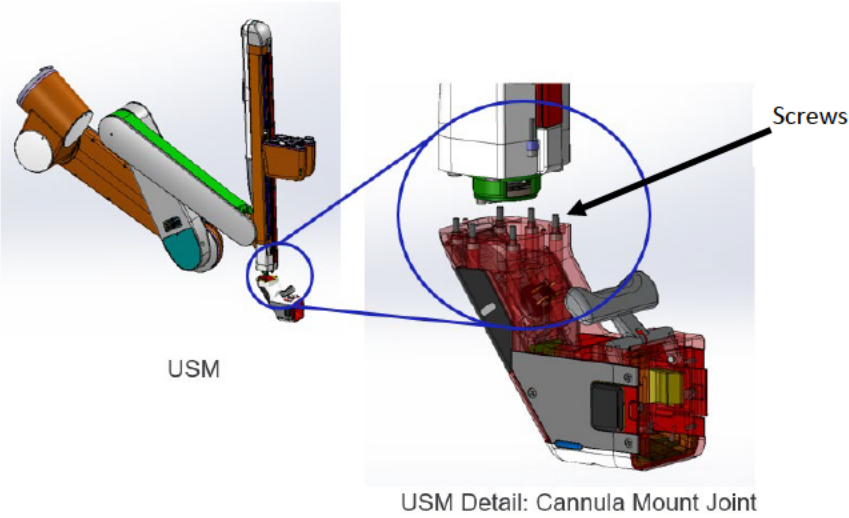


New Field Safety Notice - Urgent Medical Device Correction
da Vinci X, Xi Systems Cannula Mount Screws Breakage
 (ISIFA2026-01-C)

<p>1- Introduction and Reason for Field Action</p>	<p>Dear Intuitive Customer,</p> <p>This Field Safety notice is to advise you that Intuitive is initiating a Field Safety Corrective Action (FSCA) involving the da Vinci X, Xi systems Universal Surgical Manipulator (USM). Our records indicate that your facility has received at least one of the affected USM units that are suspected of having screws located within the arm sub-assembly that may be susceptible to breaking.</p> <p>The USM includes the cannula mount used to hold the cannula during surgery, as shown in Figure 1 below. Intuitive has identified that the screws on the cannula mount of the USM are from a specific population that are susceptible to breaking over time. When the cannula mount experiences a breakage of all six screws, the cannula mount can separate from the rest of the USM. Breakage of any fewer than six screws will not result in cannula mount separation, or impact to clinical performance.</p>  <p style="text-align: center;">USM</p> <p style="text-align: center;">USM Detail: Cannula Mount Joint</p> <p style="text-align: center;">Figure 1. Cannula Mount on USM</p>
<p>2 - Risk to Health</p>	<p>Intra-operative cannula mount separation may result in unintended motion of the instrument tip. This unintended motion may lead to tissue injury or bleeding with severities ranging from negligible to catastrophic. The severity of injury would depend on the amount of motion, proximity to tissue, type of installed instrument, and type of injured tissue. To date, there has been one serious incident related to six screws breaking in the cannula mount.</p>

	<p>How to recognize that the device may fail: Screw breakage or cannula mount loosening may be observable as visible or tactile separation of the cannula mount from the body of the USM.</p> <p>Prior to a procedure, closely inspect the joint between the cannula mount and insertion axis that is joined by the screws indicated in Figure 1 above. Manipulate the cannula mount joint by hand to ensure there is no movement or looseness. If looseness or separation is observed, discontinue use of the USM and contact your representative to schedule a site visit.</p> <p>If all six screws were to break intra-operatively, the user may also observe imprecise or unintended instrument tip motion. If you observe imprecise or unintended instrument tip motion, inspect the cannula mount for looseness or separation and if present, discontinue use of the USM and contact your representative to schedule a site visit.</p>								
<p>3- Affected Products</p>	<table border="1"> <thead> <tr> <th>Part Number</th> <th>Product Name</th> <th>Unique Device Identifier</th> <th>Affected Serial Number</th> </tr> </thead> <tbody> <tr> <td>380647</td> <td>ASSY,USM,IS4000 da Vinci Xi Surgical System da Vinci X Surgical System</td> <td>00886874114216</td> <td>See Appendix A</td> </tr> </tbody> </table>	Part Number	Product Name	Unique Device Identifier	Affected Serial Number	380647	ASSY,USM,IS4000 da Vinci Xi Surgical System da Vinci X Surgical System	00886874114216	See Appendix A
Part Number	Product Name	Unique Device Identifier	Affected Serial Number						
380647	ASSY,USM,IS4000 da Vinci Xi Surgical System da Vinci X Surgical System	00886874114216	See Appendix A						
<p>4- Actions to be taken by the Customer/User</p>	<p>Users can continue to use the da Vinci X, Xi Systems. As indicated above, if a cannula mount becomes separated, the users may identify this separation and may also notice imprecise or unintended instrument movement. If this occurs, avoid using the affected da Vinci X or Xi USM for additional procedures until Intuitive personnel have serviced the system.</p> <p><u>Please take the following Actions:</u></p> <ol style="list-style-type: none"> 1. This notice needs to be passed on to all those who need to be aware within your organization or functions where the potentially affected devices have been transferred. 2. Please retain a copy of this letter, place a copy with your affected system, and keep a copy of the acknowledgement form for your files. 3. Complete the attached Acknowledgement Form immediately and return it via fax or email to Intuitive as instructed on the form. 4. Please inform Intuitive of any Serious Incidents* or quality problems concerning the use of the subject devices via the standard complaint process. 5. Additionally, if Serious Incidents* or quality problems are experienced, please follow your standard reporting process to your health authority, if applicable. 								

<p>5- Actions to be taken by Intuitive</p>	<p>An Intuitive Representative will schedule a site visit to perform a repair of the affected system.</p>
<p>6- Further Information & Support</p>	<p>If you need further information or support concerning this Medical Device Correction, please contact your da Vinci X, Xi Sales Representative or contact Intuitive Customer Service at the numbers listed below:</p> <ul style="list-style-type: none"> • Europe: [redacted] or [redacted] (8 am to 6 pm CET) or local customer service address

Please be informed that the appropriate Regulatory Authority for your region has been notified of this Field Safety Notice.

Sincerely,

Intuitive Surgical SAS



Definitions:

*Serious Incident (EUMDR 2017/745) is defined as “any incident that directly or indirectly led, might have led or might lead to any of the following:

- a. the death of a patient, user or other person
- b. the temporary or permanent serious deterioration of a patient’s, users, or other person’s state of health,
- c. a serious public health threat”

ACKNOWLEDGMENT FORM

New Field Safety Notice - Urgent Medical Device Correction
da Vinci X, Xi Systems Cannula Mount Screws Breakage (ISIFA2026-01-C)

Ship-to:

Hospital Name: _____

Address: _____

City, State, Zip: _____

Customer ID: _____

ATTENTION: _____

PLEASE COMPLETE ALL REQUESTED INFORMATION AND RETURN IMMEDIATELY

- 1. I have received and read this notice.
- 2. I have ensured all appropriate personnel are fully informed of the contents of this notice.
- 3. I will contact Intuitive if I have any questions.

Hospital name: _____

Position:

Name (print): _____

Robotics Coordinator

Signature: _____

Operating Room Director

Phone Number: _____

Risk Manager

Email: _____

Surgeon

Date: _____

Other: _____

PLEASE EMAIL THIS ACKNOWLEDGEMENT FORM TO Intuitive
ATTN: REGULATORY COMPLIANCE FIELD ACTIONS
Subject line for email: ISIFA2026-01-C
Scan and Email: _____

Customer Service:

- Europe: _____ or _____ (8 am to 6 pm CET) or [local customer service address](#)

Appendix A: USM Serial Numbers

Country	USM SN	System Serial Number
Austria	668304	SK4493
Austria	478057	SK5864
Austria	534197	SK6237
Austria	10034717	SK6527
Austria	10047379	SK6755
Austria	10407285	SK6820
Austria	587326	SK7788
Austria	562081	SL0028
Austria	650213	SL0028
Austria	620496	SL0044
Austria	424481	SL1276
Austria	370282	SL1277
Belgium	581448	SK0321
Belgium	10033897	SK0603
Belgium	746163	SK0614
Belgium	554756	SK0719
Belgium	800233	SK0719
Belgium	939865	SK0824
Belgium	858950	SK1185
Belgium	628713	SK1191
Belgium	10328306	SK5694
Belgium	10070601	SL0166
Belgium	617481	SL0207
Belgium	681743	SL0207
Belgium	684897	SL0687
Belgium	630656	SL1121
Croatia	392661	SK7908
Croatia	10331516	SK7908
Cyprus	960600	SK5150
Czech Republic	571238	SK4850
Czech Republic	549423	SK5941
Czech Republic	789458	SK5941
Czech Republic	10052780	SK6063
Czech Republic	10040542	SK6195
Czech Republic	562437	SK7872
Czech Republic	10212835	SK7872
Czech Republic	810029	SL0333

Denmark	468252	SK0428
Denmark	477769	SK0428
Denmark	586018	SK0453
Denmark	677755	SK0908
Denmark	782517	SK1046
Denmark	475446	SK1047
Denmark	572655	SK4115
Denmark	539328	SL0061
Denmark	531837	SL0062
Finland	10001057	SK7425
Finland	566573	SL1188
France	699359	SK0253
France	739789	SK0787
France	479399	SK0832
France	669439	SK0912
France	765736	SK0912
France	818111	SK0934
France	813954	SK0956
France	929377	SK0986
France	785065	SK1190
France	758497	SK1684
France	448794	SK1948
France	723908	SK1948
France	799190	SK2240
France	585364	SK2253
France	594687	SK2255
France	478364	SK2447
France	555970	SK2447
France	543079	SK2819
France	10317028	SK2819
France	778155	SK4171
France	834363	SK5105
France	10353655	SK5111
France	581828	SK6056
France	501235	SK6190
France	958852	SK6396
France	10048632	SK6629
France	10326095	SK6652
France	697143	SK6939
France	795728	SK6943

France	10026612	SK7570
France	617781	SK7763
France	764718	SK7763
France	529785	SK7923
France	658457	SK8650
France	792161	SL0080
France	10534036	SL0080
France	554505	SL0164
France	587809	SL0164
France	686703	SL0164
France	540594	SL0165
France	790093	SL0226
France	530004	SL0317
France	694785	SL0377
France	588263	SL0449
France	569736	SL0601
France	533159	SL0641
France	678243	SL0642
France	479456	SL0738
France	721832	SL0797
France	606243	SL0819
France	679935	SL0937
France	728801	SL0975
France	888614	SL1016
France	578099	SL1074
France	559350	SL1159
France	451739	SL1219
France	10365953	SL1270
France	553438	SL1330
France	679539	SL1331
France	10632965	SL1336
France	680498	SL1393
France	783254	SL1478
France	581804	SL1480
France	540642	SL1519
Germany	597902	SK0128
Germany	10378582	SK0141
Germany	561403	SK0142
Germany	461326	SK0224
Germany	778170	SK0224

Germany	396982	SK0528
Germany	610711	SK0567
Germany	503997	SK0831
Germany	586017	SK0899
Germany	351868	SK0935
Germany	10191505	SK0935
Germany	605898	SK1083
Germany	10062001	SK1083
Germany	593071	SK1173
Germany	855771	SK1173
Germany	788384	SK1325
Germany	581831	SK1360
Germany	796748	SK1378
Germany	358030	SK1560
Germany	424902	SK1592
Germany	551805	SK1940
Germany	857608	SK1940
Germany	583058	SK2092
Germany	580603	SK2156
Germany	639125	SK2156
Germany	10052083	SK2508
Germany	649487	SK2942
Germany	671931	SK2992
Germany	956234	SK2992
Germany	10092077	SK2992
Germany	10022553	SK3218
Germany	10334560	SK3219
Germany	609901	SK3234
Germany	760678	SK3234
Germany	435269	SK4092
Germany	10497741	SK4092
Germany	10230431	SK4096
Germany	793304	SK4590
Germany	396664	SK4869
Germany	630493	SK4904
Germany	792155	SK5147
Germany	10135994	SK5211
Germany	601086	SK5357
Germany	405690	SK5565
Germany	10303334	SK5806

Germany	478755	SK5882
Germany	823553	SK5914
Germany	761661	SK6188
Germany	10161574	SK6201
Germany	546337	SK6397
Germany	603641	SK6554
Germany	693626	SK6554
Germany	369425	SK6582
Germany	792143	SK6795
Germany	581041	SK6799
Germany	10038584	SK6818
Germany	421452	SK6834
Germany	574266	SK7869
Germany	763690	SK8220
Germany	386843	SK8284
Germany	783251	SK8316
Germany	887265	SK8502
Germany	676896	SK8687
Germany	564692	SK8690
Germany	566861	SK8786
Germany	930926	SL0008
Germany	785750	SL0010
Germany	825555	SL0052
Germany	671987	SL0063
Germany	585036	SL0072
Germany	546873	SL0081
Germany	680766	SL0100
Germany	640320	SL0126
Germany	927761	SL0170
Germany	10147251	SL0170
Germany	638782	SL0195
Germany	782016	SL0198
Germany	739343	SL0220
Germany	388564	SL0303
Germany	643880	SL0303
Germany	650996	SL0360
Germany	547643	SL0428
Germany	10332065	SL0429
Germany	10394735	SL0509
Germany	402094	SL0521

Germany	555282	SL0522
Germany	398791	SL0552
Germany	781000	SL0643
Germany	571477	SL0680
Germany	747994	SL0768
Germany	764205	SL0768
Germany	553671	SL0826
Germany	686700	SL0957
Germany	10204000	SL0957
Germany	918526	SL0989
Germany	915860	SL0995
Germany	360008	SL1007
Germany	707289	SL1013
Germany	10504845	SL1065
Germany	922165	SL1096
Germany	609314	SL1235
Germany	10372470	SL1281
Germany	411298	SL1374
Germany	628910	SL1420
Greece	815656	SK1310
Greece	566387	SK1561
Greece	502089	SK2267
Greece	568155	SK2267
Greece	899262	SK5950
Greece	583483	SK6759
Greece	558555	SK6809
Greece	582713	SK6809
Greece	638446	SK6809
Greece	674054	SL1290
Greece	906484	SL1290
Greece	660514	SL1471
Hungary	376138	SK5721
Ireland	10305776	SK1355
Ireland	406613	SK2545
Ireland	10254882	SK6218
Italy	548870	SK0088
Italy	615966	SK0199
Italy	940423	SK0199
Italy	455020	SK0201
Italy	746384	SK0214

Italy	801787	SK0215
Italy	10387761	SK0256
Italy	751821	SK0336
Italy	971567	SK0395
Italy	553582	SK0517
Italy	652311	SK0592
Italy	10483094	SK0593
Italy	904943	SK0798
Italy	917115	SK1293
Italy	384374	SK1303
Italy	533846	SK1586
Italy	683671	SK1586
Italy	581391	SK1724
Italy	503430	SK1884
Italy	583860	SK1884
Italy	538608	SK1885
Italy	539772	SK2040
Italy	567265	SK2040
Italy	410267	SK3086
Italy	551527	SK3206
Italy	540343	SK3207
Italy	10538488	SK3404
Italy	572380	SK3477
Italy	538341	SK3743
Italy	537189	SK3750
Italy	744722	SK3768
Italy	398372	SK3781
Italy	906490	SK3929
Italy	10078623	SK4117
Italy	626767	SK4348
Italy	10169133	SK4350
Italy	699368	SK4664
Italy	677335	SK5053
Italy	10601534	SK5053
Italy	10487820	SK5114
Italy	628257	SK5389
Italy	543815	SK5448
Italy	10613755	SK5663
Italy	10326767	SK5668
Italy	711152	SK6439

Italy	478830	SK6701
Italy	10108785	SK7530
Italy	905960	SK7621
Italy	721836	SK7625
Italy	533859	SK8082
Italy	795743	SK8305
Italy	575518	SK8660
Italy	702019	SL0130
Italy	650983	SL0362
Italy	658202	SL0362
Italy	667656	SL0764
Italy	10365964	SL0764
Italy	10072955	SL0813
Italy	766991	SL0900
Italy	530679	SL1113
Italy	10003338	SL1113
Italy	769105	SL1250
Luxembourg	477473	SK2981
Luxembourg	10298652	SK6140
Malta	578115	SK8734
Netherlands	412629	SK0335
Netherlands	720198	SK0507
Netherlands	10599104	SK1775
Netherlands	975246	SK1784
Netherlands	954217	SK1844
Netherlands	665082	SK3666
Netherlands	969818	SK7585
Norway	542591	SK0229
Norway	551218	SK0229
Norway	888604	SK0699
Norway	477760	SK2199
Norway	807342	SK6211
Norway	641689	SL0283
Poland	841131	SK5116
Poland	452027	SK5690
Poland	739349	SK5915
Poland	10145263	SK6118
Poland	778976	SK6198
Poland	10353633	SK7199
Poland	595481	SK8202

