

Urgent Medical Device Voluntary Recall
Immediate Action Required

06/03/2016

URGENT MEDICAL DEVICE RECALL- REMOVAL

FSCA identifier: Product Field Action RA2016-088

Type of Action: RECALL-REMOVAL

Description: Target Nano

Catalog #:

M0035442540	M0035421520	M0035431520	M0035452530	M0035452040
M0035442040	M0035421030	M0035431030	M0035452060	M0035453060
M0035421540	M0035431020	M0035443560	M0035452540	M0035453040
M0035421530	M0035431010	M0035443040	M0035453080	M0035452030
M0035442030	M0035431540	M0035443060	M0035452560	M0035431510
M0035421020	M0035431530	M0035452020		

Lot Code: See Attached

Dear customer:

Stryker Neurovascular has initiated a voluntary recall and removal for the devices identified above. Our records indicate that you have been supplied with at least one of the subject devices. We therefore request that you read this notice carefully and complete the actions requested by the manufacturer. The intent of this letter is to instruct you to return all impacted product to Stryker.

Issue:

Stryker Neurovascular has become aware that some units of Target Nano product do not have the intended stretch resistance. The sutures inside the coil that provide stretch resistance may have been damaged during manufacturing which can lead to an increased occurrence of coil stretching.

Potential Risk

Patients with implanted coils are not affected by this issue.

For potential patients- Suture breaking can lead to coil stretching. The most likely adverse health consequence from coil stretching is prolongation of the procedure after introducing into the patient, as the stretched coil needs to be removed and replaced, as directed by the IFU. There is a remote potential of thrombus formation when the stretched coil is left exposed in the blood flow. There will be no long term adverse health consequence after a stretched coil is removed from the body.

Risk Mitigation:

Follow the instructions below under Immediate Actions Required.

Completed Corrective Action

This is a lot-specific manufacturing issue that has been corrected. Target Nano quality has been maintained.

Urgent Medical Device Voluntary Recall

Immediate Action Required

We request that you read this notice carefully and complete the following actions:

1. Immediately check your internal inventory for impacted Catalog and lot numbers.
2. Segregate the affected units in a secure location for return to Stryker.
3. Circulate this Field Safety Notice internally to all interested/affected parties.
4. Maintain awareness of this notice internally until all required actions have been completed within your facility.
5. Inform Stryker if any of the subject devices have been distributed to other organizations.
 - a) *Please provide contact details so that Stryker can inform the recipients appropriately.*
6. Please inform Stryker of any adverse events concerning the use of the subject devices.
7. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore please complete the form even if you no longer have any of the subject devices in your physical inventory.
8. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA.

We request that you respond to this notice within 7 calendar days from the date of receipt. The target date for completion of this action is 01 Aug 2016 and your timely response will enable us to ensure that we meet this target.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: Geraldine Ahern
Position: Quality Manager
Email: Geraldine.ahern@stryker.com
Telephone: 510 413 2593

On behalf of Stryker we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Yours Sincerely,

Geraldine Ahern

Urgent Medical Device Voluntary Recall

Immediate Action Required

List of Impacted Lots

183 lots

18391277	18391505	18391790	18393386	18393530	18393710	18393950	18397945	18398230	18398515
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184 lots

18402198	18414374	18420011	18432978	18440351	18450202	18460621	18470167	18482415	18490538
18403443	18414488	18420182	18433149	18440708	18450373	18461134	18470287	18482417	18490600
18406635	18416223	18420239	18433263	18440768	18450430	18461647	18470407	18482418	18490662
18406749	18416403	18426357	18433320	18440828	18450658	18462217	18470767	18484141	18490724
18406806	18417674	18426444	18434346	18440858	18452822	18462274	18470827	18484661	18490910
	18419555	18426504	18436562	18441368	18453278	18462388	18470857	18484777	18490972
	18419897	18426876	18436622	18441458	18453506	18462418	18471007	18486090	18491003
		18429414	18437033	18441488	18454649	18462508	18473146	18486322	18491065
		18429528	18437093	18441728	18455339	18462748	18473260	18486380	18491096
			18439343	18442058	18455453	18462838		18487470	18495363
			18439457	18442178	18455711	18465901		18487818	18499021
			18439775	18442268	18455861	18466471		18488340	18499207
			18439805	18442358	18455921	18468754		18488746	18499486
				18442388	18456041	18469498		18488920	
				18442508	18456101	18469612		18488978	
				18442538	18456191	18469669		18489183	
				18442568	18456251	18469927		18489245	
				18442688	18458590	18469957		18489524	
				18442838	18458818			18489834	
				18442958	18459616			18489927	
				18443018					
				18443048					
				18443108					
				18443198					
				18443228					
				18443258					
				18443288					
				18447937					
				18447942					
				18447952					
				18449404					
				18449575					

