

Field Safety Notice

Urgent Medical Device Correction – 2955842-11-26-2014-011-C

Wheels on da Vinci® Si® Systems (IS3000) Vision Side Carts

<p>Introduction and Reason for Field Action</p>	<p>Dear <i>da Vinci</i> Customer,</p> <p>This Medical Device Correction is to advise you that Intuitive Surgical is initiating a voluntary correction related to <i>da Vinci Si</i> System (IS3000) Vision Side Carts, with threaded-in caster wheels. This wheel design was manufactured until 2010.</p> <p>Intuitive Surgical has found that repeated attempts to move a Vision Side Cart with threaded-in caster wheels, and in which one or more of the wheels is in the locked position, can result in the caster wheel bolts gradually unthreading and the wheels loosening. In this scenario, the bolts could loosen until the wheels dislodge from the cart.</p> <p>Starting in 2010, the caster wheel design was changed to a new design. Only systems with the threaded-in caster wheels are affected by this issue. There were 202 Vision System Carts manufactured with the threaded-in design.</p> <p>Previous models of the <i>da Vinci</i> System (IS1200, IS2000) and the newer <i>da Vinci Xi</i> (IS4000) Vision Side Carts do not use this threaded-in caster wheel design in their wheel assembly and are therefore not affected by this issue.</p>				
<p>Risk to Health</p>	<p>In the identified situation, there is a risk of injury to OR staff if a wheel becomes loose, the Vision Side Cart becomes unstable and/or equipment falls from its shelves. The Vision Side Cart does not come in contact with the patient.</p>				
<p>Affected Countries and Products</p>	<p>Affected Countries: Belgium, France, Germany, India, Israel, Italy, Norway, Romania, Slovakia, South Korea, Spain, Sweden, Turkey, United Kingdom, and United States</p> <p>Affected Product: Refer to the System Serial Numbers of the affected product in Attachment 1.</p> <table border="1" data-bbox="370 1470 1429 1591"> <thead> <tr> <th data-bbox="376 1478 993 1516">Intuitive Surgical Part Number / Model Number</th> <th data-bbox="1000 1478 1422 1516">Product Name</th> </tr> </thead> <tbody> <tr> <td data-bbox="376 1524 993 1562">371683-05 / VS3000</td> <td data-bbox="1000 1524 1422 1591"><i>da Vinci Si</i> System (IS3000) Vision Side Cart</td> </tr> </tbody> </table>	Intuitive Surgical Part Number / Model Number	Product Name	371683-05 / VS3000	<i>da Vinci Si</i> System (IS3000) Vision Side Cart
Intuitive Surgical Part Number / Model Number	Product Name				
371683-05 / VS3000	<i>da Vinci Si</i> System (IS3000) Vision Side Cart				
<p>Actions to be taken by the Customer/ User</p>	<p>Please Take the Following Actions:</p> <ol style="list-style-type: none"> 1. Ensure all affected personnel are fully informed of this notice. Forward this notice to your Risk Manager, OR Director, Purchasing Manager, Biomedical Engineering staff and members of your medical staff who perform <i>da Vinci</i> Surgery procedures. 2. Review Attachment 1—Affected System Serial Numbers to identify affected 				

	<p>product.</p> <ol style="list-style-type: none"> 3. The <i>da Vinci Si</i> Vision Side Cart can continue to be used safely. Ensure that all wheels are fully unlocked before attempting to move the Vision Side Cart. Avoid rolling the Vision Side Cart over uneven surfaces (i.e., over cables or a threshold). 4. Complete and return the attached Acknowledgement Form to Intuitive Surgical using the instructions provided. 5. Please retain a copy of this notice with your <i>da Vinci Si</i> user manual.
<p>Actions to be taken by Intuitive Surgical</p>	<ol style="list-style-type: none"> 1. Intuitive Surgical representatives will be available by phone to answer questions related to this Medical Device Correction. 2. The Preventive Maintenance (PM) frequency for the VSC caster wheel assemblies will be increased from every six months, during system PM, to every three months. During these visits, the Intuitive Surgical Field Service representative will inspect the integrity of the caster wheel assembly and tighten any wheels found to be loose. 3. Intuitive Surgical is working on a newly designed wheel assembly. Upon availability, Field Service will retrofit the wheel assembly of the affected Vision Side Carts with the new design. Once the retrofit is completed, the preventive maintenance frequency for the VSC caster wheel assemblies will return to every six months.
<p>Further Information & Support</p>	<p>If you need further information or support concerning this Medical Device Correction, please contact your Clinical Sales Representative or Intuitive Surgical Customer Service at the numbers listed below:</p> <ul style="list-style-type: none"> • North America and South America: 800-876-1310 Option 3 (6 a.m. to 5 p.m. PST) • Japan: 0120-56-5635 or 03-5575-1362 (9 a.m. to 6 p.m. JST) • South Korea: 02-3271-3200 (9 a.m. to 6 p.m. KST) • Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 a.m. to 6 p.m.) or ics@intusurg.com

