XX August 2013

RA2013-060: URGENT FIELD SAFETY NOTICE

Type of Action: Field Safety Corrective Action

Description: OtisMed ShapeMatch Cutting Guides

Catalog #: **TR3100-L, TR3100-R**

Case Codes #: See attachment

Dear Surgeon/Hospital:

On April 5, 2013, Stryker Orthopaedics issued a Field Safety Notice to users of the above referenced subject devices to request that a hold be placed on further procedures involving the above referenced devices; the containment of any physical inventory of the OtisMed ShapeMatch Cutting Guides; and the postponement of any patient scans. The notice was limited to users, who at the time of notification, were in the planning phase or had procedures pending.

This notice was sent in response to complaints received involving the above referenced devices. At the time that this notice was issued, the root cause of the issue had not been identified and Stryker Orthopaedics stated that further information would be provided on completion of the investigation. The investigation has now been completed and this communication is intended to provide additional information on this issue and the associated potential hazards/harms that have been identified.

Issue

The reason for this field safety notice is multifactorial:

- The surgical protocol for the ShapeMatch Cutting Guides did not provide sufficient information on the position of the cutting guide, the need for osteophyte/soft tissue removal, the requirement for proper axial drilling, and the need to avoid angulation and mal-alignment.
- The approved pre-operative plan did not provide sufficient information regarding the need for osteophyte removal.
    - The above issues are limited to devices manufactured prior to April 2013.
- Some ShapeMatch Cutting Guides may have been manufactured using pre-operative planning values that were inconsistent with the values displayed via the OtisMed.net web portal.
    - Please note that this issue does not impact all cutting guides.
    - This issue is limited to specific case codes.
        - Refer to the attachment below indicating the exact lot numbers affected for your facility, if applicable.

Potential Hazards and Harms

1. A malaligned/malpositioned device is implanted in the patient. The potentially hazardous situation is that a patient ambulates on malaligned/malpositioned implants which may result in the following harms:

    - Joint instability
    - Loss of mobility, reduced range of motion
    - Loss of motion, functional limitations requiring revision surgery

2. A device is implanted in a patient with a joint line that is elevated. The potentially hazardous situation is that a patient ambulates with an elevated joint line which may result in the following harms:

    - Joint instability
    - Loss of mobility, reduced range of motion

3. Cutting guide(s) with unacceptable orientation and position of resection(s) are used. The potentially hazardous situation is an extension of operating room time greater than 30 minutes to correct implant alignment, implant positioning, and obtain augments which may result in the following harm:

    - Complications associated with extended surgery time

4. Excess polyethylene debris in the joint. The potentially hazardous situation is progressive osteolysis which may result in the following harm:

    - Revision surgery

5. Polyethylene fragments. The potentially hazardous situation is polyethylene fragments in the joint space which may result in the following harms:

    - Inflammatory response
    - Loss of mobility, reduced range of motion

6. Cam post fracture of PS polyethylene liner. The potentially hazardous situation is that the patient ambulates on fractured implants which may result in the following harms:

    - Joint instability
    - Loss of motion, reduced range of motion. Revision surgery is required.
    - Loss of motion, functional limitations. Revision surgery is required.

7. Subluxation of the patella. The potentially hazardous situation is dislocation of the patella which may result in the following harms:

    - Joint instability
    - Loss of motion, reduced range of motion
    - Loss of motion, functional limitations. Revision surgery is required.

8. Patella peg or substrate fracture. The potentially hazardous situation is patient ambulates on fractured implants which may result in the following harms:

    - Joint instability
    - Loss of motion, reduced range of motion
    - Loss of motion, functional limitations. Revision surgery is required.

Mitigating Factors

The potential hazards described above are mitigated by several factors:

- The ShapeMatch Cutting Guide is one tool to assist in pre-operative planning of a total knee replacement.
- The surgical technique and product labeling indicates that the surgeon should routinely perform intra-operative verification which would be expected to identify the hazards detailed above.
    - Thus, it is anticipated that no patient would leave the operating room theatre without these secondary actions such as trialing being performed.

Patient Follow up

No additional patient follow up or monitoring is required. Symptomatic patients would present to their Health Care Practitioner who would take appropriate action. Routine patient follow-up should identify any issues.

