Urgent Field Safety Notice (FSN)
DePuy Synthes ATTUNE® INTUITION™ Tibial Articulation Surface Instruments

Product Name: ATTUNE® INTUITION™ Tibial Articulation Surface Instruments

FSCA-identifier: 103045639-QRB

Type of Action: Field Safety Notice

Date: June 2015

Attention: Trust Chief Executives, the Clinical Director-Orthopaedic Department, the Orthopaedic Theatre Manager, the Safety Liaison Officer, General Managers – Private Sector Hospitals

Type of device: Instrument used in Orthopaedic Knee Joint Replacement.

Model names: ATTUNE® INTUITION™ Tibial Articulation Surface Instruments

DePuy Orthopaedics, Inc. is voluntarily issuing a Field Safety Notice for all lots of the ATTUNE® INTUITION™ Tibial Articulation Surface Instruments used in trialing with the ATTUNE Knee System. The Field Safety Notice is being issued due to the potential for the Balseal, which is a small wire spring coil located on the post feature of the Articulation Surface Instruments (Figure 1), to become damaged and disassociate (come off). The Balseal is constructed from implant grade stainless steel. If the Balseal is separated from the post, it has the potential to enter the surgical site and be left in the patient if the surgeon is unaware of the disassociation.

Affected Instruments:

Product Code: See Attachment A
Lot Number: All Lots
Barcode / GTIN: See Attachment A

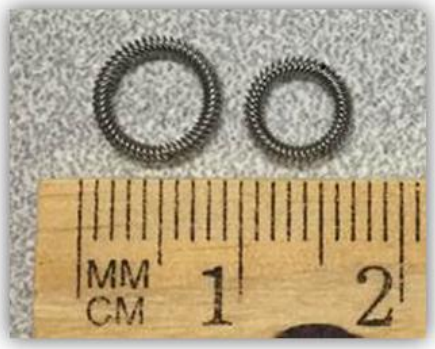

Figure 1: Balseal Image

Intended Use

The Tibial Articulation Surface Trial snaps together with the Shim component to function as the Insert Trial during a total knee replacement. A Balseal is attached to each of the two post features on the Articulation Surface to provide a connection force between the Tibial Articulation Surface and Shim to ensure secure engagement between the components (see Figure 3).

Reason for the Field Safety Notice
Complaints have been received reporting that the Balseal has disassociated from the Articulation Surface Instrument at a reported occurrence rate of 0.065%. The reported occurrence rate for a Balseal remaining in a patient is 0.002%. One reoperation occurred immediately post-operatively to remove a Balseal. No other patient harms have been reported.

Damage to the Balseal is potentially caused by:

- Inserting the Tibial Trial Extractor or other instrument between the Articulation Surface Trial and Shim Trial, causing contact with the Balseal during intraoperative trialing or back table disassembly.
- Cleaning that deviates from the IFU procedures.

Clinical Implications
Balseal disassociation, if it occurs intra-operatively, may result in the need to modify clinical management of the patient.

- If the Balseal becomes disassociated during surgery and is observed, considerations for clinical management may include:
    - Surgical Delay: Intra-operative surgical delay may occur when attempting to retrieve the disassociated Balseal.

- If the Balseal becomes disassociated and is not observed, considerations for clinical management may include:

    - Adverse tissue reaction
    - Soft tissue irritation
    - Pain
    - Poor joint mechanics

The clinical scenarios described above may potentially require surgical intervention. Following are general examples of possible risks/hazards of surgical intervention:

1. Infection
2. Additional scarring
3. Neural and vascular damage
4. Additional pain to the patient
5. Functional problems resulting from items 1 – 4 above
6. Anesthesia-associated risks

Field Safety Notice Actions:
To reduce the possibility of leaving a disassociated Balseal in a patient:

1. Closely follow the instructions for use (IFU), which include inspecting the ATTUNE Articulation Surface Instruments before, during and after use, to ensure that the Balseals are not damaged and that no instruments or pieces are left in the patient. Balseal disassociation potentially occurs secondary to damage to the Tibial Articulation Surface during removal of the trial from the joint space or reprocessing. Highlights from the IFU (Cat. No. 0902-00-836) include:
    a. "Ensure that no instruments or pieces of instruments are left in the surgical site prior to closure, as they may not be detectable using imaging techniques such as X-ray or MRI and patient injury may result."
    b. "Visually inspect the instrument and check for damage and wear."
    c. During manual cleaning, "Thoroughly brush with a soft non-metallic bristle brush to remove all traces of blood and debris. Pay close attention to threads, crevices, seams, and any hard to reach areas. Actuate any moveable mechanisms, such as hinged joints, box locks, or spring-loaded features, to free trapped blood and debris."

