



## URGENT FIELD SAFETY NOTICE / MAGEC® SYSTEM

DATE: February 13, 2020

COMMERCIAL NAME: **MAGEC® System**

TYPE OF ACTION: Advisory Notice and Product Recall

### **MAGEC® System**

NuVasive, Inc. voluntarily issues this Urgent Field Safety Notice (FSN) to inform healthcare providers caring for patients with MAGEC® System Model X rods of the following information.

#### **Description of the Issue:**

Post-implantation separation of an actuator end cap component has been observed in MAGEC® System Model X rods. Post-market surveillance data have shown this actuator end cap separation to have occurred in approximately 0.5% of this device.

This issue has only been observed in Model X rods, and therefore the prior version rods of the MAGEC® System are not affected by this FSN. Model X rods were first manufactured on July 27, 2017; the list of all potentially affected Model X lots are attached to this FSN.

The root cause of this issue is currently under investigation.

#### **Clinical Impact:**

Separation of the end cap may expose internal components of the actuator, which could lead to hastened degeneration of the internal components and egress of Titanium alloy wear debris and resultant localized tissue discoloration.

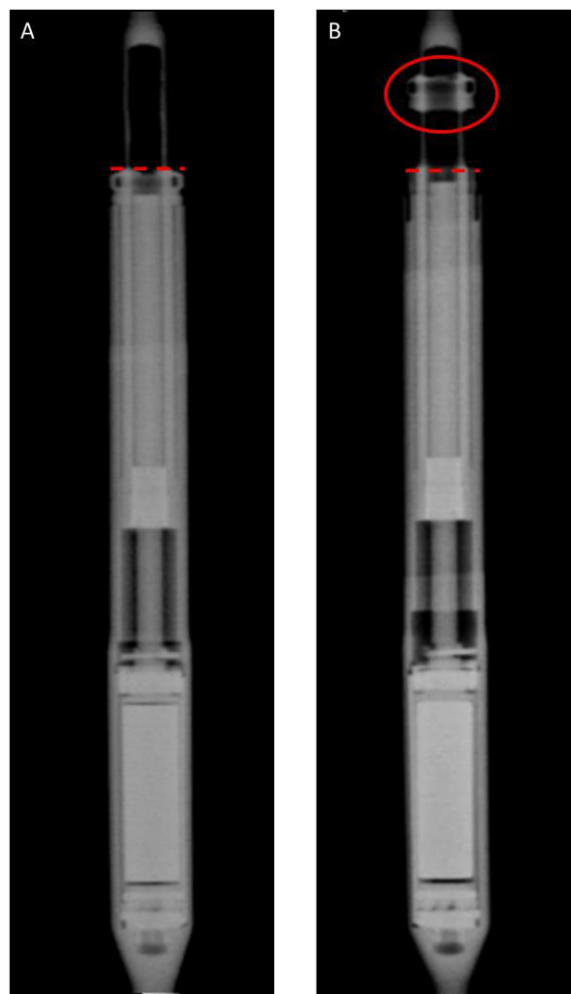
The MAGEC® System is used to brace the spine during growth to minimize the progression of scoliosis. Metallic implants can loosen, fracture, corrode, migrate, or cause pain. A Model X MAGEC® System rod may continue to lengthen/distract and/or serve as an internal brace after the separation of the end cap component. The long-term ability of a rod with a separated actuator end cap to continue to lengthen/distract is currently unknown.

The company recommends that surgeons perform routine clinical follow-up and discuss potential clinical implications and risks with patients who received affected rods. NuVasive is not recommending prophylactic revision based solely on the separation of an end cap. However, if an end cap separation is detected, removal of the device may be indicated. The decision to remove the device should be made by the physician in consultation with the patient and/or family.

