stryker

URGENT

Medical Device Recall Notification

Precision Pointer Electro Magnetic (EM)

Attn : Risk Manager, Materials Manager, OR Director

Recall Number: RA2026-4463066

October, 2026



Purpose of this letter

The purpose of this letter is to inform you that Stryker Instruments has initiated a voluntary product field action for Precision pointer Electromagnetic. The table below includes the devices impacted by the product field action:

Catalogue No.	Product Description	GTIN	Affected Serial Number
8000-050-001	Precision pointer Electromagnetic	07613327413205	212071
8000-050-001	Precision pointer Electromagnetic	07613327413205	212072
8000-050-001	Precision pointer Electromagnetic	07613327413205	212073
8000-050-001	Precision pointer Electromagnetic	07613327413205	212074
8000-050-001	Precision pointer Electromagnetic	07613327413205	212075
8000-050-001	Precision pointer Electromagnetic	07613327413205	212076
8000-050-001	Precision pointer Electromagnetic	07613327413205	212077
8000-050-001	Precision pointer Electromagnetic	07613327413205	212078
8000-050-001	Precision pointer Electromagnetic	07613327413205	212079
8000-050-001	Precision pointer Electromagnetic	07613327413205	212080
8000-050-001	Precision pointer Electromagnetic	07613327413205	212081
8000-050-001	Precision pointer Electromagnetic	07613327413205	212082
8000-050-001	Precision pointer Electromagnetic	07613327413205	212083
8000-050-001	Precision pointer Electromagnetic	07613327413205	212084
8000-050-001	Precision pointer Electromagnetic	07613327413205	212085
8000-050-001	Precision pointer Electromagnetic	07613327413205	212086
8000-050-001	Precision pointer Electromagnetic	07613327413205	212087
8000-050-001	Precision pointer Electromagnetic	07613327413205	212088
8000-050-001	Precision pointer Electromagnetic	07613327413205	212089
8000-050-001	Precision pointer Electromagnetic	07613327413205	212090
8000-050-001	Precision pointer Electromagnetic	07613327413205	212181
8000-050-001	Precision pointer Electromagnetic	07613327413205	212183
8000-050-001	Precision pointer Electromagnetic	07613327413205	212184
8000-050-001	Precision pointer Electromagnetic	07613327413205	212185
8000-050-001	Precision pointer Electromagnetic	07613327413205	212186
8000-050-001	Precision pointer Electromagnetic	07613327413205	212187
8000-050-001	Precision pointer Electromagnetic	07613327413205	212188
8000-050-001	Precision pointer Electromagnetic	07613327413205	212189
8000-050-001	Precision pointer Electromagnetic	07613327413205	212211
8000-050-001	Precision pointer Electromagnetic	07613327413205	212212
8000-050-001	Precision pointer Electromagnetic	07613327413205	212213
8000-050-001	Precision pointer Electromagnetic	07613327413205	212216
8000-050-001	Precision pointer Electromagnetic	07613327413205	212217
8000-050-001	Precision pointer Electromagnetic	07613327413205	212218
8000-050-001	Precision pointer Electromagnetic	07613327413205	212219
8000-050-001	Precision pointer Electromagnetic	07613327413205	212220
8000-050-001	Precision pointer Electromagnetic	07613327413205	212146

