

Field Safety Notice

Urgent Medical Device Recall – 2955842-11-15-2013-014-R

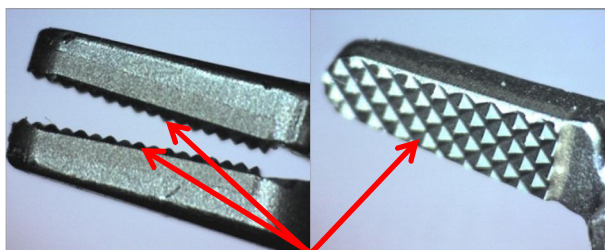
Specific Lots of Large Needle Driver and Mega Needle Driver EndoWrist® Instruments for da Vinci® Surgical Systems

Introduction and Reason for Field Action

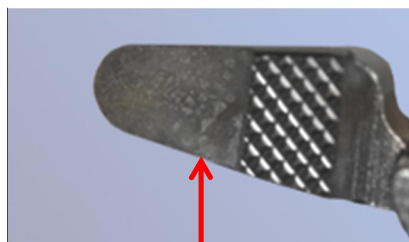
Dear *da Vinci* Customer,

The purpose of this letter is to advise you that Intuitive Surgical is voluntarily initiating a product recall for certain lots of Large Needle Driver and Mega Needle Driver *EndoWrist*® instruments. See below for instructions to identify affected products. A list of affected part numbers and lot numbers is attached to this Notice.

Intuitive Surgical has become aware of the potential for detachment of the jaw insert for Large Needle Drivers and Mega Needle Drivers. The root cause was determined to be variability in the manufacturing process for bonding the inserts to the instrument jaws. The source of variability was identified and corrected. Large Needle Driver and Mega Needle Driver instruments manufactured between July 2007 and October 2011 are affected.



Large Needle Driver with undetached jaw inserts



Example instrument with partial detachment of jaw insert

Risk to Health

If a jaw insert detaches during surgery, this could result in a device fragment falling into the patient.

Intuitive Surgical has received a total of 102 reports related to damaged or detached Large Needle Driver and Mega Needle Driver jaw inserts. Thirty (30) of these reports were for inserts falling off during surgery. Of these, there was one report of a fragment falling into the patient that was not retrieved during the surgery, so the patient underwent a second operation to remove the fragment; the other 29 were immediately retrieved. The remaining 72 reports were for damaged or detached inserts that were not reported as falling into a patient. There have been more than 998,000 uses of the affected Large Needle Driver and Mega Needle Driver instruments resulting in a reported occurrence rate of damage or detachment of 0.01%.

