



COOK MEDICAL EUROPE LTD.
O'HALLORAN ROAD
NATIONAL TECHNOLOGY PARK
LIMERICK, V94 N8X2, IRELAND
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FSN & FSCA Ref: 2020FA0007

Date: 25 Nov 2020

Urgent Field Safety Notice
Flexor[®] Check-Flo[®] Introducer
Flexor[®] Tuohy-Borst Side-Arm Introducer (Shuttle Select[®])

For Attention of: Chief Executive / Risk Management / Purchasing

Contact details of local representative (name, e-mail, telephone, address etc.)

Cook Medical Europe Ltd.
O'Halloran Road
National Technology Park
Limerick, Ireland
E-mail: European.FieldAction@CookMedical.com
Phone: Please refer to the attached Country Contacts List

For any further information or support concerning the information within this FSN, please contact your local Cook Medical Sales Representative or Cook Medical Europe Ltd.



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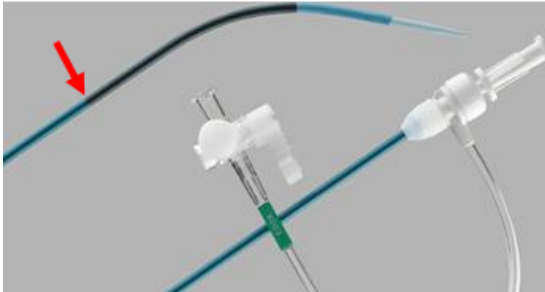

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Urgent Field Safety Notice
Flexor® Check-Flo® Introducer
Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle Select®)

Risk Addressed by FSN

1. Information on Affected Devices	
1. Device Type(s)	
1.	The products are sterile, single-use devices. The introducers incorporate a hydrophilic coated Flexor shaft involving varying stiffnesses with distal radiopaque markers. They contain a hemostasis valve and are provided with a single dilator. The products range from 55 cm to 90 cm in length; 4, 5, 6, 7, or 8 French; and have two different tip configurations.
2. Commercial name(s)	
1.	Flexor® Check-Flo® Introducer Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle Select®)
3. Primary clinical purpose of device(s)	
1.	The products are intended to introduce therapeutic or diagnostic devices into the vasculature, excluding coronary and neuro vasculature.
4. Device Model/Catalogue/Part Number(s)	
1.	Refer to Attachment 1.
5. Affected serial or lot number range	
1.	Refer to Attachment 1.

2. Reason for Field Safety Corrective Action (FSCA)

1. Description of the product problem	
2.	<p>For the impacted product lots listed in Attachment 1, Cook Medical has identified that there is an increased likelihood of the introducer sheath separating at the proximal bond site. The location of the proximal bond site is shown by the arrows in the images provided below.</p> <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"> <p>Flexor® Check-Flo® Introducer</p>  <p>~8cm from distal end of introducer sheath</p> </div> <div style="text-align: center;"> <p>Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle Select®)</p>  <p>~11cm from distal end of introducer sheath</p> </div> </div>




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2. Hazard giving rise to the FSCA	
2.	If separation occurs during use, it could result in life-threatening adverse events. The potential adverse events that may occur include, but are not limited to increased procedural time, intervention to retrieve a separated segment, embolization occluding blood flow to a vital organ, vessel injury, and hemorrhage.

3. Type of Action to Mitigate the Risk	
3.	<p>1. Action To Be Taken by the User</p> <p><input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input checked="" type="checkbox"/> Other</p> <p>Please complete the enclosed Customer Reply Form. Where product is indicated as being returned, our Customer Services department will contact you to organize the return and issue you with the relevant Returns Authorization number. Please include contact details on the Customer Reply form.</p> <p>Returned Product should be addressed to: Cook Medical EUDC Robert-Koch-Straße, 2 52499 Baesweiler GERMANY</p> <p>Credit will be provided for the returned affected products where applicable.</p>
3.	<p>2. Is Customer Reply Required? Form is attached specifying deadline for return. Yes</p>
3.	<p>3. Action Being Taken by the Manufacturer <input checked="" type="checkbox"/> Product Removal</p>