#### **Recommended User Action:**

- Immediately examine your inventory to determine if you have product subject to this action on hand and quarantine the product. Your NuVasive representative will be visiting your office or contacting you directly to provide instructions for the return of the Model X rods.
- Review, complete, sign and return the attached Consignee Confirmation Form accompanying this notification in accordance with the directions on the form.
- Do not implant Model X rods until further notice.
- Review the details below and understand how to identify a separated end cap on postoperative X-Ray imaging as shown in Figure 1 below.

- Users should follow the appropriate postoperative procedure to assess the Model X rod by X-ray imaging whenever the device is adjusted or at a minimum of once every six months. Typically, the device can be adequately visualized, and a separated end cap can be detected, on standard anteroposterior X-ray imaging.
- If an end cap is seen to have separated from the actuator, the decision to remove the device should be made by the physician in consultation with the patient and/or family.
- If a Model X rod with a separated end cap is removed, confirm that the end cap is retained on the rod and that the actuator housing and distraction rod remain intact at all times during explantation.
- If removal is deemed appropriate by the physician, the device and all associated accessories should be removed and the explanted device returned to NuVasive.
- Patients and/or families should be reminded of the importance of following the postoperative care instructions in the IFU.
- Forward this notice to anyone in your facility that needs to be informed.



**Figure 1:** Representative X-ray images of a device with a seated end cap (A) and a device with a separated end cap (B). Visual Identifiers of a separated end cap can include separation of the end cap from the device actuator housing.

### **Affected Devices**

The list of all affected lots is attached to this FSN.



Incidents of device failure should be promptly reported to the Company, irrespective of whether the failure is related to this FSN.

**Transmission of this Field Safety Notice:**

This notice needs to be passed on to all those who need to be aware within your organization.

This notice has been submitted to the appropriate regulatory authorities.

We apologize for any inconvenience that this action may create and appreciate your cooperation with our request.

If you have any questions or would like assistance with this FSN, please contact NuVasive at [FSNMAGEC@nuvasive.com](mailto:FSNMAGEC@nuvasive.com).

.....



## FIELD SAFETY NOTICE / MAGEC® SYSTEM

COMMERCIAL NAME: **MAGEC® System**

DATE: February 13, 2020

TYPE OF ACTION: Advisory Notice and Product Recall

### Consignee Confirmation Form

**It is important that your organisation takes the actions detailed in this FSN and confirms that you have received this FSN. Please complete and return this form to NuVasive per the instructions below.**

**Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.**

Customer Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
Phone: \_\_\_\_\_  
(Information required for regulatory effectiveness check)

**I acknowledge receiving and reading the February 13, 2020 MAGEC® SYSTEM FSN.**

_____ Name/Title	_____ Signature	_____ Date
_____ NuVasive Representative, if applicable	_____ Signature	_____ Date

**This form is to be returned to NuVasive**

- Scan and email this form to [FSNMAGEC@nuvasive.com](mailto:FSNMAGEC@nuvasive.com)