185 lots

18503529	18510878	18521064	18531974	18541957	18551604	18562741	18571369	18581295	18590180
	18510936	18521095	18532032	18542073	18551662	18562915	18571427	18581353	18590354
	18510994	18521126	18532556	18542189	18551778	18562973	18571601	18581469	18590412
	18511110	18521395	18532587	18542305	18551836	18563089	18571717	18581643	18590470
	18515042	18521457	18534023	18542363	18551894	18563147	18571775	18582045	18590528
	18515100	18522949	18534255	18542421	18553555	18563263	18571949	18582103	18590586
	18515274	18523236	18534545	18542479	18553671	18563321	18576579	18582275	18590644
	18515390	18523410	18534777	18543905	18553961	18564861	18576637	18582333	18590702
	18516768	18523870	18534835	18544079	18554019	18567759	18576695	18582391	18590760
	18517433	18524506	18535009	18544137	18554135	18567790	18576927	18582449	18590818
	18517549	18524564	18536525	18546117	18554193	18567883	18578953	18582507	18590876
	18517839	18524622	18538344	18546175	18554251	18567914	18579069	18582565	18590992

Urgent Medical Device Voluntary Recall

Immediate Action Required

	18517955		18538832	18546861	18554485	18567945		18582681	18591050
	18518071		18538894	18549270	18554516	18568007		18582739	18591108
	18518477		18538925		18554671	18568131		18583254	18591166
	18519562		18538956		18554733	18568193		18583312	18592036
			18539018		18556378	18568224		18583601	18592210
			18539797		18557240	18568317		18583632	18592500
					18557356	18568847		18583663	18598125
					18557472	18568905		18583694	18598183
					18557530	18568963		18583725	18598241
					18559192	18569137		18583787	18598299
					18559250	18569766		18583880	18598415
					18559308	18569824		18583942	18598589
						18569882		18584004	18598705
								18584035	18598763
								18584194	18598879
								18584252	18598937
								18585000	18598995
								18585290	18599053
								18585521	18599111
									18599227

186 lots

18601901	18619857	18620147	18630099	18641856	18651227	18660541	18676359	18685258	18693095
18601959	18619915	18620205	18630215	18641914	18651285	18660599	18676533	18685490	18694228
18602017		18623511	18633805	18641972	18651865	18660657	18676591	18685548	
18602133		18625135	18633863	18642030	18651923	18660773	18676649	18685838	
18602249		18625193	18633921	18642088	18651981	18660831	18676707	18686012	
18602307		18625251	18634037	18642146	18652851	18660889	18676881	18686302	
18602365		18625483	18637042	18642262	18653835	18660947	18676997	18686418	
18602423		18625541	18637216	18642320	18653893	18664543	18677113	18686476	
18602481		18625599	18637274	18642436	18654009	18664601	18677171	18686534	
18602655		18627281	18637332	18642494	18654067	18665561	18677229	18686650	
18603553		18627513	18637390	18642610	18654125	18666257	18677287		
18603584		18627687	18637448	18642668	18654156	18666315	18677403		
18604160		18628881	18637506	18642726	18654187	18666373	18677461		
18604218		18628939	18637564	18642784	18654249	18666489	18677519		
18604392		18629171	18637622	18642842	18654280	18666547	18677577		
18604450		18629229	18637680	18643654	18654311	18666663	18677693		
18604508		18629287	18637738	18643778	18654342	18666721	18677809		
18604566		18629461	18638260	18647115	18654373	18666779	18677925		
18606600		18629519	18638318	18647173	18654404	18666837	18679027		
18606631		18629577	18638376	18647231	18654466	18666895	18679058		
18606693		18629635		18647289	18654497	18666953	18679089		
18606940				18647347	18654528	18667011	18679120		
18607230				18647405	18654590	18667069	18679151		
18607288				18647463	18654621	18667185			
18607578				18647521	18657142	18667475			
18607752				18647637	18657200	18667537			
				18648913	18657316				
				18649087	18659056				
					18659087				