4. General Information	
4.	1. FSN Type New
4.	2. Further advice or information already expected in follow-up FSN? No
4.	3. Manufacturer information For contact details of local representative refer to page 1 of this FSN
	a. Company Name Cook Incorporated
	b. Address 750 Daniels Way Bloomington, IN 47402, United States
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.
4.	5. List of attachments/appendices: Attachment 1 – Affected Lot Numbers Globally This Attachment includes the list of affected Part Numbers (RPN), Order Numbers (GPN), and Lot Numbers.
4.	6. Name/Signature  Larry D. Pool Director, Post Market Cook Incorporated



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Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Flexor® Check-Flo® Introducer

Reference Part Number (RPN)	Order Number (GPN)	Lot Numbers
KCFW-4.0-35-55-RB-HFANL0-HC	G56229	13047587, 13089578, 13089579, 13126439, 13138927, 13197460, 13197462, 13203165, 13219551, 13221814, 13276233, 13312697, 13349024, 13380378, NS13094335, NS13226779
KCFW-4.0-35-55-RB-HFANL1-HC	G56234	13047588, 13050227, 13050229, 13130291, 13138925, 13203167, 13226780, 13276230, 13315165, 13332154, 13375204, 13375207
KCFW-4.0-35-70-RB-HFANL0-HC	G56219	13059453, 13059454, 13059455, 13059463, 13126438, 13197461, 13197463, 13207360, 13207367, 13234807, 13279094, 13346108, 13279103X, NS13059462, NS13260029, NS13304443, NS13312714, NS13346096, NS13352471, NS13372477, NS13410219, NS13426314
KCFW-5.0-35-55-RB-HFANL0-HC	G56230	13029693, 13029694, 13039738, 13039739, 13094338, 13094339, 13094340, 13094344, 13112923, 13112926, 13112927, 13119643, 13121403, 13124432, 13124433, 13126447, 13126448, 13126462, 13135821, 13135822, 13138934, 13138941, 13143088, 13143089, 13143090, 13145948, 13145949, 13153368, 13155283, 13158193, 13158194, 13158195, 13159695, 13163184, 13172666, 13172667, 13172668, 13189166, 13189167, 13189168, 13189171, 13194980, 13197476, 13197477, 13197478, 13197479, 13197480, 13202941, 13202942, 13202943, 13202944, 13202945, 13202946, 13202947, 13202948, 13202949, 13202950, 13202951, 13202953, 13207444, 13207445, 13207446, 13207447, 13207448, 13207449, 13207450, 13207451, 13207452, 13207453, 13207454, 13207455, 13207456, 13207457, 13207458, 13262315, 13262317, 13262321, 13265318, 13268024, 13268028, 13268030, 13268031, 13276235, 13276239, 13276242, 13279088, 13279105, 13281543, 13281544, 13288125, 13291883, 13301861, 13304456, 13318043, 13323500, 13323501, 13337799, 13337809, 13346109, 13352474, 13354244, 13357252, 13363227, 13366216, 13372480, 13391143, NS13108032
KCFW-5.0-35-55-RB-HFANL1-HC	G56235	13101181, 13121311, 13141330, 13153425, 13159709, 13170659, 13175451, 13186259, 13205335, 13205336, 13205337, 13205338, 13205339, 13205340, 13205341, 13214445, 13217109, 13217110, 13219549, 13226821, 13226822, 13226823, 13226824, 13226825, 13262316, 13262318, 13262383, 13262384, 13262385, 13262386, 13262387, 13262388, 13265309, 13265310, 13265311, 13265312, 13265313, 13265314, 13265315, 13265316, 13265317, 13265319, 13265321, 13268016, 13268018, 13268019, 13268020, 13268021, 13268022, 13268023, 13268025, 13268026, 13268027, 13268029, 13276232, 13276234, 13276236, 13276243, 13279089, 13315183, 13346074, 13346097, 13391157, NS13108062