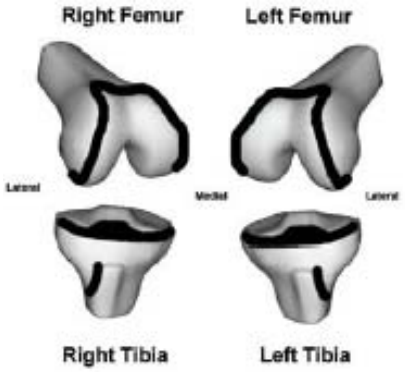
Corrective Actions

Internal manufacturing and quality control measure enhancements are currently being implemented. Additional corrective actions are as follows:

- The approved pre-operative plan has been revised to include both a written and illustrated warning for osteophyte removal.

The surgical protocol will be revised to include the following additional details:

- The below image was added to illustrate areas requiring osteophyte removal:



- The Surgical Procedure Overview section was updated to add the following text to ensure proper soft tissue is removed to help assist the seating of the femoral cutting guide:
    - “Excise soft tissue from the anterior cortex of the femur above the inflection point.”

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- The attached femoral and tibial preparation sections of the surgical protocol were updated as follows:
    - Inclusion of new images to better illustrate the following:
        - Final seating location for the femoral cutting guide
        - Proper direction for compression of the femoral cutting guide on to the femur.
        - Proper pin positioning of the femoral guide, specifically the relationship between the distal pints and the cutting slot.
        - Final seating position for the tibial cutting guide.
        - Proper angle of compression for guide placement.
        - Proper pin positioning of the tibial guide, specifically the relationship between the anterior pins and the cutting slot.

    - Additional text to provide:
        - Detail for the process of seating the femoral and tibial cutting guide in the proper location.
        - Detail regarding femoral and tibial cutting guide positioning and pinning, to ensure the guide is placed in the proper location.
        - A recommendation for surgeons to confirm alignment through the use of the Extra-Medullary Universal Goniometer verifying guide position after guide placement, and prior to bone resections. (Femoral and Tibial Preparation Steps).

Please follow the below instructions:

1. Ensure that unused subject devices are returned to your Stryker Distributor by **(INSERT DATE - 2 weeks after date of letter.)**
2. Circulate this Field Safety Notice internally to all interested/affected parties.
3. Maintain awareness of this notice internally until all required actions have been completed within your facility.
4. Inform Stryker if any of the subject devices have been distributed to other organisations.
    a. *Provide contact details so that Stryker can inform the recipients appropriately.*
5. Complete the attached customer response form.
    a. *Complete this form even if you do not have any product to return. This will preclude the need to Stryker to send any reminder notice*
    b. *Return the completed form by **(INSERT DATE)***
        i. *On receipt of the completed form, a Stryker representative will contact you to arrange for return of the subject devices.*
6. Please inform Stryker of any adverse events.
    a. Comply with any local regulations concerning the reporting of adverse events to your National Competent Authority

Stryker® Orthopaedics maintains its commitment to developing, manufacturing and marketing the highest quality products for surgeons and patients. We apologize for any inconvenience this Field Corrective Action may create and appreciate your cooperation with our request.

If you have any further enquiries, please contact **(INSERT LOCAL STRYKER REPRESENTATIVE).**

Yours

RA2013-060: List of Case Codes affected for your facility

Affected Case Codes by Issue	
Update to surgical protocol	**Inconsistent Values (Y or N)**

RA2013-060: Updates to the Femoral and Tibial Preparation Sections of the ShapeMatch Surgical Protocol are included in the following pages.

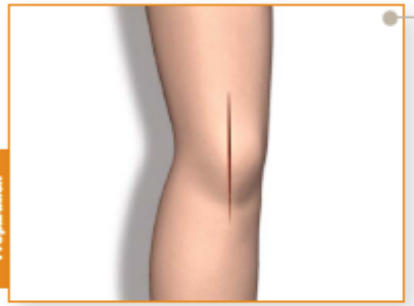


Figure 1: Exposure

Step 1: Surgical Approach and Exposure

1. Many surgical approaches may be utilized with the ShapeMatch Technology. Care should be taken to provide enough exposure to allow proper seating of the guide.
2. Flex the knee and make an anterior skin incision just medial to the mid-line. Start 1-2 finger breadths proximal to the patella and end at the tibial tubercle.
3. Release the medial synovium from the mid-point of the patella superiorly to the anterior surface of the distal femur proximal to the trochlear groove.
4. Excise the fat pad behind the patellar tendon from the jointline to the tibial tubercle.
5. Removal of anterior and distal femoral osteophytes is crucial to ensure proper seating of the Femoral ShapeMatch Cutting Guide.