Urgent Medical Device Voluntary Recall

Immediate Action Required

187 lots

18700158	18710356	18721125	18730042	18740007	18750193	18760112	18770164	18780350	18790021
18700216	18714014	18721156	18730158	18740154	18750398	18760113	18770369	18780961	18790079
18700274	18714072	18721938	18730274	18740448	18750603	18760116	18770574	18781019	18790137
18700332	18714130	18722263	18730570	18740738	18750808	18760117	18771042	18781251	18790253
18700448	18714188	18722727	18732530	18741144	18752256	18760119	18771506	18782584	18790369
18700622	18714246	18723052	18732878	18741318	18754448	18760120	18771622	18783540	18790427
18700680	18714304	18723226	18734430	18741434	18754879	18760121	18771711	18784557	18790485
18700796	18714420	18723284	18734778	18741608	18755053	18760123	18771773	18784673	18790543
18700912	18714478	18723864	18735178	18741898	18755514	18760129	18771835	18784731	18790601
18700970	18714536	18723922	18735209	18741929	18755945	18760130	18772009	18785369	18790659
18701028	18714594	18725103	18735646	18741991	18756119	18760131	18772067	18785485	18790717
18701086	18714652	18725503	18735994	18742022	18757273	18760132	18772125	18786181	18790775
18701144	18714768	18725944	18736394	18742080	18758018	18762227	18772183	18786297	18794100
18701202	18715147	18725975	18736425	18742196	18758049	18764659	18774611	18786355	18794216
18701260	18715383	18726180	18736746	18742312	18758107	18765615	18775373	18787213	18794332
18701318	18715530	18726354	18736862	18742370	18758254	18765704	18776301	18787244	18794421
18701434	18715561	18726385	18736978	18742428	18758370	18766571	18776332	18787418	18794568
18701492	18719333	18727594	18737036	18742602	18758428	18767070	18776363	18787449	18796245
18701550		18727625	18738163	18742660	18758459	18767279	18776421	18787623	18797083
18701608		18727714	18739085	18742718	18758575	18767569	18776711	18787654	
18701724		18727745		18742776	18758722	18767778	18776885	18787828	
18701782		18727834		18742834	18758780	18767952	18777349	18787859	
18701840		18727865		18742892	18758838	18768041	18777380	18788265	
18701898		18728186		18742950	18758869	18768273	18777411	18788439	
18702304		18729346		18743910	18758958	18768594	18777759	18789193	
18702335		18729520		18744204	18758989	18768683	18778397	18789313	
18702459				18746995	18759109	18769352	18778428	18789344	
18702490				18747459	18759314	18769468	18778602	18789433	
18702552				18748105	18759372	18769642	18778633	18789464	
18703233				18748163	18759430	18769700	18778807	18789553	
18703264				18748395	18759488	18769816	18779217	18789584	
18703469				18748453		18769874	18779248	18789673	
18708724				18748627		18769932	18779279	18789731	
18708786				18749033		18769990		18789789	
18709049				18749439				18789847	
18709428								18789905	
18709486								18789963	
18709718									

188 lots

18800019	18810030	18820005	18830181	18841964	18852438	18860449	18870025	18881017	18893301
18800256	18810061	18820036	18830247	18842022	18852469	18860564	18870085	18881222	18893417
18801344	18810150	18820067	18830452	18842138	18852906	18860682	18870160	18881427	18893506
18801433	18810181	18820098	18830541	18842254	18853712	18861952	18870222	18881632	18893796
18801491	18810270	18820477	18830630	18842831	18853805	18862068	18870284	18881663	18893885
18801549	18810301	18820593	18830688	18842889	18853836	18862184	18870346	18881694	18894059
18801607	18810390	18820709	18831210	18843005	18854389	18864702	18870425	18881725	18894175
18801665	18810506	18820825	18831276	18843121	18855184	18864775	18870480	18881756	18894264
18801847	18810622	18820941	18831481	18843698	18857263	18864836	18870593	18881787	18894438
18801963	18810738	18821057	18831539	18843756	18857373	18865965	18870712	18881818	18894554
18802659	18810854	18821173	18831597	18843872	18858983	18866197	18870833	18881876	18894643