2. Closely follow the instructions in the ATTUNE INTUITION Instruments Surgical Technique, Cat. No. DSUS/JRC/0115/0680. Highlights include:

    a. "Check for Balseal damage. If damage is observed, replace the damaged instrument." See Figure 2.

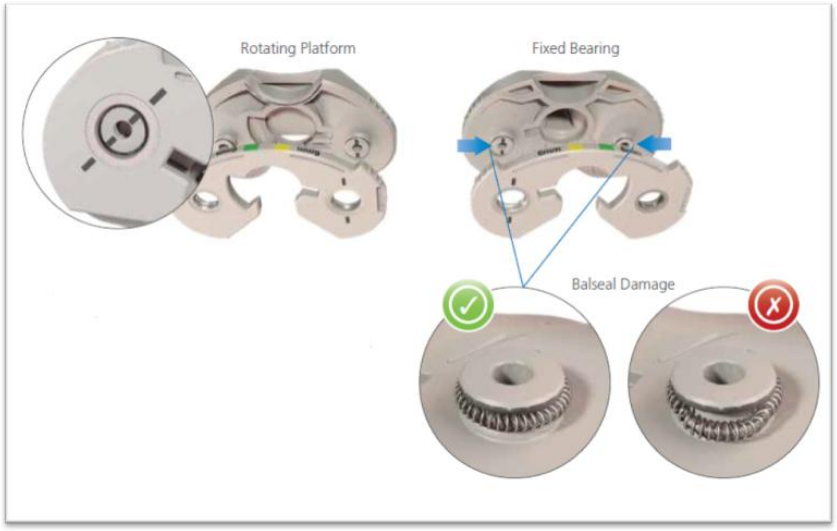

Figure 2: Image is From the ATTUNE® INTUITION™ Instruments Surgical Technique and Provides a Visual Comparison Between Undamaged and Damaged Balseals

    b. To avoid damaging the Balseal: "Caution: Do not insert the Tibial Trial Extractor between the Shim and the articulation surface in order to prevent damage to the connection feature." Also, "Fully flex

the knee, and remove the Insert Trial. The Tibial Trial Extractor can be used to aid in the removal of the Insert Trials. Insert the Tibial Trial Extractor between the Tibial Base Trial and the Shim, and lever the handle upwards toward the femur in order to remove the Insert Trial." See Figure 3 and Attachment B.