<p>Affected Regions and Products</p>	<p>Affected regions: Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Chile, Cyprus, Czech Republic, Denmark, Egypt, Finland, France, Germany, Greece, India, Ireland, Israel, Italy, Japan, Mexico, Netherlands, Norway, Pakistan, Poland, Portugal, Puerto Rico, Qatar, Romania, Russia, Saudi Arabia, South Korea, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, Taiwan, Thailand, Turkey, United Kingdom, United States of America, Venezuela</p> <p>Affected products:</p> <table border="1" data-bbox="407 422 1442 594"> <tr> <td>420006</td> <td>Large Needle Driver, da Vinci S and da Vinci Si</td> </tr> <tr> <td>420194</td> <td>Mega Needle Driver, da Vinci S and da Vinci Si</td> </tr> <tr> <td>400006</td> <td>Large Needle Driver, da Vinci Standard</td> </tr> <tr> <td>400194</td> <td>Mega Needle Driver, da Vinci Standard</td> </tr> </table> <p>The lot numbers affected by this recall are provided in the attachment.</p>	420006	Large Needle Driver, da Vinci S and da Vinci Si	420194	Mega Needle Driver, da Vinci S and da Vinci Si	400006	Large Needle Driver, da Vinci Standard	400194	Mega Needle Driver, da Vinci Standard
420006	Large Needle Driver, da Vinci S and da Vinci Si								
420194	Mega Needle Driver, da Vinci S and da Vinci Si								
400006	Large Needle Driver, da Vinci Standard								
400194	Mega Needle Driver, da Vinci Standard								
<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 appropriate personnel are fully informed of this Notification. Forward this letter to your Risk Manager, OR Director, Purchasing, Biomedical Engineering staff and members of your medical staff who perform <i>da Vinci</i> surgery procedures. 2. Discontinue use of affected product. 3. Use the attached instructions to identify and segregate affected product. 4. Return affected product to Intuitive Surgical following the established Returned Materials Authorization (RMA) process. 5. Complete the Acknowledgement Form at the end of this letter and return it to Intuitive Surgical. 6. Contact Intuitive Surgical Customer Service if you have questions regarding this notification. 7. Please retain a copy of this letter and the acknowledgement form for your files. 								
<p>Action to be taken by Intuitive Surgical</p>	<p>Intuitive Surgical representatives will be available by phone to answer customer questions, issue RMA numbers and process customer orders to facilitate your site's replenishment of instruments.</p>								
<p>Further Information & Support</p>	<p>If you need further information or support concerning this recall, please contact your Clinical Sales Representative or Intuitive Surgical Customer Service at the numbers listed below:</p> <ul style="list-style-type: none"> • North and South America: 800-876-1310 Option 3 (6 am to 5pm 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) <p>Europe, Middle East, Asia and Africa: +800 0821 2020 or +41 21 821 2020 (8 am to 6 pm CET)</p>								

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

Sincerely,



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 Recall – 2955842-11-15-2013-014-R

Specific Lots of Large Needle Driver and Mega Needle Driver EndoWrist® Instruments for da Vinci® Surgical Systems

Hospital Name: <mail merge field>

Address: <mail merge field>

City, State, Zip: <mail merge field>

ATTENTION: <mail merge field>

I have received and read the attached Recall Notification regarding the jaw insert for the Large Needle Driver and the Mega Needle Driver *Endowrist* Instruments. I have reviewed my site's inventory of these products and identified and segregated the following quantities of affected product based on the list of affected lot numbers provided with this Notice.

Part Number	Description	Quantity Shipped (ship dates were between July 2007 and December 2011)	Number of Affected Product Identified and Segregated for Return (completed by customer)
420006	Large Needle Driver, da Vinci S and da Vinci Si	<mail merge field>	
420194	Mega Needle Driver, da Vinci S and da Vinci Si	<mail merge field>	
400006	Large Needle Driver, da Vinci Standard	<mail merge field>	
400194	Mega Needle Driver, da Vinci Standard	<mail merge field>	

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)
- 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 CET)

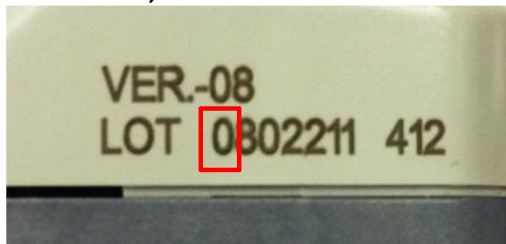
PLEASE FAX THIS ACKNOWLEDGEMENT FORM TO
Intuitive Surgical, Inc.
ATTN: REGULATORY COMPLIANCE
U.S. +1 (408) 716-3040, or Scan and Email: isi.compliance@intusurg.com

Instructions to Identify Affected Large Needle Driver / Mega Needle Driver

Step	
1	Using the following process, identify and return all affected instruments following the RMA process. Credit will be granted for remaining lives on each instrument.
2	<p>Review your inventory of da Vinci instruments for the following part numbers:</p> <p>420006: Large Needle Driver, da Vinci S, Si or Si-e 420194: Mega Needle Driver, da Vinci S, Si or Si-e 400006: Large Needle Driver, da Vinci Standard 400194: Mega Needle Driver, da Vinci Standard</p> <div data-bbox="527 562 1187 989" data-label="Image"> </div> <p data-bbox="464 991 1252 1020">Example: Part Numbers are found on the face of the instrument housing.</p>
3	<p>For each instrument identified in Step 2, locate the instrument Lot number:</p> <div data-bbox="427 1119 1289 1543" data-label="Image"> </div> <p data-bbox="509 1545 1208 1575">Example: Lot numbers are on the side of the instrument housing</p>

