

[Recipients Address]

April 22, 2020

**URGENT FIELD SAFETY NOTICE:
 Medical Device Field Safety Notice for Recall**

Reference: R-2020-04
 Concerned Devices: R3[◊] Acetabular Shells

Product No.	Description	Batch No.
See appendix 1	R3 Acetabular Shells	See appendix 2

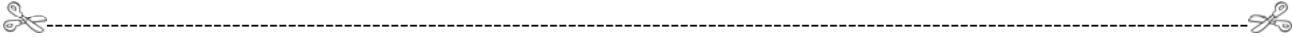
Dear Customer:

This letter is to inform you that Smith+Nephew has initiated a voluntary recall to remove specific lots of R3 Acetabular Shells due to a manufacturing error. Use of the affected devices, which may not have been manufactured to their design specifications, may result in an intraoperative locking failure.

This field action has been reported to the relevant competent authorities.

Risks to Health	In the most likely scenario, the devices will function as intended. To date, we have received six complaints regarding intraoperative locking failure. In the worst-case, a ceramic liner, appearing to fully lock intraoperatively with the acetabular shell, may fracture post-operatively necessitating a revision procedure. There have been no reports of occurrence of the worst-case scenario.
Actions to be taken by the user	<ol style="list-style-type: none"> 1. Locate and quarantine affected unused devices immediately. 2. Please provide a copy of the attached Physician Communication to the surgical staff. 3. Return quarantined product to your national Smith+Nephew agency/distributor. 4. Complete the return slip and e-mail or fax it to your national Smith+Nephew agency/distributor. 5. Please make sure this safety information is passed on to all those who need to be aware of it within your organization. 6. Please maintain awareness on this notice and resulting action until the Field Safety Notice for Recall is terminated to ensure effectiveness of the action.

Smith+Nephew is committed to distribute only products of the highest quality standards and to provide any required support. We regret that this has occurred and any inconvenience it may cause or has caused you, your patients, or your staff.



If you have any questions please feel free to contact us under the following contact details:

Contact Details of Subsidiary / Distributor

Return Slip

Please complete and return this feedback information to the contact specified above to prevent repetitive enquires.

We hereby confirm that we are aware of this Field Safety Corrective Action and it has been communicated within our organization and surgical staff.

In our facility we have _____ [Qty] concerned devices which we will return.
_____ [Qty] concerned devices have been discarded in our facility.

Institution: _____ Reference: R-2020-04

Name: _____ Date / Signature: _____

Enclosure:

- Product Number and Product Description List (Appendix 1)
- Product and Lot Number List (Appendix 2)
- Physician Communication

Appendix 1: Product Number and Product Description List

Product Number	Description	Product Number	Product Description
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		

Appendix 2: Product and Lot Number List

Product Number	Lot Number
71331842	18HM20691, 18KM15724, 18LM09819
71331848	18HM01685, 19AM15804, 19AM15805, 19AM15809, 19AM15828, 19AM15829
71331850	18LM00667, 18LM00668, 18LM00668A, 18LM00670, 18LM00671, 18LM00671A, 18LM00702
71331852	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
71331854	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
71331856	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
71331858	19AM03504, 19AM03511
71331860	18JM10154, 18JM10154A
71331942	18EM07919, 18HM20692
71331946	18GM07650, 18GM18521, 18GM18522, 18JM01361, 18JM14484, 18JM14573, 19DM10929, 19DM10931, 19DM17866, 19DM17868, 19DM17869, 19DM17871, 19DM17872, 19EM20018, 19EM20020
71331948	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, 19DM17879, 19DM17879, 19EM05719, 19EM05725, 19EM05727, 19EM05734, 19EM05735, 19EM05738, 19EM05739, 19EM11935, 19EM11942, 19EM11943, 19EM19991, 19EM19995
71331950	18EM19483, 18EM19487, 18EM19487A, 18EM19523, 18FM17575, 18FM17581, 18FM17585, 18GM01189, 18GM01189A, 18GM01198, 18GM01198A, 18GM01210, 18GM01210A, 18GM04645, 18GM04664, 18HM16471, 18HM16477, 18HM16477A, 18HM16490, 18JM05420, 18JM12752, 18JM12754, 18JM12755, 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
71331952	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
71331954	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
71331956	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
71331958	18FM02438, 18FM02438B, 18FM09877, 18FM12880, 18GM09602, 18HM15999, 18HM21285, 18HM21291, 18HM21291A, 18KM00263, 18KM00268, 18KM00268A, 18KM00271, 18KM00271A, 18KM00272, 18KM00272A, 18LM17980, 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

