

[Naslov prejemnika]

22. aprila 2020

## **NUJNO OBVESTILO O VARNOSTNEM POPRAVLJALNEM UKREPU**

### **Obvestilo o varnostnem odpoklicu medicinskega pripomočka**

Referenca: R-2020-04  
Zadevni pripomočki: R3<sup>◊</sup> Acetabular Shell

<b>Številka izdelka</b>	<b>Opis</b>	<b>Številka serije</b>
Glejte prilogo 1	R3 Acetabular Shell	Glejte prilogo 2

Spoštovani,

s tem dopisom vas obveščamo, da družba Smith+Nephew zaradi proizvodne napake izvaja prostovoljni odpoklic določenih serij pripomočka R3 Acetabular Shell. Uporaba zadevnih pripomočkov, ki morda niso bili izdelani v skladu z načrtovanimi specifikacijami, lahko povzroči neuspešno fiksiranje med operacijo.

Varnostni popravljalni ukrep je bil prijavljen ustreznim pristojnim organom.

<b>Tveganje za zdravje</b>	Pripomočki bodo najverjetneje delovali, kot je predvideno. Do danes smo prejeli šest pritožb glede neuspešnega fiksiranja med operacijo. V najslabšem primeru lahko keramična obloga, ki se med operacijo navidezno popolnoma fiksira z acetabularno ponvico, po operaciji počni, zaradi česar je potreben revizijski poseg. Ni poročil o pojavu najslabšega scenarija.
<b>Ukrepi, ki jih mora izvesti uporabnik</b>	<ol style="list-style-type: none"><li>1. Nemudoma poiščite vse zadevne neuporabljene pripomočke in jih dajte v karanteno.</li><li>2. Kopijo priloženega sporočila za zdravnika posredujte kirurškemu osebju.</li><li>3. Izločene izdelke vrnite zastopništvu oziroma distributerju izdelkov Smith+Nephew v svoji državi.</li><li>4. Izpolnite povratni list in ga po faksu ali e-pošti pošljite zastopništvu oziroma distributerju izdelkov Smith-Nephew v svoji državi.</li><li>5. Zagotovite, da bodo te varnostne informacije posredovane vsem osebam v organizaciji, ki morajo biti z njimi seznanjene.</li></ol>

6. Da bo ukrep učinkovit, poskrbite tudi za upoštevanje tega obvestila in ustrezno ukrepanje, dokler obvestilo o varnostnem odpoklicu ni zaključeno.
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Podjetje Smith+Nephew prodaja samo izdelke, ki ustrezajo najvišjim standardom kakovosti, in zagotavlja vso potrebno podporo. Obžalujemo ta zaplet in morebitne nevšečnosti, ki jih je povzročil vam, vašim pacientom ali osebju.



Če imate dodatna vprašanja, se lahko kadar koli obrnete na nas:

**Kontaktne podatke podružnice/distributerja**

## Povratni list

**Izpolnite ta list s povratnimi informacijami in ga vrnite na zgornji naslov. Vprašanja se tako ne bodo ponavljala.**

Potrjujemo, da smo seznanjeni z varnostnim korektivnim ukrepom ter da smo z njim seznanili tudi osebje v naši organizaciji in kirurško osebje.

V ustanovi imamo \_\_\_\_\_ [kol.] zadevnih pripomočkov, ki jih bomo vrnili.

\_\_\_\_\_ [kol.] zadevnih pripomočkov smo v naši ustanovi že zavrgli.

Ustanova: \_\_\_\_\_ Referenca: R-2020-04

Ime: \_\_\_\_\_ Datum/podpis: \_\_\_\_\_

Priloga:

- Seznam števil in opisov izdelkov (priloga 1)
- Seznam izdelkov in števil serije (priloga 2)
- Sporočilo za zdravnika