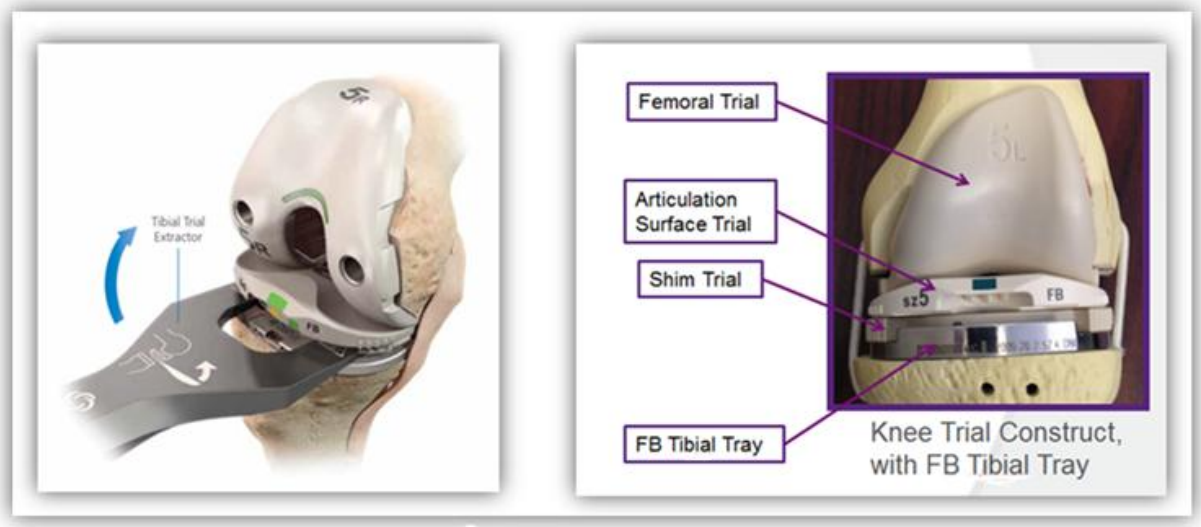

Figure 3: Image on the left shows proper insertion of the Tibial Trial Extractor. Image on Left is from the ATTUNE® INTUITION™ Instruments Surgical Technique. The Image on Right Shows the Trialing Configuration

c. When using the Tibial Trial Extractor with the fixed bearing implant (Figure 4):

"The Tibial Trial Extractor is designed to aid in the removal of insert trials. The instrument can be used with the Tibial Base Implant as well as with the Tibial Base Trials.

With the knee in flexion, the surgeon inserts the Tibial Trial Extractor first on the medial side, underneath the Shim and Articulation Surface construct. After inserting one side of the Tibial Trial Extractor, the surgeon then levers up the Insert Trial."

"Next, the surgeon pivots the Tibial Trial Extractor such that both ends are underneath the Shim and Articulation Surface construct, followed by pushing the Tibial Trial Extractor into the joint and underneath the Tibial Insert Trials as far as possible.

The surgeon then should lift the handle of the Tibial Trial Extractor UPWARDS. This upward movement works with the geometry of the condyles to aid in removal of the Tibial Insert Trials."