71331960	18EM23148, 18FM02384, 18FM02384A, 18FM11142, 18FM11145, 18FM17591, 18FM17591A, 18FM17593, 18GM06745, 18HM10451, 18HM20601, 19CM17416, 19DM12906, 19DM12911, 19DM12912
71331962	18EM23155, 18FM11149, 18JM01367, 18JM02759, 18LM17982, 19CM17431, 19EM05746
71331964	18FM02445, 18FM02445A, 19EM17714
71331968	19CM04528
71332242	18HM20693, 18HM20693A
71332246	19EM17729, 19EM17730, 19EM17730A
71332248	18GM04752, 18GM04753, 18HM00807, 18MM01856, 19BM08386, 19DM17881, 19DM17884, 19DM17885, 19DM17890, 19EM11946, 19EM11947
71332250	18EM13916, 18EM13916A, 18EM13916B, 18EM13934, 18FM00218, 18FM17594, 18GM01199, 18JM05435, 18JM05436, 18JM12796, 18JM12800, 19BM17961, 19BM17964, 19CM15771, 19DM06430, 19DM06500, 19EM03956, 19EM03960, 19EM03970
71332252	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
71332254	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
71332256	18FM11173, 18FM11177, 18GM07672, 18GM16978, 18MM07589, 18MM07597, 18MM07597A, 18MM07599, 18MM07622, 19BM12636, 19BM12639, 19EM09583
71332258	18EM23220, 18EM23223, 18FM02458, 18GM09584, 18GM16981, 18GM18527, 18GM18527B, 18GM18527C, 18LM17983, 18LM17984, 19BM07201, 19BM07202, 19BM07214, 19CM11413, 19CM11417, 19CM11417A, 19DM12931, 19DM12936, 19EM03998, 19EM03999, 19EM04000, 19EM04001
71332260	18FM02468, 18FM02468B, 18FM21552, 18HM08736, 18HM16487, 18HM16487A, 18HM16488, 18HM19141
71332262	18MM02014, 19EM11295, 19EM11296
71332264	19EM17718
71335540	18JM08648, 18JM08650, 18MM12391
71335542	18HM20695, 18LM09821, 19DM12897, 19DM12898, 19DM12899
71335544	18LM02189, 18LM02191, 18LM02192, 18MM08580, 18MM08582
71335546	18HM04443, 18HM04443A, 18HM04455, 18HM04455A, 18HM04461, 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
71335548	18GM04646, 18GM04651, 18GM04658, 18GM04669, 18GM04677, 18GM04679, 18GM16200, 18GM16201, 18GM16201A, 18GM16203, 18GM16208, 18GM16210, 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, 18LM19145, 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, 18MM14693, 18MM14700, 18MM14700A, 18MM14700B, 18MM14703, 18MM14703A, 18MM14704, 18MM14705, 18MM14708, 18MM14709, 19AM00787, 19AM15799, 19AM15807, 19AM15808, 19AM15831, 19AM15834, 19AM15837, 19AM15839, 19EM11800
71335550	18GM06120, 18GM06191, 18GM06248, 18GM06259, 18GM06259A, 18GM06367, 18GM06374, 18GM06376, 18GM06381, 18GM06384, 18GM06446, 18GM06448, 18GM06454, 18GM06460, 18GM06462, 18GM06481, 18GM16261, 18GM16275, 18GM16277, 18GM16279A, 18GM16281, 18GM16281A, 18GM16291, 18GM16291A, 18GM18647, 18GM18648, 18GM19999, 18HM12250, 18HM12251, 18HM12251A, 18HM12291, 18HM12294, 18HM12308, 18HM12311, 18HM12311A, 18HM12313, 18HM12326, 18HM12367, 18HM12372, 18HM13026, 18HM13027, 18HM13031, 18HM14835, 18HM14852, 18HM14852A, 18HM14880, 18HM14880A, 18HM14881, 18HM15459, 18HM15459A, 18HM15461, 18HM15468, 18HM15484, 18HM15507, 18HM15507A, 18JM00831, 18JM00831A, 18JM00833, 18JM00833A, 18JM00834, 18JM00835, 18JM00837, 18JM00838, 18JM00844, 18JM04484, 18JM04485, 18JM04486, 18JM04487, 18JM04490, 18JM04497, 18JM04499, 18JM04897, 18JM04898, 18JM06646, 18JM16421, 18JM16421A, 18KM16035, 18KM24783, 18KM24791, 18KM24811, 18LM02324, 18LM02325, 18LM02325A, 18LM02328, 18LM13776, 18LM13789, 18MM11293, 18MM11294, 18MM11296, 18MM11303, 18MM11305, 18MM11309, 18MM14680, 18MM14683, 18MM14686, 18MM14688, 18MM14694, 18MM14694A, 18MM14698, 18MM14701, 18MM14713, 18MM14714, 18MM14715, 18MM14715A, 19AM00774, 19AM00774A, 19AM00779, 19AM00779A, 19AM00780, 19AM00785, 19AM00789, 19AM00813, 19AM00823, 19AM00824, 19AM00827, 19AM00828, 19AM00830, 19AM00855, 19CM16250
71335552	18GM07455, 18GM20288, 18GM20291, 18GM20296, 18GM20309, 18GM20309A, 18GM20331, 18GM20343, 18GM20389, 18HM16439, 18HM16440, 18HM16443, 18HM16444, 18HM16444, 18HM16452, 18HM16472, 18HM16489, 18HM16518, 18HM16522, 18HM16522A, 18HM16522B, 18HM16528, 18HM16550, 18HM16550A, 18HM16552, 18HM16552A, 18HM16553, 18HM16627, 18HM19802, 18HM19802A, 18HM19822, 18HM19826, 18HM19826A, 18HM19829, 18HM19829A, 18HM19835, 18HM19835A, 18HM19837, 18JM09331, 18JM09332, 18JM09333, 18JM09338, 18JM09338A, 18JM09339, 18JM09343, 18JM10883, 18JM12790, 18JM12793, 18JM12795, 18JM12831, 18JM12835, 18JM12858, 18JM12859, 18JM12859A, 18JM12861, 18JM12861A, 18JM12869, 18JM17664, 18JM17671,