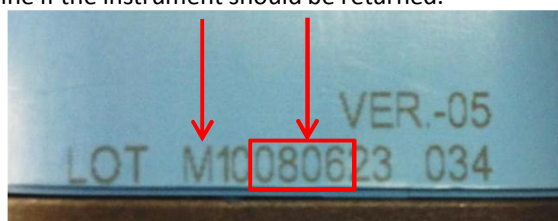
4

- a. If the first character is a number, RETURN the instrument to Intuitive Surgical.



Leading character is a number.

- b. If the first character is either an "S" or "M" as in the example below, review the four-digit number in the middle of the lot code, the 4th, 5th, 6th and 7th characters, and use the table in [step c](#) to determine if the instrument should be returned.



- c. Based on the four-digit number in the middle of the lot code, take the following actions:

Four-digit number	Action
13 followed by any two numbers	Keep Instrument; Not affected by this recall
12 followed by any two numbers	
1112	
1111	
1110	
1109	Do not use and return the instrument
1108	
1107	
1106	
1105	
1104	
1103	
1102	
1101	
10 followed by any two numbers	
09 followed by any two numbers	
08 followed by any two numbers	

List of Affected Part Numbers and Lot Numbers

Part Number	Lot Number								
	40006	710182	801282	805131	M10080716	M10080910	M10090216	M10091104	M10100728
710192		802042	805221	M10080718	M10081014	M10090225	M10091110	M10100729	S10080618
710262		802052	805271	M10080721	M10081024	M10090325	M10091113	M10100804	S10080624
710301		802061	910072	M10080722	M10081027	M10090325	M10091120	M10100810	S10080626
710302		802072	1610072	M10080723	M10081028	M10090401	M10091130	M10100813	S10080708
711052		802082	M10080603	M10080724	M10081029	M10090407	M10091209	M10100820	S10080709
711062		802122	M10080603	M10080725	M10081031	M10090415	M10091211	M10100902	S10080711
711072		802131	M10080603	M10080728	M10081104	M10090417	M10091214	M10100924	S10080712
711082		802152	M10080605	M10080729	M10081110	M10090427	M10091216	M10100927	S10080715
711092		802202	M10080606	M10080730	M10081111	M10090505	M10100113	M10100929	S10080718
711122		802212	M10080609	M10080731	M10081112	M10090514	M10100118	M10101026	
711142		802252	M10080610	M10080801	M10081117	M10090519	M10100123	M10101103	
711152		802262	M10080612	M10080804	M10081119	M10090521	M10100128	M10101118	
711262		802272	M10080616	M10080805	M10081120	M10090526	M10100129	M10101123	
711282		803042	M10080617	M10080806	M10081124	M10090604	M10100209	M10101124	
711302		803101	M10080618	M10080807	M10081125	M10090605	M10100212	M10101209	
712042		803112	M10080618	M10080808	M10081127	M10090616	M10100222	M10110113	
712062		803132	M10080618	M10080811	M10081128	M10090704	M10100225	M10110131	
712102		803172	M10080619	M10080812	M10081201	M10090713	M10100302	M10110208	
712112		803192	M10080620	M10080813	M10081204	M10090717	M10100308	M10110210	
712142		803212	M10080623	M10080814	M10081205	M10090728	M10100312	M10110217	
712182		803241	M10080624	M10080815	M10081209	M10090810	M10100323	M10110224	
712192		803261	M10080625	M10080818	M10081210	M10090811	M10100326	M10110304	
712212		803271	M10080626	M10080819	M10081211	M10090817	M10100408	M10110310	
801021		804081	M10080627	M10080820	M10081218	M10090826	M10100430	M10110317	
801072		804101	M10080630	M10080821	M10090107	M10090901	M10100506	M10110323	
801092		804121	M10080701	M10080825	M10090112	M10090905	M10100507	M10110419	
801142		804171	M10080702	M10080828	M10090115	M10090911	M10100511	M10110506	
801152		804221	M10080704	M10080901	M10090127	M10090922	M10100518	M10110523	
801171		804231	M10080707	M10080902	M10090127	M10091001	M10100601	S10080603	
801212		804241	M10080708	M10080903	M10090128	M10091002	M10100602	S10080606	
801222		804261	M10080709	M10080904	M10090203	M10091015	M10100607	S10080606	
801242		804291	M10080710	M10080905	M10090205	M10091027	M10100625	S10080612	
801252		805071	M10080711	M10080909	M10090209	M10091102	M10100722	S10080612	

