

URGENT MEDICAL DEVICE RECALL



Asia Implant Support & Services

16 New Industrial Road
Hudson TechnoCentre
536204 Singapore
Tel: (65)62232229 Fax: (65)62203538

December 29, 2015

To: Dentists and Health Care Professionals

Affected Products: All Items identified in **Attachment 1**,

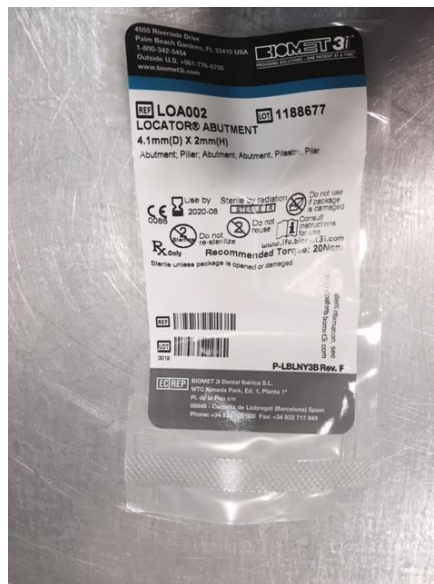
All lots with expiration dates between **November 2015** and **November 2020**

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



Not Sealed



Sealed

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 (65)62203538 or email it to admin@implant.com.sg 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 Asia Implant 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.

Asia Implant Support & Services 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 Asia Implant Support & Services at (65)62232229. Team members are available to assist you 9:00am to 6:00pm, Monday through Friday.

Thank you for your assistance.

Sincerely,



Raymond Loh
Managing Director
On behalf of Biomet 3i

URGENT: DEVICE RECALL NOTICE



Asia Implant Support & Services

16 New Industrial Road
Hudson TechnoCentre
536204 Singapore
Tel: (65)62232229 Fax: (65)62203538

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.

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

CONICAL EP® PICK-UP COPING (HEXED)
CONICAL EP® PICK-UP COPING (NON-HEXED)
CONICAL EP® TWIST LOCK TM COPING
CONICAL HEALING CAP
COVER SCREW
COVER SCREW, HEADLESS
DAL-RO HOUSING / FEMALE ASSEMBLY
DAL-RO ABUTMENT
DAL-RO THREADED FEMALE
DRILL STOP

CNRIC
CSQI7, CSQ06, CSQ07
CIC55, CIC56, CIC57
MHC33
CS375, CS500, CS600
CS275
DRTH
DRH20, DRH40, DRH60
DRAF
DS2310, DS2315, DS2320, DS4513, DS4518,
DS458
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

EP® HEALING ABUTMENT

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
GOLD-TITE® HEXED RETAINING SCREW
HEALING ABUTMENT
IMPLANT COVER SCREW
IMPLANT EP® PICK-UP COPING

GS200, GS300
GSH20, GSH30, GSH70
THA42, THA43, THA44, THA46, THA48
MMCS1
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
INDEX COPING SURGICAL
IOL® ABUTMENT AND SCREW
IOL® DISTAL EXTENSION
IOL® HEALING CAP
IOL® PICK-UP IMPRESSION COPING
IOL® TITANIUM TEMPORARY CYLINDER
IOL® TRANSFER IMPRESSION COPING
LOCATOR® ABUTMENT

IIC44
IC100
IOL20T, IOL55T, IOL70T
IOLDE
IOLHC
IOLPIC
IOLTIC
IOLTIC
MLOA001, MLOA002, MLOA003, MLOA004,
MLOA005, MLOA006, LOA001, LOA002,
LOA003, LOA004, LOA005, LOA006

LOCATOR® ABUTMENT IMPRESSION COPING
LOCATOR® EXTENDED RANGE MALES 4PK.
LOCATOR® EXTRA LIGHT ANGLED
REPLACEMENT MALES 4 PK.

LAIC1
LAERM
LELARM

LOCATOR® EXTRA LIGHT RETENTION
MALES 4PK.

LAELM

LOCATOR® LIGHT RETENTION
REPLACEMENT MALES 4PK.

LLRMS

LOCATOR® REPLACEMENT HOUSING
LOCATOR® REPLACEMENT HOUSING KIT
LOCATOR® REPLACEMENT MALES 4PK.
PICK-UP IMPRESSION COPING

LOAH
LORHK
LARMS
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

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 TM 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

URGENT MEDICAL DEVICE RECALL



Asia Implant Support & Services

16 New Industrial Road
Hudson TechnoCentre
536204 Singapore
Tel: (65)62232229 Fax: (65)62203538

ATTACHMENT 2

BUSINESS REPLY FORM / PACKING SLIP

Instructions:

1. Complete the form below and fax to (65)62232229 **or** email a copy to admin@implant.com.sg or;
2. If you have product to return, include a copy of the Business Reply Form and return the affected product to the location shown below.
3. Replacement product will be ordered by Asia Implant Support & Services customer service upon receipt of returned affected product. The replacement product will ship upon availability.

Please Return Affected Product to:

Asia Implant Support & Services

Attention: Hui Shan
16 New Industrial Road
Hudson TechnoCentre
Singapore 536204

Please complete this Business Reply Form within five (5) business days. Please complete the information below:

Item #	Lot #	Quantity on hand	Quantity returning

Name _____

Address _____

Phone Number: _____

Signature _____ Date _____

Please complete and fax or email to: **Fax –(65)62232229 Email – admin@implant.com.sg**