Flexor® Check-Flo® Introducer

Reference Part Number (RPN)	Order Number (GPN)	Lot Numbers
KCFW-5.0-35-70-RB-HFANL0-HC	G56220	13089576, 13105053, 13130281, 13130282, 13135871, 13159711, 13159712, 13162740, 13166130, 13170660, 13175442, 13175443, 13186252, 13189278, 13192082, 13192083, 13192085, 13192086, 13192087, 13194970, 13194971, 13194973, 13194974, 13200438, 13203161, 13203162, 13203164, 13205342, 13205343, 13207358, 13207359, 13207361, 13207362, 13207363, 13207364, 13207365, 13207366, 13217123, 13219553, 13219554, 13223827, 13223828, 13226776, 13240001, 13243202, 13262322, 13276244, 13279106, 13304457, 13310767, 13315203, 13323502, 13329236, 13332175, 13337810, 13352475, 13360432, 13291884X, NS13077815, NS13077819, NS13105057, NS13105059, NS13192090, NS13226781, NS13315204, NS13376992
KCFW-5.0-35-70-RB-HFANL1-HC	G56225	13077814, 13089577, 13105054, 13140910, 13159710, 13162739, 13170661, 13186251, 13192084, 13194969, 13194972, 13200439, 13203160, 13203163, 13203166, 13214447, 13214449, 13217121, 13217122, 13219552, 13223826, 13223829, 13237651, 13276238, 13276245, 13286649, 13357239, 13366218, 13391145, NS13089580, NS13105058, NS13130292, NS13138931, NS13192091, NS13234809, NS13252367, NS13252368, NS13286655, NS13349016, NS13352450, NS13366219, NS13372482, NS13375232, NS13401834, NS13420125

Flexor® Check-Flo® Introducer

Reference Part Number (RPN)	Order Number (GPN)	Lot Numbers
KCFW-6.0-35-55-RB-HFANL0-HC	G56231	13135825, 13138939, 13138940, 13143095, 13143096, 13143097, 13150435, 13150438, 13150439, 13150440, 13150441, 13153382, 13153386, 13153387, 13155287, 13155288, 13155295, 13155296, 13158205, 13159698, 13159699, 13159701, 13159702, 13159703, 13159704, 13159705, 13166156, 13166160, 13166161, 13166162, 13172674, 13172679, 13172680, 13172681, 13175467, 13175468, 13175472, 13180819, 13186324, 13186325, 13186326, 13186329, 13186331, 13189188, 13189189, 13189190, 13189195, 13189196, 13189197, 13192073, 13197482, 13200417, 13200418, 13202955, 13202956, 13205308, 13207461, 13207462, 13207463, 13207464, 13211828, 13214464, 13214465, 13217129, 13217132, 13217133, 13217134, 13217135, 13217136, 13217137, 13221800, 13221806, 13221807, 13226796, 13226797, 13226798, 13226799, 13226800, 13226801, 13231821, 13237671, 13237672, 13240020, 13240021, 13240022, 13240023, 13240024, 13240025, 13246564, 13246565, 13256701, 13256707, 13256708, 13256709, 13256710, 13256711, 13262346, 13262347, 13268037, 13281553, 13281792, 13281793, 13281794, 13281795, 13281796, 13281797, 13281798, 13281799, 13291872, 13291875, 13294539, 13294540, 13294541, 13294542, 13297253, 13297254, 13297255, 13297256, 13297257, 13301868, 13301869, 13301870, 13304446, 13307201, 13307202, 13307203, 13307204, 13310756, 13310757, 13310758, 13312696, 13312701, 13312702, 13312703, 13315213, 13315214, 13315215, 13315216, 13318057, 13318058, 13320584, 13320592, 13320593, 13329231, 13329243, 13329244, 13329245, 13329247, 13332165, 13332166, 13334765, 13334766, 13334772, 13342864, 13342865, 13342866, 13346103, 13346104, 13346117, 13349025, 13349035, 13349036, 13352476, 13352477, 13352478, 13352479, 13352480, 13352481, 13352482, 13352483, 13357255, 13357256, 13360433, 13360434, 13360435, 13360436, 13360437, 13360439, 13366224, 13366225, 13372603, 13372604, 13375216, 13375217, 13375218, 13375219, 13375220, 13376996, 13380383, 13382713, 13382714, 13382715, 13382716, 13388322, 13388323, 13388324, 13391160, 13398852, 13423953, 13432833, 13446739, 13446740, 13455461, 13334771X

