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20 March 2015

URGENT NOTICE:
MEDICAL DEVICE RECALL – R2014204R
Trauma DHS/DCS Impactor Tip

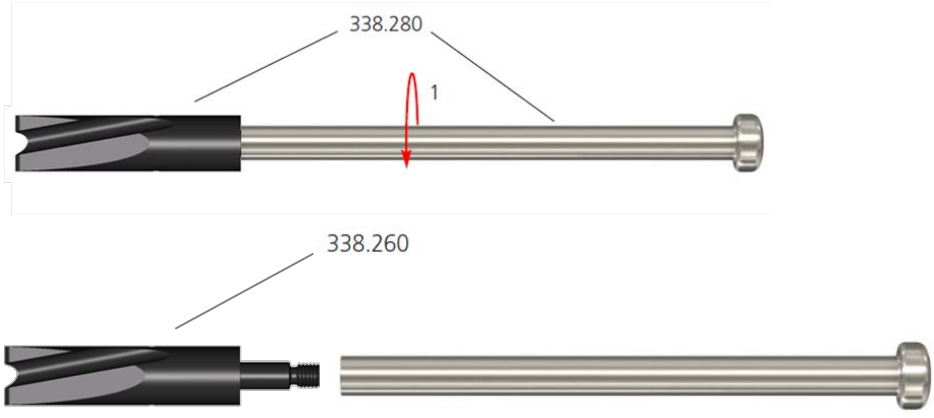
Please distribute this information to the appropriate personnel at your facility

Part Description, Part and Lot Numbers

Part Description	Part Number	Lot Number
Insert for DHS/DCS Impactor No. 338.280, Single	338.260	All lot numbers ≤ 8016184 See attachment 1
DHS/DCS Impactor, for One-Step Insertion Technique, for No. 338.300	338.280	All lot numbers ≤ 7985313 See attachment 1

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device recall of the DHS/DCS Impactor (part numbers 338.260 & 338.280). The DHS/DCS Impactor (338.280) is a reusable hand-held manual surgical instrument used to transmit hammer blows via the metallic shaft onto the plastic tip driving the DHS plate into its final position. The DHS/DCS Impactor is composed of two parts: a replaceable plastic tip which is the Insert for DHS/DCS Impactor (338.260), and a metallic shaft (338.280).



The voluntary device recall is with respect to the tip (338.260). Our records indicate that you may have inventory that is impacted by this recall or have been using affected product(s) from a loan set. Affected tips can be identified as follows:

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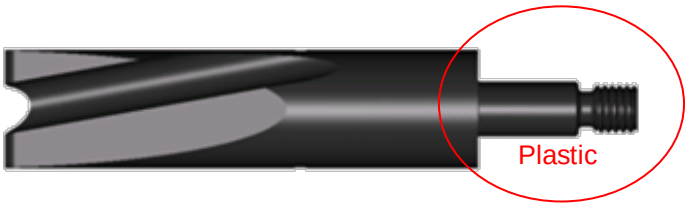
Old, affected, Insert for DHS/DCS Impactor (to be replaced, see affected lots):

Shaft mating part with thread is made of plastic material.



New Insert for DHS/DCS Impactor (no action required):

Shaft mating part with thread is made of steel.

Reason for the Recall:
There is a lack of proof of material biocompatibility for the Insert for DHS/DCS Impactor No. 338.280, Single (part number 338.260) used in the existing product (lots specified) (Polyamide 6.6 with 20% carbon fiber reinforcement, Tecamid 66 CF 20). No biocompatibility testing has ever been completed by Synthes for this material and no evidence was found that it has been completed by other entities.

Clinical Implications:
Potential for harm exists due to the potential for device breakage and may include surgical delay and adverse tissue reaction. If breakage occurs during impaction it would be readily detectable but could lead to a marginal to moderate surgical delay as a replacement is being procured or pieces are located and retrieved. Any un-retrieved or undetectable debris could lead to a marginal to moderate adverse tissue reaction.

Synthes GmbH provides instruction clearly outlining the reprocessing steps and stating damaged and excessively worn products should not be used (SE_023827, Rev.AJ).

Customer immediate actions:
We have record that your facility has received the product(s) subject to this recall. It is important to note that the removal of the product would prevent the performance of emergency surgery, thus Synthes GmbH is not requiring an immediate removal of the affected product(s). Synthes GmbH is in the process of developing the replacement and recovery plan for indicated devices and will contact you as replacement becomes available.

1. Review, complete, sign and return the attached reply form on page 6 & 7 of this letter to your local Depuy Synthes sales organization in accordance with the directions on the form within 5 business days of receipt of this notification.

2. If your facility chooses to return the product(s) at this time, return any affected product within 30 business days. A credit note will be issued for the returned items.

3. Forward this notice to anyone in your facility that needs to be informed.

4. If any of the affected products has been forwarded to another facility, contact that facility to arrange return, if applicable.

5. Maintain awareness of this notice until all products listed below have been returned to Depuy Synthes.

6. Keep a copy of this notice.

7. As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported as a complaint to Johnson & Johnson Medical Singapore following the usual procedure.

The applicable regulatory agencies are being notified.

We apologize for any inconvenience that this product recall may create and appreciate your cooperation with our request. Should you have any inquiries, please do not hesitate to contact your Depuy Synthes sales consultant.

Thank you for your attention and cooperation.