Catalogue No.	Product Description	GTIN	Affected Serial Number
8000-050-001	Precision pointer Electromagnetic	07613327413205	212251
8000-050-001	Precision pointer Electromagnetic	07613327413205	212252
8000-050-001	Precision pointer Electromagnetic	07613327413205	212256
8000-050-001	Precision pointer Electromagnetic	07613327413205	212316
8000-050-001	Precision pointer Electromagnetic	07613327413205	212351
8000-050-001	Precision pointer Electromagnetic	07613327413205	212392
8000-050-001	Precision pointer Electromagnetic	07613327413205	212394
8000-050-001	Precision pointer Electromagnetic	07613327413205	212399
8000-050-001	Precision pointer Electromagnetic	07613327413205	212400
8000-050-001	Precision pointer Electromagnetic	07613327413205	212391
8000-050-001	Precision pointer Electromagnetic	07613327413205	212373
8000-050-001	Precision pointer Electromagnetic	07613327413205	212393
8000-050-001	Precision pointer Electromagnetic	07613327413205	212395
8000-050-001	Precision pointer Electromagnetic	07613327413205	212397
8000-050-001	Precision pointer Electromagnetic	07613327413205	212362
8000-050-001	Precision pointer Electromagnetic	07613327413205	212363
8000-050-001	Precision pointer Electromagnetic	07613327413205	212368
8000-050-001	Precision pointer Electromagnetic	07613327413205	212369
8000-050-001	Precision pointer Electromagnetic	07613327413205	212370
8000-050-001	Precision pointer Electromagnetic	07613327413205	212378
8000-050-001	Precision pointer Electromagnetic	07613327413205	212379
8000-050-001	Precision pointer Electromagnetic	07613327413205	212361
8000-050-001	Precision pointer Electromagnetic	07613327413205	212365
8000-050-001	Precision pointer Electromagnetic	07613327413205	212366
8000-050-001	Precision pointer Electromagnetic	07613327413205	212372
8000-050-001	Precision pointer Electromagnetic	07613327413205	212374
8000-050-001	Precision pointer Electromagnetic	07613327413205	212371
8000-050-001	Precision pointer Electromagnetic	07613327413205	212381
8000-050-001	Precision pointer Electromagnetic	07613327413205	212401
8000-050-001	Precision pointer Electromagnetic	07613327413205	212404
8000-050-001	Precision pointer Electromagnetic	07613327413205	212408
8000-050-001	Precision pointer Electromagnetic	07613327413205	212409
8000-050-001	Precision pointer Electromagnetic	07613327413205	212382
8000-050-001	Precision pointer Electromagnetic	07613327413205	212384
8000-050-001	Precision pointer Electromagnetic	07613327413205	212385
8000-050-001	Precision pointer Electromagnetic	07613327413205	212388
8000-050-001	Precision pointer Electromagnetic	07613327413205	212390
8000-050-001	Precision pointer Electromagnetic	07613327413205	212415
8000-050-001	Precision pointer Electromagnetic	07613327413205	212416
8000-050-001	Precision pointer Electromagnetic	07613327413205	212419
8000-050-001	Precision pointer Electromagnetic	07613327413205	212421
8000-050-001	Precision pointer Electromagnetic	07613327413205	212428
8000-050-001	Precision pointer Electromagnetic	07613327413205	212481
8000-050-001	Precision pointer Electromagnetic	07613327413205	212483
8000-050-001	Precision pointer Electromagnetic	07613327413205	212443
8000-050-001	Precision pointer Electromagnetic	07613327413205	212445
8000-050-001	Precision pointer Electromagnetic	07613327413205	212447
8000-050-001	Precision pointer Electromagnetic	07613327413205	212450
8000-050-001	Precision pointer Electromagnetic	07613327413205	212469
8000-050-001	Precision pointer Electromagnetic	07613327413205	212486
8000-050-001	Precision pointer Electromagnetic	07613327413205	212488
8000-050-001	Precision pointer Electromagnetic	07613327413205	212495
8000-050-001	Precision pointer Electromagnetic	07613327413205	212550
8000-050-001	Precision pointer Electromagnetic	07613327413205	212559

