective. The long term failure rates for these devices are not known at this time. We have taken corrective action, implemented improved process controls, and continue to monitor complaint data to determine the effectiveness of the corrective actions. Devices with serial numbers not contained within Attachment A are not impacted.

Recommendations:

St. Jude Medical understands that each patient is different and recommends you discuss this issue with your patients as you consider necessary. To further assist in your patient care, and following discussions with our external Medical Advisory Board, St. Jude Medical recommends:

- For Eon Mini or Brio IPGs not included in the enclosed serial number listing (Attachment A), no actions are necessary. These devices do not contain batteries affected by this issue.
- For product within your **unused inventory** included in the serial number listing (Attachment A), please isolate the device(s) for return to St. Jude Medical. A replacement device will be provided at no additional cost to you.
- For **implanted product** included in the serial number (Attachment A), as advised by our Medical Advisory Board:
 1. **We recommend that you do not unnecessarily explant the devices associated with this advisory if the IPGs are functioning as intended.**
 2. If the duration between recharges becomes significantly shorter or there is a sudden loss of power, contact your St. Jude Medical representative to evaluate if
 - the recharge burden is within normal operating expectations based on the patient's programmed parameters
 - the device is approaching normal end of life expectancy, or
 - a device replacement is warranted.
 3. If device replacement is required due to weld failures within the inner battery, St. Jude Medical will provide a free replacement IPG.

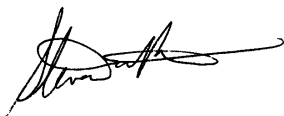
Transfer of this Information:

Please distribute this information to all who need to be aware of it within your institution. In the event that one or more patients have transferred to other institutions for their care or unused inventory has been transferred to other hospitals for use, please contact your St. Jude Neuromodulation representative so that we can provide this information to them and address any further questions. The appropriate local Regulatory Agencies have been notified of this action.

St. Jude Medical is committed to keeping customers informed about important product information. If you have questions regarding this action, please contact your local St. Jude Medical representative.

Please rest assured that we will continue to monitor supplier and product performance for opportunities to improve our products, services and instructions for use, in order to continue providing the highest standards of health care instrumentation. We thank you for your continued support.

Sincerely,



Steven Robertson
Vice President, Quality Assurance
St. Jude Medical, Neuromodulation Division

Attachment A

Model 65-3788 (Eon Mini):

Serial Number	Serial Number	Serial Number	Serial Number	Serial Number	Serial Number	Serial Number	Serial Number
701892	701967	701997	702046	702056	702380	702382	702402
702500	702511	702564	702571	702585	702586	702592	702593
702658	702671	702703	702710	702761	702779	702822	702832
702840	702958	703005	703020	703043	703069	703073	703130
703145	703177	703184	703185	703201	703245	703252	703256
703259	703269	703280	703283	703286	703297	703299	703301
703302	703304	703306	703321	703323	703326	703328	703393
703406	703409	703423	703431	703499	703553	703601	703616
703658	703681	703731	703736	703760	703765	703785	703808
703809	703810	703811	703812	703814	703815	703817	703843
703846	703854	703857	703859	703869	703885	703894	703895
703902	703921	703992	704083	704100	704118	704247	704277
704282	704285	704416	704428	704445	704508	704528	704533
704543	704560	704674	704675	704683	704684	704694	704723
704724	704730	704739	704780	704789	704806	704863	704868
704881	704952	704953	704967	705030	705036	705043	705066
705084	705092	705105	705115	705168	705225	705265	705270
705277	705278	705314	705326	705415	705424	705426	705467
705508	705527	705533	705538	705542	705552	705560	705561
705566	705587	705639	705643	705658	705664	705674	705675
705688	705699	705702	705718	705720	705740	705741	705745
705750	705754	705759	705760	705762	705768	705792	705795
705803	705858	705876	705878	705886	705892	705948	705951
705955	705966	705970	705975	706012	706109	706176	706194
706249	706264	706300	706325	706331	706346	706371	706380
706422	706436	706437	706449	706458	706465	706476	706514
706534	706540	706545	706549	706565	706578	706586	706608
706634	706676	706677	706678	706680	706690	706716	706733
706746	706747	706754	706780	706781	706787	706803	706845
706864	706888	706924	706954	706983	706992	707001	707002
707008	707035	707088	707090	707122	707128	707133	707154
707155	707158	707178	707191	707196	707213	707216	707228
707270	707274	707368	707417	707422	707424	707429	707457
707479	707480	707487	707495	707503	707509	707516	707523
707535	707542	707543	707555	707560	707601	707607	707609
707610	707613	707615	707617	707618	707621	707646	707650
707654	707655	707657	707710	707722	707723	707743	707744
707747	707752	707761	707781	707837	707839	707840	707849
707868	707878	707901	707912	707937	707951	707978	708010
708025	708031	708036	708057	708071	708081	708098	708105
708117	708121	708126	708167	708194	708200	708203	708204
708210	708213	708234	708261	708262	708284	708297	708301
708302	708333	708334	708357	708372	708381	708389	708407
708414	708420	708424	708470	708476	708490	708493	708501
708508	708577	708578	708599	708672	708685	708687	708712
708781	708806	708807	708811	708815	708836	708866	708871
708943	708948	708956	708978	708980	708992	709013	709020
709106	709117	709148	709155	709173	709194	709220	709243
709244	709250	709279	709322	709328	709356	709371	709382
709403	709417	709419	709428	709441	709444	709447	709453