Urgent Medical Device Voluntary Recall

Immediate Action Required

18802748	18810970	18824328	18831744	18845411	18859100	18866429	18870941	18881934	18894982
18802806	18811086	18824386	18831860	18845469	18859219	18866658	18871055	18881992	18895098
18802864	18811144	18824444	18832034	18845527		18866890	18871174	18882050	18895156
18802922	18811202	18824502	18832208	18845790		18867586	18871292	18882108	18895272
18802980	18811260	18824618	18832355	18845848		18867934	18871405	18882166	18895388
18803162	18811318	18824649	18832645	18845906		18868279	18871523	18882224	18895446
18803278	18811376	18824738	18832819	18846169		18868628	18871639	18882282	18895678
18807570	18811434	18824769	18832966	18846227		18868972	18871763	18882340	18895736
18807744	18811550	18824858	18833082	18846285		18869318	18871880	18882398	18895852
18807918	18811608	18824889	18833256	18846548		18869664	18871997	18882456	18895968
18808498	18811666	18824978	18837651	18846606		18869748	18872114	18882514	18896026
18808529	18811724	18825009	18838703	18846664		18869810	18875322	18882572	18896142
18808618	18811840	18825098		18846927		18869869	18875384	18883033	18896258
18808792	18812672	18825156		18846985		18869954	18875473	18883354	18896316
18808823	18812788	18825214		18847043			18875678	18883412	18896432
18808912	18814099	18825272		18847101			18875709	18885142	18896463
18809086	18814270	18825330		18847159			18876352	18885200	18896521
18809117	18814328	18825388		18847217			18876468	18885258	18896552
18809206	18815140	18825446		18847275			18876957	18885463	18896610
18809411	18815198	18825562		18847333			18877220	18885637	18896641
18809500	18816010	18825620		18847391			18877336	18885811	18896699
18809674	18816099	18825736		18847507			18877825	18886556	18896730
18809705	18816588	18825794		18847681			18878088	18886614	18896843
18809794	18816704	18825910		18847712			18878146	18886672	18896901
18809910	18817251	18825968		18847859			18878204	18886877	18897014
18809941	18817309	18826084		18847890			18878607	18887051	18897185
	18817367	18826142		18848037			18879010	18887225	18897356
	18817914	18826258		18848068				18887573	18897414
	18817972	18826316		18848215				18887631	18897527
	18818030	18826432		18848246				18887689	18897585
	18818177	18826490		18848277				18887747	18897698
	18818208	18826606		18848335				18888037	18897756
	18818239	18826753		18848393				18888559	18897814
	18818270	18826900		18848451				18889081	18897845
	18818328	18827047		18848509					18897876
	18818444	18827194		18848567					18897907
	18818502	18827341		18848625					18897938
	18818618	18827488		18848741					18897969
	18818676	18827994		18848857					18898116
	18818792	18829512		18848973					18898321
	18818850	18829601		18849089					18899164
	18819711	18829659		18849205					18899967
	18819769			18849321					18899998
	18819827			18849495					
	18819885								
	18819943								
	18819974								