Flexor® Check-Flo® Introducer

Reference Part Number (RPN)	Order Number (GPN)	Lot Numbers
KCFW-6.0-35-55-RB-HFANL1-HC	G56236	13135824, 13140931, 13141304, 13141305, 13145950, 13145951, 13150436, 13150442, 13150443, 13153380, 13153383, 13153384, 13153385, 13155286, 13155289, 13155291, 13158203, 13158204, 13158208, 13162736, 13162737, 13163193, 13166157, 13166158, 13166159, 13172675, 13172676, 13172677, 13172678, 13175465, 13175466, 13175469, 13175470, 13175471, 13180815, 13180818, 13186322, 13186327, 13186328, 13189186, 13189191, 13189192, 13189193, 13189194, 13189198, 13189199, 13197483, 13200412, 13200413, 13200414, 13202954, 13205305, 13205306, 13207459, 13211825, 13211829, 13214442, 13214443, 13214444, 13217124, 13219557, 13219561, 13219562, 13219563, 13219564, 13221801, 13221808, 13221809, 13226802, 13226803, 13226804, 13229671, 13229678, 13229679, 13231822, 13234798, 13243204, 13243215, 13243216, 13243217, 13243218, 13243219, 13252359, 13260007, 13260018, 13262325, 13262326, 13265328, 13279083, 13279084, 13281529, 13281779, 13281780, 13281781, 13281782, 13288114, 13291865, 13294510, 13297239, 13301844, 13301845, 13301846, 13307175, 13307176, 13307177, 13310722, 13310723, 13310730, 13310731, 13312686, 13315170, 13315171, 13315172, 13318023, 13318033, 13318034, 13318035, 13332157, 13332158, 13334762, 13337772, 13337776, 13337777, 13337778, 13337779, 13337794, 13337795, 13342831, 13342837, 13342838, 13342839, 13342857, 13342858, 13342859, 13346085, 13348996, 13348997, 13348998, 13348999, 13349000, 13349001, 13352433, 13352440, 13352468, 13354239, 13354247, 13354248, 13354249, 13354250, 13354251, 13357224, 13357225, 13360405, 13360406, 13363206, 13363207, 13363215, 13363216, 13363217, 13369413, 13369414, 13369422, 13369423, 13372605, 13375223, 13375224, 13375225, 13376997, 13380390, 13380391, 13382717, 13384997, 13384998, 13391147, 13391148, 13391149, 13396148, 13398853, 13398854, 13398855, 13401842, 13407495, 13432838, 13375222X
KCFW-6.0-35-70-RB-HFANL0-HC	G56221	13143098, 13143099, 13143100, 13145952, 13145953, 13145955, 13150444, 13150446, 13159696, 13159697, 13159706, 13159708, 13166164, 13166165, 13166168, 13175473, 13175474, 13175480, 13178582, 13186336, 13192068, 13192074, 13211826, 13211827, 13214440, 13217125, 13217126, 13221802, 13223830, 13223831, 13229680, 13231823, 13231824, 13240026, 13240027, 13243203, 13246547, 13246566, 13252353, 13260022, 13260023, 13265330, 13265331, 13265335, 13268038, 13279080, 13281540, 13281800, 13281801, 13286656, 13286658, 13286659, 13286660, 13286662, 13288115, 13304447, 13306333, 13306334, 13307178, 13307189, 13315200, 13315217, 13320585, 13320594, 13329232, 13329248, 13332167, 13334774, 13334775, 13342868, 13349026, 13352485, 13366188, 13366191, 13366194, 13366195, 13366196, 13369415, 13369426, 13380379, 13382712, 13391138, 13391139, 13396128, 13404831, 13404832, 13416497, 13420104, 13420105, 13281802X, NS13315219, NS13315220, NS13329249, NS13334773, NS13349037, NS13352484, NS13352486, NS13401845, NS13426336