**Dodatek 1: Seznam števil in opisov izdelkov**

Številka izdelka	Opis	Številka izdelka	Opis izdelka
71331842	R3 0 HOLE ACETABULAR SHELL 42MM	71335540	R3 3 HOLE ACETABULAR SHELL 40MM
71331848	R3 0 HOLE ACETABULAR SHELL 48MM	71335542	R3 3 HOLE ACETABULAR SHELL 42MM
71331850	R3 0 HOLE ACETABULAR SHELL 50MM	71335544	R3 3 HOLE ACETABULAR SHELL 44MM
71331852	R3 0 HOLE ACETABULAR SHELL 52MM	71335546	R3 3 HOLE ACETABULAR SHELL 46MM
71331854	R3 0 HOLE ACETABULAR SHELL 54MM	71335548	R3 3 HOLE ACETABULAR SHELL 48MM
71331856	R3 0 HOLE ACETABULAR SHELL 56MM	71335550	R3 3 HOLE ACETABULAR SHELL 50MM
71331858	R3 0 HOLE ACETABULAR SHELL 58MM	71335552	R3 3 HOLE ACETABULAR SHELL 52MM
71331860	R3 0 HOLE ACETABULAR SHELL 60MM	71335553	R3 3 HOLE ACETABULAR SHELL 53MM
71331942	R3 3 HOLE HA COATED ACETABULAR SHELL 42MM	71335554	R3 3 HOLE ACETABULAR SHELL 54MM
71331946	R3 3 HOLE HA COATED ACETABULAR SHELL 46MM	71335556	R3 3 HOLE ACETABULAR SHELL 56MM
71331948	R3 3 HOLE HA COATED ACETABULAR SHELL 48MM	71335558	R3 3 HOLE ACETABULAR SHELL 58MM
71331950	R3 3 HOLE HA COATED ACETABULAR SHELL 50MM	71335560	R3 3 HOLE ACETABULAR SHELL 60MM
71331952	R3 3 HOLE HA COATED ACETABULAR SHELL 52MM	71338663	R3 MULTI HOLE ACET SHELL 48MM
71331954	R3 3 HOLE HA COATED ACETABULAR SHELL 54MM	71338664	R3 MULTI HOLE ACET SHELL 50MM
71331956	R3 3 HOLE HA COATED ACETABULAR SHELL 56MM	71338665	R3 MULTI HOLE ACET SHELL 52MM
71331958	R3 3 HOLE HA COATED ACETABULAR SHELL 58MM	71338666	R3 MULTI HOLE ACET SHELL 54MM
71331960	R3 3 HOLE HA COATED ACETABULAR SHELL 60MM	71338667	R3 MULTI HOLE ACET SHELL 56MM
71331962	R3 3 HOLE HA COATED ACETABULAR SHELL 62MM	71338668	R3 MULTI HOLE ACET SHELL 58MM
71331964	R3 3 HOLE HA COATED ACETABULAR SHELL 64MM	71338733	R3 HA MULTI-HOLE ACETABULAR SHELL 48MM
71331968	R3 3 HOLE HA COATED ACETABULAR SHELL 68MM	71338734	R3 HA MULTI-HOLE ACETABULAR SHELL 50MM
71332242	R3 0 HOLE HA COATED ACETABULAR SHELL 42MM	71338735	R3 HA MULTI-HOLE ACETABULAR SHELL 52MM
71332246	R3 0 HOLE HA COATED ACETABULAR SHELL 46MM	71338736	R3 HA MULTI-HOLE ACETABULAR SHELL 54MM
71332248	R3 0 HOLE HA COATED ACETABULAR SHELL 48MM	71338737	R3 HA MULTI-HOLE ACETABULAR SHELL 56MM
71332250	R3 0 HOLE HA COATED ACETABULAR SHELL 50MM	71338738	R3 HA MULTI-HOLE ACETABULAR SHELL 58MM
71332252	R3 0 HOLE HA COATED ACETABULAR SHELL 52MM	71338740	R3 HA MULTI-HOLE ACETABULAR SHELL 62MM
71332254	R3 0 HOLE HA COATED ACETABULAR SHELL 54MM	71338741	R3 HA MULTI-HOLE ACETABULAR SHELL 64MM
71332256	R3 0 HOLE HA COATED ACETABULAR SHELL 56MM		
71332258	R3 0 HOLE HA COATED ACETABULAR SHELL 58MM		
71332260	R3 0 HOLE HA COATED ACETABULAR SHELL 60MM		
71332262	R3 0 HOLE HA COATED ACETABULAR SHELL 62MM		
71332264	R3 0 HOLE HA COATED ACETABULAR SHELL 64MM		