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

Sincerely,

Intuitive Surgical

1266 Kifer Road, Building 101
Sunnyvale, CA 94086-5304 USA
+1-800-876-1310

ACKNOWLEDGEMENT FORM

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Wheels on da Vinci® Si® Systems (IS3000) Vision Side Carts

Hospital Name: <mail merge>

Address: <mail merge>

City, Postal Code: <mail merge>

NSID : <mail merge>

ATTENTION: <mail merge>

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

Name (print): _____

Signature: _____

Hospital Name: _____

Phone Number: _____

Email: _____

Date: _____

Position:

Robotics Coordinator

Operating Room Director

Risk Manager

Recall Coordinator

Other: _____

PLEASE FAX THIS ACKNOWLEDGEMENT FORM TO Intuitive Surgical, Inc.

ATTN: REGULATORY COMPLIANCE

Subject line for email: Si VSC Cart Wheels

U.S. Fax +1 (408) 716-3040, or Scan and Email: isi.compliance@intusurg.com

Customer Service:

- North America 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)
- South Korea: 02-3271-3200 (9 am to 6 pm KSTJ)
- Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm) or ics@intusurg.com

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Attachment 1 – Affected System Serial Numbers

UNITED STATES						OUTSIDE UNITED STATES	
SH0018	SH0057	SH0097	SH0132	SH0165	SH0235	Belgium	SH0034
SH0019	SH0058	SH0098	SH0133	SH0167	SH0248		USG217
SH0021	SH0059	SH0099	SH0134	SH0168	USG015	France	SH0086
SH0024	SH0060	SH0100	SH0135	SH0169	USG072		SH0087
SH0025	SH0064	SH0101	SH0136	SH0170	USG146	Germany	SH0028
SH0026	SH0065	SH0102	SH0137	SH0171	USG213		SH0084
SH0029	SH0066	SH0103	SH0138	SH0172	USG317		SH0111
SH0030	SH0067	SH0104	SH0139	SH0175	USG352		SH0191
SH0031	SH0068	SH0105	SH0140	SH0177	USG353		USG754
SH0032	SH0069	SH0106	SH0141	SH0179	USG445	India	SH0114
SH0033	SH0070	SH0107	SH0142	SH0180	USG519	Israel	SH0116
SH0035	SH0071	SH0109	SH0143	SH0182	USG559	Italy	SH0063
SH0036	SH0072	SH0110	SH0144	SH0184	USG631		SH0148
SH0038	SH0073	SH0112	SH0145	SH0185	USG700		USG484
SH0039	SH0076	SH0113	SH0146	SH0186	USG701	Norway	USG727
SH0040	SH0077	SH0115	SH0147	SH0187	USG702	Romania	SH0161
SH0041	SH0078	SH0117	SH0149	SH0188	USG703		SH0162
SH0042	SH0079	SH0118	SH0150	SH0189	USG721	Slovakia	SH0061
SH0044	SH0080	SH0119	SH0151	SH0190	USG728	South Korea	SH0093
SH0045	SH0081	SH0120	SH0152	SH0194	USG748	Spain	SH0238
SH0046	SH0082	SH0121	SH0153	SH0196	USG750	Sweden	USG726
SH0047	SH0085	SH0123	SH0154	SH0202	USG764	Turkey	SH0062
SH0048	SH0088	SH0124	SH0155	SH0203	USG769	United Kingdom	SH0037
SH0050	SH0089	SH0125	SH0156	SH0204	USG770		USG806
SH0051	SH0090	SH0126	SH0157	SH0206	USG775		
SH0052	SH0091	SH0127	SH0158	SH0211	USG786		
SH0053	SH0092	SH0128	SH0159	SH0215	USG787		
SH0054	SH0094	SH0129	SH0160	SH0216	USG788		
SH0055	SH0095	SH0130	SH0163	SH0223			
SH0056	SH0096	SH0131	SH0164	SH0224			