

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

26 February 2015

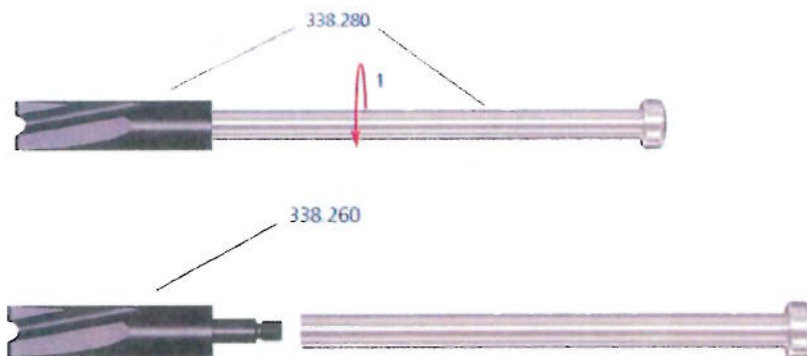
**URGENT NOTICE:
MEDICAL DEVICE RECALL – R2014204R
Trauma DHS/DCS Impactor Tip**

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 \leq 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 | |

Return Receipt Requested

| Attachment 1: Product / Lots Subject to this Recall | | | | | | |
|---|-------------|---|---------|---------|---------|---------|
| Product Description | Part Number | Lot Numbers (All lot numbers \leq 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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| 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 | | | |

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 | | |