Catalogue No.	Product Description	GTIN	Affected Serial Number
8000-050-001	Precision pointer Electromagnetic	07613327413205	212482
8000-050-001	Precision pointer Electromagnetic	07613327413205	212490
8000-050-001	Precision pointer Electromagnetic	07613327413205	212491
8000-050-001	Precision pointer Electromagnetic	07613327413205	212492
8000-050-001	Precision pointer Electromagnetic	07613327413205	212494
8000-050-001	Precision pointer Electromagnetic	07613327413205	212433
8000-050-001	Precision pointer Electromagnetic	07613327413205	212489
8000-050-001	Precision pointer Electromagnetic	07613327413205	212493
8000-050-001	Precision pointer Electromagnetic	07613327413205	212439
8000-050-001	Precision pointer Electromagnetic	07613327413205	212567
8000-050-001	Precision pointer Electromagnetic	07613327413205	212570
8000-050-001	Precision pointer Electromagnetic	07613327413205	212571
8000-050-001	Precision pointer Electromagnetic	07613327413205	212573
8000-050-001	Precision pointer Electromagnetic	07613327413205	212436
8000-050-001	Precision pointer Electromagnetic	07613327413205	212575
8000-050-001	Precision pointer Electromagnetic	07613327413205	212576
8000-050-001	Precision pointer Electromagnetic	07613327413205	212577
8000-050-001	Precision pointer Electromagnetic	07613327413205	212578
8000-050-001	Precision pointer Electromagnetic	07613327413205	212579
8000-050-001	Precision pointer Electromagnetic	07613327413205	212580
8000-050-001	Precision pointer Electromagnetic	07613327413205	212581
8000-050-001	Precision pointer Electromagnetic	07613327413205	212584
8000-050-001	Precision pointer Electromagnetic	07613327413205	212587
8000-050-001	Precision pointer Electromagnetic	07613327413205	212588
8000-050-001	Precision pointer Electromagnetic	07613327413205	212606
8000-050-001	Precision pointer Electromagnetic	07613327413205	212607
8000-050-001	Precision pointer Electromagnetic	07613327413205	212608
8000-050-001	Precision pointer Electromagnetic	07613327413205	212609
8000-050-001	Precision pointer Electromagnetic	07613327413205	212610
8000-050-001	Precision pointer Electromagnetic	07613327413205	212611
8000-050-001	Precision pointer Electromagnetic	07613327413205	212612
8000-050-001	Precision pointer Electromagnetic	07613327413205	212613
8000-050-001	Precision pointer Electromagnetic	07613327413205	212614
8000-050-001	Precision pointer Electromagnetic	07613327413205	212615
8000-050-001	Precision pointer Electromagnetic	07613327413205	212616
8000-050-001	Precision pointer Electromagnetic	07613327413205	212617
8000-050-001	Precision pointer Electromagnetic	07613327413205	212618
8000-050-001	Precision pointer Electromagnetic	07613327413205	212619
8000-050-001	Precision pointer Electromagnetic	07613327413205	212620
8000-050-001	Precision pointer Electromagnetic	07613327413205	212639
8000-050-001	Precision pointer Electromagnetic	07613327413205	212640
8000-050-001	Precision pointer Electromagnetic	07613327413205	212641
8000-050-001	Precision pointer Electromagnetic	07613327413205	212644
8000-050-001	Precision pointer Electromagnetic	07613327413205	212645
8000-050-001	Precision pointer Electromagnetic	07613327413205	212646
8000-050-001	Precision pointer Electromagnetic	07613327413205	212440
8000-050-001	Precision pointer Electromagnetic	07613327413205	212568
8000-050-001	Precision pointer Electromagnetic	07613327413205	212437
8000-050-001	Precision pointer Electromagnetic	07613327413205	212586
8000-050-001	Precision pointer Electromagnetic	07613327413205	212585
8000-050-001	Precision pointer Electromagnetic	07613327413205	212589
8000-050-001	Precision pointer Electromagnetic	07613327413205	212600
8000-050-001	Precision pointer Electromagnetic	07613327413205	212561
8000-050-001	Precision pointer Electromagnetic	07613327413205	212563

