

URGENT: FIELD SAFETY NOTICE (REMOVAL)
GLOBAL UNITE STEMS (SELECT LOTS ONLY)

Dear Valued Customer,

Please be advised that DePuy (Ireland) is initiating a voluntary removal of the Global UNITE Stem sizes listed in Table 1 (see below). The GLOBAL UNITE Platform Shoulder System is intended for cemented or uncemented total or hemi-shoulder arthroplasty. *Please carefully review this document for the steps that you should take to respond to this medical device removal and distribute to appropriate personnel at your facility who may use the subject product.*

Reason for the Medical Device Removal:

The subject product is being removed because DePuy (Ireland) has determined that select lots of Global UNITE Stems may have an undersized spigot bore diameter (**See Figure A**).

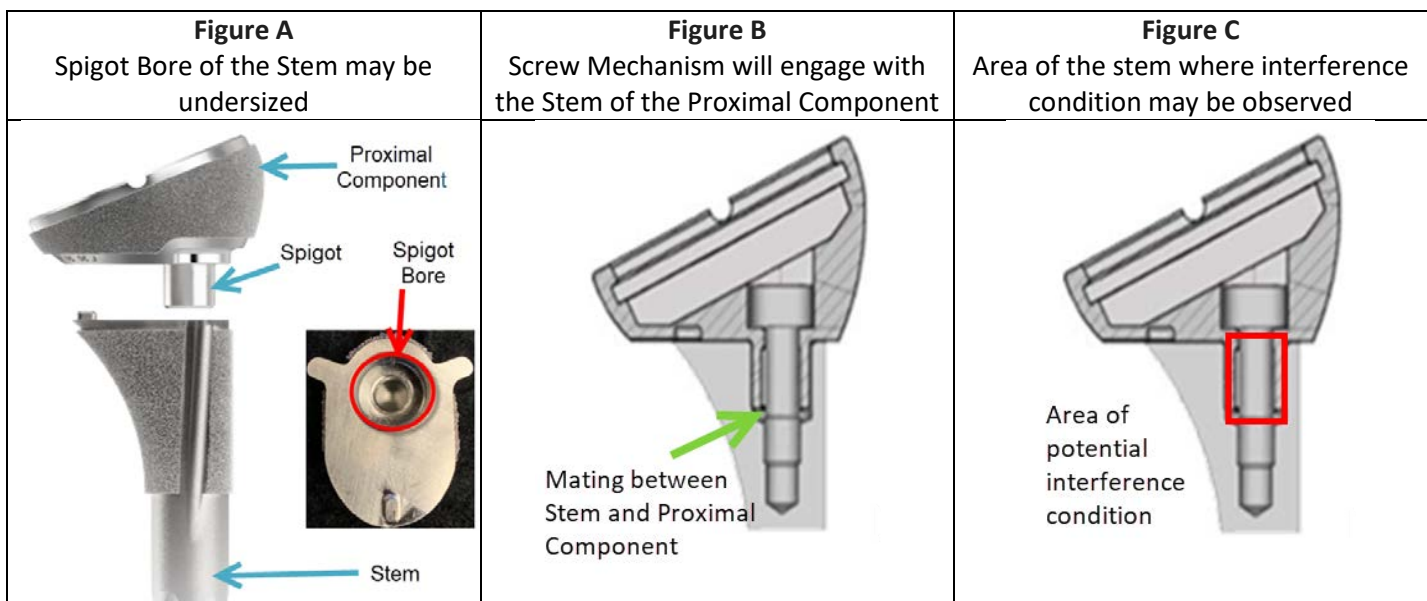
Potential Patient Impact:

The undersized spigot bore diameter of the stem may impact the index procedure in the form of surgical delay and/or bone damage.

- Surgical delay may occur if another stem needs to be obtained to finalize the procedure.
- Bone damage may be observed if the original stem size cannot mate with the proximal body and a different stem size is used by the surgeon because a duplicate of the original stem size is unavailable.