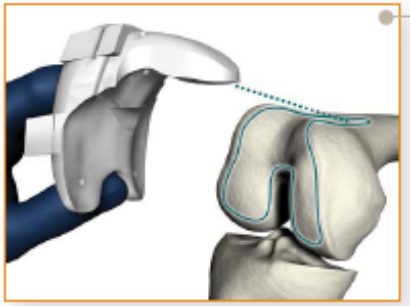


Figure 2a: Femoral Preparation

Step 2: Femoral Preparation

1. Position the knee in 70-90 degrees of flexion and retract the quadriceps muscle laterally to expose the anterior femoral cortex. Remove soft tissue from the anterior cortex, which allows the femoral cutting guide to seat directly on the anterior femoral cortex.
2. Place the femoral guide onto the distal femur by first contacting the anterior flange on the anterior cortex and then contacting the feet on the distal condyles. Center the guide medially and laterally on the distal femur (Figure 2a).
3. Seat the guide on the distal femur by compressing the guide as indicated in Figure 2b. Compress the guide simultaneously in the proximal and posterior directions. Maintain compression and toggle the guide internally and externally to allow the guide to find the intended seating position.

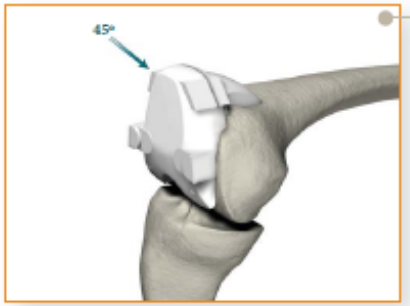


Figure 2b: Femoral Guide Placement

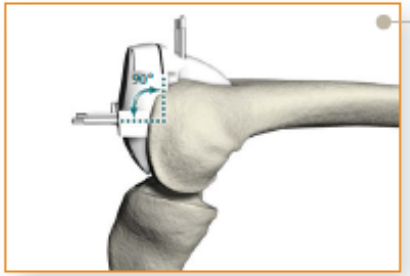


Figure 2c: Securing the Femoral Guide

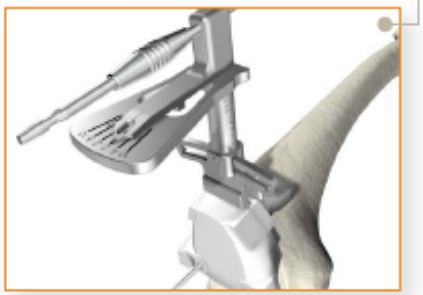


Figure 3: Alignment Check

Step 2: Femoral Preparation

4. Inspect the contact between the feet of the guide and the distal femoral condyles. The contour of the femoral guide feet should closely resemble the anatomy of the distal femoral condyle. Confirm the most proximal area of the anterior flange of the guide rests on the anterior femoral cortex. This aids in proper positioning of the femoral cutting guide.
5. Continue compression on the femoral guide in a manner that prevents any flexion or extension translation of the femoral guide. Drill the two articular pins into the distal femur (perpendicular to the cut plane and parallel to each other). Drill the two anterior pins next (parallel to the cut plane and each other). Inspect the contact between the feet and condyles, the contact between the anterior flange, and femoral cortex, and the medial-lateral positioning of the guide on the distal femur (Figure 2c), which verifies the position of the Femoral ShapeMatch Cutting Guide did not change during pinning.