Catalogue No.	Product Description	GTIN	Affected Serial Number
8000-050-001	Precision pointer Electromagnetic	07613327413205	212569
8000-050-001	Precision pointer Electromagnetic	07613327413205	212657
8000-050-001	Precision pointer Electromagnetic	07613327413205	212660
8000-050-001	Precision pointer Electromagnetic	07613327413205	212630
8000-050-001	Precision pointer Electromagnetic	07613327413205	212623
8000-050-001	Precision pointer Electromagnetic	07613327413205	212651
8000-050-001	Precision pointer Electromagnetic	07613327413205	212653
8000-050-001	Precision pointer Electromagnetic	07613327413205	212661
8000-050-001	Precision pointer Electromagnetic	07613327413205	212662
8000-050-001	Precision pointer Electromagnetic	07613327413205	212621
8000-050-001	Precision pointer Electromagnetic	07613327413205	212624
8000-050-001	Precision pointer Electromagnetic	07613327413205	212632
8000-050-001	Precision pointer Electromagnetic	07613327413205	212633
8000-050-001	Precision pointer Electromagnetic	07613327413205	212635
8000-050-001	Precision pointer Electromagnetic	07613327413205	212681
8000-050-001	Precision pointer Electromagnetic	07613327413205	212686
8000-050-001	Precision pointer Electromagnetic	07613327413205	212687
8000-050-001	Precision pointer Electromagnetic	07613327413205	212688
8000-050-001	Precision pointer Electromagnetic	07613327413205	212668
8000-050-001	Precision pointer Electromagnetic	07613327413205	212670
8000-050-001	Precision pointer Electromagnetic	07613327413205	212673
8000-050-001	Precision pointer Electromagnetic	07613327413205	212674
8000-050-001	Precision pointer Electromagnetic	07613327413205	212676
8000-050-001	Precision pointer Electromagnetic	07613327413205	212671
8000-050-001	Precision pointer Electromagnetic	07613327413205	212675
8000-050-001	Precision pointer Electromagnetic	07613327413205	212684
8000-050-001	Precision pointer Electromagnetic	07613327413205	212685
8000-050-001	Precision pointer Electromagnetic	07613327413205	212689
8000-050-001	Precision pointer Electromagnetic	07613327413205	212690
8000-050-001	Precision pointer Electromagnetic	07613327413205	212682
8000-050-001	Precision pointer Electromagnetic	07613327413205	212233
8000-050-001	Precision pointer Electromagnetic	07613327413205	212234
8000-050-001	Precision pointer Electromagnetic	07613327413205	212235
8000-050-001	Precision pointer Electromagnetic	07613327413205	212239
8000-050-001	Precision pointer Electromagnetic	07613327413205	212243
8000-050-001	Precision pointer Electromagnetic	07613327413205	212281
8000-050-001	Precision pointer Electromagnetic	07613327413205	212288
8000-050-001	Precision pointer Electromagnetic	07613327413205	212295
8000-050-001	Precision pointer Electromagnetic	07613327413205	212297
8000-050-001	Precision pointer Electromagnetic	07613327413205	212364
8000-050-001	Precision pointer Electromagnetic	07613327413205	212367
8000-050-001	Precision pointer Electromagnetic	07613327413205	212375
8000-050-001	Precision pointer Electromagnetic	07613327413205	212376
8000-050-001	Precision pointer Electromagnetic	07613327413205	212377
8000-050-001	Precision pointer Electromagnetic	07613327413205	212380
8000-050-001	Precision pointer Electromagnetic	07613327413205	212383
8000-050-001	Precision pointer Electromagnetic	07613327413205	212386
8000-050-001	Precision pointer Electromagnetic	07613327413205	212387
8000-050-001	Precision pointer Electromagnetic	07613327413205	212389
8000-050-001	Precision pointer Electromagnetic	07613327413205	212402
8000-050-001	Precision pointer Electromagnetic	07613327413205	212403
8000-050-001	Precision pointer Electromagnetic	07613327413205	212405
8000-050-001	Precision pointer Electromagnetic	07613327413205	212406
8000-050-001	Precision pointer Electromagnetic	07613327413205	212407