## Dodatek 2: Seznam izdelkov in številke serije

Številka izdelka	Številka serije
<b>71331842</b>	18HM20691, 18KM15724, 18LM09819
<b>71331848</b>	18HM01685, 19AM15804, 19AM15805, 19AM15809, 19AM15828, 19AM15829
<b>71331850</b>	18LM00667, 18LM00668, 18LM00668A, 18LM00670, 18LM00671, 18LM00671A, 18LM00702
<b>71331852</b>	18KM00744, 18KM00775, 18KM00779, 18KM00833, 18KM06667, 18KM06675, 18KM06676, 18KM06680, 18KM06681, 18KM06682, 18KM13594, 18KM13632, 18KM15736, 18KM15736A, 18KM15737, 18KM15738, 18KM15739, 18KM20281, 18KM20281A, 18KM20284, 18KM20289, 18KM20291, 18KM20292, 18KM20293A, 18KM20315, 18KM24785, 18KM24785A, 18KM24792, 18KM24795, 18KM24805, 18LM02315, 18LM02317, 18LM02337, 18LM07653, 18LM14077, 18LM17941, 18LM17942, 18LM17946, 19EM10292
<b>71331854</b>	18GM07436, 18GM07437, 18GM07438, 18GM07445, 18GM07469, 18GM07522, 18GM07533, 18JM13874, 18JM13875, 18KM03144, 18KM03147, 18KM03148, 18KM23654, 18KM23655, 18KM23662, 18MM08650, 18MM08650A, 18MM08663, 18MM08663A, 18MM08676, 18MM08678, 18MM08683, 18MM08695, 18MM08697, 18MM08723, 18MM08724, 19AM17823, 19AM17833, 19AM17833A, 19AM17837, 19AM17837A, 19AM17845, 19AM17845A, 19AM17866, 19AM17869
<b>71331856</b>	18HM19101, 18HM19116, 18HM19117, 18HM19123, 18JM15940, 18JM15941, 18JM15947, 18JM15949, 18JM15949A, 18JM15950, 18KM04226, 18KM04250, 18KM04251, 18KM04252, 18KM04253, 18KM04254, 18KM13646, 18KM15773, 18KM17025, 18KM17026, 18KM17029, 18KM17031, 18KM17031A, 18KM17032, 18LM05390, 18LM18544, 18LM18546, 18LM18550, 18LM18550A, 18MM12424, 18MM12426, 18MM12428, 18MM12475, 18MM15587, 18MM15611
<b>71331858</b>	19AM03504, 19AM03511
<b>71331860</b>	18JM10154, 18JM10154A
<b>71331942</b>	18EM07919, 18HM20692
<b>71331946</b>	18GM07650, 18GM18521, 18GM18522, 18JM01361, 18JM14484, 18JM14573, 19DM10929, 19DM10931, 19DM17866, 19DM17868, 19DM17869, 19DM17871, 19DM17872, 19EM20018, 19EM20020
<b>71331948</b>	18DM20332, 18GM04745, 18GM04750, 18GM16845, 18GM16860, 18GM16862, 18GM16874, 18GM16878, 18JM08597, 18JM08598, 18JM08599, 18JM08600, 18JM18993, 18LM03812, 18LM03848, 18LM03851, 18LM17674, 18MM01811, 18MM01816, 18MM01818, 18MM01825, 19BM08346, 19BM08353, 19BM08371, 19BM08373, 19BM08377, 19BM21631, 19BM21634, 19BM21637, 19BM21639, 19BM21642, 19BM21643, 19CM00707, 19CM00729, 19CM00735, 19DM10935, 19DM17873, 19DM17874, 19DM17875, 19DM17878, 19DM17879, 19EM05719, 19EM05725, 19EM05727, 19EM05734, 19EM05735, 19EM05738, 19EM05739, 19EM11935, 19EM11942, 19EM11943, 19EM19991, 19EM19995
<b>71331950</b>	18EM19483, 18EM19487, 18EM19487A, 18EM19523, 18FM17575, 18FM17581, 18FM17585, 18GM01189, 18GM01189A, 18GM01198, 18GM01198A, 18GM01210, 18GM01210A, 18GM04645, 18GM04664, 18HM16471, 18HM16477, 18HM16477A, 18HM16490, 18JM05420, 18JM12752, 18JM12754, 18JM12755, 18JM12814, 18JM12814, 18KM08903, 18KM08903A, 18LM02612, 18LM02613, 18LM02630, 18LM11113, 19AM02040, 19AM02041, 19AM07778, 19BM12905, 19CM01534, 19CM01543, 19CM15757, 19CM15761, 19CM15763, 19CM15765, 19CM15767, 19CM15767A, 19DM06283, 19DM06289, 19DM06292, 19DM06486, 19DM10837, 19DM10838, 19DM10840, 19DM10842, 19DM10846, 19DM10851, 19DM21848, 19EM11934, 19EM11937, 19EM23498, 19EM23519