List of Affected Part Numbers and Lot Numbers

Part Number	Lot Number										
	420006	610072	801252	804221	M10080624	M10080815	M10081020	M10081219	M10090501	M10090813	M10091209
710222		801282	804231	M10080624	M10080818	M10081021	M10081222	M10090504	M10090814	M10091210	S10080705
710242		801302	804241	M10080624	M10080819	M10081022	M10081223	M10090509	M10090820	M10091211	S10080705
711052		802042	804291	M10080625	M10080820	M10081023	M10090105	M10090511	M10090821	M10091212	S10080707
711062		802052	805051	M10080626	M10080821	M10081024	M10090106	M10090513	M10090831	M10091215	S10080710
711072		802072	805091	M10080703	M10080822	M10081028	M10090109	M10090514	M10090901	M10091217	S10080714
711082		802082	805121	M10080704	M10080825	M10081029	M10090116	M10090519	M10090905	M10091218	S10080715
711092		802131	805171	M10080707	M10080827	M10081030	M10090119	M10090520	M10090907	M10091221	S10080717
711122		802142	805201	M10080708	M10080828	M10081031	M10090122	M10090521	M10090909	M10100104	S10081120
711128		802152	805231	M10080709	M10080901	M10081103	M10090123	M10090526	M10090910	M10100105	
711132		802202	805241	M10080710	M10080902	M10081107	M10090126	M10090529	M10090916	M10100112	
711142		802212	805291	M10080711	M10080903	M10081110	M10090129	M10090603	M10090921	M10100115	
711152		802252	805311	M10080716	M10080904	M10081111	M10090130	M10090605	M10090924	M10100119	
711272		802262	1110072	M10080718	M10080908	M10081112	M10090204	M10090611	M10090929	M10100122	
711282		802272	1710072	M10080721	M10080909	M10081114	M10090206	M10090612	M10091005	M10100126	
711302		803041	M10080603	M10080721	M10080910	M10081118	M10090213	M10090615	M10091010	M10100129	
712042		803062	M10080605	M10080722	M10080911	M10081119	M10090220	M10090617	M10091012	M10100203	
712062		803101	M10080606	M10080723	M10080919	M10081120	M10090223	M10090625	M10091019	M10100204	
712102		803112	M10080609	M10080723	M10080922	M10081124	M10090224	M10090703	M10091022	M10100205	
712122		803132	M10080610	M10080724	M10080923	M10081125	M10090225	M10090710	M10091026	M10100208	
712142		803172	M10080612	M10080725	M10080924	M10081127	M10090226	M10090711	M10091029	M10100211	
712182		803192	M10080616	M10080728	M10080925	M10081128	M10090303	M10090715	M10091102	M10100216	
712192		803212	M10080617	M10080729	M10080926	M10081201	M10090304	M10090716	M10091105	M10100217	
712212		803241	M10080618	M10080730	M10080929	M10081202	M10090305	M10090717	M10091111	M11090226	
712262		803261	M10080618	M10080731	M10080930	M10081203	M10090309	M10090718	M10091117	M10080605	
712272		803271	M10080618	M10080801	M10081001	M10081205	M10090310	M10090720	M10091118	M10080605	
801022		803281	M10080619	M10080804	M10081002	M10081208	M10090311	M10090728	M10091119	M10080605	
801072		804031	M10080619	M10080805	M10081003	M10081209	M10090327	M10090729	M10091125	S10080618	
801092		804081	M10080619	M10080806	M10081008	M10081210	M10090406	M10090730	M10091126	S10080620	
801141		804101	M10080620	M10080807	M10081009	M10081211	M10090414	M10090731	M10091127	S10080624	
801152		804141	M10080620	M10080808	M10081010	M10081212	M10090417	M10090803	M10091201	S10080626	
801172		804151	M10080620	M10080811	M10081013	M10081215	M10090421	M10090804	M10091202	S10080627	
801212		804161	M10080623	M10080812	M10081015	M10081216	M10090424	M10090805	M10091204	S10080628	
801222		804181	M10080623	M10080813	M10081016	M10081217	M10090427	M10090806	M10091207	S10080629	
801242	804191	M10080623	M10080814	M10081017	M10081218	M10090429	M10090812	M10091208	S10080630		