Urgent Medical Device Voluntary Recall

Immediate Action Required

189 lots

18900809	18910290	18922370	18930269	18940339	18950060	18960301	18970562	18984769	18990009
18900840	18910638	18922401	18930614	18940954	18950234	18960332	18970593	18984771	18990624
18901428	18911270	18922696	18930672	18941012	18950323	18960708	18971469	18984787	18990655
18901486	18911301	18922785	18930959	18941128	18950354	18961060	18971500	18984845	18991100
18901660	18911332	18923191	18931017	18941418	18950385	18961118	18971589	18984903	18991622
18901691	18911418	18923481	18931307	18941476	18950416	18961180	18971989	18984961	18991796
18901749	18911592	18925282	18931365	18941592	18950447	18961238	18972020	18985193	18992349
18902302	18911821	18925429	18931539	18941882	18950826	18961269	18972051	18985483	18992380
18902333	18911995	18926529	18931597	18941940	18950884	18963382	18972140	18985514	18992566
18902391	18912224	18927253	18931771	18942056	18950942	18963440	18972772	18986505	18992597
18902944	18912398	18927369	18931829	18943082	18951000	18963556	18972803	18986652	18992628
18902975	18912627	18927485	18932632	18943198	18951058	18963846	18972861	18987031	18992659
18903033	18912801	18928012	18932663	18943369	18951116	18963904	18973029	18987089	18992690
18905625	18913323	18928128	18932694	18943458	18951205	18964020	18973118	18987445	18998464
18905687	18913354	18928244	18932725	18943605	18951441	18964310	18973149	18987592	18998522
18905718	18913412	18928771	18932988	18943721	18951588	18964368	18973207		18998580
18905865	18913586	18928887	18933046	18943892	18951677	18964484	18973495		18998638
18905896	18913617	18929003	18933104	18943981	18951824	18964774	18973553		18998696
18905927	18913675	18929924	18933162	18944128	18951913	18964832	18973721		18998754
18905990	18913849	18929982	18933220	18944244	18952060	18964948	18974152		18998812
18906402	18913880		18933278	18944415	18952149	18965644	18974210		18998870
18906549	18913938		18933336	18944504	18952296	18965760	18974268		18998928
18906580	18914112		18933425	18944651	18952385	18965876	18974589		18998990
18906669	18914143		18933514	18944767	18953265	18965992	18974705		18999021
18906932	18914201		18933603	18944938	18953296		18974821		
18909768	18914375		18933692	18945174	18953644		18975026		
18909826	18914406		18933781	18945290	18953849		18975084		
18909942	18914464		18933839	18945406	18953907		18975142		
	18914812		18933897	18946218	18954139		18975258		
	18915017		18933955	18946365	18954631		18975463		
	18915222		18934013	18946691	18954755		18975521		
	18915458		18934071	18946749	18955103		18975579		
	18915516		18934129	18946780	18955537		18975695		
	18915574		18935083	18946838	18955661		18975900		
	18915632		18935230	18946869	18956009		18975958		
	18915690		18935435	18946927	18956241		18975989		
	18915748		18936943	18946958	18956299		18976047		
	18916212		18938172	18947016	18956531		18976078		
	18916270		18938917	18947047	18956647		18976136		
	18916328		18939358	18947105	18956763		18976167		
	18916386		18939389	18947136	18957111		18976225		
	18916444		18939594	18947194	18957227		18976256		
	18916502			18947310	18957343		18976403		
				18947368	18957691		18976461		
				18947484	18957807		18976550		
				18947542	18959391		18976608		
				18947658			18976697		
				18947716			18976755		
				18947832			18976844		
				18948006			18976902		
				18948064			18977223		

Urgent Medical Device Voluntary Recall

Immediate Action Required

				18948180			18977312		
				18948238			18977370		
				18949712			18977459		
				18949886			18977490		
							18977548		
							18977579		
							18977637		
							18977668		
							18977726		
							18977900		
							18977958		
							18978132		
							18978190		
							18978364		
							18978422		
							18978596		
							18978654		
							18978828		
							18979060		
							18979118		

190 Lots

19000510	19010180	19022830	19030017	19040295	19050397	19060071	19070054	19080007
19000541	19010580	19025429	19030075	19041022	19050513	19060245	19070286	19080038
19000572	19012044	19025545	19030133	19041285	19050975	19060276	19070518	19080127
19001620	19012218	19025829	19030191	19041517	19051953	19060307	19070750	19080185
19001678	19012392	19026038	19030249	19041807	19052011	19060338	19070866	19080216
19002155	19012985	19026353	19030307	19042039	19052274	19060369	19071040	19080305
19002213	19013074	19026562	19030365	19042329	19052332	19061363	19071071	19080839
19002271	19013163	19026877	19030423	19042561	19052595	19062764	19071102	19080897
19002329	19013252	19027086	19030481	19042851	19052653	19062880	19071276	19081044
19002677	19013341	19027905	19030512	19043083	19052916	19063170	19071307	19081102
19002735	19013399	19027936	19030570	19043373	19052974	19063228	19071338	19081307
19002793	19013430	19028025	19030601	19043431	19053585	19063344	19071512	19081659
19002851	19013488	19028056	19030659	19043547	19053759	19063669	19071543	19081717
19002909	19013519	19028145	19030690	19043605	19053933	19063700	19073781	19082823
19003141	19013577	19028176	19030779	19043636	19054107	19064636	19074243	19082881
19003547	19013608	19028265	19030837	19043694	19054629	19064752	19075513	19083403
19003721	19013666	19028296	19030868	19043725	19054660	19065042	19075571	19086497
19003895	19013697	19028733	19030926	19043783	19054691	19065216	19075803	19086586
19004069	19013755	19028965	19031155	19043814	19054722	19065247	19076325	19086644
19004359	19013786	19029197	19031329	19043872	19054753	19065278	19079949	
19004417	19013844	19029429	19031387	19043961	19054784	19065336		
19004475	19013875	19029661	19031445	19043992	19054815	19065394		
19004533	19013933	19029893	19031619	19044050	19054846	19065452		
19004591	19013991	19029924	19031677	19044108	19054877	19065510		
19005113	19014049	19029955	19031735	19044166	19054908	19065568		