Catalogue No.	Product Description	GTIN	Affected Serial Number
8000-050-001	Precision pointer Electromagnetic	07613327413205	212410
8000-050-001	Precision pointer Electromagnetic	07613327413205	212412
8000-050-001	Precision pointer Electromagnetic	07613327413205	212417
8000-050-001	Precision pointer Electromagnetic	07613327413205	212431
8000-050-001	Precision pointer Electromagnetic	07613327413205	212432
8000-050-001	Precision pointer Electromagnetic	07613327413205	212434
8000-050-001	Precision pointer Electromagnetic	07613327413205	212435
8000-050-001	Precision pointer Electromagnetic	07613327413205	212438
8000-050-001	Precision pointer Electromagnetic	07613327413205	212562
8000-050-001	Precision pointer Electromagnetic	07613327413205	212564
8000-050-001	Precision pointer Electromagnetic	07613327413205	212566
8000-050-001	Precision pointer Electromagnetic	07613327413205	212574
8000-050-001	Precision pointer Electromagnetic	07613327413205	212652
8000-050-001	Precision pointer Electromagnetic	07613327413205	212654
8000-050-001	Precision pointer Electromagnetic	07613327413205	212655
8000-050-001	Precision pointer Electromagnetic	07613327413205	212656
8000-050-001	Precision pointer Electromagnetic	07613327413205	212658
8000-050-001	Precision pointer Electromagnetic	07613327413205	212659
8000-050-001	Precision pointer Electromagnetic	07613327413205	212663
8000-050-001	Precision pointer Electromagnetic	07613327413205	212664
8000-050-001	Precision pointer Electromagnetic	07613327413205	212665

Product Description

The Precision Pointer Electromagnetic (EM) is an accessory used with the Stryker ENT Navigation System and Cranial Guidance Software. The device is a tracked pointing instrument designed to assist with navigation during surgical procedures.

Product issue

Stryker has identified that the tip of the Precision Pointer EM may potentially fracture at the laser welding seam.

Potential risks

Although remote, the greatest severity of harm occurs if the tip breaks off while the device is inside the patient. The fractured tip is approximately 8cm/3.15 inch and is visually apparent. Given the nature of exposure and the typical use environment in the operating room, if the device breaks while inside the patient, the fragment should be removed.

Requested Customer Actions

As the manufacturer, Stryker Instruments, we ask you please review the requested actions below:

1. If you have received this notice directly from Stryker, please complete and return the enclosed Business Reply Form (BRF) to fieldactionnby@stryker.com , even if the affected product is no longer in your inventory. Submitting the BRF prevents duplicate notices from being sent.
2. Inform all appropriate members of your organization who need to be made aware of this action.
3. Product returns are not required. However, if you would like to receive a replacement, you may choose one of the following options:
   - Option 1: Destroy the affected products onsite with your Stryker representative and send a completed Certificate of Destruction (COD, pg. 7) to fieldactionnby@stryker.com . Replacements will be issued by Stryker once both the BRF and COD are received.
   - Option 2: Return the products to your Stryker Distribution Center.
4. If you have further distributed the affected product, please notify the applicable parties at once about this recall. You may copy and distribute this notification letter.
   a. If possible, inform us if any of the subject devices have been distributed to other organizations, including contact details.
   b. If you are a distributor, note that you are responsible for notifying your affected customers.

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: Jamie Harvey
Position: Post-Market Surveillance
email: jamie.harvey@stryker.com

In line with the recommendations of the Medical Device Coordination Group Guidance document Ref MDCG 2023-3 and EU MDR 2017/745, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

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

Sincerely,

Jamie Harvey – Stryker UK LTD

Business Reply Form

Precision Pointer Electro Magnetic (EM)

Recall Number: RA2026 – 4463066

October, 2026

Please complete and sign this form. Email the completed form to fieldactionnby@stryker.com .

RESPONSE IS REQUIRED

Catalogue number	Product Description	Affected lots	Qty of product (EA)

***If all devices have been used and no affected devices are available for return, please enter 0 (zero).**

Form completed by:

Hospital Name			
Facility Address			
Printed Name		**Title**	
Email		**Phone**	
Signature		**Date**	
Kindly confirm that you have selected one of the options above and completed the table, if applicable.			

Note: Your signature indicates that you have received and understand the enclosed notification and that you have performed all actions requested.

If you have further distributed any affected products, please indicate to whom:

Product(s) Distributed		**Quantity Distributed**	
Facility Name		**Contact Person**	
Full Address			

☐ **I have read and understand the instructions provided and acknowledge receipt of the subjected FSN.**

☐ **I also agree to further distribute and communicate this important information from this letter to those whom I have distributed any of subjected devices noted in this letter.**

Name (print)_____Signature_____Date :_____