List of Affected Part Numbers and Lot Numbers

Part Number	Lot Number						
420006	M10100219	M10100514	M10100730	M10101015	M10101217	M10110318	M10110526
	M10100222	M10100517	M10100802	M10101019	M10110104	M10110322	M11100303
	M10100223	M10100518	M10100805	M10101020	M10110111	M10110323	M11100416
	M10100224	M10100520	M10100806	M10101022	M10110117	M10110324	M11100419
	M10100225	M10100524	M10100809	M10101025	M10110121	M10110325	M11100420
	M10100301	M10100525	M10100811	M10101026	M10110124	M10110328	M11100514
	M10100303	M10100526	M10100812	M10101027	M10110125	M10110329	M11100517
	M10100304	M10100528	M10100818	M10101028	M10110127	M10110330	M11100621
	M10100310	M10100531	M10100819	M10101101	M10110128	M10110331	M11100623
	M10100311	M10100601	M10100823	M10101105	M10110201	M10110401	M11100624
	M10100312	M10100603	M10100824	M10101108	M10110202	M10110404	M11100719
	M10100315	M10100607	M10100826	M10101110	M10110204	M10110406	M11100823
	M10100318	M10100608	M10100903	M10101111	M10110208	M10110407	M11100910
	M10100322	M10100609	M10100907	M10101112	M10110209	M10110411	M11100930
	M10100325	M10100617	M10100910	M10101115	M10110210	M10110412	M11101004
	M10100331	M10100618	M10100913	M10101116	M10110211	M10110414	M11101022
	M10100405	M10100621	M10100914	M10101118	M10110215	M10110418	M11101025
	M10100408	M10100622	M10100915	M10101123	M10110216	M10110419	M11101204
	M10100409	M10100623	M10100916	M10101124	M10110221	M10110420	M11101207
	M10100412	M10100624	M10100920	M10101125	M10110223	M10110425	M11110119
	M10100413	M10100625	M10100921	M10101126	M10110224	M10110427	M11110204
	M10100414	M10100705	M10100922	M10101127	M10110225	M10110429	M11110223
	M10100415	M10100706	M10100923	M10101129	M10110228	M10110502	M11110310
	M10100416	M10100707	M10100924	M10101201	M10110301	M10110503	M11110408
	M10100419	M10100708	M10100927	M10101202	M10110302	M10110504	M11110420
	M10100420	M10100715	M10100928	M10101204	M10110307	M10110510	M11110510
	M10100423	M10100719	M10100930	M10101206	M10110308	M10110513	M12100623
	M10100426	M10100720	M10101004	M10101207	M10110309	M10110516	M12100624
	M10100427	M10100721	M10101006	M10101210	M10110310	M10110517	M12110420
	M10100505	M10100722	M10101007	M10101213	M10110311	M10110519	
	M10100507	M10100723	M10101011	M10101214	M10110315	M10110520	
	M10100511	M10100726	M10101012	M10101215	M10110316	M10110524	
M10100512	M10100727	M10101014	M10101216	M10110317	M10110525		