	18JM17674, 18JM17683, 18JM17684, 18JM17685, 18JM17688, 18JM17689A, 18KM00789, 18KM00790B, 18KM00810, 18KM00825, 18KM05958, 18KM06647, 18KM06654, 18KM06668A, 18KM13657, 18KM13659, 18KM13660, 18KM13665, 18KM13666, 18KM13667, 18KM13667A, 18KM13668, 18KM13668, 18KM13685, 18KM13687, 18KM15744, 18KM15746, 18KM15747, 18KM15750, 18KM17682B, 18KM20295, 18KM20307, 18KM20311, 18KM23741, 18KM24186, 18KM24813, 18KM24815, 18KM24816, 18KM24818, 18LM00739, 18LM00749A, 18LM00752, 18LM00756, 18LM00756A, 18LM02334, 18LM02335, 18LM02335A, 18LM09352, 18LM17954, 18LM17955, 18LM17959, 18LM17965, 18LM17977, 19AM06094, 19AM06098, 19AM06100, 19AM06104, 19AM06104A, 19AM06111, 19AM06118, 19AM06122, 19AM06125, 19AM06127, 19AM06140, 19AM06141, 19AM06147, 19AM06150, 19AM06152, 19AM13012, 19AM13015, 19DM00942
71335554	18HM00801, 18HM04947, 18HM04957, 18HM04957A, 18HM04969, 18HM04973, 18HM05002, 18HM05005, 18HM05015, 18HM05019, 18HM05044, 18HM05044B, 18HM05065, 18HM19077, 18HM19078, 18HM19079, 18HM19082, 18HM19085, 18HM19085A, 18HM19086, 18HM19087, 18HM19087B, 18JM13880, 18JM13881, 18JM13892, 18JM15275, 18JM17713, 18JM17714, 18JM17715, 18JM17719, 18JM17730, 18JM18174, 18JM19382, 18JM19382A, 18KM03153, 18KM03154, 18KM03154A, 18KM03158, 18KM03161, 18KM09521, 18KM09521A, 18KM09523, 18KM09525, 18KM09526, 18KM09533, 18KM09537, 18KM09538, 18KM09538A, 18KM09546, 18KM09546A, 18KM09548, 18KM13702, 18KM13706, 18KM13709, 18KM13711A, 18KM13713, 18KM13715, 18KM13715A, 18KM13719, 18KM13721, 18KM13722, 18KM13725, 18KM13726, 18KM13728, 18KM13729, 18KM13731, 18KM16116, 18KM16119, 18KM16119A, 18KM16120, 18KM16130, 18KM16249, 18KM26035, 18KM26067, 18KM26073, 18KM26078, 18LM05195, 18LM05196, 18LM05199, 18LM05208, 18LM10963, 18LM18558, 18LM18565, 18MM03110, 18MM03110A, 18MM03115, 18MM07166, 18MM07198, 18MM07198A, 18MM07208, 18MM07209, 18MM07209A, 18MM07211, 18MM07212, 18MM07217, 18MM07237, 18MM11338, 19AM07762, 19AM07769, 19AM07772, 19AM07773, 19AM07782, 19AM07783, 19AM18491, 19AM18599, 19FM00485
71335556	18JM15968, 18JM15974, 18JM15977, 18JM15977A, 18JM16124, 18JM16126, 18JM16130, 18JM16153, 18JM16162, 18JM16167, 18JM16171, 18JM16171A, 18JM18077, 18JM18077A, 18JM18077B, 18JM18080, 18JM18081, 18JM18086, 18JM18086A, 18JM18087, 18JM18087A, 18JM18088, 18JM18095, 18JM18096, 18KM04256, 18KM04258, 18KM11126, 18KM11127, 18KM11129, 18KM11131, 18KM11135, 18KM11158, 18KM11174, 18KM11174A, 18KM11175, 18KM11176, 18KM11177, 18KM11191, 18KM18727, 18LM00990, 18LM02892A, 18LM13830, 18LM13844, 18LM13844A, 18MM03107, 18MM03107A, 18MM12430, 18MM12431, 18MM12432, 18MM12433, 18MM12437, 18MM12438, 18MM12440, 18MM12440A, 18MM12442, 18MM12476, 18MM15598, 18MM15609, 18MM15609A, 18MM15620, 18MM15620A, 19BM07512A, 19BM07512B, 19BM07521A, 19BM07553, 19BM07567