### MAGEC X Lot Numbers

0010301AAA	0012201AAA	7090805AAA	8020716AAA	8051004AAA	8061106AAA	8062318AAA	8071032AAA
0010333AAA	0012202AAA	7090806AAA	8030601AAA	8051101AAA	8061116AAA	8062322AAA	8071101AAA
0010334AAA	0012222AAA	7090902AAA	8030603AAA	8051105AAA	8061126AAA	8062511AAA	8071105AAA
0010335AAA	0012301AAA	7090903AAA	8040902AAA	8051107AAA	8061203AAA	8062602AAA	8071113AAA
0010336AAA	0012302AAA	7091505AAA	8040917AAA	8051112AAA	8061204AAA	8062622AAA	8071116AAA
0010401AAA	0012304AAA	7091506AAA	8041114AAA	8051201AAA	8061206AAA	8062625AAA	8071118AAA
0010402AAA	0012317AAA	7091514AAA	8041635AAA	8051203AAA	8061210AAA	8062628AAA	8071204AAA
0010403AAA	0012318AAA	7091601AAA	8041646AAA	8051205AAA	8061213AAA	8062702AAA	8071208AAA
0010404AAA	0012401AAA	7091602AAA	8041808AAA	8051402AAA	8061214AAA	8062705AAA	8071213AAA
0010620AAA	0012415AAA	7091603AAA	8041901AAA	8051409AAA	8061218AAA	8062713AAA	8071214AAA
0010621AAA	0012419AAA	7091604AAA	8042002AAA	8051501AAA	8061303AAA	8062718AAA	8071219AAA
0010742AAA	0012713AAA	7092101AAA	8042101AAA	8051503AAA	8061318AAA	8062808AAA	8071304AAA
0010743AAA	0012714AAA	7092214AAA	8042102AAA	8051511AAA	8061323AAA	8062810AAA	8071316AAA
0010770AAA	0012801AAA	7092301AAA	8042304AAA	8051511AAB	8061403AAA	8062810AAB	8071327AAA
0010771AAA	0012802AAA	7092302AAA	8042402AAA	8051601AAA	8061411AAA	8062818AAA	8071402AAA
0010773AAA	0012829AAA	7092303AAA	8042404AAA	8051614AAA	8061419AAA	8062821AAA	8071403AAA
0010818AAA	0012901AAA	7092506AAA	8042406AAA	8051711AAA	8061419AAB	8062828AAA	8071601AAA
0011023AAA	0012910AAA	7092605AAA	8042408AAA	8051715AAA	8061508AAA	8062902AAA	8071608AAA
0011317AAA	0012922AAA	7092802AAA	8042507AAA	8051804AAA	8061808AAA	8062905AAA	8071701AAA
0011318AAA	0013001AAA	7100219AAA	8042603AAA	8052101AAA	8061809AAA	8062920AAA	8071706AAA
0011319AAA	0013002AAA	7100401AAA	8042614AAA	8052105AAA	8061910AAA	8063003AAA	8071709AAA
0011401AAA	0013115AAA	7100409AAA	8042703AAA	8052201AAA	8061921AAA	8063005AAA	8071711AAA
0011402AAA	0013116AAA	7100501AAA	8042704AAA	8052308AAA	8061931AAA	8063010AAA	8071801AAA
0011506AAA	7072701AAA	7101309AAA	8042705AAA	8052309AAA	8061932AAA	8063011AAA	8071814AAA
0011524AAA	7080101AAA	7101310AAA	8042804AAA	8060103AAA	8062001AAA	8070206AAA	8071902AAA
0011525AAA	7080701AAA	7101604AAA	8043003AAA	8060107AAA	8062009AAA	8070211AAA	8071907AAA
0011601AAA	7081001AAA	7102419AAA	8043008AAA	8060109AAA	8062014AAA	8070223AAA	8071910AAA
0011602AAA	7082501AAA	7102501AAA	8043010AAA	8060409AAA	8062017AAA	8070303AAA	8072007AAA
0011643AAA	7082502AAA	7110102AAA	8043013AAA	8060503AAA	8062019AAA	8070502AAA	8072011AAA
0011644AAA	7083001AAA	7112002AAA	8050118AAA	8060517AAA	8062023AAA	8070505AAA	8072103AAA
0011714AAA	7083002AAA	7112003AAA	8050203AAA	8060601AAA	8062101AAA	8070512AAA	8072105AAA
0011715AAA	7083105AAA	7112213AAA	8050207AAA	8060605AAA	8062107AAA	8070601AAA	8072109AAA
0011803AAA	7083108AAA	7112214AAA	8050303AAA	8060608AAA	8062112AAA	8070615AAA	8072110AAA
0011804AAA	7090110AAA	7112803AAA	8050312AAA	8060611AAA	8062113AAA	8070701AAA	8072305AAA
0012003AAA	7090111AAA	7121217AAA	8050401AAA	8060613AAA	8062118AAA	8070702AAA	8072309AAA
0012020AAA	7090112AAA	7121218AAA	8050703AAA	8060702AAA	8062121AAA	8070901AAA	8072311AAA
0012024AAA	7090516AAA	7121410AAA	8050804AAA	8060705AAA	8062123AAA	8070902AAA	8072409AAA
0012101AAA	7090517AAA	7121411AAA	8050808AAA	8060723AAA	8062124AAA	8071001AAA	8072421AAA
0012102AAA	7090608AAA	7121601AAA	8050905AAA	8060724AAA	8062125AAA	8071003AAA	8072421AAB
0012128AAA	7090701AAA	7121602AAA	8050908AAA	8060727AAA	8062301AAA	8071005AAA	8072501AAA
0012129AAA	7090702AAA	8020207AAA	8051003AAA	8061101AAA	8062307AAA	8071020AAA	8072505AAA