List of Affected Part Numbers and Lot Numbers

Part Number	Lot Number		Part Number	Lot Number		
400194	710191	M10110114	420194	510071	M10090629	S10080802
	710197	M10110204		710191	M10090706	S10080818
	710261	M10110217		710261	M10090724	S10080822
	711061	M10110307		711061	M10090727	S10080902
	711121	M10110321		711121	M10090731	S10080910
	711191	M10110425		711151	M10090810	S10080917
	712071	M10110523		711191	M10090825	S10080926
	712171	M10110603		712051	M10090828	S10080930
	801041	M10110621		712131	M10090909	S10081002
	801151	M10110725		712262	M10090916	S10081009
	801171	M10110728		801021	M10091005	S10081014
	801301	M10110810		801151	M10091008	S10081016
	803171	M10110816		801181	M10091012	S10081029
	804121	M10110831		801241	M10091030	S10081106
	805091	M10110909		801301	M10091105	S10081114
	805271	M10110920		802121	M10091123	S10081119
	M10090320	S10080609		802201	M10091124	S10081202
	M10090512	S10080621		802251	M10091130	S10081209
	M10090709	S10080729		803121	M10091204	S10081218
	M10090731	S10080812		803211	M10091211	S10081229
	M10090812	S10080822		803261	M10091217	S10090106
	M10090824	S10080910		804031	M10100105	S10090112
	M10090909	S10080918		804111	M10100112	S10090114
	M10091020	S10081010		804221	M10100114	S10090119
	M10091110	S10081029		805121	M10100120	S10090121
	M10091130	S10081106		805271	M10100122	S10090227
	M10091211	S10081114		805301	M10100208	S10090302
	M10100114	S10081201		M10090316	M10100216	S10090305
	M10100216	S10081215		M10090324	S10080609	S10090312
	M10100218	S10090106		M10090423	S10080618	S10090316
	M10100428	S10090210		M10090505	S10080625	S10090318
	M10100526	S10090303		M10090512	S10080708	S10090320
	M10101026	S10090318		M10090528	S10080714	S10090327
M10101103	S10090320	M10090609	S10080723	S10090402		
M10101125	S10090410	M10090624	S10080729	S10090406		

List of Affected Part Numbers and Lot Numbers

Part Number	Lot Number		
420194	M10100218	M10110112	M10110726
	M10100224	M10110117	M10110802
	M10100311	M10110131	M10110805
	M10100318	M10110202	M10110809
	M10100407	M10110208	M10110811
	M10100412	M10110210	M10110817
	M10100415	M10110218	M10110825
	M10100429	M10110301	M10110901
	M10100519	M10110302	M10110906
	M10100526	M10110321	M10110913
	M10100527	M10110323	M10110920
	M10100531	M10110328	M10110923
	M10100603	M10110330	S10110307
	M10100615	M10110401	
	M10100713	M10110412	
	M10100714	M10110419	
	M10100722	M10110429	
	M10100723	M10110503	
	M10100802	M10110511	
	M10100809	M10110512	
	M10101001	M10110523	
	M10101008	M10110527	
	M10101019	M10110602	
	M10101026	M10110609	
	M10101029	M10110614	
	M10101104	M10110616	
	M10101109	M10110620	
	M10101115	M10110622	
	M10101117	M10110624	
	M10101122	M10110627	
	M10101127	M10110701	
	M10101206	M10110706	
	M10101215	M10110707	
	M10101217	M10110714	
	M10110107	M10110720	