Urgent Medical Device Voluntary Recall

Immediate Action Required

19005171	19014107		19031909	19044456	19054939	19065626		
19005287	19014165		19031967	19044514	19055055	19065684		
19005345	19014223		19032025	19044572	19055171	19065742		
19005403	19014281		19032199	19044630	19055287	19065800		
19005693	19014339		19032257	19044688	19055403	19065916		
19005724	19014397		19032837	19044746	19055519	19066241		
19006438	19014455		19032868	19044862	19055635	19066272		
	19014513		19032899	19044951	19055751	19067208		
	19014571		19032930	19045040	19055809	19068422		
	19014602		19032961	19045129	19055925	19068743		
	19014633		19032992	19045218	19055983	19069064		
	19014664		19033487	19045249	19056041	19069385		
	19014695		19033545	19045311	19056099	19069822		
	19014726		19034203	19045342	19056157			
	19014757		19034292	19045373	19056273			
	19014788		19034323	19045404	19056331			
	19014819		19034354	19046456	19056621			
	19014850		19035290	19046694	19056652			
	19014881		19036655	19046992	19056683			
	19014943		19036717	19047456	19058510			
	19014974		19037618	19047487				
			19037908	19047725				
			19037939	19048139				
			19037970	19048197				
			19039567	19048313				
				19048891				
				19049355				
				19049471				
				19049933				

Urgent Medical Device Voluntary Recall
Immediate Action Required

STRYKER® NEUROVASCULAR
URGENT MEDICAL DEVICE RECALL- REMOVAL
ACKNOWLEDGMENT FORM

FSCA identified: Product Field Action RA2016-088

Type of Action: RECALL-REMOVAL

Description: Target Nano

Catalog #:

M0035442540	M0035421520	M0035431520	M0035452530	M0035452040
M0035442040	M0035421030	M0035431030	M0035452060	M0035453060
M0035421540	M0035431020	M0035443560	M0035452540	M0035453040
M0035421530	M0035431010	M0035443040	M0035453080	M0035452030
M0035442030	M0035431540	M0035443060	M0035452560	M0035431510
M0035421020	M0035431530	M0035452020		

Lot Code: Per listing supplied by Stryker

Product Disposition				
Product Code/Cat No.	Lot/ Serial No	Qty to be returned	Qty /Used Implanted	Qty not located

I have received the notification from Stryker stating that they have initiated a product field action for the above referenced product.

☐ I acknowledge receipt of the of this **URGENT MEDICAL DEVICE RECALL- REMOVAL**

Form completed by:			
Contact Name		Facility	
Contact address		Signature	
		Phone	
Date		Email	

Please fax or email this signed and dated form to fax number: 1 (866) 876-4355 or
NeuroComplaints@stryker.com

Urgent Medical Device Voluntary Recall

Immediate Action Required

Medical Device Recall **Frequently Asked Questions**

- (1) Why are the Target Nano Coils being recalled?**
In certain lots of Target Nano detachable coils, the suture may be broken and this can lead to coil stretching.
- (2) What is the potential root cause?**
As part of normal manufacturing processes, Target Nano Coils are exposed to heat during an electrical placement test. In certain lots where there was an equipment malfunction, the coils were exposed to temperatures higher than the suture melting temperature. In a portion of coils in the affected lots, this heat caused the suture to melt and break. Corrective action has been taken to address this issue.
- (3) Does this Recall involve global markets?**
Yes, countries impacted include EMEA, Japan, China, and US.
- (4) Is the FDA aware of this recall?**
The FDA and all affected worldwide regulatory authorities are being notified about this voluntary recall.
- (5) Have there been any patient injuries?**
There have been 10 complaints from customers related to this issue. There have been no patient injuries reported in association with these complaints.
- (6) Are all Target Nano Detachable Coils impacted by this recall?**
No. Only a limited specific lot numbers of Target Nano Detachable Coils are impacted. A list of all affected product has been included in each Customer Notification Letter.
- (7) If a customer has to return their Target Nano Detachable Coils, will they get a replacement?**
Yes. Corrective action has been taken to address the manufacturing issue. New units are being manufactured with full replenishment over the next several weeks. All other coils are available and are suitable for patient treatment
- (8) Are there risks to patients in whom the affected lots have already been implanted?**
No, coil stretching is evidence on coil deployment and does not occur post deployment and as a result there is no risk to patients who currently have units from the impacted lots implanted.
- (9) Is the quality of Target Nano detachable coils impacted?**
No, we have taken immediate corrective action to the equipment malfunction to avoid any future issues.