

Field Safety Notice

Urgent Medical Device Correction – 2955842-11-11-2013-013-C

Certain Instrument Arms on da Vinci® S, Si™ and Si-e systems listed in attachment

<p>Introduction and Reason for Field Action</p>	<p>Dear <i>da Vinci</i> Customer,</p> <p>The purpose of this letter is to advise you that Intuitive Surgical is voluntarily initiating this correction for the Patient Side Manipulators on the <i>da Vinci S</i>, <i>Si</i> and <i>Si-e</i> Patient Side Cart. The Patient Side Manipulator is commonly referred to as the “instrument arm,” which holds and drives <i>EndoWrist</i>® instruments. The surgeon positions instruments using the Master Tool Manipulators, commonly referred to as the “masters.”</p> <p>The company has become aware that friction within certain instrument arms can interrupt smooth instrument motion. This interruption is felt by the surgeon as resistance in the movement of the master. In this situation, the instrument can stall momentarily and then suddenly catch-up to the master position if the surgeon pushes through the resistance. This resistance is most noticeable when moving the instruments at very slow speeds and during small movements of the masters. This system behavior is not autonomous instrument motion.</p> <p>An Intuitive Surgical Representative will visit your site to test the instrument arms and repair or replace instrument arms as needed based on the test results. Until such a visit takes place, affected <i>da Vinci</i> Systems can be used safely by following the steps outlined below in the section titled “Actions to be taken by the Customer/User.”</p> <p>It is important to ensure that all users of the affected devices understand all of the information in this communication and the below actions to be taken.</p>
<p>Risk to Health</p>	<p>There has been one reported instance where this interrupted motion resulted in an imprecise cut during the planned transection of a urethra. During this instance, the instrument remained in the surgeon’s field of view. The surgeon subsequently modified the plane of transection and completed the procedure using the <i>da Vinci</i> system without reported complications. There were two additional reports of similar imprecise motion that resulted in conversion of the procedures to alternative surgical methods; no complications were reported. There have been more than 55,000 procedures completed with the instrument arms identified in this letter.</p>
<p>Affected Regions and Products</p>	<p>Affected regions</p> <p>The regions affected by this medical device correction are listed below:</p> <p>Australia, Austria, Belgium, Brazil, Bulgaria, Canada, China, Columbia, Denmark, France, Germany, India, Israel, Italy, Japan, Luxembourg, Mexico, Monaco, Netherlands, Norway, Romania, Russia, Singapore, Spain, South Korea, Sweden, Switzerland, Taiwan, Thailand, Turkey, United Kingdom, United States of America.</p> <p>Affected products</p> <p>The products affected by this medical device correction are listed below.</p>

	Intuitive Surgical Part Number	Product Name
	380430	<i>da Vinci S</i> System, Patient Side Cart
	380614	<i>da Vinci Si</i> System, Patient Side Cart
	380649	<i>da Vinci Si-e</i> System, Patient Side Cart
Action to be taken by Intuitive Surgical	<p>The serial numbers affected by this correction are noted in the detailed product and distribution information attached to this letter which is organized by geographic region.</p> <p>An Intuitive Surgical Representative will schedule a site visit with your hospital to perform the testing and potential correction activity for the instrument arms of your system(s). The site visit is expected to take approximately 4 hours per system.</p>	
Actions to be taken by the Customer/User	<p>Affected <i>da Vinci</i> Systems can be used safely by following these steps:</p> <ol style="list-style-type: none"> 1. Be aware that the friction within the instrument arm is detectable and will manifest itself as resistance at the master tool manipulators. 2. If there is resistance felt at the masters, do NOT push through the resistance. Pushing through the resistance will result in the system behavior described above. <ol style="list-style-type: none"> a. Check for potential sources of resistance, such as internal instrument collisions, external arm collisions or other obstructions. b. If collisions or obstruction are identified, clear the collision per normal practice. c. If collisions or obstructions are not identified, move the masters back slightly, reposition the instrument tip, and determine if the resistance is no longer felt at the masters. d. If the resistance is no longer felt, proceed as normal. e. If resistance continues to be felt at the masters, call Customer Service (see below) for assistance. <p>Please take the following actions:</p> <ol style="list-style-type: none"> 1. Ensure all appropriate personnel are fully informed of this Notification. Forward this letter to all Surgeons and OR staff who perform <i>da Vinci</i> surgical procedures, Risk Manager, OR Director, Purchasing, and Biomedical Engineering staff. 2. Complete the attached Acknowledgement Form and return it to Intuitive Surgical as instructed. 3. An Intuitive Surgical Representative will contact your site to schedule the inspection of the instrument arms on your system(s) as indicated above. Please work with the Intuitive Surgical Representative to schedule this activity. 4. Please inform appropriate personnel when the correction has been completed. 5. Please retain a copy of this letter and the Acknowledgement Form for your files. 	