For purposes of clarity, even if the diameter of the spigot bore stem is undersized, the screw mechanism may still engage with the proximal body, resulting in a secure assembly of the components (**See Figure B**). However, an interference condition may be observed due to compression between the spigot and the spigot bore of the stem (**See Figure C**). In such a scenario, separating the proximal body from the stem may not be possible without surgical delay and/or bone damage. Thus, in cases when the surgeon, in his or her professional opinion, concludes that a revision procedure with a well-fixed stem is necessary, the surgeon should exercise care in removing the stem in conjunction with the proximal body.

Health care providers who have treated patients using the subject lot should continue to follow those patients pursuant to the health care provider’s standard of care. No adverse events have been reported for this issue.



Date: 08-December-2021

Requested Actions:

Our records show that your facility received one or more of the products in Table 1. Please take the following actions:

1. Examine your inventory immediately to determine if you have the select lots and quarantine the product.
2. Return the subject product(s) using the normal returns process. Work with your sales consultant to return subject product(s). To receive replacement product(s) or reimbursement, customers must return the products subject to this removal.
3. Review, complete **all** fields, sign, and return the attached business response form (BRF) on the last page of this letter to OneMD-Field-Actions@its.jnj.com within three (3) business days of receipt of this Removal Letter. Please include in the email subject: FA 2044436 - 2021 – GLOBAL UNITE Stems with undersized Spigot Bore Diameter.
4. Forward this Removal Letter to any personnel in your facility who need to be informed.
5. If any of the product(s) subject to this Removal have been forwarded to another facility, contact that facility and provide a copy of this Removal Letter to the relevant personnel.
6. Post a copy of this Removal Letter in a visible area for awareness of this Removal.

This medical device product removal has been reported to the appropriate Health Authority. We apologize for any inconvenience that this removal may cause and appreciate your cooperation with our request. If you have any questions, please contact your local DePuy Synthes Sales Consultant. For Medical Information request, please visit our website: <https://www.jnjmedicaldevices.com/mir>.

Thank you for your attention and cooperation.

Kindest regards,

Kimberly Long, Senior Field Action Coordinator

Email: OneMD-Field-Actions@its.jnj.com | Telephone: + 1 574-221-8156

Table 1: Subject Lots

PLEASE DISTRIBUTE THIS INFORMATION TO APPROPRIATE PERSONNEL AT YOUR FACILITY WHO MAY USE THE SUBJECT PRODUCT

PRODUCT DESCRIPTION	CATALOG NO.	GTIN
GLOBAL UNITE STD STEM SZ 6	110006100	10603295004011
LOTS: 9792595, 9792596, 9793039, 9802121, 9813506, 9818509, 9830921, 9830922, 9832800, 9834900, 9840359, 9858603, 9862058, 9865933, 9887438, 9904862		
GLOBAL UNITE REV STEM SZ 6	110006600	10603295004028
LOTS: 9810524, 9812295, 9865934, 9906103		
GLOBAL UNITE STD STEM SZ 8	110008100	10603295004042
LOTS: 9772091, 9772092, 9772093, 9772094, 9772095, 9772096, 9772097, 9772098, 9772099, 9772100, 9793035, 9802124, 9802125, 9802126, 9802127, 9802128, 9802129, 9802130, 9802131, 9802132, 9802133, 9802134, 9802135, 9802136, 9802137, 9802138, 9802139, 9802140, 9802141, 9802142, 9802143, 9802144, 9802145, 9802146, 9802147, 9802148, 9802149, 9802150, 9802151, 9814515, 9817165, 9817166, 9817167, 9817168, 9817632, 9817633, 9818331, 9818332, 9818508, 9824331, 9824332, 9824334, 9824335, 9824336, 9824337, 9824338, 9824339, 9824340, 9824341, 9824342, 9824343, 9824344, 9824345, 9824346, 9824347, 9832804, 9851702, 9851703, 9851704, 9851705, 9851706, 9851707, 9851708, 9859764, 9861010, 9862057, 9862153, 9864147, 9864852, 9865155, 9865287, 9865947, 9865948, 9874667, 9874668, 9874669, 9874670, 9874671, 9874672, 9874673, 9874674, 9874675, 9874676, 9874678, 9874679, 9874680, 9874681, 9874682, 9874683, 9874685, 9874686, 9874687, 9874688, 9874689, 9887446, 9887770, 9887776, 9887777, 9888982, 9888983, 9888984, 9888985, 9889213, 9889214, 9897371, 9897372, 9897373, 9897374, 9897376, 9897377, 9897378, 9904861, 9906306, 9909028, 9910026		
GLOBAL UNITE REV STEM SZ 8	110008600	10603295004059
LOTS: 9802322, 9802325, 9824506, 9824507, 9824508, 9824509, 9836678, 9837044, 9837327, 9887448, 9887449, 9904863		
GLOBAL UNITE STD STEM SZ 10	110010100	10603295004080
LOTS: 9793653, 9793654, 9802152, 9802153, 9802154, 9802155, 9802156, 9802157, 9802158, 9802159, 9802160, 9802161, 9802162, 9802163, 9802164, 9802165, 9802166, 9802167, 9802168, 9802169, 9802170, 9802171, 9802172, 9802173, 9802174, 9802175, 9802176, 9802177, 9802178, 9802179, 9802180, 9802181, 9802182, 9802183, 9802184, 9802185, 9802186, 9802187, 9802188, 9802189, 9802190, 9802191, 9818344, 9818345, 9824348, 9824349, 9824350, 9824351, 9824352, 9824353, 9824354, 9824355, 9824356, 9824357, 9824358, 9824359, 9824360, 9824366, 9824367, 9824368, 9824371, 9824372, 9824373, 9824374, 9824375, 9824376, 9824377, 9824378, 9824379, 9824380, 9824381, 9824382, 9824383, 9824384, 9824385, 9824386, 9824387, 9824388, 9824389, 9824390, 9824391, 9824392, 9824393, 9824394, 9824395, 9824398, 9824399, 9824400, 9824401, 9824402, 9824403, 9832827, 9841210, 9841211, 9841212, 9842704, 9842705, 9842706, 9842707, 9842708, 9842709, 9842710, 9842711, 9843084, 9844090, 9844091, 9844092, 9844093, 9851709, 9851710, 9851711, 9851712, 9851713, 9851714, 9851715, 9851716, 9851717, 9851718, 9851719, 9851720, 9851721, 9851722, 9851723, 9851724, 9851725, 9851727, 9851728, 9851729, 9851730, 9851731, 9851732, 9851733, 9851734, 9851735, 9851736, 9851737, 9851738, 9851739, 9851740, 9851742, 9851743, 9851744, 9864145, 9864146, 9865949, 9865950, 9865951, 9866463, 9866464, 9874690, 9874691, 9874692, 9874693, 9874694, 9874695, 9874696, 9874698, 9874699, 9874700, 9874701, 9874702, 9874703, 9874704, 9874705, 9874709, 9874710, 9874711, 9874712, 9874713, 9874714, 9874718, 9874719, 9874720, 9874721, 9874722, 9874723, 9874724, 9874726, 9874727, 9874728, 9874729, 9874730, 9874731, 9874732, 9874733, 9874734, 9874735, 9874736, 9874737, 9874738, 9874739, 9874740, 9874741, 9874742, 9874743, 9874744, 9874745, 9888980, 9888981, 9888985, 9888982, 9897381, 9897382, 9897383, 9897384, 9897385, 9897386, 9897388, 9897389, 9897390, 9897391, 9897392, 9897393, 9897394, 9897395, 9897402		

PRODUCT DESCRIPTION	CATALOG NO.	GTIN
GLOBAL UNITE REV STEM SZ 10	110010600	10603295004097
LOTS: 9763435, 9772310, 9793037, 9802326, 9802327, 9809673, 9809983, 9812296, 9824510, 9824511, 9824512, 9865935, 9883171, 9884604, 9887450. 9887774		
GLOBAL UNITE STD STEM SZ 12	110012100	10603295004127
LOTS: 9772206, 9772208, 9772209, 9772210, 9772211, 9772212, 9772213, 9772214, 9772215, 9772216, 9772217, 9772218, 9772219, 9772220, 9772221, 9772222, 9772223, 9772224, 9772225, 9772226, 9772227, 9772228, 9772229, 9772230, 9772231, 9772232, 9793650, 9793651, 9793652, 9802193, 9802195, 9802196, 9802197, 9802198, 9802199, 9802200, 9802201, 9802202, 9802203, 9802204, 9802205, 9802206, 9802207, 9802208, 9802209, 9802210, 9802211, 9802212, 9802213, 9802214, 9802215, 9802216, 9802217, 9802218, 9802219, 9802220, 9802221, 9802222, 9802223, 9802224, 9802225, 9802226, 9802227, 9802228, 9802229, 9802230, 9802231, 9802232, 9802233, 9802234, 9802235, 9802236, 9802237, 9802238, 9802239, 9802240, 9802241, 9802242, 9802243, 9802244, 9802245, 9802246, 9802249, 9802250, 9802251, 9802253, 9802254, 9802255, 9802256, 9802257, 9802258, 9802259, 9824404, 9824405, 9824406, 9824407, 9824408, 9824409, 9824410, 9824411, 9824412, 9824413, 9824414, 9824415, 9824416, 9824417, 9824418, 9824419, 9824420, 9824421, 9824422, 9824423, 9824424, 9824425, 9824426, 9824427, 9824428, 9824429, 9824430, 9824431, 9824432, 9824433, 9824434, 9824439, 9824440, 9824441, 9824442, 9824443, 9824444, 9824445, 9824446, 9824447, 9824448, 9824449, 9824450, 9824451, 9824457, 9824458, 9824459, 9824461, 9824462, 9824463, 9824464, 9824465, 9824466, 9824467, 9824468, 9824469, 9824470, 9824471, 9824472, 9824473, 9824474, 9824475, 9832805, 9834400, 9851745, 9851746, 9851747, 9851748, 9851749, 9851750, 9851751, 9851752, 9851753, 9851754, 9851755, 9851756, 9851757, 9851758, 9851759, 9851760, 9851761, 9851762, 9851763, , 9851764, 9851765, 9851766, 9851767, 9851768, 9851769, 9851770, 9851771, 9851772, 9851773, 9851774, 9851775, 9851776, 9851777, 9851778, 9851779, 9851780, 9851781, 9851782, 9851783, 9851784, 9851785, 9851786, 9851787, 9851788, 9851789, 9851790, 9851791, 9851793, 9851794, 9851795, 9851796, 9851797, 9851798, 9851799, 9851800, 9851801, 9851802, 9851803, 9851804, 9851805, 9851806, 9851807, 9851808, 9851809, 9874754, 9874755, 9874756, 9874757, 9874758, 9874759, 9874760, 9874761, 9874762, 9874763,, 9874764, 9874765, 9874766, 9874767, 9874768, 9874769, 9874770, 9874771, 9874772, 9874773, 9874774, 9874775, 9874776, 9874777, 9874778, 9874779, 9874780, 9874781, 9874782, 9874783, 9874784, 9874785, 9874786, 9874787, 9874788, 9874789, 9874790, 9874791, 9874792, 9874793, 9874794, 9874795, 9874796, 9874797, 9874798, 9874799, 9874800, 9874801, 9874802, 9874803, 9874804, 9874805, 9874806, 9874807, 9874808, 9874809, 9874810, 9874811, 9874812, 9874813, 9874815, 9874816, 9874817, 9874818, 9874819, 9874820, 9874821, 9874822, 9874823, 9874824, 9874825, 9874826, 9874827, 9874828, 9874829, 9874830, 9874831, 9874832, 9874834, 9874835, 9897430, 9897431, 9897433, 9897434, 9897435, 9897437, 9897438, 9897439, 9897440, 9897441, 9897444, 9897445, 9897450		
GLOBAL UNITE REV STEM SZ 12	110012600	10603295004134
LOTS: 9791138, 9791139, 9802328, 9802329, 9824513, 9824514, 9887655		
GLOBAL UNITE STD STEM SZ 14	110014100	10603295004158
LOTS: 9792322, 9792323, 9793655, 9793656, 9793939, 9793940, 9793941, 9793942, 9793943, 9802260, 9802261, 9802264, 9802266, 9802270, 9802271, 9802272, 9802273, 9802274, 9802276, 9802277, 9802278, 9802279, 9802280, 9802281, 9802282, 9802283, 9802284, 9802285, 9802286, 9802287, 9802288, 9802289, 9802290, 9802291, 9802292, 9802293, 9802294, 9802295, 9802296, 9802297, 9802298, 9802299, 9802300, 9802301, 9802302, 9802306, 9802307, 9802308, 9802309, 9824476, 9824477, 9824478, 9824480, 9824481, 9824482, 9824484, 9824485, 9824486, 9824487, 9824488, 9824489, 9824490, 9824491, 9824492, 9824493, 9824494, 9824495, 9824496, 9832812, 9832813, 9832814, 9832815, 9832816, 9832828, 9841206, 9841207, 9851810, 9851811, 9851812, 9851813, 9851814, 9851815, 9851816, 9851817, 9851818, 9851819, 9851820, 9851821, 9851822, 9851823, 9851824, 9851825, 9851826, 9851827, 9851828, 9851829, 9851830, 9851831, 9851832, 9851833, 9851834, 9851835, 9851836, 9851837, 9851838, 9851839, 9851840, 9885297, 9888307, 9888308, ,		

PRODUCT DESCRIPTION	CATALOG NO.	GTIN
CONTINUED LOTS FOR CATALOG NO. 110014100: 9888309, 9888551, 9897472, 9897473, 9897474, 9897475, 9897476, 9897477, 9897478, 9897479, 9897480, 9897481, 9897482, 9897483, 9897484, 9897485, 9897486, 9897487, 9897488, 9897489, 9897490, 9897491, 9897492		
GLOBAL UNITE STD STEM SZ 16	110016100	10603295004189
LOTS: 9793944, 9793945, 9793946, 9793947, 9802310, 9802311, 9802312, 9802313, 9802314, 9802315, 9802316, 9802317, 9802318, 9802319, 9802320, 9813856, 9814516, 9814517, 9817630, 9824502, 9824503, 9824505, 9832803, 9832829, 9832830, 9833534, 9833538, 9834401, 9834402, 9836078, 9841198, 9841208, 9841209, 9858604, 9880972, 9883174, 9883176, 9884875, 9885283, 9885840, 9886688, 9887441, 9887442, 9887451, 9887452, 9904859, 9906104, 9908614, 9909021		

URGENT: FIELD SAFETY NOTICE (REMOVAL)
GLOBAL UNITE STEMS (SELECT LOTS ONLY)

Product Subject to this Removal:

Catalog Number	GTIN	Lot / Batch Numbers	Description
See Table 1			

Please complete this BRF **within three (3) business days upon receipt of the Removal Letter** and email this form to **[Affiliate to enter Email for Country/Region]**.

The facility located the affected product in stock and is returning products (see below). A copy of this letter is being retained in the facility's records. I have read and understand the notification.

For product returns: Please call customer service following the typical returns process in order to acquire a return number prior to shipping product. Please enclose a photocopy of the completed Business Response Form as a packing slip in the box containing the product(s) you are returning. Return all identified affected product to: GMED Healthcare | JDE 8.12 Returns Dept. | ATTN: RETURNS FA 2044436 (NR-0168411) | Rue de Luxembourg 5 | ZI Trazegnies | BE - 6180 Courcelles | Belgium | TEL: 32-7-146-9404

The facility has no affected product for return. A copy of this letter is being retained in the facility's records. I have read and understand the notification.

Your Name:	Facility/Business Name:
Signed*:	Date:
Facility/Business Address, City:	
Account Number:	
J&J Sales Rep (as applicable):	
Date the notification was received:	
Email Address:	Telephone Number:
<i>*Your signature provides confirmation that you have received and understood this notification.</i>	
<i>Your comments are always welcome:</i>	

J&J Representative: Complete this section **only** if the notice was delivered to the Medical Facility named above but **you were unable to secure a signature**, or if the **facility has closed**. Within three (3) business days of initiation, return the form to **[Affiliate to enter Email for Country/Region]**. **Complete Product Disposition Section above:**

- Medical Facility was notified and refused to sign. **Indicate where the Removal Letter was delivered: (e.g. address above or email):** _____
- After three attempts to contact the Medical Facility, I delivered the information, but was not able to secure the signature. **Indicate where the Removal Letter was delivered: (e.g. address above or email):** _____
List dates of contact attempts:
First Attempt: _____
Second Attempt: _____
Third Attempt: _____
- Medical Facility is no longer in business.

J&J Representative Name (Print)

J&J Representative Signature

Date