8072508AAA	8081103AAA	8082902AAA	8091909AAA	8101813AAA	8111254AAA	8121406AAA	9011812AAA
8072510AAA	8081104AAA	8082903AAA	8091915AAA	8101901AAA	8111257AAA	8121407AAA	9011816AAA
8072518AAA	8081313AAA	8082905AAA	8092001AAA	8101904AAA	8111306AAA	8121704AAA	9011901AAA
8072520AAA	8081316AAA	8082909AAA	8092007AAA	8101905AAA	8111322AAA	8121705AAA	9011903AAA
8072623AAA	8081317AAA	8083003AAA	8092012AAA	8102003AAA	8111325AAA	8121717AAA	9012002AAA
8072626AAA	8081404AAA	8083006AAA	8092014AAA	8102201AAA	8111411AAA	8121801AAA	9012003AAA
8072627AAA	8081408AAA	8083007AAA	8092102AAA	8102209AAA	8111414AAA	8121802AAA	9012125AAA
8072628AAA	8081416AAA	8083008AAA	8092107AAA	8102212AAA	8111415AAA	8121805AAA	9012204AAA
8072701AAA	8081503AAA	8083101AAA	8092402AAA	8102306AAA	8111421AAA	8121810AAA	9012209AAA
8073004AAA	8081508AAA	8090401AAA	8092404AAA	8102313AAA	8111504AAA	8121813AAA	9012301AAA
8073005AAA	8081511AAA	8090402AAA	8092405AAA	8102314AAA	8111508AAA	8121902AAA	9012309AAA
8073006AAA	8081602AAA	8090504AAA	8092411AAA	8102320AAA	8111511AAA	8121904AAA	9012332AAA
8073105AAA	8081605AAA	8090508AAA	8092414AAA	8102323AAA	8111603AAA	8121913AAA	9012402AAA
8073109AAA	8081610AAA	8090604AAA	8092415AAA	8102411AAA	8111901AAA	8121915AAA	9012402AAB
8080101AAA	8081611AAA	8090609AAA	8092502AAA	8102501AAA	8111908AAA	8121923AAA	9012404AAA
8080103AAA	8081701AAA	8090615AAA	8092505AAA	8102503AAA	8112008AAA	8122007AAA	9012410AAA
8080105AAA	8081703AAA	8090705AAA	8092508AAA	8102504AAA	8112015AAA	8122011AAA	9012422AAA
8080112AAA	8081713AAA	8090709AAA	8092602AAA	8102511AAA	8112026AAA	8122101AAA	9012424AAA
8080113AAA	8081714AAA	8090724AAA	8092608AAA	8102902AAA	8112108AAA	8122106AAA	9012425AAA
8080202AAA	8081715AAA	8091005AAA	8092609AAA	8102902AAB	8112112AAA	8122110AAA	9020405AAA
8080217AAA	8082002AAA	8091011AAA	8092702AAA	8102910AAA	8112604AAA	8122112AAA	9021209AAA
8080316AAA	8082017AAA	8091013AAA	8092702AAB	8103001AAA	8112610AAA	8122606AAA	9021216AAA
8080401AAA	8082022AAA	8091101AAA	8092703AAA	8103027AAA	8120619AAA	8122607AAA	9021302AAA
8080402AAA	8082105AAA	8091103AAA	8092738AAA	8103050AAA	8120625AAA	8122610AAA	9021306AAA
8080403AAA	8082111AAA	8091118AAA	8100101AAA	8103102AAA	8120705AAA	9010801AAA	9021317AAA
8080605AAA	8082201AAA	8091122AAA	8100305AAA	8103117AAA	8120722AAA	9010806AAA	9021401AAA
8080612AAA	8082204AAA	8091211AAA	8100311AAA	8103150AAA	8120727AAA	9010807AAA	9021402AAA
8080613AAA	8082213AAA	8091221AAA	8100314AAA	8103165AAA	8120902AAA	9010909AAA	9021404AAA
8080703AAA	8082215AAA	8091311AAA	8100403AAA	8110104AAA	8120903AAA	9010919AAA	9021405AAA
8080705AAA	8082309AAA	8091324AAA	8100410AAA	8110105AAA	8120904AAA	9011002AAA	9021502AAA
8080705AAB	8082311AAA	8091401AAA	8100414AAA	8110203AAA	8120905AAA	9011102AAA	9021520AAA
8080706AAA	8082313AAA	8091401AAB	8100505AAA	8110223AAA	8121051AAA	9011103AAA	9021601AAA
8080805AAA	8082401AAA	8091403AAA	8100509AAA	8110306AAA	8121056AAA	9011112AAA	9021603AAA
8080809AAA	8082410AAA	8091404AAA	8100533AAA	8110501AAA	8121060AAA	9011114AAA	9021606AAA
8080812AAA	8082419AAA	8091701AAA	8100803AAA	8110505AAA	8121109AAA	9011428AAA	9021607AAA
8080902AAA	8082701AAA	8091702AAA	8100809AAA	8110514AAA	8121111AAA	9011429AAA	9021802AAA
8080905AAA	8082713AAA	8091704AAA	8100810AAA	8110515AAA	8121205AAA	9011502AAA	9021807AAA
8081001AAA	8082718AAA	8091705AAA	8100811AAA	8110601AAA	8121211AAA	9011601AAA	9021903AAA
8081010AAA	8082802AAA	8091706AAA	8100818AAA	8110621AAA	8121214AAA	9011611AAA	9021906AAA
8081011AAA	8082805AAA	8091801AAA	8100919AAA	8110703AAA	8121312AAA	9011627AAA	9021908AAA
8081012AAA	8082813AAA	8091806AAA	8101015AAA	8110915AAA	8121328AAA	9011712AAA	9022001AAA
8081102AAA	8082814AAA	8091906AAA	8101159AAA	8111202AAA	8121330AAA	9011803AAA	9022002AAA