Step 3: Extra-Medullary Alignment Check

1. It is recommended that surgeons should verify alignment prior to resection using the Triathlon Extra-Medullary (EM) Universal Goniometer. Insert EM Universal Goniometer into the Femoral ShapeMatch Cutting Guide by inserting the tongue into the resection slot and insert the Universal Alignment Rod into the EM Universal Goniometer.
2. Intra-operative alignment is verified when alignment rod intersects center of femoral head and surgeon confirms the corresponding angle referenced on the goniometer is satisfactory. After alignment is confirmed, remove EM Universal Goniometer from the Femoral ShapeMatch Cutting Guide. Additionally, the alignment rod can be viewed in the sagittal plane to assess flexion/extension orientation.

Note: If surgeon deems alignment or stability of the Femoral ShapeMatch Cutting Guide is unsatisfactory, discontinue use of the cutting guide and revert to standard Triathlon Knee Instruments which will be sterile and available as back-up for each procedure.

Figure 4: Distal Femoral Resection

Step 4: Distal Femoral Resection

1. Insert saw blade into the saw slot to start the distal femoral resection. Ensure that the saw is fully inserted and touching cortical bone before cutting is started.
2. Remove the medial pin and resect the medial femoral condyle.
3. Replace the medial pin, remove the lateral pin and resect the lateral femoral condyle.

Note: Femoral Sizing/Rotation: The Femoral ShapeMatch Cutting Guide identifies the femoral component size and rotational alignment as indicated in the surgeon pre-operative approval form.

For an alternative method to establish rotation, the traditional Triathlon Femoral Sizer can be used as described in the Triathlon surgical procedure.

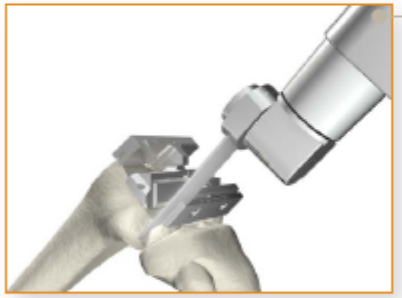


Figure 5: Femoral Anterior, Posterior and Chamfer Cuts

Step 5: Femoral Anterior, Posterior and Chamfer Cuts

1. Remove debris with pulse lavage and identify the two holes made by insertion of distal articular pins.
2. Insert the two pins on the Standard Triathlon 4-in-1 cutting block into the two holes identified.
3. Impact and fix 4-in-1 cutting block with pins.
4. Resect through 4-in-1 Cutting block slots.

Tips:

1. After inserting the two pins on the 4-in-1 cutting block, check that the anterior cut is flush with the anterolateral surface of the femur by inserting a saw blade or notch checker into the anterior saw slot.
2. Recommended sequence for bone resections using the 4-in-1 Cutting Block is:
   a) Anterior cortex b) Posterior condyles c) Posterior chamfer d) Anterior chamfer

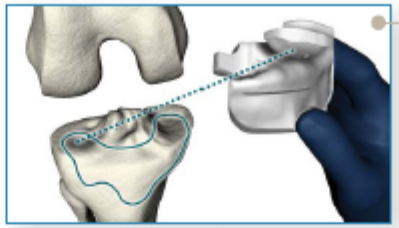


Figure 6a: Tibial Preparation

Figure 6b: Tibial Guide Placement

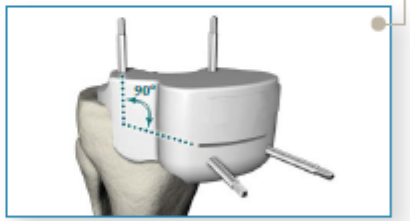


Figure 6c: Securing the Tibial Guide

Step 6: Tibial Exposure

1. Expose the tibia.
2. Excise the anterior cruciate ligament, menisci, and prominent anterior osteophytes. Preserve the posterior cruciate ligament.
3. Place retractor to protect the posterior cruciate ligament and present the tibia.

