

To the ATTENTION of: Operating Room Manager

20 May 2014

URGENT VOLUNTARY FIELD SAFETY NOTIFICATION

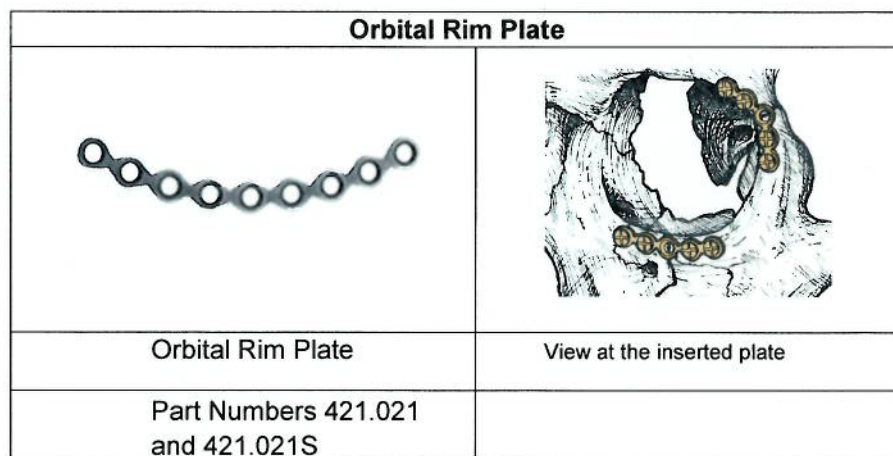
Part Description	Part Numbers	Lot numbers
Orbital Rim Plate 1.3, curved, 9 holes, Pure Titanium (incorrectly labeled as an "Orbital Floor Plate")	421.021	See attachment
Orbital Rim Plate 1.3, curved, 9 holes, Pure Titanium, sterile (incorrectly labeled as an "Orbital Floor Plate")	421.021S	See attachment




Dear Valued Customer,

Synthes GmbH is initiating a voluntary Field Safety Notification for the above mentioned articles and lots of "Orbital Floor Plate" which should have been labeled with "Orbital Rim Plate". Our records indicate that you may have inventory that is subject to this Field Safety Notification. Synthes kindly requests you to review the information contained in this Field Safety Notification and complete the Verification Section on page 8.

Description of the problem:

Product numbers 421.021 and 421.021S are mislabeled as "Orbital Floor Plate" instead of "Orbital Rim Plate".



Orbital Floor Plates		
Small size	Medium size	Large size
		 View at the inserted plate
Anatomic Orbital Floor Plate 1.3, small, Pure Titanium*	Anatomic Orbital Floor Plate 1.3, medium, Pure Titanium*	Anatomic Orbital Floor Plate 1.3, large, Pure Titanium*
Part number 421.048	Part number 421.043	Part number 421.049

*offered sterile and non-sterile

Potential hazard:

Non-sterile Part 420.021: The non-sterile Orbital Rim Plate, labeled as an “Orbital Floor Plate” will be received by Sterile Processing and Distribution personnel (SPD), who will open the packaging and place the part in the graphics tray in preparation for sterilization. If the SPD notice that the label incorrectly calls out an “Orbital Floor Plate,” there will be no patient impact, but this may result in personnel’s confusion and dissatisfaction. Once the labeling is separated from the non-sterile part, the opportunity for confusion is eliminated as the rim plate looks distinctly different from the foot plate. For sterilization the parts will be placed in the correct slot in the portable graphic case, which shows the correct part number.

Sterile Part 420.021S: Sterile packs are typically used intraoperatively. Operating personnel would be asked for a specific part; they would obtain the part and likely read the label. There may be confusion if the correct part number (420.021S) is associated with the incorrect labeling of “Orbital Floor Plate.” Because there is a large discrepancy between the orbital rim plate and the orbital floor plate in terms of both size and shape, it is likely that the personnel retrieving the part will immediately recognize that the description is incorrect, but that the part itself is the correct part, corresponding with the correct part number. The personnel will also be able to see the part through the back of the packaging and recognize the 9 holes orbital rim plate.

The mislabeling nonconformance may result in user dissatisfaction, but is not likely to impact the patient. There is no increased harm related to the nonconformance, and no new risk to patient identified.



Requested Immediate Customer actions:

1. Review, complete, sign and return the attached Verification form to your local DePuy Synthes sales organisation within 5 business days of receipt of this notification.
2. Forward this notice to anyone in your facility that needs to be informed.
3. If any product listed below has been forwarded to another facility, contact that facility and provide them with this letter.
4. Maintain a copy of this notice.

The applicable regulatory agencies are being notified. Synthes GmbH is taking this action voluntarily.

