

Smith & Nephew, Inc.

Global Field Actions
1450 Brooks Road
Memphis, TN 38116
Tennessee, USA

T: + 1 901 396 2121
T: 1 800 821 5700 (USA toll free)
www.smith-nephew.com

Smith+Nephew**Urgent Medical Device Recall Notice
R-2020-13**

July 16, 2020

<Insert Address>

This letter is to inform you that Smith & Nephew, Inc. has initiated a field action to voluntarily remove multiple lots of GENESIS II Tibial Base Plates due to an inconsistency in the raw material process. A review of the raw material manufacturing process identified that specific lots may contain units with internal non-homogenous material defects.

Please see product details below:

Product Number	Description	Lot Numbers
71420164	GENESIS II CMT TIB SIZE 3 LEFT	See attached
71420166	GENESIS II CMT TIB SIZE 4 LEFT	
71420184	GENESIS II CMT TIB SIZE 4 RIGHT	

Shipment Dates: December 16, 2019 through June 15, 2020

Potential Risk of Use of the Product

In the most likely scenario, the device is free of internal defects and performs as intended. In the worst-case scenario, the material defect is present in the tibia base plate which could lead to premature failure of the device resulting in fracture. A failure resulting in fracture would lead to a revision surgery. There have been no instances of the worst-case scenario reported to date.

Required Actions:

Please follow the instructions on the attached Response Form.

Enclosure: Response Form, Product and Lot Numbers and Physician Communication

1450 Brooks Road
Memphis, TN 38116
USA

1-901-396-2121
1-800-821-5700
www.smith-nephew.com

Urgent Medical Device Recall Notice R-2020-13

July 16, 2020

<Insert Address>

PLEASE COMPLETE ALL ITEMS AND RETURN WITHIN 5 DAYS OF RECEIPT

Required Actions:

1. Please inspect your inventory and locate any devices from the listed product and batch numbers enclosed with this Urgent Medical Device Recall Notice, and quarantine them immediately.
 - a. If you are a sales rep or distributor, you must notify your customers of the field action and ensure that the required actions are complete.
 - b. Include the customer's account number and name in the table below.
2. Please provide a copy of the attached Physician Communication to the surgical staff.
3. If you have no product to return, please put an X in the appropriate location below.
4. If you have product to return, please list the item, batches and quantities that you are returning in the appropriate boxes below.
5. Complete the remainder of the form, sign and send to FieldActions@smith-nephew.com.
Please Note – even if you have no product to return, this form must be completed, signed and returned.
6. Once the form is received by Smith & Nephew, you will be sent a Return Authorization (RA) number.

If you have any questions or concerns regarding this recall please contact FieldActions@smith-nephew.com.

No Product to Be Returned

☐

Hospital Account #/ District Office Name	Sales Area #/Name	Product Part Number	Batch Number	Quantity of Units to be Returned	RA Number (for internal use only)

We hereby confirm that we are aware of this Medical Device Field Action and it has been communicated within our organization and surgical staff.

Printed Name (required): _____ Title: _____

District Name or Institution: _____ Address: _____

Signature (required): _____ Date (required): ____/____/____

Email: _____ Telephone: (____) _____ - _____

Return affected product to: Smith & Nephew | Attn: Global Field Actions | Building G, 1450 Brooks Rd. East | Memphis, TN 38116