Flexor® Check-Flo® Introducer		
Reference Part Number (RPN)	Order Number (GPN)	Lot Numbers
KCFW-6.0-35-70-RB-HFANL1-HC	G56226	13143101, 13150445, 13159707, 13159715, 13166166, 13168195, 13186332, 13186337, 13214441, 13217127, 13221797, 13223835, 13229666, 13237660, 13246546, 13249446, 13262327, 13265329, 13291866, 13294513, 13307179, 13318024, 13332149, 13332159, 13337780, 13337796, 13346086, 13352434, 13352441, 13354252, 13366190, 13366197, 13382711, 13396125, 13398833, 13398835, 13413758, 13420106
KCFW-7.0-35-55-RB-HFANL0-HC	G56232	13205314, 13205322, 13229673, 13229685, 13234800, 13249450, 13256702, 13262338, 13265332, 13265337, 13279097, 13288121, 13291877, 13297249, 13297260, 13297261, 13301872, 13310761, 13312706, 13318040, 13318062, 13332170, 13346105, 13349029, 13354271, 13354272, 13357259, 13360427, 13360442, 13366230, 13372465, 13372469, 13375211, 13375227, 13377002, 13391151, 13398856, 13426338, 13329254X, 13332169X, 13342871X
KCFW-7.0-35-55-RB-HFANL1-HC	G49043	13192055, 13192067, 13200423, 13200424, 13202961, 13202963, 13205309, 13205315, 13205323, 13205324, 13223833, 13229686, 13229687, 13231803, 13234792, 13234801, 13237654, 13243208, 13243209, 13246544, 13246548, 13249451, 13249452, 13249453, 13254617, 13254618, 13262329, 13262330, 13279085, 13281530, 13281531, 13281790, 13281791, 13286645, 13286646, 13286647, 13286648, 13286650, 13286651, 13286652, 13303358, 13303361, 13303362, 13303366, 13303367, 13303368, 13303371, 13303372, 13303373, 13303374, 13303375, 13306335, 13306336, 13319484, 13319489, 13319495, 13346087, 13349006, 13352444, 13354260, 13354261, 13354262, 13357229, 13357230, 13360411, 13360412, 13360413, 13363220, 13363221, 13366231, 13366232, 13372470, 13372491, 13380384, 13382718, 13388328, 13391161, 13398857, 13401849, 13435154, 13438159, 13449366, 13449367, 13455464, 13279081X
KCFW-7.0-35-70-RB-HFANL0-HC	G56222	13197465, 13203168, 13203169, 13205344, 13205348, 13229675, 13229688, 13265333, 13268039, 13281806, 13310762, 13318041, 13329229, 13329233, 13342873, 13349039, 13354264, 13357260, 13372472, 13398839, 13441228, NS13186257, NS13186258, NS13246550, NS13260027, NS13304448, NS13329255, NS13329256, NS13333102, NS13354273, NS13354274, NS13360443, NS13360444, NS13388330, NS13401851
KCFW-7.0-35-70-RB-HFANL1-HC	G56227	13189185, 13194984, 13202958, 13205307, 13207466, 13207473, 13231809, 13234793, 13249454, 13262331, 13268033, 13288117, 13303369, 13303376, 13315174, 13332151, 13337783, 13337797, 13346088, 13346089, 13357215, 13357232, 13360414, 13366236, 13377003, 13401855, NS13357214, NS13366235