9022011AAA	9031511AAA	9041005AAA	9051104AAA	9060317AAA	9062005AAA	9071826AAA	9081601AAA
9022102AAA	9031601AAA	9041008AAA	9051306AAA	9060408AAA	9062018AAA	9071905AAA	9081901AAA
9022110AAA	9031814AAA	9041701AAA	9051407AAA	9060411AAA	9062106AAA	9071906AAA	9081902AAA
9022114AAA	9031821AAA	9041706AAA	9051411AAA	9060413AAA	9062107AAA	9072003AAA	9081911AAA
9022204AAA	9031901AAA	9041707AAA	9051419AAA	9060516AAA	9062403AAA	9072004AAA	9081917AAA
9022526AAA	9032002AAA	9041817AAA	9051431AAA	9060604AAA	9062411AAA	9072215AAA	9082001AAA
9022536AAA	9032005AAA	9041906AAA	9051501AAA	9060611AAA	9062412AAA	9072222AAA	9082002AAA
9022605AAA	9032006AAA	9041918AAA	9051504AAA	9060614AAA	9062413AAA	9072313AAA	9082004AAA
9022703AAA	9032007AAA	9042001AAA	9051506AAA	9060703AAA	9062508AAA	9072314AAA	9082101AAA
9022801AAA	9032014AAA	9042002AAA	9051601AAA	9060707AAA	9062517AAA	9072315AAA	9082102AAA
9022811AAA	9032101AAA	9042004AAA	9051602AAA	9060714AAA	9062519AAA	9072318AAA	9082113AAA
9022814AAA	9032102AAA	9042209AAA	9051603AAA	9060804AAA	9062520AAA	9072319AAA	9082201AAA
9030102AAA	9032119AAA	9042214AAA	9051624AAA	9061006AAA	9062622AAA	9072415AAA	9082202AAA
9030104AAA	9032120AAA	9042216AAA	9051701AAA	9061018AAA	9062623AAA	9072420AAA	9082216AAA
9030111AAA	9032205AAA	9042301AAA	9051708AAA	9061032AAA	9062702AAA	9072421AAA	9082301AAA
9030205AAA	9032212AAA	9042305AAA	9051801AAA	9061105AAA	9062729AAA	9072424AAA	9082302AAA
9030206AAA	9032213AAA	9042308AAA	9051802AAA	9061106AAA	9062801AAA	9072516AAA	9082305AAA
9030207AAA	9032217AAA	9042308AAB	9051803AAA	9061120AAA	9062802AAA	9072601AAA	9082306AAA
9030412AAA	9032222AAA	9042309AAA	9052008AAA	9061120AAB	9062803AAA	9072701AAA	9082601AAA
9030415AAA	9032503AAA	9042401AAA	9052010AAA	9061124AAA	9062819AAA	9072702AAA	9082602AAA
9030504AAA	9032511AAA	9042412AAA	9052120AAA	9061125AAA	9070104AAA	9072705AAA	9082613AAA
