

**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 |
|----------|----------|----------|----------|----------|----------|----------|----------|----------|----------|

**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

|                           |  |                  |  |
|---------------------------|--|------------------|--|
| <b>Form completed by:</b> |  |                  |  |
| <b>Contact Name</b>       |  | <b>Facility</b>  |  |
| <b>Contact address</b>    |  | <b>Signature</b> |  |
|                           |  | <b>Phone</b>     |  |
| <b>Date</b>               |  | <b>Email</b>     |  |

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.