Flexor® Check-Flo® Introducer

Reference Part Number (RPN)	Order Number (GPN)	Lot Numbers
KCFW-8.0-35-55-RB-HFANL0-HC	G56233	13135874, 13141336, 13162743, 13168158, 13192089, 13214454, 13229690, 13237656, 13265339, 13297262, 13312708, 13320587, 13323491, 13342872, 13349041, 13363230, 13382710, 13407498, NS13140914, NS13219558, NS13221811, NS13246568, NS13265338, NS13291878, NS13291879, NS13312707, NS13342874, NS13349040, NS13360428, NS13372495
KCFW-8.0-35-55-RB-HFANL1-HC	G49045	13105055, 13124400, 13124401, 13135880, 13138926, 13140911, 13141335, 13162741, 13162742, 13168155, 13168156, 13170665, 13189283, 13214450, 13214451, 13214452, 13214455, 13221812, 13231810, 13237657, 13249434, 13252354, 13252362, 13262332, 13288118, 13291868, 13294511, 13307182, 13315176, 13337784, 13337785, 13337786, 13346090, 13354241, 13357216, 13360416, 13366208, 13366240, 13380385, 13388332
KCFW-8.0-35-70-RB-HFANL0-HC	G56223	13297248, 13318063, 13320595, 13334764, 13388304, 13435140, 13291880X, NS13246556, NS13265340, NS13288123
KCFW-8.0-35-70-RB-HFANL1-HC	G56228	13229667, 13231805, 13254613, 13291858, 13291869, 13310725, 13318020, 13337787, 13337798, 13346070, 13354237, 13366209, 13369431, 13375208, 13391162, 13407499, 13435157, NS13401856,

Flexor® Tuohy-Borst Side-Arm Introducer (Shuttle Select®)

Reference Part Number (RPN)	Order Number (GPN)	Lot Numbers
KSAW-5.0-38-90-RB-SHTL-FLEX-HC	G31133	13029776, 13050652, 13082600, 13082601, 13082603, 13101307, 13101310, 13131722, 13141048, 13141049, 13150557, 13155318, 13155322, 13179880, 13186371, 13186372, 13192133, 13211850, 13237759, 13274344,
KSAW-6.0-38-90-RB-SHTL-FLEX-HC	G31138	10332622, 10332623, 10335453, 10335456, 10338048, 10338049, 10338050, 10342579, 10342580, 10342581, 10342582, 10342590, 13002891, 13002897, 13006165, 13006166, 13006181, 13008773, 13008784, 13008785, 13008786, 13008787, 13011537, 13011538, 13014541, 13014545, 13020497, 13020498, 13020511, 13023868, 13023878, 13023879, 13029745, 13029746, 13029747, 13029748, 13029749, 13029750, 13029751, 13035275, 13039774, 13043788, 13043802, 13043803, 13043804, 13043805, 13043806, 13043807, 13047789, 13047790, 13050311, 13050324, 13050325, 13086346, 13086347, 13086348, 13089656, 13089657, 13094405, 13097678, 13097679, 13097681, 13097691, 13097692, 13101233, 13105097, 13105098, 13105099, 13105100, 13105101, 13126489, 13126490, 13126491, 13128737, 13128738, 13134895, 13134897, 13141007, 13141008, 13141009, 13141010, 13143117, 13143120, 13143121, 13143129, 13143130, 13143131, 13178615, 13178617, 13186365, 13186366, 13189358, 13192148, 13192149, 13195043, 13197524, 13197525, 13197526, 13197533, 13200500, 13205399, 13205415, 13205416, 13205417, 13205418, 13207558, 13207586, 13219603, 13221896, 13221903, 13223326, 13223327, 13223328, 13223329, 13223330, 13223331, 13223332, 13223333, 13226894, 13229771, 13229772, 13231878, 13231879, 13234846, 13234847, 13237736, 13240039, 13240048, 13240066, 13246623, 13246624, 13246625, 13249506, 13249507, 13249508, 13254754, 13260085, 13268159, 13274346, 13274363, 13274364, 13274365, 13276219, 13276220, 13276221, 13276222, 13279330, 13281720, 13281732, 13281733, 13284579, 13284580, 13284581, 13284582, 13284583, 13288184, 13288185, 13292062, 13294665, 13312741, 13312742, 13312750, 13315287, 13315288, 13315289, 13318101, 13318109, 13320658, 13320659, 13320660, 13320661, 13323519, 13323520, 13323521, 13323546, 13327092, 13327093, 13329060, 13329061, 13332072, 13332073, 13346140, 13346160, 13346161, 13346162, 13349095, 13349100, 13349125, 13352236, 13352237, 13352238, 13352239, 13352240, 13354220, 13363114, 13363115, 13363140, 13363141, 13363142, 13410269, 13458470, 13458471