9030521AAA	9032601AAA	9042414AAA	9052121AAA	9061126AAA	9070112AAA	9072706AAA	9082614AAA
9030610AAA	9032603AAA	9042501AAA	9052122AAA	9061220AAA	9070807AAA	9073001AAA	9082701AAA
9030612AAA	9032628AAA	9042508AAA	9052209AAA	9061221AAA	9070808AAA	9073007AAA	9082702AAA
9030613AAA	9032633AAA	9042601AAA	9052210AAA	9061224AAA	9070915AAA	9073022AAA	9082704AAA
9030703AAA	9032701AAA	9042611AAA	9052304AAA	9061225AAA	9070916AAA	9073023AAA	9082706AAA
9030707AAA	9032704AAA	9050704AAA	9052316AAA	9061310AAA	9071111AAA	9073115AAA	9082707AAA
9030810AAA	9032708AAA	9050706AAA	9052321AAA	9061314AAA	9071114AAA	9080301AAA	9082801AAA
9030823AAA	9032711AAA	9050712AAA	9052406AAA	9061412AAA	9071201AAA	9080812AAA	9082802AAA
9030826AAA	9032714AAA	9050806AAA	9052407AAA	9061503AAA	9071208AAA	9080813AAA	9082933AAA
9030901AAA	9032801AAA	9050818AAA	9052408AAA	9061510AAA	9071209AAA	9080814AAA	9083001AAA
9030902AAA	9032807AAA	9050819AAA	9052409AAA	9061712AAA	9071301AAA	9080815AAA	9090410AAA
9030904AAA	9032810AAA	9050902AAA	9052804AAA	9061722AAA	9071302AAA	9081301AAA	9090438AAA
9031102AAA	9032812AAA	9050905AAA	9052805AAA	9061812AAA	9071517AAA	9081307AAA	9090444AAA
9031107AAA	9032814AAA	9050907AAA	9052816AAA	9061819AAA	9071521AAA	9081312AAA	9090511AAA
9031113AAA	9032901AAA	9050909AAA	9052817AAA	9061901AAA	9071610AAA	9081401AAA	9090512AAA
9031208AAA	9032914AAA	9051004AAA	9053025AAA	9061902AAA	9071617AAA	9081402AAA	9090517AAA
9031406AAA	9032915AAA	9051008AAA	9053112AAA	9061911AAA	9071717AAA	9081412AAA	9090518AAA
9031409AAA	9040102AAA	9051011AAA	9060105AAA	9061912AAA	9071718AAA	9081417AAA	9090608AAA
9031410AAA	9040110AAA	9051016AAA	9060107AAA	9061929AAA	9071726AAA	9081501AAA	9090609AAA
9031414AAA	9040114AAA	9051101AAA	9060306AAA	9062003AAA	9071727AAA	9081502AAA	9090930AAA
9031501AAA	9040201AAA	9051103AAA	9060309AAA	9062004AAA	9071732AAA	9081508AAA	9090931AAA