<b>71331952</b>	18EM13854, 18EM13857, 18EM13857A, 18FM02425, 18FM02426, 18FM02427, 18FM02564, 18FM07528, 18FM11963, 18FM11965, 18FM11967, 18FM14864, 18FM14867, 18FM14868, 18GM00538, 18GM00538A, 18GM00584, 18GM00584A, 18GM00587, 18GM00592, 18GM06508, 18GM06508A, 18GM06515, 18GM06533, 18GM06538, 18GM06541, 18GM06541A, 18GM06550, 18GM06555, 18GM07654, 18GM07666, 18GM09578, 18GM16948, 18HM23446, 18HM23446B, 18HM23462, 18JM07185, 18JM12782, 18JM12786, 18JM17200, 18KM06737, 18KM06740, 18KM06742, 18KM26470, 18KM26470A, 18KM26471, 18KM26480, 18LM02631, 18LM02644, 18LM02666, 18LM10385, 18LM13667, 18LM13681, 18LM13690, 18LM13690A, 18LM18647, 18MM02039, 18MM02055, 18MM02057, 18MM05761, 18MM05761A, 18MM05762, 18MM05762A, 18MM05765, 18MM05765A, 18MM05787, 18MM14820, 19AM02947, 19BM20198, 19BM20216, 19BM20216A, 19BM20220, 19BM20220A, 19BM22771, 19BM22774, 19BM22783, 19BM22788, 19CM22628, 19CM22632, 19CM22636, 19DM21882, 19DM21888, 19DM21896, 19DM21899, 19DM21901, 19DM21904, 19DM21905, 19DM21909, 19DM21913, 19DM21914, 19EM05796, 19EM05797, 19EM05799, 19EM05807, 19EM05808, 19EM17702, 19EM17702A, 19EM17709, 19EM17711
<b>71331954</b>	18EM17276, 18EM19555, 18EM19576, 18EM19577, 18FM01943, 18FM02432, 18FM02432B, 18FM02434, 18FM02434A, 18FM10239, 18FM16470, 18FM16474, 18FM16474A, 18FM16474B, 18FM16499, 18FM16548, 18FM21531, 18FM21557, 18FM21566, 18GM16959, 18GM16960, 18HM15320, 18HM15321, 18HM15321A, 18HM15321B, 18HM15322A, 18JM19411, 18KM01915, 18KM01915A, 18KM01929, 18LM02198, 18LM02200, 18LM02201, 18LM02228, 18LM02230, 18LM02234, 18LM02255, 18LM10394, 18LM10395, 19BM06530, 19BM06543, 19BM06588, 19BM06623, 19BM06638, 19BM06662, 19BM15988, 19BM16038, 19BM16039, 19BM16041, 19BM16043, 19BM16046, 19BM16048, 19BM20209, 19BM20210, 19BM20214, 19BM20215, 19BM20222, 19BM20225, 19BM20227, 19BM20229, 19CM03984, 19CM04002, 19CM04002A, 19CM04027, 19CM04033, 19CM04039, 19CM04040, 19CM04043, 19CM04043A, 19CM04045, 19CM04076, 19CM07039, 19CM07047, 19CM07054, 19CM07055, 19CM07055A, 19CM07056, 19CM07064, 19CM13919, 19CM13954, 19CM19644, 19CM24281, 19DM07241, 19DM07247, 19DM07256, 19DM07281, 19DM15692A, 19DM15693, 19EM17720, 19EM17724, 19EM20003, 19EM23472
<b>71331956</b>	18EM18364, 18EM20515, 18EM20519, 18EM20521, 18GM00125, 18GM00126, 18GM00127, 18GM00131, 18GM06708, 18GM06721, 18GM06734, 18GM07670, 18GM16963, 18GM16965, 18GM17029, 18GM17029A, 18HM04576, 18HM04581, 18HM04584, 18HM16084, 18JM04042, 18KM01961, 18KM01961A, 18LM02244, 18LM03826, 18LM03836, 18LM18627, 18LM18627A, 18MM01835, 18MM07586, 19CM03364, 19CM03365, 19CM03379, 19CM17413, 19CM17414, 19CM18371, 19DM07294, 19DM07296, 19DM07297, 19DM07302, 19DM15696, 19DM15697, 19DM15700, 19DM15704, 19DM15706, 19DM15707, 19DM15710, 19DM29300, 19DM29305, 19DM29332, 19DM29332A, 19EM09543, 19EM09555, 19EM09556, 19EM09558, 19EM20026
<b>71331958</b>	18FM02438, 18FM02438B, 18FM09877, 18FM12880, 18GM09602, 18HM15999, 18HM21285, 18HM21291, 18HM21291A, 18KM00263, 18KM00268, 18KM00268A, 18KM00271, 18KM00271A, 18KM00272, 18KM00272A, 18LM17981, 18LM17981, 19BM07155, 19BM07167, 19BM07168, 19BM07170, 19BM07171, 19BM07186, 19BM07191, 19BM07192, 19BM07195, 19BM22782, 19BM22784, 19BM22785, 19BM22786, 19BM22787, 19CM11388, 19CM11394, 19CM11398, 19CM11400, 19CM11411, 19CM11412, 19CM11421, 19DM10942, 19DM10943, 19DM10945, 19DM10947, 19DM10949, 19EM11290, 19EM11291, 19EM23518, 19EM23518A