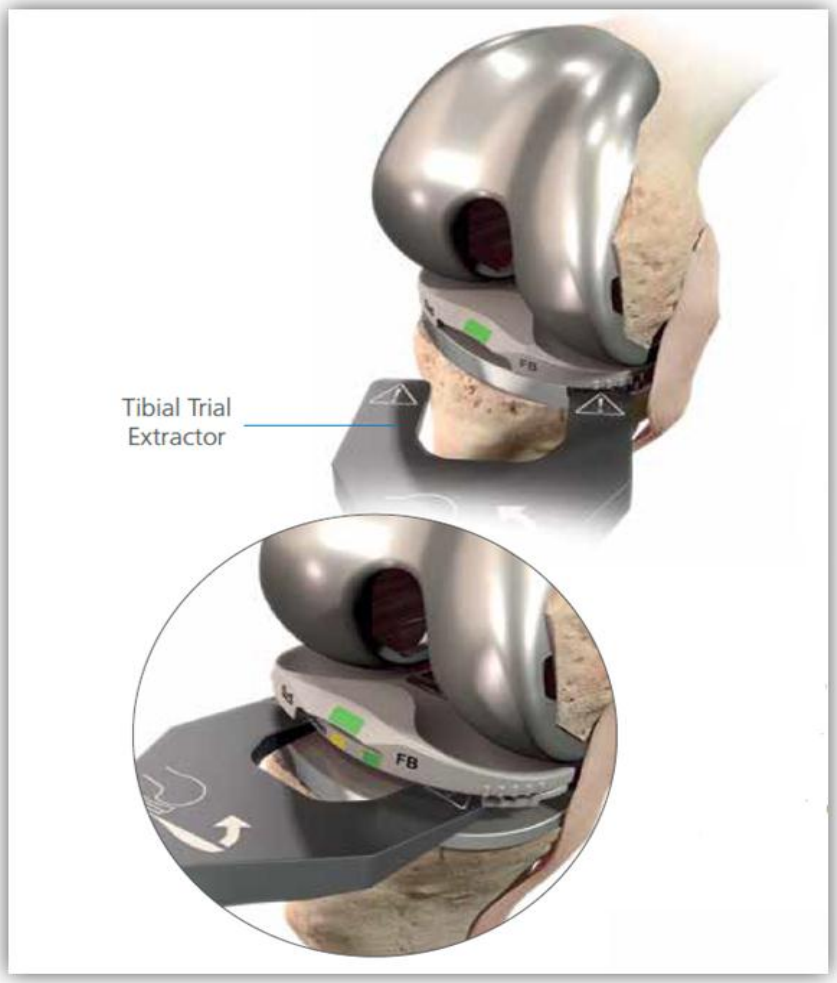

Figure 4: Image is From the ATTUNE® INTUITION™ Instruments Surgical Technique and Shows the Correct Use of the Tibial Trial Extractor

If a Balseal is damaged or becomes disassociated, please file a report through the normal DePuy Synthes complaint reporting process or your local DePuy Synthes Account Manager.

Units Affected

Since 2011, there have been approximately 132,300 Articulation Surface Trial instruments distributed in the US and approximately 56,900 distributed outside of the US. This Field Safety Notice does not affect any other INTUITION instruments.

Depth of Field Safety Notice

This Field Safety Notice provides instructions for notifying medical professionals who may have used the affected instruments. The purpose of this Field Safety Notice is to make users aware of this issue and actions to take.

Required Actions

The purpose of this communication is to inform you of this Field Safety Notice and request acknowledgement of the notice. Please take the following actions:

- Review this notice and complete the Acknowledgement section Attachment C to signify that your facility has been informed of this device correction. Return the completed Acknowledgement to your DePuy Synthes Orthopaedics Sales Consultant within four (4) weeks of this notice.
- Retain a copy of the completed Acknowledgement in your files along with this notice.
- Forward this notice to others in your facility/facilities who may be responsible for maintaining medical instruments in service. Notify surgeon users at your facility/facilities by providing them with a copy of this notice to ensure surgeon users are aware of this device correction.

Transmission of this Field Safety Notice:

This notice has been sent to you as records indicate that your organization/hospital has purchased the ATTUNE® INTUITION™ Tibial Articulation Surface Instruments.

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where these products may have been transferred.

To confirm receipt of this FSN please complete and return the acknowledgement in Attachment C to your DePuy Synthes representative.

For any enquiries about the ATTUNE® INTUITION™ Tibial Articulation Surface Instruments contact:

Brid Horgan
Vigilance and Recall Associate
e-mail –*bhorgan@its.jnj.com*
Tel no - +353 21 4914128

This FSN has been notified to the appropriate Regulatory Agency.