9090956AAA	9091805AAA	9100407AAA	9110110AAA	9112020AAA	9120414AAA	9121203AAA	9121938AAA
9091001AAA	9091905AAA	9100408AAA	9110401AAA	9112021AAA	9120416AAA	9121309AAA	9121941AAA
9091002AAA	9091906AAA	9100701AAA	9110407AAA	9112022AAA	9120417AAA	9121310AAA	9122001AAA
9091019AAA	9092001AAA	9100705AAA	9110408AAA	9112023AAA	9120501AAA	9121311AAA	9122059AAA
9091021AAA	9092011AAA	9101401AAA	9110901AAA	9112101AAA	9120502AAA	9121311AAB	9122063AAA
9091116AAA	9092414AAA	9101403AAA	9110902AAA	9112102AAA	9120510AAA	9121312AAA	9122101AAA
9091201AAA	9092415AAA	9101415AAA	9110903AAA	9112119AAA	9120511AAA	9121316AAA	9122102AAA
9091202AAA	9092417AAA	9101416AAA	9110904AAA	9112201AAA	9120517AAA	9121317AAA	9122334AAA
9091301AAA	9093010AAA	9101501AAA	9111109AAA	9112209AAA	9120518AAA	9121401AAA	9122337AAA
9091302AAA	9093011AAA	9101502AAA	9111110AAA	9112210AAA	9120519AAA	9121402AAA	9122338AAA
9091317AAA	9093018AAA	9101514AAA	9111222AAA	9112211AAA	9120521AAA	9121437AAA	9122401AAA
9091318AAA	9100115AAA	9101516AAA	9111223AAA	9112214AAA	9120526AAA	9121439AAA	9122602AAA
9091601AAA	9100116AAA	9101516AAB	9111301AAA	9112216AAA	9120528AAA	9121441AAA	9122603AAA
9091619AAA	9100117AAA	9101601AAA	9111302AAA	9112301AAA	9120531AAA	9121635AAA	9122620AAA
9091620AAA	9100126AAA	9101610AAA	9111306AAA	9112302AAA	9120632AAA	9121711AAA	9122621AAA
9091701AAA	9100203AAA	9101612AAA	9111310AAA	9112303AAA	9120633AAA	9121712AAA	9122622AAA
9091702AAA	9100204AAA	9101613AAA	9112013AAA	9112523AAA	9120901AAA	9121713AAA	9122709AAA
9091712AAA	9100207AAA	9101701AAA	9112014AAA	9112611AAA	9121009AAA	9121719AAA	
9091714AAA	9100301AAA	9101803AAA	9112015AAA	9120306AAA	9121015AAA	9121809AAA	
9091801AAA	9100302AAA	9102401AAA	9112016AAA	9120307AAA	9121016AAA	9121810AAA	
9091803AAA	9100333AAA	9110107AAA	9112017AAA	9120401AAA	9121201AAA	9121815AAA	
9091804AAA	9100334AAA	9110108AAA	9112019AAA	9120402AAA	9121202AAA	9121924AAA	