<b>71331960</b>	18EM23148, 18FM02384, 18FM02384A, 18FM11142, 18FM11145, 18FM17591, 18FM17591A, 18FM17593, 18GM06745, 18HM10451, 18HM20601, 19CM17416, 19DM12906, 19DM12911, 19DM12912
<b>71331962</b>	18EM23155, 18FM11149, 18JM01367, 18JM02759, 18LM17982, 19CM17431, 19EM05746
<b>71331964</b>	18FM02445, 18FM02445A, 19EM17714
<b>71331968</b>	19CM04528
<b>71332242</b>	18HM20693, 18HM20693A
<b>71332246</b>	19EM17729, 19EM17730, 19EM17730A
<b>71332248</b>	18GM04752, 18GM04753, 18HM00807, 18MM01856, 19BM08386, 19DM17881, 19DM17884, 19DM17885, 19DM17890, 19EM11946, 19EM11947
<b>71332250</b>	18EM13916, 18EM13916A, 18EM13916B, 18EM13934, 18FM00218, 18FM17594, 18GM01199, 18JM05435, 18JM05436, 18JM12796, 18JM12800, 19BM17961, 19BM17964, 19CM15771, 19DM06430, 19DM06500, 19EM03956, 19EM03960, 19EM03970
<b>71332252</b>	18EM06114, 18EM06116, 18FM00161, 18FM00235, 18FM01038, 18FM01063, 18FM02450, 18FM11167, 18GM01228, 18GM04749, 18GM06567, 18GM09577, 18GM17030, 18HM15279, 18HM15304, 18HM23477, 18HM23481, 18JM12802, 18JM12811, 18KM03172, 18LM10404, 18LM10407, 18MM02061, 18MM05779, 19DM21920, 19DM21920A, 19DM21921, 19DM21922, 19DM21925, 19DM21927, 19EM09563, 19EM09574
<b>71332254</b>	18FM02451, 18FM16504, 18FM16506, 18GM16977, 18HM15323, 18JM08634, 18JM08635, 18JM08636, 18KM04390, 18LM10411, 18LM10411A, 18LM10411B, 18LM10414, 18LM10415, 18MM10067, 18MM10067A, 18MM10070, 18MM10127, 18MM10127A, 18MM10144, 19BM06673, 19BM16061, 19BM16064, 19BM16066, 19BM16067, 19BM16068, 19CM04082, 19CM04084, 19CM08204, 19CM08206, 19CM08207, 19CM08208, 19CM08209, 19CM08211, 19CM19656, 19CM19658, 19CM19658A, 19CM19703, 19CM19760, 19CM19765, 19CM19769, 19CM19838, 19CM19838A, 19CM19839, 19CM19843, 19DM05672, 19EM09578, 19EM09588, 19EM09588A
<b>71332256</b>	18FM11173, 18FM11177, 18GM07672, 18GM16978, 18MM07589, 18MM07597, 18MM07597A, 18MM07599, 18MM07622, 19BM12636, 19BM12639, 19EM09583
<b>71332258</b>	18EM23220, 18EM23223, 18FM02458, 18GM09584, 18GM16981, 18GM18527, 18GM18527B, 18GM18527C, 18LM17983, 18LM17984, 19BM07201, 19BM07202, 19BM07214, 19CM11413, 19CM11417, 19CM11417A, 19DM12931, 19DM12936, 19EM03998, 19EM03999, 19EM04000, 19EM04001
<b>71332260</b>	18FM02468, 18FM02468B, 18FM21552, 18HM08736, 18HM16487, 18HM16487A, 18HM16488, 18HM19141
<b>71332262</b>	18MM02014, 19EM11295, 19EM11296
<b>71332264</b>	19EM17718
<b>71335540</b>	18JM08648, 18JM08650, 18MM12391
<b>71335542</b>	18HM20695, 18LM09821, 19DM12897, 19DM12898, 19DM12899
<b>71335544</b>	18LM02189, 18LM02191, 18LM02192, 18MM08580, 18MM08582