71335558	18GM06066, 18GM16317, 18GM16321, 18GM16321A, 18GM16321B, 18GM16322, 18GM16322A, 18JM01324, 18KM17664, 18KM17664A, 18KM17666B, 18KM17667, 18LM09314, 18LM09315, 18LM09318, 18LM09318A, 18LM09319, 18LM09319A, 18LM09324, 18LM09324A, 18LM09325, 18LM09333, 18LM09336, 18LM11687, 18LM18593, 18LM18593A, 19AM04787, 19AM20552, 19AM20554, 19AM20555, 19AM20559, 19AM20562, 19AM20563, 19AM20564, 19AM20577, 19AM20586, 19AM20595
71335560	18HM00793, 18HM10463, 18HM10463A, 18JM01330, 18JM01331, 18JM01331A, 18JM01336, 18JM01336A, 18JM01338, 18JM10162, 18JM10165, 18JM10166, 18JM10168, 18LM09340, 18LM09342, 18MM02930, 18MM02946A, 19BM12443
71338663	18EM10564, 18EM23226, 18EM23226A, 18GM18693, 18GM18693A, 18GM18700, 18GM18700A, 18HM04587, 18HM04588, 18HM04588A, 18HM04593, 18HM14882, 18HM14887, 18HM14887A, 18JM02705, 18JM12818, 18JM12819, 18JM12819A, 18KM09644, 18KM25982, 18KM25982A, 18LM19836, 18MM07580, 18MM07583, 19BM10203, 19CM19574, 19CM19582, 19DM15683, 19DM28076, 19EM19652, 19EM19655, 19EM19656, 19EM19657
71338664	18EM01929, 18EM14265, 18GM04676, 18GM04678, 18GM04680, 18HM05120, 18HM14311, 18JM00846, 18JM00851, 18JM03933, 18JM03940, 18JM03940A, 18JM03964, 18KM11934, 18KM14029, 18KM25957, 18KM25958, 18LM19837, 18LM21024, 19AM05159, 19AM05159A, 19AM23671, 19AM23674, 19BM12881, 19DM15685, 19DM15687, 19DM15688, 19DM28078, 19DM28079, 19DM28083, 19DM28083A, 19DM28084, 19DM28085, 19DM28086, 19EM19658, 19EM19659, 19EM19660, 19EM19661, 19EM19662
71338665	18DM18282, 18DM18284, 18EM17244, 18EM17247, 18GM06572, 18GM06573, 18GM06581, 18GM07678, 18GM20396, 18GM20401, 18GM20401A, 18GM20402, 18GM20402A, 18GM21563, 18HM16458, 18HM16467, 18JM01340, 18JM01342, 18JM08808, 18JM13325, 18JM17690, 18JM17693, 18JM17696, 18KM09552, 18KM21705, 18LM11838, 19AM05177, 19AM05185, 19AM05188, 19BM02834, 19BM02835, 19BM02836, 19BM02838, 19BM02839, 19CM19591, 19CM19858, 19DM28090, 19DM28092, 19DM28094, 19DM28096, 19DM28098, 19DM28099, 19DM28102, 19EM19663, 19EM19669, 19EM19670
71338666	18HM00329, 18HM00347, 18HM00347A, 18HM03514, 18HM03834, 18HM03836, 18JM12829, 18JM12830, 18JM15041, 18KM06619, 18KM09560, 18KM09561, 18KM09562, 18KM09563, 18KM25967, 18LM11826, 18LM15102, 19BM10927, 19BM10928, 19BM10930, 19BM10931, 19BM10932, 19BM10935
71338667	18EM18375, 18GM06752, 18GM06759, 18GM07679, 18GM17009, 18HM00298, 18HM12336, 18HM12361, 18HM12363, 18HM12366, 18HM12366A, 18HM12384, 18JM00895, 18JM05154, 18JM07422, 18JM07424, 18JM12833, 18JM12857, 18KM09948, 18KM14060, 18KM17057, 18KM25971, 18KM25971A, 18KM25976, 19BM07656, 19BM07657, 19BM07662, 19BM07666, 19DM15699, 19DM15702, 19DM15703, 19DM15708, 19DM15711
71338668	18EM18377, 18EM18377A, 18HM00300, 18HM13061, 18HM13079, 18HM13079A, 18HM13079B, 18HM22354, 18HM22357, 19BM06037, 19BM06042, 19BM06043, 19EM19997
71338733	19DM28106, 19DM28106A, 19DM28110
71338734	19DM28114
71338735	19DM28116
71338736	19EM19673, 19EM19678, 19EM19683
71338737	18JM12872
71338738	18FM02387
71338740	18JM02713
71338741	19AM22770, 19AM22770A