Yours sincerely,

Simon Sinclair PhD MB BChir
Worldwide Vice President, Strategic Medical Affairs

Attachment A: ATTUNE® INTUITION™ Articulation Surface Instrument Product Codes

Product Codes	Description	GTIN
254500503	ATTUNE FB PS ARTICULATION SURFACE SIZE 3	10603295132431
254500504	ATTUNE FB PS ARTICULATION SURFACE SIZE 4	10603295132448
254500505	ATTUNE FB PS ARTICULATION SURFACE SIZE 5	10603295132455
254500506	ATTUNE FB PS ARTICULATION SURFACE SIZE 6	10603295132462
254500507	ATTUNE FB PS ARTICULATION SURFACE SIZE 7	10603295132479
254500508	ATTUNE FB PS ARTICULATION SURFACE SIZE 8	10603295132486
254500523	ATTUNE FB CR ARTICULATION SURFACE SIZE 3	10603295132639
254500524	ATTUNE FB CR ARTICULATION SURFACE SIZE 4	10603295132646
254500525	ATTUNE FB CR ARTICULATION SURFACE SIZE 5	10603295132653
254500526	ATTUNE FB CR ARTICULATION SURFACE SIZE 6	10603295132660
254500527	ATTUNE FB CR ARTICULATION SURFACE SIZE 7	10603295132677
254500528	ATTUNE FB CR ARTICULATION SURFACE SIZE 8	10603295132684
254500543	ATTUNE RP PS ARTICULATION SURFACE SIZE 3	10603295132837
254500544	ATTUNE RP PS ARTICULATION SURFACE SIZE 4	10603295132844
254500545	ATTUNE RP PS ARTICULATION SURFACE SIZE 5	10603295132851
254500546	ATTUNE RP PS ARTICULATION SURFACE SIZE 6	10603295132868
254500547	ATTUNE RP PS ARTICULATION SURFACE SIZE 7	10603295132875
254500548	ATTUNE RP PS ARTICULATION SURFACE SIZE 8	10603295132882
254500981	ATTUNE CONV RP CR ARTICULATION SURFACE SZ1	10603295135586
254500982	ATTUNE CONV RP CR ARTICULATION SURFACE SZ2	10603295135593
254500563	ATTUNE RP CR ARTICULATION SURFACE SIZE 3	10603295133032
254500564	ATTUNE RP CR ARTICULATION SURFACE SIZE 4	10603295133049
254500565	ATTUNE RP CR ARTICULATION SURFACE SIZE 5	10603295133056
254500566	ATTUNE RP CR ARTICULATION SURFACE SIZE 6	10603295133063
254500567	ATTUNE RP CR ARTICULATION SURFACE SIZE 7	10603295133070
254500568	ATTUNE RP CR ARTICULATION SURFACE SIZE 8	10603295133087
254501989	ATTUNE CONV RP CR ARTICULATION SURFACE SZ9	10603295423492
254501990	ATTUNE CONV RP CR ARTICULATION SURFACE SZ10	10603295423959
254500971	ATTUNE CONV FB PS ARTICULATION SURFACE SZ1	10603295135487
254500972	ATTUNE CONV FB PS ARTICULATION SURFACE SZ2	10603295135494
254500973	ATTUNE CONV FB PS ARTICULATION SURFACE SZ3	10603295135500
254500974	ATTUNE CONV FB PS ARTICULATION SURFACE SZ4	10603295135517