<b>71335546</b>	18HM04443, 18HM04443A, 18HM04455, 18HM04455A, 18HM04461, 18HM04474, 18HM04483, 18HM04487, 18HM04488, 18HM04488A, 18HM04492, 18HM04495, 18HM04926, 18HM19845, 18HM19846, 18HM19848, 18HM19851, 18HM20664, 18JM06297, 18JM06307, 18JM06308, 18KM17658, 18KM17659, 18KM17660, 18KM17662, 18KM17662A, 18MM08596, 18MM08601, 18MM08602, 18MM08604, 18MM08607, 18MM08608, 18MM08609, 18MM08610, 18MM11254, 18MM11255, 19AM07907, 19AM07908, 19AM07909, 19AM07916, 19AM07922, 19AM07922A, 19AM10686
<b>71335548</b>	18GM04646, 18GM04651, 18GM04658, 18GM04669, 18GM04677, 18GM04679, 18GM16200, 18GM16201, 18GM16201A, 18GM16203, 18GM16208, 18GM16210, 18GM16222, 18GM16240, 18GM18532, 18GM18541, 18GM18541A, 18GM18547, 18GM18567, 18GM18567A, 18GM18570, 18HM01688, 18HM01688A, 18HM01700, 18HM01709, 18HM01730, 18HM11151, 18HM11151A, 18HM11151B, 18HM11155, 18HM11167, 18HM11185, 18HM11192, 18HM11194, 18HM11207, 18HM19069, 18JM02729, 18JM03521, 18JM12746, 18JM12746A, 18JM12750, 18JM12750A, 18JM12751, 18JM12753, 18JM12760, 18JM12761, 18JM12765, 18JM12768, 18JM12771, 18JM16121, 18KM09496, 18KM09497, 18KM09498, 18KM09501, 18KM09502, 18KM09504, 18KM09505, 18KM09505A, 18KM09510, 18KM13647, 18KM13648, 18KM13649, 18KM13649A, 18KM13650, 18KM13650A, 18KM13651, 18KM13652, 18KM13654, 18KM13655, 18KM13655A, 18KM20263, 18KM20264, 18KM20264A, 18KM20265A, 18KM20266, 18LM00736, 18LM09824, 18LM09827, 18LM09828, 18LM09829, 18LM09835, 18LM09839, 18LM09852, 18LM09852A, 18LM09852B, 18LM09853, 18LM13765, 18LM13771, 18LM13771A, 18LM13774, 18LM13785, 18LM13786, 18LM13794, 18LM13797, 18LM13799, 18LM13800, 18LM13809, 18LM13809A, 18LM13814, 18LM19129, 18LM19138, 18LM19139, 18LM19141, 18LM19142, 18LM19745, 18LM19747, 18LM19749, 18LM19749A, 18LM19755, 18LM19756, 18LM19760, 18LM19762, 18LM19765, 18LM19771, 18MM01152, 18MM02358, 18MM02927, 18MM02933, 18MM02938, 18MM07668, 18MM09564, 18MM11257, 18MM11260, 18MM11262, 18MM11265, 18MM11266, 18MM11268, 18MM11269, 18MM11275, 18MM14687, 18MM14691, 18MM14692, 18MM14693, 18MM14697, 18MM14700, 18MM14700A, 18MM14700B, 18MM14703, 18MM14703A, 18MM14704, 18MM14705, 18MM14708, 18MM14709, 19AM00787, 19AM15799, 19AM15807, 19AM15808, 19AM15831, 19AM15834, 19AM15837, 19AM15839, 19EM11800
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<b>71338734</b>	19DM28114
<b>71338735</b>	19DM28116
<b>71338736</b>	19EM19673, 19EM19678, 19EM19683
<b>71338737</b>	18JM12872
<b>71338738</b>	18FM02387
<b>71338740</b>	18JM02713
<b>71338741</b>	19AM22770, 19AM22770A