Serial Number	Serial Number	Serial Number	Serial Number	Serial Number	Serial Number	Serial Number	Serial Number
709459	709464	709470	709479	709505	709519	709587	709611
709655	709672	709675	709676	709746	709758	709777	709798
709813	709820	709850	709851	709859	709894	709904	709931
710004	710006	710034	710070	710071	710102	710104	710169
710188	710189	710197	710228	710230	710235	710252	710309
710310	710311	710312	710327	710338	710342	710356	710377
710410	710416	710425	710435	710472	710473	710533	710551
710583	710606	710620	710621	710634	710641	710646	710651
710685	710692	710707	710719	710723	710727	710735	710755
710756	710766	710775	710784	710791	710795	710806	710808
710809	710821	710829	710833	710838	710844	710856	710895
710934	710937	710944	710950	710956	710966	710970	710987
711005	711048	711098	711131	711134	711153	711154	711160
711166	711167	711195	711196	711200	711202	711204	711213
711228	711243	711250	711254	711265	711266	711269	711271
711299	711304	711310	711313	711317	711320	711322	711323
711326	711329	711332	711340	711344	711345	711346	711371
711388	711397	711402	711415	711419	711421	711422	711430
711433	711451	711454	711458	711466	711476	711478	711479
711481	711485	711489	711499	711501	711517	711550	711576
711579	711622	711647	711666	711680	711682	711694	711697
711720	711765	711770	711777	711786	711787	711791	711793
711794	711804	711807	711812	711819	711827	711828	711834
711857	711865	711871	711872	711882	711902	711903	711913
711914	13501487	13501491	13501501	13501507	13501508	13501512	13501513
13501516	13501522	13501523	13501527	13501528	13501531	13501533	13501542
13501546	13501549	13501550	13501551	13501556	13501558	13501563	13501564
13501574	13501588	13501590	13501591	13501593	13501607	13501613	13501640
13501647	13501655	13501661	13501668	13501682	13501684	13501685	13501688
13501691	13501693	13501696	13501697	13501705	13501730	13501732	13501737
13501739	13501747	13501750	13501751	13501766	13501777	13501785	13501792
13501794	13501798	13501829	13501868	13501877	13501882	13501889	13501893
13501901	13501903	13501911	13501915	13501916	13501918	13501922	13501928
13522570	13522572	13522573	13542448	13542488	13542498	13542542	13542543
13542553	13542557	13542560	13542563	13542564	13542599	13542619	13542620
13542645	13542688	13542689	13542697	13542740	13542742	13542750	13542756
13542761	13542766	13542767	13542794	13542809	13542815	13542834	13542857
13542896	13542903	13542923	13542931	13542954	13542955	13542964	13542993
13542994	13542996	13543001	13543044	13543047	13543062	13543101	13543108
13543113	13543114	13543115	13543125	13543135	13543137	13543145	13543147
13543162	13543192	13543194	13543202	13543226	13543234	13543245	13543246
13543296	13543318	13543352	13543362	13543378	13543432	13543438	13543443
13543458	13543468	13543475	13543490	13543503	13543541	13543564	13543567
13543593	13543600	13543615	13543631	13543642	13543644	13543646	13543657
13543660	13543664	13543691	13543702	13543707	13543711	13543718	13543723
13543757	13543758	13543770	13556108	13556116	13556122	13556144	13556150
13556162	13556170	13556177	13556201	13556202	13556213	13556216	13556250
13556253	13556274	13556278	13556280	13556281	13556282	13556296	13556305
13556326	13556329	13556333	13556338	13556340	13556373	13556394	13556396
13556397	13556399	13556400	13556405	13556408	13556440	13556456	13556457
13556463	13556469	13556474	13556480	13556487	13556488	13556497	13556502
13556547	13556565	13556575	13556582	13556584	13556593	13556601	13556603
13556605	13556621	13556636	13556639	13556650	13556651	13556653	13556682
13556703	13556709	13556713	13556723	13556730	13556751	13556754	13556757