We apologise for any inconvenience that this Field Safety Notification may create and appreciate your cooperation with our request. Should you have any queries please do not hesitate to contact your DePuy Synthes sales consultant.

Synthes GmbH


Dr. med. Maria I. Behrens MDRA

Field Action Manager


Markus Wien

Director Quality Assurance Operations

Attachment: Affected Lot numbers

Affected Lot number for Part Number 421.021				
047107	1524773	3325292	7669139	8407284
047110	1533133	3326240	7685457	8407285
077111	1543095	3326244	7685458	8407286
1000873	1552925	3333662	7685459	8407287
1005	1552928	3359342	7685461	8407288
1007199	1572902	3367721	7693264	8407289
1008	1576292	3367727	7700229	8407290
1012	1576293	3375587	7700230	8472738
1012542	1583594	3389507	7700231	8472739
1016167	1598502	3402380	7700232	8480282
1017824	1598503	3425260	7707535	8480283
1018	1606017	3428732	7712657	8480284
1019	1626917	3455911	7712658	8480285
1019922	1639254	3468329	7725089	8489652
1022604	1639255	3468330	7725090	8489653
1023152	1663089	3468331	7725092	8489654
1024026	1663090	3468332	7728451	8489655
1024712	1699730	3480705	7728452	8500583
1025437	1700733	3480706	7742482	8500585
1026885	1702975	3490645	7742483	8500586
1029726	1702976	3490647	7742484	8513845
1030221	1702977	3504693	7757584	8513846
1032378	1703077	3504696	7757585	8513848
1034366	1711049	3504697	7757587	8513849
1037735	1713796	3515210	7757588	8513857
1040361	1716956	3518547	7781545	8513861
1041356	1716957	3518549	7784416	8513863
1042221	1716958	3518550	7784417	8513866
1043282	1716959	3518551	7798490	8513867
1045777	1716960	3518553	7798491	8513869
1047057	1724054	3518554	7798492	8555340
1049112	1728890	3518560	7807805	8598086
1051773	1730072	3527873	7807807	8598088
1054449	1735172	3533010	7807809	8598089
1055256	1761819	3533011	7815513	8598091
1056825	1767950	3560558	7815515	8598092
1059394	1769990	3560559	7815517	8598094
1060951	1783738	3560560	7815518	8608395
1060960	1787875	3560561	7839079	8608400
1061427	1815560	3573453	7858044	8608403
1065803	1823339	3573455	7858045	8608608
1067320	1826426	3573456	7858047	8608611
1069214	1833453	3573457	7875322	8608613
1071308	1844932	3616811	7888717	8608615
1072827	1850595	3618608	7888718	8650071
1073489	1850603	3618611	7888720	8650073
1076163	1850605	3623736	7894443	8650074
1077766	1850606	3623967	7907723	8653875
1079096	1850607	3623981	7907724	8653876
1083214	1850608	3623982	7907726	8653877
1083215	1850609	3623983	7907727	8653879

Affected Lot number for Part Number 421.021

1085044	1850610	3623984	7907729	8653882
1093029	1850611	3627203	7907730	8653883
1094823	1866467	3627205	7907731	8679115
1094824	1896564	3627206	7907737	8691199
1099818	1913083	3627207	7907738	8691200
1101394	1928039	3637936	7907740	8691201
1107083	1935753	3638149	7907742	8691202
1113550	1954482	3638150	7915976	8691203
1116662	1963581	3650346	7915977	8691204
1119583	1972103	3650347	7915978	8701159
1119584	1975872	3650348	7915979	8701160
1120517	2004701	3650349	7915980	8701161
1124453	2057583	3650350	7919520	8732840
1125113	2067329	3656562	7949719	8732841
1128623	2073389	3659043	7949720	8732842
1132847	2088134	3659045	7960188	8747227
1136129	2093179	3659046	7960190	8747228
1139038	2104324	3659047	7960192	8747229
1143476	2110002	3688895	7960194	8756366
1144695	2113008	3688896	7960196	8758160
1144700	2117249	3688897	7969905	8758162
1147241	2120869	3691879	7969962	8758163
1148920	2132217	3692170	7990242	8758164
1155976	2133754	3692171	7990243	8760760
1167181	2134593	3692172	7998907	8769622
1168768	2148502	3692173	8008335	8769624
1175090	2148503	3703380	8008336	8769626
1178963	2152388	3703382	8051700	8769627
1180757	2164943	3703383	8051702	8769630
1186088	2167713	3714850	8051703	8791389
1198992	2170425	3714852	8051707	8791390
1201664	2176157	3714854	8051708	8791391
1203817	2179912	3714855	8082664	8791392
1208228	2191346	3719685	8082669	8791393
1208494	2195396	3721986	8082674	8791517
1219032	2206054	3721988	8082677	8791518
1235571	2206055	3809434	8082678	8791519
1241290	2206056	3814403	8082679	8840367
1248890	2210978	3814405	8082680	8840368
1249549	2211147	3814406	8082682	8840369
1250567	2217830	3814407	8111062	8840370
1258357	2217831	3814408	8123824	8948892
1261792	2228013	3817670	8136069	8948893
1263654	2230489	3817671	8138954	8948894
1266842	2234817	3817672	8146984	8948895
1271176	2235157	3817673	8146987	8948896
1280554	2236986	3825499	8146992	8948898
1289296	2241985	3825500	8155205	8948899
1296233	2250505	3825501	8155207	8948900
1299184	2251013	3825719	8155208	8948901
1299554	2252210	3825722	8155210	8948902
1301647	2254774	6509675	8155212	8948904

