

URGENT MEDICAL DEVICE RECALL



BIOMET 3i
4555 Riverside Drive.
Palm Beach Gardens, FL 33410
1.800.342.5454
www.biomet3i.com

December 3, 2015

To: Dentists and Health Care Professionals

Affected Product:

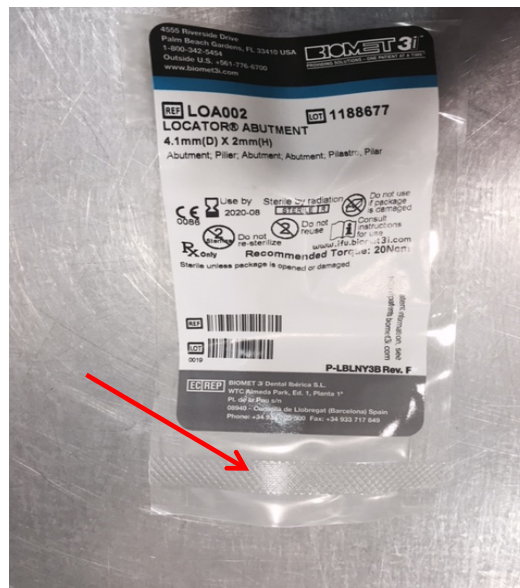
All Items identified in **Attachment 1**,
All lots—with expiration dates between **November 2015** and **November 2020**

Dear Valued Customer:

BIOMET **3i** is conducting a voluntary recall of the products listed in **Attachment 1**. Our records indicate that your office has previously received a shipment(s) of the affected products originating between November 1, 2010 and November 19, 2015.

Through investigation, BIOMET **3i** determined that a limited number of product pouches may not have been sealed during packaging. The occurrence rate to date of a pouch not being sealed during packaging is approximately 0.008%. In the event the product pouch is unsealed, the sterility of the product contained within the pouch cannot be assured and/or the component may be missing.

Photograph examples of sealed and unsealed pouches are shown below:



Seal Location



Sealed



Not Sealed



URGENT: DEVICE RECALL NOTICE

Unsealed Pouches

Risks:

- If the clinician notices the open seal and does not use the product, this could delay treatment while the clinician obtains appropriate replacement product.
- If the clinician notices the open seal and decides to use the product despite the compromised sterile barrier, the patient may experience soft tissue irritation, up to and including infection.

Responsibilities:

1. Please review this notice.
2. Identify affected product in your inventory as indicated in **Attachment 1**.
3. Complete the attached Business Reply Form and:
 - a. Fax it to **561-514-6316** or email it to postmarket@biomet.com or [Steri-cycle insert here]
 - b. Return a copy of the Business Reply Form along with the affected product to the location shown on the Business Reply Form.
 - c. Replacement product will be ordered by BIOMET **3i** customer service upon receipt of returned affected product, the replacement product will ship upon availability.

Please maintain a copy of this notice and a signed copy of **Attachment 2** for your records to assist in any future regulatory agencies audits of this field action.

Other Information

This voluntary notification will be reported to the U.S. Food and Drug Administration.

BIOMET **3i** prioritizes quality and patient safety, and we are committed to helping improve lives by developing and delivering high quality, safe and effective products. We apologize for any inconvenience this may have caused and appreciate your continued business.

For assistance or other questions that you may have relative to this notice, please contact BIOMET **3i** at **1-800-342-5454** or 1-561-776-6700. Team members are available to assist you 8:00am to 6:00pm (Eastern), Monday through Friday.



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Unsealed Pouches

ATTACHMENT 1

Affected Product List

The following list of items with expiration dates between **November 2015** and **November 2020** are within the scope of this product recall.