Physician Communication

Smith+Nephew Action: Voluntary Recall
Recall Reference: R-2020-04
Affected Product: R3 Acetabular Shells
Details of Affected Product: See attached

Dear Doctor,

This letter is to inform you of a voluntary recall for specific lots of R3 Acetabular Shells manufactured by Smith+Nephew, Inc. USA.

Background

Smith+Nephew has received six complaints related to intraoperative locking failure of R3 Acetabular Shells. A review of the manufacturing process identified that specific lots may not have been manufactured to their design specifications. While only some of the devices in the specified lots are potentially out of specification, Smith+Nephew is performing a voluntary recall of all the units from the specified lots.

Actions

In the most likely scenario, the devices will function as intended. In all six complaints received for the locking failure, a substitute device was used and the procedure was completed successfully. In the worst-case scenario, a ceramic liner, appearing to fully lock intraoperatively with the acetabular shell, may fracture post-operatively necessitating a revision procedure. However, there have been no reports of this occurring.

Smith+Nephew recommends that physicians maintain their routine patient follow-up protocol for implanted R3 Acetabular Shells identified in the scope of this voluntary recall.

As part of the execution of the voluntary recall, your facility manager is asked to acknowledge receipt and distribution of this letter, as applicable. In addition, they are asked to manage affected devices per the associated Urgent Medical Device Recall Notice.

Smith+Nephew is committed to distributing quality products that are safe and effective and providing support to surgeons who use those products.

If you have any questions, please contact me on the following email fielddactions@smith-nephew.com.

Yours sincerely,



Dr. Luca Orlandini MD
Vice President Medical Affairs