**Further
Information &
Support**

If you need further information or support concerning this medical device correction, then please contact your Clinical Sales Representative or contact Intuitive Surgical Customer Service at the numbers listed below.

- North and South America: 800-876-1310 Option 3 (6 am to 5pm PST)
- Japan: 0120-56-5635 or 03-5575-1362 (9am to 6pm JST)
- South Korea: 02-3271-3200 (9am to 6pm KSTJ)
- Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm CET)

Please be informed that the appropriate Regulatory Authority for your region has been notified of this medical device correction.

Sincerely,



Richard Reeves
Vice President, Regulatory Affairs

Intuitive Surgical, Inc.
1266 Kifer Road, Building 101
Sunnyvale, CA 94086-5304

European Office
Intuitive Surgical, Sàrl
1 Chemin des Mûriers
1170 Aubonne, Switzerland

Acknowledgement Form Field Safety Notice

Urgent Medical Device Correction – 2955842-11-11-2013-013-C

Certain Instrument Arms identified on da Vinci® S, Si™ and Si-e systems listed below

PLEASE COMPLETE ALL REQUESTED INFORMATION AND RETURN IMMEDIATELY

ATTENTION Robotics Coordinator:

I have received, read and understand the attached Notification regarding the *da Vinci* Patient Side Manipulators (PSMs), commonly referred to as the instrument arms. I acknowledge that I have informed all necessary parties at my facility of this Notification. I will contact Intuitive Surgical if I have any questions.

Hospital Name: _____
Address: _____
City, State, Zip: _____
Country: _____
Name (print): _____
Signature: _____
Phone Number: _____
Date: _____

Position:

- Robotics Coordinator
 Operating Room Director
 Risk Manager
 Surgeon
 Other: _____

Customer Service:

- North and South America: 800-876-1310 Option 3 (6 am to 5 pm PST)
- Japan: 0120-56-5635 or 03-5575-1362 (9 am to 6 pm JST)
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PLEASE FAX THIS ACKNOWLEDGEMENT FORM TO
Intuitive Surgical, Inc.
ATTN: REGULATORY AFFAIRS
U.S. +1 (408) 716-3040, or Scan and Email: isi.compliance@intusurg.com

**Affected Product List (*da Vinci* system serial numbers by region)
United States of America (USA)**

United States	System ID									
<i>da Vinci Si</i>	SH0018	SH0206	SH0407	SH0752	SH0981	SH1179	SH1417	SH1690	SH1785	SH1887
	SH0022	SH0214	SH0408	SH0755	SH0983	SH1180	SH1418	SH1699	SH1786	SH1889
	SH0025	SH0216	SH0409	SH0756	SH0987	SH1186	SH1430	SH1706	SH1787	SH1890
	SH0030	SH0223	SH0414	SH0762	SH0989	SH1191	SH1437	SH1707	SH1789	SH1891
	SH0032	SH0226	SH0423	SH0765	SH0994	SH1194	SH1441	SH1709	SH1790	SH1892
	SH0036	SH0228	SH0427	SH0769	SH0997	SH1199	SH1445	SH1710	SH1791	SH1893
	SH0038	SH0232	SH0428	SH0770	SH1007	SH1201	SH1448	SH1711	SH1792	SH1894
	SH0040	SH0240	SH0431	SH0772	SH1011	SH1203	SH1459	SH1719	SH1793	SH1896
	SH0042	SH0243	SH0436	SH0781	SH1012	SH1215	SH1461	SH1721	SH1794	SH1897
	SH0049	SH0245	SH0437	SH0791	SH1013	SH1246	SH1507	SH1727	SH1795	SH1899
	SH0053	SH0248	SH0438	SH0808	SH1014	SH1259	SH1517	SH1728	SH1797	SH1900
	SH0055	SH0254	SH0439	SH0819	SH1016	SH1269	SH1518	SH1729	SH1798	SH1903
	SH0057	SH0258	SH0448	SH0821	SH1024	SH1269	SH1531	SH1731	SH1808	SH1904
	SH0060	SH0262	SH0453	SH0823	SH1027	SH1273	SH1539	SH1733	SH1809	SH1905
	SH0065	SH0265	SH0454	SH0829	SH1029	SH1283	SH1564	SH1735	SH1810	SH1906
	SH0066	SH0266	SH0466	SH0838	SH1030	SH1285	SH1580	SH1736	SH1811	SH1907
	SH0067	SH0268	SH0473	SH0845	SH1031	SH1286	SH1581	SH1739	SH1812	SH1908
	SH0068	SH0272	SH0475	SH0847	SH1032	SH1288	SH1583	SH1741	SH1814	SH1909
	SH0070	SH0275	SH0489	SH0849	SH1034	SH1290	SH1589	SH1743	SH1815	SH1910
	SH0076	SH0282	SH0490	SH0850	SH1036	SH1293	SH1594	SH1744	SH1817	SH1912
SH0078	SH0284	SH0493	SH0853	SH1050	SH1294	SH1598	SH1746	SH1822	SH1913	
SH0082	SH0292	SH0521	SH0855	SH1053	SH1306	SH1599	SH1747	SH1823	SH1915	
SH0085	SH0296	SH0524	SH0858	SH1055	SH1322	SH1605	SH1748	SH1824	SH1916	
SH0108	SH0304	SH0525	SH0862	SH1059	SH1324	SH1606	SH1749	SH1827	SH1922	