Step 7: Tibial Preparation

1. Place antero-lateral flange of Tibial ShapeMatch Cutting Guide behind patellar tendon to ensure lateral flange touches antero-lateral cortex (Figure 6a).
2. Internally rotate the guide while delivering the guide onto the articular surface ensuring the "feet" of the guide are seated on the articular surface.
3. While avoiding overly internally rotating the guide, causing the lateral flange to lose contact with the antero-lateral tibia, rotate the guide sufficiently to ensure that it is in contact with the antero-medial cortex directly behind the saw slot and anterior pin-hole position. Care should be taken to assure the guide is not resting on soft tissue, such as the meniscus that may be left. Verify that the "feet" of the guide are seated in the compartment and the guide is in contact across the entire anterior cortex, which will ensure a proper positioning of the guide (Figure 6b).
4. Fix the tibial guide by holding it in place, compressing at a 45 degree angle into the tibia, and drilling the two proximal the two proximal (articular) pins (perpendicular to the saw slot, parallel to each other). Ensure that the pins are fully inserted into the Tibial ShapeMatch Cutting Guide before drilling is started. Care should be taken to maintain Tibial ShapeMatch Cutting Guide position during pinning (Figure 6c).
5. Keeping the tibial guide fixed, drill the two the two anterior pins pins (parallel to the saw slot and each other).

Tips:

1. Approximately 70° of flexion allows for tibial tendon laxity to aid in guide placement. If needed, as an additional step to ensure accurate seating of the guide, you may compress and externally rotate the guide against the antero-lateral cortex. Do not externally rotate to the point that the tibial feet rise up or the guide loses contact on the antero-medial cortex.
2. The flange and the two tibial 'feet' on the guide should be in intimate contact with the surface of the tibial compartment.
3. Confirm that the guide fits snugly in place and the edges rest on bone or cartilage. Verify that the guide is secure on cortical bone and is not resting on soft tissue or instrumentation being utilized to gain access to the anatomy.
4. For Triathlon Tibial sizes 1 and 2: If there is a possibility that the tibial spines may interfere with the posterior drilling pin locations on the Tibial ShapeMatch Cutting Guide (due to the location of the posterior holes for these sizes as depicted in Figure 9A), the surgeon will be notified when reviewing the surgical plan. In these instances, the tibial guide may rock and not seat properly. It is advised that the surgeon evaluate the guide in these cases and if impingement or rocking is noted, the surgeon may remove the portion of the tibial spine height in this area to allow the guide to seat properly.

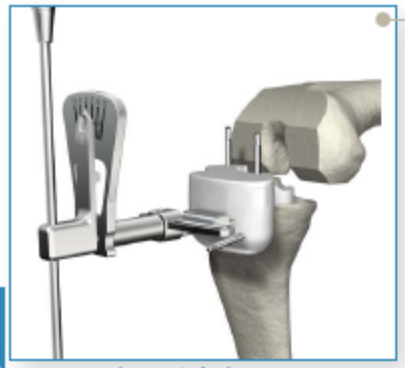
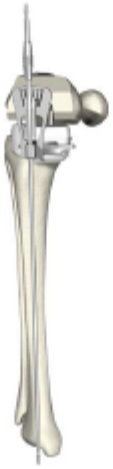


Figure 7: Alignment Check

Step 8: Extra-Medullary Alignment Check

1. It is recommended that surgeons should verify alignment prior to resection using the Triathlon Extra-Medullary (EM) Universal Goniometer. Insert EM Universal Goniometer into the Tibial ShapeMatch Cutting Guide by inserting the tongue into the resection slot and Universal Alignment Rod into the EM Universal Goniometer.
2. Intra-operative alignment is verified when the proximal portion of the EM Universal Goniometer is placed over the medial one third of the tibial tubercle, the alignment rod intersects the center of the ankle and surgeon confirms the corresponding angle referenced on the goniometer is satisfactory. After alignment is confirmed, remove EM Universal Goniometer from the Femoral ShapeMatch Cutting Guide. Additionally, the alignment rod can be viewed in the sagittal plane to assess flexion/extension orientation.



Note: If surgeon deems alignment or stability of the Tibial ShapeMatch Cutting Guide is unsatisfactory, discontinue use of the cutting guides and revert to standard Triathlon Knee Instruments which will be sterile and available as back-up for each procedure.

Note: The two anterior pins on the Tibial ShapeMatch Cutting Guide will align with the holes identified by the "0" mark on the standard Triathlon Tibial Resection Guide (part # 6541-2-700,701). The "-2" holes will lower the resection slot 2mm from the level of the resection slot of the Tibial ShapeMatch Cutting Guide.