Description	Item
BELLATEK® ENCODE® HEALING ABUTMENT	EHA343, EHA344, EHA346, EHA348, EHA353, EHA354, EHA356, EHA358, EHA443, EHA444, EHA446, EHA448, EHA453, EHA454, EHA456, EHA458, EHA463, EHA464, EHA466, EHA468, EHA473, EHA474, EHA476, EHA478, EHA553, EHA554, EHA556, EHA558, EHA563, EHA564, EHA566, EHA568, EHA573, EHA574, EHA576, EHA578, EHA663, EHA664, EHA666, EHA668, EHA673, EHA674, EHA676, EHA678
CERTAIN® EP® TWIST LOCK TM COPING	IMIT33
CERTAIN® BELLATEK® ENCODE® HEALING ABUTMENT	IEHA343, IEHA344, IEHA346, IEHA348, IEHA353, IEHA354, IEHA356, IEHA358, IEHA443, IEHA444, IEHA446, IEHA448, IEHA453, IEHA454, IEHA456, IEHA458, IEHA463, IEHA464, IEHA466, IEHA468, IEHA473, IEHA474, IEHA476, IEHA478, IEHA553, IEHA554, IEHA556, IEHA558, IEHA563, IEHA564, IEHA566, IEHA568, IEHA573, IEHA574, IEHA576, IEHA578, IEHA663, IEHA664, IEHA666, IEHA668, IEHA673, IEHA674, IEHA676, IEHA678
CERTAIN® CONICAL 17° ANGLED ABUTMENT	IAC4217, IAC4417
CERTAIN® CONICAL 25° ANGLED ABUTMENT	IAC4225, IAC4425
CERTAIN® CONICAL ABUTMENT	IMCA31, IMCA32, IMCA33, IMCA34, ICA001, ICA002, ICA003, ICA004, IWCA51, IWCA52, IWCA53, IWCA54, IWCA55
CERTAIN® COVER SCREW	IMMCS1
CERTAIN® EP® HEALING ABUTMENT	IMHA352, IMHA353, IMHA354, IMHA356, ITHA58, ITHA63, ITHA64, ITHA66, ITHA68, ITHA73, ITHA74, ITHA76, ITHA78, IWTH52, IWTH54, IWTH56, IWTH58, IWTH562, IWTH564, IWTH566, IWTH568, IWTH572, IWTH573, IWTH574, IWTH576, IWTH578, IWTH62, IWTH63, IWTH64, IWTH66, IWTH68, IWTH672, IWTH673, IWTH674, IWTH676, IWTH678
CERTAIN® EP® PICK-UP COPING	IMIC35
CERTAIN® EP® TWIST LOCK TM COPING	IMIT35
CERTAIN® FLAT IMPLANT COVER SCREW	ICSF41, ICSF50, ICSF60
CERTAIN® GINGHUE TM 15° ANGLED POST	IMPAP34G
CERTAIN® GINGIHUE® 15° PRE-ANGLED POST	IMPAP352G, IMPAP354G
CERTAIN® GINGIHUE® POST	IMAP352G, IMAP354G, IAPP462G, IAPP464G, IAPP472G, IAPP474G, IWPP564G, IWPP572G, IWPP574G, IWPP662G, IWPP664G, IWPP672G, IWPP674G
CERTAIN® GINGIHUE® 15° ANGLED POST	IPAP464G, IPAP472G, IPAP474G, IPAP462G, IPAP554G, IPAP562G, IPAP564G, IPAP572G, IPAP574G, IPAP662G, IPAP664G, IPAP672G, IPAP674G



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Description	Item
CERTAIN® HEX TRY-IN SCREW (5 PK)	IUNITS
CERTAIN® IMPLANT COVER SCREW	ICS375, ICS500, ICS600
CERTAIN® IMPLANT EP® TWIST LOCK TM COPING	IWIT67
CERTAIN® IMPLANT STRAIGHT COVER SCREW	ICS400
CERTAIN® IOL® ABUTMENT	IOL55S, IOL70S
CERTAIN® LOCATOR® ABUTMENT	IMLOA001, IMLOA002, IMLOA003, IMLOA004, IMLOA005, IMLOA006, ILOA001, ILOA002, ILOA003, ILOA004, ILOA005, ILOA006
CERTAIN® MICROMINI FLAT IMPLANT COVER SCREW	IMCSF34
CERTAIN® NON-HEXED IMPLANT PICK-UP COPING	IIIC42
CERTAIN® PICK-UP COPING	IMIC33, IIIC60, IIIC75, IWIP56, IWIP57, IWIP66, IWIP67
CERTAIN® PERFORMANCE® 15° PRE-ANGLED POST	IMPAPF36, IMPAPF354, IMPAPF356
CERTAIN® PERFORMANCE® POST	IMPFP34, IMPFP36, IMPFP354, IMPFP356, IPFP456, IWPPFP554, IWPPFP556, IWPPFP664, IWPPFP666
CERTAIN® PERFORMANCE® TEMPORARY CYLINDER	IMPFTC34, IMPFTC32, IPFTC41, IPFTC42, IWPFPTC51, IWPFPTC52, IWPFPTC61, IWPFPTC62
CERTAIN® PROVIDE® ABUTMENT	IPA4140, IPA4155, IPA4240, IPA4255, IPA4340, IPA4355, IPA4440, IPA4455, IPA5140, IPA5155, IPA5240, IPA5255, IPA5340, IPA5355, IPA5440, IPA5455, IPA6140, IPA6155, IPA6240, IPA6255, IPA6340, IPA6355, IPA6440, IPA6455
CERTAIN® STANDARD ABUTMENT	IAB200, IAB300, IAB400, IAB550, IAB700
CERTAIN® STRAIGHT HEALING ABUTMENT	ISMHA32, ISMHA33, ISMHA34, ISMHA36, ISHA46, ISHA48, ISWHA52, ISWHA53, ISWHA54, ISWHA56, ISWHA58, ISWHA62, ISWHA63, ISWHA64, ISWHA66, ISWHA68
CERTAIN® STRAIGHT PICK UP COPING	IMIC30, IWIP60
CERTAIN® TEMPORARY HEXED CYLINDER	IMMTCS1, IITCS41, IWTC51, IWTC61
CERTAIN® TEMPORARY NON-HEXED CYLINDER	IITCS42, IWTC52, IWTC62
CERTAIN® TITANIUM LARGE HEXED SCREW	ILRGHT
CERTAIN® TWIST LOCK TM COPING	IIIC46, IIIC47, IWIT55, IWIT56, IWIT57
CERTAIN® TWIST LOCK TM STRAIGHT TRANSFER COPING	IWIT50, IWIT60
CERTAIN® TWIST LOCK TM COPING	IWIT66
CONICAL 17° ANGLED ABUTMENT	AC4217, AC4417
CONICAL 25° ANGLED ABUTMENT	AC4225, AC4425
CONICAL ABUTMENT	MCA31, MCA33, MCA34, CA001, CA002, CA004, WCA51, WCA53
CONICAL ABUTMENT GOLD STANDARD ZR TM	SCA001, SCA002, SCA003, SCA004, SCA055, SWCA51, SWCA52, SWCA53, SWCA54, SWCA55
CONICAL ABUTMENT PICK-UP COPING	MEC33
CONICAL EP® HEALING CAP	CS250, CS260, CS270



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CONICAL EP® PICK-UP COPING (HEXED)	CNRIC
CONICAL EP® PICK-UP COPING (NON-HEXED)	CSQI7, CSQ06, CSQ07
CONICAL EP® TWIST LOCK TM COPING	CIC55, CIC56, CIC57
CONICAL HEALING CAP	MHC33
COVER SCREW	CS375, CS500, CS600
COVER SCREW, HEADLESS	CS275
DAL-RO HOUSING / FEMALE ASSEMBLY	DRTH
DAL-RO ABUTMENT	DRH20, DRH40, DRH60
DAL-RO THREADED FEMALE	DRAF
DRILL STOP	DS2310, DS2315, DS2320, DS4513, DS4518, DS458
EP® HEALING ABUTMENT	MHA32, MHA33, MHA34, MHA36, THA58, THA63, THA64, THA66, THA68, THA73, THA74, THA76, THA78, WTH52, WTH53, WTH54, WTH56, WTH58, WTH562, WTH563, WTH564, WTH566, WTH568, WTH572, WTH573, WTH574, WTH576, WTH578, WTH62, WTH63, WTH64, WTH66, WTH68, WTH672, WTH673, WTH674, WTH676, WTH678
GINGIHUE® 15° PRE-ANGLED POST	MPAP32G, MPAP34G, PAP454G, PAP462G, PAP464G, PAP472G, PAP474G, PAP552G, PAP554G, PAP562G, PAP564G, PAP572G, PAP574G, PAP662G, PAP664G, PAP672G, PAP674G
GINGIHUE® POST	MAP32G, MAP34G, APP462G, APP464G, APP472G, APP474G, WPP554G, WPP562G, WPP564G, WPP572G, WPP574G, WPP662G, WPP664G, WPP672G, WPP674G
GOLD SLOTTED SCREW	GS200, GS300
GOLD-TITE® HEXED RETAINING SCREW	GSH20, GSH30, GSH70
HEALING ABUTMENT	THA42, THA43, THA44, THA46, THA48
IMPLANT COVER SCREW	MMCS1
IMPLANT EP® PICK-UP COPING	IIC60, IIC75, WIP55, WIP56, WIP57, WIP66, WIP67
IMPLANT EP® TWIST LOCK TM COPING	IIC46, IIC47, IIC45, WIT56, WIT57, WIT55, WIT66, WIT67
IMPLANT TWIST LOCK TM COPING	IIC44
INDEX COPING SURGICAL	IC100
IOL® ABUTMENT AND SCREW	IOL20T, IOL55T, IOL70T
IOL® DISTAL EXTENSION	IOLDE
IOL® HEALING CAP	IOLHC
IOL® PICK-UP IMPRESSION COPING	IOLPIC
IOL® TITANIUM TEMPORARY CYLINDER	IOLTC
IOL® TRANSFER IMPRESSION COPING	IOLTIC
LOCATOR® ABUTMENT	MLOA001, MLOA002, MLOA003, MLOA004, MLOA005, MLOA006, LOA001, LOA002, LOA003, LOA004, LOA005, LOA006
LOCATOR® ABUTMENT IMPRESSION COPING	LAIC1
LOCATOR® EXTENDED RANGE MALES 4PK.	LAERM
LOCATOR® EXTRA LIGHT ANGLED REPLACEMENT MALES 4 PK.	LELARM



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Description	Item
LOCATOR® EXTRA LIGHT RETENTION MALES 4PK.	LAELM
LOCATOR® LIGHT RETENTION REPLACEMENT MALES 4PK.	LLRMS
LOCATOR® REPLACEMENT HOUSING	LOAH
LOCATOR® REPLACEMENT HOUSING KIT	LORHK
LOCATOR® REPLACEMENT MALES 4PK.	LARMS
PICK-UP IMPRESSION COPING	MIC33
PREFORMANCE® 15° PRE-ANGLED POST	MPAPF34, MPAPF36, PAPF454, PAPF456, PAPF554, PAPF556, PAPF666
PREFORMANCE® POST	MPFP34, MPFP36, PFP454, PFP456, WPFP554, WPFP556, WPFP666
PREFORMANCE® TEMPORARY CYLINDER	MPFTC34, MPFTC32, PFTC41, PFTC42, WPFTC51, WPFTC52, WPFTC61, WPFTC62
PREP-TITE® CAP	PTC345, PTC455, PTC465, PTC475, PTC555, PTC665, PTC347, PTC457, PTC467, PTC477, PTC557, PTC667
PREP-TITE® POST	APP42, WPP552, WPP662
PROVIDE® IMPRESSION COPING	PIC484, PIC485, PIC654, PIC655, PIC484H, PIC485H, PIC654H
PROVIDE® PROTECTION CAP	PPC484, PPC485, PPC654, PPC655
QUICKBRIDGE™ CAP	QBCAP
STANDARD ABUTMENT	AB200, AB300, AB400, AB550, AB700
STANDARD ABUTMENT PICK-UP COPING	SQIC7
STANDARD ABUTMENT TEMPORARY SCREW	TS250
STANDARD ABUTMENT TRANSFER COPING	SIC70
TEMPORARY HEALING RETENTION CYLINDER	THRC4, THRC6
TEMPORARY HEXED CYLINDER	MMTCS1, ITCS41, WTCS51, WTCS61
TEMPORARY NON-HEXED CYLINDER	ITCS42, WTCS52, WTCS62
TITANIUM HEXED UNISCREW	UNIHT
TITANIUM SQUARE UNISCREW	UNIST



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Some products with specific lot numbers are also impacted. The products with the affected lot number are listed in the table below. **Please note that only those lot numbers listed are included in this recall.**

Item	Description	Affected Lot Numbers
ITHA52	CERTAIN® EP® HEALING ABUTMENT 4.1MM(D) X 5MM(P) X 2MM(H)	1152783
IWTH52	CERTAIN® EP® HEALING ABUTMENT 5MM(D) X 5.6MM(P) X 2MM(H)	1152118
IWTH54	CERTAIN® EP® HEALING ABUTMENT 5MM(D) X 5.6MM(P) X 4MM(H)	1153081
IWTH564	CERTAIN® EP® HEALING ABUTMENT 5MM(D) X 6MM(P) X 4MM(H)	1150836
IMPAP32G	CERTAIN® GINGHUE™ 15° ANGLED POST 3.4MM(D) X 3.8MM(P) X 2MM(H)	1154709-5
IPAP454G	CERTAIN® GINGIHUE® 15° ANGLED POST 4.1MM(D) X 5MM(P) X 4MM(H)	1154388-5
IWPP552G	CERTAIN® GINGIHUE® POST 5MM(D) X 5MM(P) X 2MM(H)	1147381, 1153937, 1153938
IMAP32G	CERTAIN® GINGIHUE® POST 3.4MM(D) X 3.8MM(P) X 2MM(H)	1151936, 1151937, 1151938
IAPP454G	CERTAIN® GINGIHUE® POST 4.1MM(D) X 5MM(P) X 4MM(H)	1148354, 1155382
IIIC41	CERTAIN® PICK-UP COPING 4.1MM(D) X 4.1MM(P)	1152085
IIIC12	CERTAIN® PICK-UP COPING 4.1MM(D) X 5MM(P)	1154337, 1154338
IWIP55	CERTAIN® PICK-UP COPING 5MM(D) X 5MM(P)	1152487
ISHA44	CERTAIN® STRAIGHT HEALING ABUTMENT 4.1MM(D) X 4.1MM(P) X 4MM(H)	1155282, 1155283
IWIP50	CERTAIN® STRAIGHT PICK-UP COPING 5.0MM(D) X 0MM(P)	1157768-CN, 1160929-CN, 1160930-CN, 1160931-CN, 987129-5, 996343-5, 998147-5
PAP452G	GINGIHUE® 15° PRE-ANGLED POST 4MM(D) X 5MM(P) X 2MM(H)	1154271-5
GSH30	GOLD-TITE® HEXED RETAINING SCREW - 3MM	1071150, 1071151, 1071152, 1071190
UNISG	GOLD-TITE® SQUARE UNISCREW	1152611, 1153193
SCRSBL1	LDA SCREW SBL 3MM(D)	1087614
SCRSBL2	LDA SCREW SBL 4MM(D)	1087616
OSO20	O-RING ABUTMENT 4.1MM (D) X 2MM (H)	1002024, 1014103, 1022623, 1030863, 1031271, 1051924, 1054014, 1057816, 1068294, 1069738, 1071756, 1078857, 1082342, 1095159, 1095387, 1129684, 1131304, 1141288, 1161312, 1168381, 1169242, 1169931, 1170162, 1173357, 987787, 987884
OSO40	O-RING ABUTMENT 4.1MM (D) X 4MM (H)	1014104, 1022991, 1033058, 1041417, 1052716, 1054542, 1060675, 1069646, 1088483, 1094776, 1106610, 1129686, 1141289, 1168523, 1168829, 1172024, 996069
OSO60	O-RING ABUTMENT 4.1MM (D) X 6MM (H)	1068337, 1116902, 997344

