

URGENT – Field Safety Notice

Commercial name of the affected product	GMK UNI Femur sizes 3 & 4 – non anatomic version
FSCA-identifier	FSCA 2019-01 of 22 Feb 2019
Type of action	Advisory notice

Affected Product

Description	Reference code	Lot numbers
GMK UNI Femur size 3 – non anatomic version	02.08.0003	070924, 080221, 082174, 083387, 090647, 092150, 092991, 102937, 103938, 104394, 110623, 112137, 112683, 114335
GMK UNI Femur size 4 – non anatomic version	02.08.0004	070923, 080222, 082173, 083385, 090646, 091365, 103652, 104393

1. Description of advisory:

Based on post-market surveillance monitoring, it has been observed that the occurrence rates for “breakage” are higher than anticipated for the GMK UNI Cemented Femur sizes 3 & 4, non-anatomic version manufactured between 2007 and 2011 (lot numbers and reference codes listed above).

Size 3:

The involved version of this device was utilized between August 2007 and August 2014, with a total of 263 cases. To date, we have registered 2 reports of breakage for the involved femoral component, with no discernible correlation to time, patient population, or other factors.

No breakages have been notified following surgeries performed after August 2014. No unused items of the listed lots remain on the market.

Size 4:

The involved version of this device was utilized between September 2007 and April 2011, with a total of 130 cases. To date, we have registered 14 reports of breakage for the involved femoral component, with no discernible correlation to time, patient population, or other factors.

No breakages have been notified following surgeries performed after April 2011. No unused items of the listed lots remain on the market.

No breakages have ever been reported on any lot of the other two existing sizes of the device: size 1 and size 2.

2. Action to take:

- Even though breakage of the component cannot be discerned before it has actually happened, we recommend surgeons that have implanted the involved lots to be mindful of this potential issue during patient follow-ups conducted in alignment with the Instructions for Use of the system.
- Forward this notice to all people and organizations potentially affected.

3. Contact person and return address:

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We apologize for this inconvenience and confirm our commitment to patient safety and surgeon support.

Sincerely,

Stefano Baj
Regulatory Affairs Manager