Affected Lot number for Part Number 421.021

1307505	2256125	6524062	8167946	8948905
1311041	2258910	7515051	8167948	8948906
1312992	2259007	7515053	8167950	8948908
1314228	2260329	7520789	8167952	8948909
1319839	2261523	7520790	8177464	8948911
1319840	2268610	7524769	8177465	8955969
1319841	2277540	7524770	8177466	8955971
1323176	2279478	7524771	8177467	8955972
1326582	2281884	7524772	8177468	8955973
1326582T	2284687	7533123	8200091	8955976
1332690	2287220	7533124	8200095	8955978
1332691	2289127	7533125	8200102	8965521
1339911	2309112	7545942	8201582	8965524
1345261	2309113	7545943	8215237	8965526
1349633	2310660	7551675	8215238	8965532
1356649	2310664	7551676	8215241	8965534
1364451	2560561	7564951	8248868	8965582
1374037	3002973	7564952	8248869	8975258
1374038	3019457	7564954	8248870	8975259
1374039	3020031	7564955	8248871	8975260
1374040	3029390	7571561	8248872	8977372
1380339	3031207	7571562	8248873	8977373
1380341	3054537	7580658	8258157	8977375
1380372	3074459	7580659	8258158	8977376
1381945	3091379	7580660	8258159	8977378
1389409	3115789	7580662	8258160	8977379
1400073	3127319	7580663	8258161	8977381
1400074	3139956	7584678	8269274	8977383
1406267	3146455	7584680	8269275	8977384
1413043	3158571	7584681	8348021	999
1422148	3173079	7584683	8348022	9991
1428037	3191805	7586885	8348023	9993
1434395	3209504	7586886	8348024	9999
1436704	3221304	7586887	8348025	A3GO652
1442887	3236306	7586888	8397670	K
1443842	3249914	7591404	8397673	SN271337
1461216	3252623	7591405	8397675	
1477421	3256189	7611903	8397676	
1491107	3269340	7611904	8397677	
1491108	3273267	7615480	8397678	
1498834	3278453	7615691	8407279	
1498837	3299793	7615692	8407280	
1500926	3306536	7615694	8407281	
	3318254	7615698	8407282	
	3325288	7627913	8407283	
	3325291	7654885		

Affected Lot number for Part Number 421.021S

8943534	8252619	7774646	3648301	3218927
8887327	8222950	7744441	3629773	3193761
8806199	8164358	7709803	3556495	3177320
8797408	8166161	7680807	3548252	3149650
8773752	8145237	7652842	3525643	3125971
8733549	8098854	7632089	3517016	3046066
8671029	8068959	7605293	3490340	2003283
8596922	8039706	7584343	3482385	1974241
8592425	7994661	7561426	3453619	1885416
8499319	7960960	7552190	3438269	1880555
8500056	7942417	7511400	3394699	1819628
8486302	7936517	3795303	3376283	1784101
8402374	7903856	3788668	3345792	1801594
8384079	7896373	3750099	3302626	1792220
8378977	7844938	3729444	3285602	
8332816	7830206	3685220	3257652	
8284620	7800552	3676433	3229241	

NOTICE: FIELD SAFETY NOTIFICATION FSN2014075

Orbital Rim Plate 1.3, curved, 9 holes, Pure Titanium

Verification Section

Part Description	Part Numbers	Lot numbers
Orbital Rim Plate 1.3, curved, 9 holes, Pure Titanium (incorrectly labeled as an "Orbital Floor Plate")	421.021	See attachment
Orbital Rim Plate 1.3, curved, 9 holes, Pure Titanium, sterile (incorrectly labeled as an "Orbital Floor Plate")	421.021S	See attachment

- We have located the identified product in stock; a copy of this letter is being retained for our records.
- We do not have any identified product in stock. We have retained a copy of this letter for our records.

Hospital name: _____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____