## Sporočilo za zdravnika

<b>Ukrep družbe Smith+Nephew</b>	Prostovoljni odpoklic
<b>Sklic odpoklica</b>	R-2020-04
<b>Zadevni izdelek</b>	R3 Acetabular Shell
<b>Podrobnosti zadevnega izdelka</b>	Glejte priloženo

Spoštovani zdravnik,

s tem dopisom vas obveščamo o prostovoljnem odpoklicu določenih serij pripomočka R3 Acetabular Shell, ki ga proizvaja družba Smith+Nephew, Inc. ZDA.

### Ozadje

Družba Smith+Nephew je prejela šest pritožb v zvezi neuspelo intraoperativno fiksacijo pri pripomočkih R3 Acetabular Shell. Ob pregledu proizvodnega postopka smo ugotovili, da določene serije morda niso bile izdelane v skladu z načrtovanimi specifikacijami. Čeprav od specifikacij potencialno odstopajo samo nekateri pripomočki zadevnih serij, smo se pri družbi Smith+Nephew odločili za prostovoljni odpoklic vseh izdelkov iz teh serij.

### Ukrepi

Pripomočki bodo najverjetneje delovali, kot je predvideno. Pri vseh šestih pritožbah, prejetih v zvezi z neuspehim fiksiranjem, so lahko poseg uspešno zaključili z uporabo nadomestnega pripomočka. V najslabšem primeru lahko keramična obloga, ki se med operacijo navidezno popolnoma fiksira z acetabularno ponvico, po operaciji počni, zaradi česar je potreben revizijski poseg. Vendar poročil o takem primeru ni bilo.

Smith+Nephew zdravnikom priporoča, da paciente z vsajenimi pripomočki R3 Acetabular Shell, ki so predmet tega odpoklica, še naprej spremljajo po običajnem protokolu.

V okviru prostovoljnega odpoklica mora vodja vaše ustanove potrditi prejem in posredovanje tega dopisa, kot je primerno. Poleg tega morajo urediti nadaljnje postopke z zadevnimi pripomočki v skladu z obvestilom o nujnem odpoklicu medicinskega pripomočka.

Podjetje Smith+Nephew prodaja kakovostne izdelke, ki so varni in učinkoviti, in zagotavlja vso potrebno podporo kirurgom, ki te izdelke uporabljajo.

Če imate dodatna vprašanja, mi lahko kadar koli pišete na elektronski naslov [fieldactions@smith-nephew.com](mailto:fieldactions@smith-nephew.com).

S spoštovanjem,



Dr. Luca Orlandini MD  
Vice President Medical Affairs

**Smith+Nephew**