Yours sincerely,

[redacted]

Lee Ching Hwee
Professional Affairs Executive

Return Receipt Requested

Attachment 1: Product / Lots Subject to this Recall						
Product Description	**Part Number**	**Lot Numbers (All lot numbers ≤ 8016184)**				
Insert for DHS/DCS Impactor No. 338.280, Single	338.260	1009	1129597	1381183	1845737	3413305
		1040	1133524	1383145	1861719	3427515
		1041	1137306	1394258	1867164	3446555
		1042	1148612	1412173	1872142	3473816
		9991	1160132	1412179	1893050	3505774
		9999	1165709	1420374	1902649	3531665
		1001011	1172943	1426060	1919950	3557322
		1003902	1176124	1443572	1941817	3569370
		1005330	1176148	1459728	1947062	3609314
		1006292	1178615	1466257	1956663	3634695
		1006989	1179986	1482899	1971307	3666363
		1009833	1181326	1499840	1997826	3691151
		1010969	1188003	1527653	1998175	3716139
		1017044	1203338	1527715	3004282	3728871
		1032863	1206943	1541829	3008488	3748554
		1035673	1213731	1555562	3019768	3777734
		1039468	1219382	1568296	3030527	3801337
		1043245	1224331	1588979	3054474	3824277
		1044999	1234910	1588981	3066043	3824574
		1045049	1234938	1605085	3066044	7528423
		1048753	1246100	1612087	3073551	7544641
		1053287	1247730	1624994	3078205	7547263
		1058962	1251731	1629200	3095666	7573353
		1063563	1256895	1645746	3103040	7618801
		1067827	1259525	1661101	3114082	7620076
		1070779	1267656	1676644	3123371	7639269
		1076280	1269743	1702227	3136504	7669874
		1078922	1274170	1719477	3158562	7681296
		1084479	1285787	1721830	3180113	7707071
		1084506	1292082	1727505	3202377	7707076
		1089294	1302148	1727643	3211636	7751746
		1093191	1313276	1733923	3242848	7821744
		1097521	1325109	1767685	3259260	7878197
		1099545	1334438	1783129	3289728	7902865
		1104664	1334439	1794318	3299822	8008513
		1111178	1348477	1815940	3329754	8008515
		1113533	1358928	1821630	3351164	8016184
		1120294	1365299	1829660	3373444	
		1124170	1368889	1834821	3388851	

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Attachment 1: Product / Lots Subject to this Recall						
Product Description	**Part Number**	**Lot Numbers (All lot numbers ≤ 7985313)**				
DHS/DCS Impactor, for One-Step Insertion Technique, for No. 338.300	338.280	0	1231019	1709496	3095617	3566389
		1008	1242050	1713110	3099089	3581240
		1010	1244007	1713135	3123367	3591854
		1011	1248117	1727542	3136505	3594712
		1013	1251721	1729830	3153120	3629127
		1018	1259483	1749364	3175434	3647485
		1019	1261094	1753511	3196653	3659629
		1020	1274174	1769401	3211630	3668123
		1021	1292100	1776136	3228043	3668124
		1022	1319529	1787287	3228300	3681460
		1023	1323567	1802658	3238238	3700643
		1024	1325063	1806186	3250521	3717219
		1034	1336346	1821629	3273439	3740308
		9991	1341195	1839274	3289347	3759319
		9993	1343207	1845763	3289727	3767340
		9999	1352794	1861730	3299813	3781639
		1004562	1368864	1867170	3299814	3805703
		1009830	1383137	1873330	3329750	3822242
		1013926	1399875	1892920	3334181	4400410
		1013942	1399919	1896870	3343262	4666209
		1044995	1412128	1898703	3358621	7510883
		1048481	1417504	1898705	3360132	7520217
		1055615	1466294	1899861	3376053	7546494
		1075852	1485237	1917159	3390417	7558715
		1082300	1506418	1941683	3414575	7593209
		1097212	1516647	1966690	3427512	7618809
		1113530	1527712	1990528	3447684	7625637
		1121224	1541828	1992275	3456302	7647974
		1127555	1559712	2000000	3465690	7676468
		1148757	1601270	3020865	3479452	7699159
		1149802	1608134	3031666	3496511	7742505
		1165692	1612061	3035518	3521020	7751744
		1172896	1620804	3063646	3536331	7791397
		1179975	1629198	3067570	3547487	7873523
		1200264	1671237	3083076	3554850	7901129
		1224328	1704539	3086998	3560373	7985313

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URGENT NOTICE:
MEDICAL DEVICE RECALL – R2014204R
Trauma DCS/DCS Impactor Tip

Verification Section

Please distribute this information to the appropriate personnel at your facility

Part Description / Part Number:

Product Description	Part Number	Lot Numbers
Insert for DHS/DCS Impactor No. 338.280, Single	338.260	All lot numbers ≤ 8016184 See attachment 1
DHS/DCS Impactor, for One-Step Insertion Technique, for No. 338.300	338.280	All lot numbers ≤ 7985313 See attachment 1

____ We have located the identified product in stock and acknowledge the potential hazards involved with continuing to use this product. Our facility will continue to use the DHS/DCS Impactor until replacement product becomes available. (Please indicate the number of products and lot number(s) below)

____ We acknowledge receipt of this information. Our facility will not continue using the DHS/DCS Impactor. (Please indicate the number of products and lot(s) returned below)

____ We acknowledge receipt of this information, but do not have any identified product in stock; returned quantity is zero.

RETURNED DEVICES and Lot Number(s) (including quantity):

_____

_____

Please sign, date and stamp below. Your signature provides confirmation that you have received and understood this notification.

_____ Customer Name

_____ Title

_____ Signature & Date

_____ Stamp ***(Stamp shall bear facility name)***

Return Receipt Requested

Please complete this **Verification Section** and return to your Depuy Synthes representative or fax it to +65 6720 0750 within **(2) two business days** of receipt of the Field Safety Notice.

Note: If the Verification Section is answered on behalf of more than one facility and/or individual, please clearly indicate the name and address of the facility and/or individual on this page of the notification.