United States	System ID									
<i>da Vinci Si</i>	SH0112	SH0309	SH0527	SH0865	SH1069	SH1331	SH1612	SH1750	SH1831	SH1923
	SH0113	SH0310	SH0543	SH0866	SH1080	SH1332	SH1617	SH1752	SH1840	SH1924
	SH0115	SH0314	SH0548	SH0867	SH1081	SH1333	SH1629	SH1753	SH1841	SH1925
	SH0134	SH0318	SH0557	SH0871	SH1082	SH1334	SH1630	SH1754	SH1842	SH1926
	SH0141	SH0319	SH0577	SH0873	SH1085	SH1335	SH1631	SH1760	SH1846	SH1933
	SH0145	SH0326	SH0585	SH0875	SH1091	SH1336	SH1632	SH1761	SH1847	SH1934
	SH0147	SH0327	SH0592	SH0877	SH1096	SH1337	SH1633	SH1763	SH1850	SH1935
	SH0149	SH0330	SH0619	SH0883	SH1099	SH1343	SH1634	SH1764	SH1855	SH1942
	SH0157	SH0331	SH0633	SH0886	SH1110	SH1347	SH1635	SH1765	SH1856	SH1952
	SH0160	SH0332	SH0644	SH0904	SH1120	SH1363	SH1636	SH1766	SH1857	SH1955
	SH0165	SH0335	SH0653	SH0905	SH1124	SH1365	SH1645	SH1767	SH1862	
	SH0167	SH0341	SH0670	SH0920	SH1125	SH1367	SH1646	SH1769	SH1864	
	SH0171	SH0343	SH0684	SH0925	SH1131	SH1370	SH1650	SH1770	SH1865	
	SH0172	SH0344	SH0695	SH0928	SH1132	SH1371	SH1651	SH1771	SH1867	
	SH0180	SH0355	SH0700	SH0932	SH1133	SH1372	SH1655	SH1772	SH1872	
	SH0181	SH0374	SH0710	SH0936	SH1134	SH1375	SH1658	SH1773	SH1873	
	SH0182	SH0378	SH0717	SH0942	SH1137	SH1376	SH1665	SH1774	SH1876	
	SH0183	SH0384	SH0722	SH0946	SH1139	SH1381	SH1669	SH1775	SH1877	
	SH0184	SH0385	SH0723	SH0949	SH1142	SH1386	SH1670	SH1777	SH1878	
	SH0187	SH0390	SH0731	SH0962	SH1157	SH1390	SH1673	SH1778	SH1882	
	SH0190	SH0391	SH0734	SH0966	SH1165	SH1396	SH1679	SH1780	SH1883	
	SH0196	SH0398	SH0739	SH0972	SH1170	SH1400	SH1680	SH1782	SH1884	
	SH0198	SH0401	SH0748	SH0973	SH1177	SH1401	SH1683	SH1783	SH1885	
SH0202	SH0403	SH0751	SH0976	SH1178	SH1402	SH1689	SH1784	SH1886		