Serial Number	Serial Number	Serial Number	Serial Number	Serial Number	Serial Number	Serial Number	Serial Number
13556759	13556768	13556779	13556808	13556810	13556835	13556838	13556842
13556844	13556846	13556849	13556853	13556860	13556862	13556870	13556877
13556900	13556912	13556922	13556936	13556947	13556960	13556974	13556997
13557002	13557023	13557027	13557035	13557036	13557048	13557052	13557053
13557088	13557128	13557134	13557137	13557146	13557208	13557214	13557218
13557220	13557226	13557235	13557236	13557238	13557243	13557248	13557274
13750610	13750627	13750629	13750639	13750657	13750665	13750673	13750674
13750683	13750685	13750697	13750709	13750710	13750717	13750726	13750727
13750752	13750755	13750760	13750761	13750786	13750790	13750811	13750837
13750854	13750892	13750893	13750895	13750905	13750948	13750958	13750979
13750999	13751001	13751026	13751060	13751088	13751095	13751096	13751103
13751126	13751135	13751145	13751158	13751166	13751182	13751188	13751192
13751214	13751219	13751226	13751228	13751232	13751239	13751278	13751281
13751288	13751326	13751351	13751361	13751389	13751393	13751409	13751418
13751448	13751457	13751464	13751466	13751500	13751503	13751533	13751539
13751543	13751550	13751551	13751566	13751567	13751580	13751598	13751601
13751603	13751608	13751625	13751631	13751641	13751646	13751653	13751661
13751706	13751735	13751738	13751757	13751758	13751786	13751788	13751900
13751904	13751909	13751924	13751927	13751934	13751935	13751944	13751949
13751973	13751988	13751996	13758003	13758010	13758026	13758031	13758043
13758045	13758049	13758070	13758080	13758096	13758101	13758104	13758117
13758120	13758126	13758130	13758135	13758142	13758145	13758164	13758179
13758194	13758203	13758213	13758219	13758222	13758223	13758226	13758253
13758269	13758290	13758304	13758318	13758321	13758330	13758372	13758376
13758402	13758404	13758409	13758441	13758463	13758465	13758466	13758472
13758480	13758489	13758498	13758502	13758506	13758534	13758552	13758553
13758555	13758562	13758565	13758566	13758576	13758579	13758580	13758585
13758586	13758602	13758607	13758642	13758649	13758664	13758667	13758669
13758670	13758672	13758673	13758684	13758693	13758694	13758696	13758697
13758703	13758709	13758710	13758729	13758732	13758764	13758766	13758769
13758777	13758781	13758799	13758800	13758823	13758839	13758857	13758869
13758871	13758874	13758875	13758891	13758893	13758897	13758908	13758913
13758933	13758944	13758977	13758984	13758995	13759019	13759021	13759027
13759032	13759039	13759041	13759049	13759053	13759058	13759059	13759060
13759082	13759097	13759124	13759131	13759143	13759145	13759150	13759156
13759161	13759208	13759225	13759257	13759264	13759266	13759276	13759301
13759345	13759346	13759371	13759377	13762145	13762152	13762160	13762163
13762168	13762173	13762175	13762179	13762182	13762186	13762195	13762215
13762224	13762230	13762237	13762254	13762255	13762260	13762278	13762308
13762310	13762312	13762314	13762316	13762335	13762354	13762363	13762364
13762367	13762370	13762375	13762376	13762380	13762387	13762398	13762404
13762475	13762501	13762509	13762516	13762523	13762538	13762541	13762552
13762565	13762574	13762576	13762578	13762582	13762586	13762587	13762592
13762604	13762635	13762636	13762645	13762647	13762658	13762696	13762702
13762708	13762724	13762740	13762775	13762778	13762779	13762793	13762797
13762799	13762802	13762829	13762847	13762856	13762869	13762877	13762878
13762881	13762890	13762901	13762913	13762956	13762980	13762986	13762991
13763023	13763034	13763046	13763054	13763069	13763074	13763075	13763080
13763087	13763105	13763106	13763109	13763119	13763125	13763152	13763153
13763157	13763165	13763169	13763178	13763220	13763225	13763230	13763233
13763235	13763254	13763272	13763287	13763290	13763303	13763305	13763312
13763315	13763316	13763338	13763351	13763353	13763361	13763363	13763369
13763394	13763415	13763435	13763450	13763483	13763511	13763525	13763652
13763666	13763706	13763741	13763744	13763774	13763813	13763821	13763846