Figure 8: The Tibial Resection

Step 9: The Tibial Resection

1. Insert sawblade into the saw slot to make the proximal tibial resection. Ensure that the saw is fully inserted and touching cortical bone before the resection is started.
2. Remove medial pin and cut the medial half of the tibia. Replace medial pin. Remove lateral pin and cut the remaining tibia.
3. Remove tibial guide and elevate resected bone fragment. Remove cut portion of tibial plateau, preserving posterior insertion of the PCL.

Tips:

1. Remove all osteophytes including femoral ones obscured by overlying collaterals. For posterior osteophytes, flex knee to 90°, insert a laminar spreader and use a curved ½ inch osteotome.
2. Remove any soft tissue (meniscus) that could potentially be trapped behind the posterior retractor during initial menisci resection.

3. In certain instances, the MRI may indicate the location of the cut plane may be near the insertion point of the Posterior Cruciate Ligament. In these instances, the surgeon will be notified when reviewing the surgical plan.

   The Posterior Cruciate Ligament may still be vulnerable, proceed with caution making the posterior cut with the tibial guide. If it is necessary to sacrifice the Posterior Cruciate Ligament, utilize a Triathlon CS insert.

4. In certain instances, the MRI indicates that the insertion point for the patellar ligament is unusually high. The location of the tibial cut plane may be very near the insertion point for the patella ligament. As a result, the cut plane has been raised slightly to compensate for this.

   Due to the unique anatomy of the patient, the cut plane may not be raised enough to eliminate the tissue. Proceed with caution when making the horizontal cut with the tibial guide. The patellar ligament may still be exposed to the cut blade.

   If any or all of the above information is relevant to a patient it will be noted when the surgeon reviews the surgical plan.

Important Note – To set rotation:

For Triathlon Sizes 1 and 2 Tibial Components

There are no anterior holes on the Universal Tibial Template Sizes 1 & 2 to help set rotation.

Use the two posterior holes on the Tibial ShapeMatch Cutting Guide to help set rotation for sizes 1 & 2.

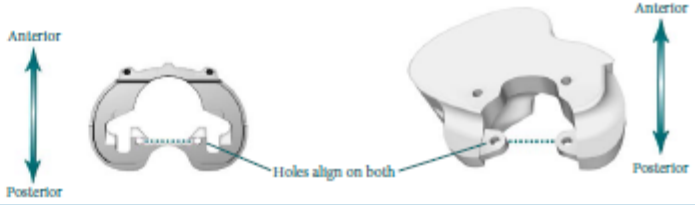


Figure 9A: For Triathlon Sizes 1 and 2 Tibial Components

For Triathlon Sizes 3–8 Tibial Components

Use anterior holes on Universal Tibial Template for Sizes 3-8 to help set rotation.

Holes in Custom-Fit guides for Sizes 3-8 do align with anterior holes on Universal Tibial Template to help set rotation.

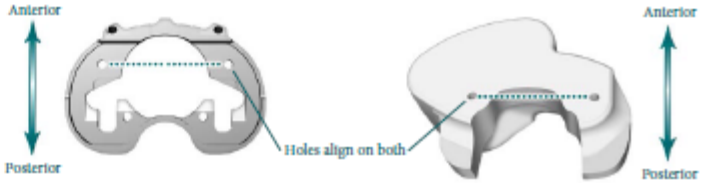


Figure 9B: For Triathlon Sizes 3–8 Tibial Components

RA2013-060: PFA ACKNOWLEDGMENT FORM

Description: OtisMed ShapeMatch Cutting Guides
Catalogue No: TR3100-L, TR3100-R
Case Codes Noted below

I acknowledge receipt of the Field Safety Notice for RA2013-060 and can confirm that:

We have not located any of these devices in our inventory: *(please delete if not applicable)*				
We have located the following devices:				
Product description	**Case Codes**		**Qty**	**Qty Quarantined**
We have further distributed subject devices to the following organizations:				
Facility Name				
Facility Address				
Form completed by:				
Contact Name		**Contact Facility**		
Contact Address		**Contact Position**		
		Contact Tel No		
		Contact Fax No		
		Contact e-mail		

Please return the completed form to: