

**To the ATTENTION of:
Operating Room Manager**

23 March 2015

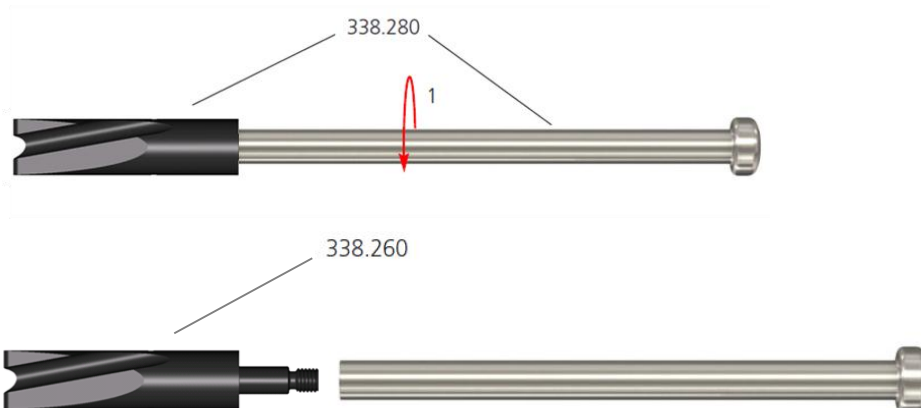
**URGENT NOTICE:
MEDICAL DEVICE RECALL – R2014204R
Trauma DHS/DCS Impactor Tip**

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).



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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:

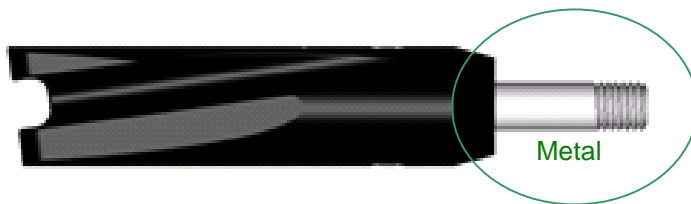
Old, affected, Insert for DHS/DCS Impactor (to be replaced, see affected lots):

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

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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 4 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.

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.

Synthes GmbH

Pierre van Iwaarden
Field Action Manager

Charles Goldberg
WW Director, Complaint Management

Cc:

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Account Name: _____

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

Verification Section

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):

Name/Title (please print): _____

Address: _____

Phone Number: _____

Signature and Date: _____

Please complete and return this page your local Synthes GmbH sales organization.

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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
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
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		