Product Codes	Description	GTIN
254500975	ATTUNE CONV FB PS ARTICULATION SURFACE SZ5	10603295135524
254500976	ATTUNE CONV FB PS ARTICULATION SURFACE SZ6	10603295135531
254500977	ATTUNE CONV FB PS ARTICULATION SURFACE SZ7	10603295135548
254500978	ATTUNE CONV FB PS ARTICULATION SURFACE SZ8	10603295135555
254500979	ATTUNE CONV FB PS ARTICULATION SURFACE SZ9	10603295135562
254500980	ATTUNE CONV FB PS ARTICULATION SURFACE SZ10	10603295135579
254500991	ATTUNE CONV RP PS ARTICULATION SURFACE SZ1	10603295135685
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254500995	ATTUNE CONV RP PS ARTICULATION SURFACE SZ5	10603295135722
254500996	ATTUNE CONV RP PS ARTICULATION SURFACE SZ6	10603295135739
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254500998	ATTUNE CONV RP PS ARTICULATION SURFACE SZ8	10603295135753
254500999	ATTUNE CONV RP PS ARTICUL SURF SZ9	10603295135760
254501000	ATTUNE CONV RP PS TB TRL SZ10	10603295135777
254500961	ATTUNE CONV FB CR ARTICULATION SURFACE SZ1	10603295135388
254500962	ATTUNE CONV FB CR ARTICULATION SURFACE SZ2	10603295135395
254501963	ATTUNE CONV FB CR TB TRL SZ3	10603295423355
254501964	ATTUNE CONV FB CR TB TRL SZ4	10603295423362
254501965	ATTUNE CONV FB CR TB TRL SZ5	10603295423379
254501966	ATTUNE CONV FB CR TB TRL SZ6	10603295423386
254501967	ATTUNE CONV FB CR TB TRL SZ7	10603295423393
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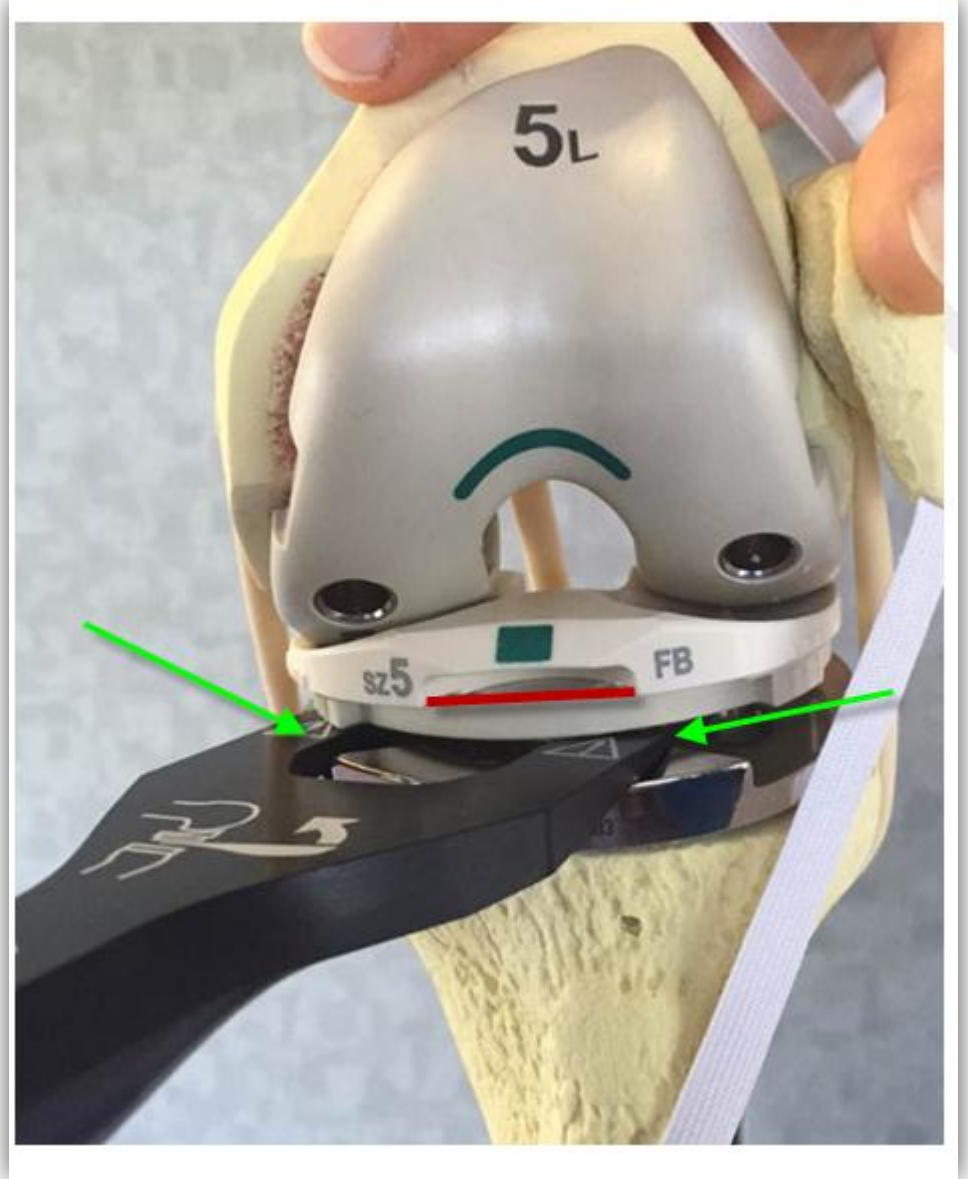
254501969	ATTUNE CONV FB CR TB TRL SZ9	10603295423416
254501970	ATTUNE CONV FB CR TB TRL SZ10	10603295423423

Attachment B: Proper Use of the Tibial Trial Extractor Instrument

Note: The Tibial Trial Extractor Instrument should be inserted under the Shim Trial as shown below by the green arrows. The red line shows where the instrument should **not** be inserted.



ATTACHMENT C

This Letter acknowledges receipt of the Field Safety Notice related to ATTUNE® INTUITION™ Articulation Surface Instrument Product

(Please check as appropriate)

☐ Yes, I have received the FSN

Please fax or e-mail this completed document to [INSERT DePuy Marketing Company/Affiliate contact details]

Print Name: _____

_____
Signature

_____
Hospital Name

_____
City

_____
Country

_____
Telephone Number or e-mail address