Poland	10053909	SK8244
Poland	10102539	SL0238
Poland	10632953	SL0375
Poland	726571	SL0514
Poland	452026	SL0530
Poland	10040336	SL1006
Poland	616677	SL1298
Poland	649895	SL1324
Poland	10086180	SL1454
Poland	10288833	SL1454
Portugal	782521	SK7655
Romania	548942	SK0381
Romania	478550	SK1573
Romania	678945	SK1573
Romania	574371	SK4074
Romania	10057758	SK5609
Romania	441584	SL1470
Slovakia	10512063	SK5943
Slovenia	762176	SK1886
Spain	353046	SK0841
Spain	668773	SK0841
Spain	10075108	SK0841
Spain	564931	SK1647
Spain	664996	SK1799
Spain	938717	SK1799
Spain	961141	SK1799
Spain	787957	SK2020
Spain	663920	SK2025
Spain	540647	SK2466
Spain	416347	SK2585
Spain	461301	SK2894
Spain	563682	SK2894
Spain	586021	SK2894
Spain	530200	SK4614
Spain	10368744	SK4614
Spain	478549	SK4618
Spain	10191488	SK5288
Spain	609000	SK5692
Spain	368212	SK5869
Spain	897737	SK5892

Spain	949734	SK6440
Spain	579219	SK6442
Spain	653305	SK6748
Spain	452971	SK8509
Spain	10055324	SL0041
Spain	823557	SL0146
Spain	657325	SL0714
Spain	608102	SL1401
Spain	378560	SL1439
Spain	694277	SL1456
Spain	730554	SL1456
Spain	10134832	SL1456
Sweden	719553	SK0407
Sweden	574369	SK0582
Sweden	542857	SK1021
Sweden	596081	SK1730
Sweden	684300	SK1730
Sweden	630306	SK3973
Sweden	619897	SK4086
Sweden	788500	SK4129
Sweden	951940	SK5279
Sweden	676891	SK6673
Sweden	569723	SK7084
Sweden	771193	SL0082
Sweden	10323693	SL0082
Sweden	634525	SL0121
Sweden	545022	SL0921
Switzerland	567021	SK0501
Switzerland	688594	SK0501
Switzerland	564633	SK1327
Switzerland	783262	SK2207
Switzerland	698669	SK2371
Switzerland	10303361	SK2371
Switzerland	412994	SK3871
Switzerland	10355341	SK6745
Turkey	10041780	SL1245
United Kingdom	937325	SK0108
United Kingdom	10402557	SK0108
United Kingdom	575470	SK0213
United Kingdom	577853	SK0379

United Kingdom	10317018	SK0562
United Kingdom	572117	SK0751
United Kingdom	613563	SK1643
United Kingdom	10365115	SK1767
United Kingdom	611834	SK1812
United Kingdom	562693	SK3257
United Kingdom	760332	SK3257
United Kingdom	560360	SK3568
United Kingdom	10323097	SK3568
United Kingdom	919849	SK3659
United Kingdom	667645	SK3821
United Kingdom	595113	SK3999
United Kingdom	10548240	SK4387
United Kingdom	804422	SK4397
United Kingdom	546957	SK4400
United Kingdom	973488	SK4400
United Kingdom	763689	SK4480
United Kingdom	381755	SK5148
United Kingdom	570212	SK5148
United Kingdom	588760	SK5148
United Kingdom	10066508	SK5251
United Kingdom	10276899	SK5273
United Kingdom	889794	SK5361
United Kingdom	713433	SK5367
United Kingdom	10203984	SK5395
United Kingdom	10152302	SK5435
United Kingdom	778978	SK5673
United Kingdom	428171	SK5946
United Kingdom	616661	SK6493
United Kingdom	544141	SK6539
United Kingdom	558292	SK6539
United Kingdom	10036884	SK6550
United Kingdom	455966	SK7080
United Kingdom	829271	SK7730
United Kingdom	560367	SL0087
United Kingdom	629809	SL0625
United Kingdom	628259	SL0670
United Kingdom	773033	SL0702
United Kingdom	599547	SL0704
United Kingdom	531740	SL0769

United Kingdom	600834	SL0772
United Kingdom	555975	SL0947
United Kingdom	475960	SL1317
United Kingdom	10028450	SL1317