United States		System ID USG							
<i>da Vinci Si</i>	USG008	USG077	USG113	USG166					
	USG013	USG092	USG114	USG168					
	USG020	USG093	USG136	USG169					
	USG044	USG095	USG146	USG170					
	USG050	USG104	USG151	USG172					
	USG074	USG105	USG156	USG180					
United States		System ID SG							
<i>da Vinci S</i>	SG014	SG163	SG235	SG382	SG457	SG546	SG627	SG699	
	SG031	SG182	SG247	SG387	SG503	SG555	SG629	SG706	
	SG049	SG194	SG273	SG408	SG504	SG590	SG633	SG712	
	SG084	SG2020	SG278	SG437	SG507	SG594	SG641	SG751	
	SG117	SG2024	SG282	SG442	SG523	SG595	SG688	SG781	
	SG138	SG205	SG329	SG450	SG528	SG607	SG691	SG801	
	SG161	SG224	SG358	SG454	SG530	SG613	SG698	SG824	
United States		System ID SH							
<i>da Vinci Si-e</i>	SH0584	SH1603	SH1788						
	SH0628	SH1656	SH1898						
	SH0999	SH1657	SH1902						
	SH1075	SH1658	SH1954						
	SH1108	SH1667	SH1994						
	SH1340	SH1692							
	SH1374	SH1720							
	SH1578	SH1759							

European Union and Regions outside the USA

Country	System ID
Australia	SH0689
	SH0690
	SH1275
	SH1278
	SH1486
	SH1861
	SH1875
	SH1879
	USG319
	USG332
Austria	SG579
Belgium	SG430
	SH0034
	SH1405
	SH1406
	SH1638
Bulgaria	SH1692
Brazil	SH1768
	SG664
	SH1866

Country	System ID
Canada	SG242
	SG345
	SH0260
	SH0370
	SH1095
China	SG815
	SG831
	SH0965
	SH1062
	SH1582
Colombia	SH1161
Denmark	SH0975
	SH1168
	SH1455
	SH1716
	SH1756
France	SG140
	SH0086
	SH0372
	SH0546
	SH0939

Country	System ID
France (continued)	SH0971
	SH1075
	SH1108
	SH1639
	SH1686
	SH1688
	SH1740
	SH1843
	SH1844
	USG323
	USG798
	Germany
SH0028	
SH0593	
SH0745	
SH0809	
SH0924	
SH1642	
USG106	
USG122	
USG145	

Country	System ID
India	SG817
	SH0812
	SH0968
	SH0969
	SH1228
	SH1229
	SH1762
	SH1762
Israel	SH0816
Italy	SG489
	SH0148
	SH0209
	SH0329
	SH0757
	SH0878
	SH0991
	SH1587
	SH1588
	SH1880
SH1881	
USG103	

Country	System ID
Italy (continued)	USG364
	USG398
Luxembourg	SH1853
Mexico	SH1931
	SH1920
Monaco	SH1316
Netherlands	SH0827
	SH0923
	SH1579
SH0208	SH1863
Norway	SH0205
	SH1159
	SH1297
	SH1361
Romania	SH0161
Russia	SH1796
	SH1868
	SH1869
	SH1870
	SH1871
	SH1936

Country	System ID		
Japan	SG845	SH1821	SH1859
	SG865	SH1829	SH1927
	SG893	SH1830	SH1832
	SG895	SG862	SH1835
	SG898	SH1695	SH1848
	SG901	SH1698	SH1849
	SH1693	SH1700	SH1918
	SH1694	SH1701	SH1921
	SH1696	SH1702	SH1929
	SH1697	SH1705	SH1930
	SH1703	SH1712	SH1943
	SH1704	SH1713	USG572
	SH1708	SH1715	
	SH1714	SH1718	
	SH1722	SH1723	
	SH1726	SH1724	
	SH1801	SH1725	
	SH1802	SH1742	
	SH1803	SH1800	
	SH1804	SH1818	
	SH1819	SH1851	
	SH1820	SH1858	

Country	System ID
South Korea	SG259
	SG435
	SG537
	SG740
	SG883
	SH0285
	SH0663
	SH1845
	SH1860
	SG258
Spain	SG2045
	SG210
	SG796
	SG840
	SH1443
Sweden	SH1607
	SH1608
	SH1757
	SH1854
	SH1874
	SH1938

Country	System ID
Singapore	SH1340
Switzerland	SH0301
	SH0553
	SH0719
	SH1086
	SH1103
	SH1114
Taiwan	SH0738
	SH1121
	SH1615
	SH1755
	SH1758
	SH1807
	SH1813
Turkey	SG452
	SH0251
	SH0328
	SH1691
	SH1779
	SH1781
	SH1901

Country	System ID
United Kingdom	SH0589
	SH1000
	SH1759
	SH1776
	SH1806
	USG432