Serial Number	Serial Number	Serial Number	Serial Number	Serial Number	Serial Number	Serial Number	Serial Number
13763849	13763861	13764554	13764607	13764616	13764638	13764646	13764662
13764680	13764681	13764683	13764692	13764693	13764702	13764705	13764709
13764717	13764721	13764734	13764740	13764760	13764764	13764771	13764776
13764789	13764797	13764798	13764800	13764801	13764803	13764809	13764810
13764812	13764813	13764818	13764822	13764836	13764857	13764863	13764939
13764979	13765006	13765021	13765025	13765026	13765027	13765048	13765055
13765059	13765094	13765103	13765104	13765113	13765120	13765131	13765149
13765150	13765155	13765158	13765163	13765164	13765165	13765166	13765170
13765174	13765180	13765213	13765224	13765241	13765276	13765277	13765279
13765281	13765289	13765290	13765292	13765294	13765296	13765299	13765302
13765314	13765316	13765344	13765352	13765362	13765365	13765385	13765390
13765432	13765433	13765439	13765449	13765454	13765466	13765473	13765479
13765492	13765504	13765508	13765511	13765513	13765515	13765520	13765521
13765529	13765540	13765559	13765568	13765581	13765585	13765595	13765596
13765598	13765604	13765708	13765762	13765766	13765768	13765789	13765791
13765825	13765829	13765835	13765853	13765854	13765855	13765857	13765861
13765885	13765887	13765889	13765890	13765900	13765902	13765911	13765937
13765942	13765968	13765971	13765977	13765989	13765995	13765999	13766019
13766022	13766024	13766044	13766083	13766103	13766107	13766124	13766125
13766130	13766131	13766134	13766154	13766211	13766234	13766238	13766242
13766243	13766245	13766252	13766254	13766263	13766285	13766289	13766294
13766299	13766304	13766307	13766314	13766319	13766320	13766323	13766326
13766329	13766330	13766333	13766337	13766342	13766344	13766348	13766350
13766368	13766374	13766375	13766396	13766410	13766429	13766432	13766435
13766443	13766448	13766449	13766452	13766464	13766476	13766479	13766480
13766485	13766487	13766488	13766489	13766491	13766500		

Model 65-6788 (Brio):

Serial Number	Serial Number	Serial Number	Serial Number	Serial Number	Serial Number	Serial Number
800022	800023	800024	800027	800028	800030	800033
800035	13751804	13751805	13751806	13751807	13751808	13751809
13751810	13751811	13751812	13751815	13751816	13751817	13751818
13751819	13751820	13751821	13751822	13751823	13751824	13751825
13751826	13751827	13751828	13751829	13751830	13751831	13751833
13751834	13751835	13751836	13751837	13751838	13751839	13751840
13751841	13751842	13751844	13751845	13751846	13754681	13754682
13754683	13754684	13754685	13754686	13754688	13754689	13754691
13754692	13754693	13754694	13754695	13754696	13754697	13754698
13754699	13754700	13754701	13754702	13754703	13754705	13754706
13754707	13754708	13754709	13754710	13754711	13754712	13754713
13754714	13754715	13754716	13754717	13754718	13754719	13754720
13754721	13754722	13754725	13754726	13754727	13754728	13754747
13754748	13754749	13754750	13754751	13754752	13754753	13754754
13754755	13754756	13754757	13754758	13754759	13754761	13754762
13754763	13754764	13754766	13754767	13754769	13754770	13754771
13754772	13754773	13754774	13754775	13758738	13758740	13758742
13758744	13758746	13758747	13758761	13758762	13763532	13763534
13763537	13763539	13763540	13763541	13763548	13763550	13763554
13763557	13763558	13763561	13763579	13763581	13763582	13763583
13763585	13763592	13763598	13763600	13763602	13763605	13763609
13763610	13763612	13763614	13763615	13763620	13763623	13763890
13763909	13763910	13763911	13763912	13763915	13763916	13763918
13763919	13763924	13763926	13763930	13763935	13765609	13765610
13765613	13765615	13765616	13765617	13765638	13765640	13765646
13765649	13765656					