1450 Brooks Road
Memphis, TN 38116
USA

1-901-396-2121
1-800-821-5700
www.smith-nehew.com

List of affected batches – Tuttlingen

Material	Batch	Material Description
71420184	19MT31457	GNS II CMT TIB SIZE 4 Ø RIGHT
71420184	19MT31458	GNS II CMT TIB SIZE 4 Ø RIGHT
71420184	19MT31459	GNS II CMT TIB SIZE 4 Ø RIGHT
71420166	20AT32611	GNS II CMT TIB SIZE 4 LEFT
71420166	20AT32612	GNS II CMT TIB SIZE 4 LEFT
71420166	20AT32613	GNS II CMT TIB SIZE 4 LEFT
71420166	20AT33540	GNS II CMT TIB SIZE 4 LEFT
71420166	20AT33541	GNS II CMT TIB SIZE 4 LEFT
71420166	20AT33542	GNS II CMT TIB SIZE 4 LEFT
71420166	20AT33543	GNS II CMT TIB SIZE 4 LEFT
71420166	20AT33544	GNS II CMT TIB SIZE 4 LEFT
71420166	20AT33545	GNS II CMT TIB SIZE 4 LEFT
71420166	20AT33546	GNS II CMT TIB SIZE 4 LEFT
71420166	20AT33547	GNS II CMT TIB SIZE 4 LEFT
71420166	20AT33548	GNS II CMT TIB SIZE 4 LEFT
71420184	20AT33569	GNS II CMT TIB SIZE 4 Ø RIGHT
71420184	20AT33570	GNS II CMT TIB SIZE 4 Ø RIGHT
71420184	20AT33571	GNS II CMT TIB SIZE 4 Ø RIGHT
71420166	20BT33856	GNS II CMT TIB SIZE 4 LEFT
71420166	20BT33857	GNS II CMT TIB SIZE 4 LEFT
71420166	20BT33858	GNS II CMT TIB SIZE 4 LEFT
71420166	20BT33859	GNS II CMT TIB SIZE 4 LEFT
71420166	20BT33860	GNS II CMT TIB SIZE 4 LEFT
71420166	20BT33861	GNS II CMT TIB SIZE 4 LEFT
71420166	20BT33862	GNS II CMT TIB SIZE 4 LEFT
71420166	20BT33863	GNS II CMT TIB SIZE 4 LEFT
71420166	20BT33864	GNS II CMT TIB SIZE 4 LEFT
71420166	20BT33865	GNS II CMT TIB SIZE 4 LEFT
71420166	20BT33866	GNS II CMT TIB SIZE 4 LEFT
71420184	20BT33878	GNS II CMT TIB SIZE 4 Ø RIGHT
71420184	20BT33879	GNS II CMT TIB SIZE 4 Ø RIGHT
71420184	20BT33880	GNS II CMT TIB SIZE 4 Ø RIGHT
71420184	20BT33881	GNS II CMT TIB SIZE 4 Ø RIGHT
71420184	20BT33882	GNS II CMT TIB SIZE 4 Ø RIGHT
71420184	20BT33883	GNS II CMT TIB SIZE 4 Ø RIGHT
71420184	20BT33884	GNS II CMT TIB SIZE 4 Ø RIGHT
71420184	20BT33885	GNS II CMT TIB SIZE 4 Ø RIGHT
71420184	20BT33886	GNS II CMT TIB SIZE 4 Ø RIGHT
71420184	20BT33887	GNS II CMT TIB SIZE 4 Ø RIGHT
71420184	20BT33888	GNS II CMT TIB SIZE 4 Ø RIGHT
71420184	20BT33889	GNS II CMT TIB SIZE 4 Ø RIGHT
71420166	20BT34357	GNS II CMT TIB SIZE 4 LEFT
71420166	20BT34358	GNS II CMT TIB SIZE 4 LEFT
71420166	20BT34359	GNS II CMT TIB SIZE 4 LEFT
71420166	20BT34360	GNS II CMT TIB SIZE 4 LEFT
71420184	20BT34379	GNS II CMT TIB SIZE 4 Ø RIGHT
71420184	20BT34380	GNS II CMT TIB SIZE 4 Ø RIGHT
71420184	20BT34381	GNS II CMT TIB SIZE 4 Ø RIGHT
71420184	20BT34382	GNS II CMT TIB SIZE 4 Ø RIGHT
71420184	20BT34383	GNS II CMT TIB SIZE 4 Ø RIGHT
71420184	20BT34384	GNS II CMT TIB SIZE 4 Ø RIGHT
71420184	20BT34385	GNS II CMT TIB SIZE 4 Ø RIGHT
71420184	20BT34386	GNS II CMT TIB SIZE 4 Ø RIGHT

1450 Brooks Road
Memphis, TN 38116
USA

1-901-396-2121
1-800-821-5700
www.smith-nehew.com

List of affected batches – Aarau

Material	Material Description	Batch
71420164	GNS II CMT TIB SIZE 3 LEFT	H2008427
71420166	GNS II CMT TIB SIZE 4 LEFT	G1923903
71420166	GNS II CMT TIB SIZE 4 LEFT	G1923904
71420166	GNS II CMT TIB SIZE 4 LEFT	G1923905
71420166	GNS II CMT TIB SIZE 4 LEFT	G1923933
71420166	GNS II CMT TIB SIZE 4 LEFT	G1923934
71420166	GNS II CMT TIB SIZE 4 LEFT	G1923935
71420166	GNS II CMT TIB SIZE 4 LEFT	G1923936
71420166	GNS II CMT TIB SIZE 4 LEFT	G1923964
71420166	GNS II CMT TIB SIZE 4 LEFT	G1923965
71420166	GNS II CMT TIB SIZE 4 LEFT	G1923966
71420166	GNS II CMT TIB SIZE 4 LEFT	G1923967
71420166	GNS II CMT TIB SIZE 4 LEFT	G1923992
71420166	GNS II CMT TIB SIZE 4 LEFT	G1923993
71420166	GNS II CMT TIB SIZE 4 LEFT	G1923994
71420166	GNS II CMT TIB SIZE 4 LEFT	G1924450
71420166	GNS II CMT TIB SIZE 4 LEFT	G1924451
71420166	GNS II CMT TIB SIZE 4 LEFT	G1924452
71420166	GNS II CMT TIB SIZE 4 LEFT	G1924453
71420166	GNS II CMT TIB SIZE 4 LEFT	G1924480
71420166	GNS II CMT TIB SIZE 4 LEFT	G1924481
71420166	GNS II CMT TIB SIZE 4 LEFT	G1924482
71420166	GNS II CMT TIB SIZE 4 LEFT	G1924483
71420166	GNS II CMT TIB SIZE 4 LEFT	G1924512
71420166	GNS II CMT TIB SIZE 4 LEFT	G1924513
71420166	GNS II CMT TIB SIZE 4 LEFT	G1924514
71420166	GNS II CMT TIB SIZE 4 LEFT	G1924543
71420166	GNS II CMT TIB SIZE 4 LEFT	G1924544
71420166	GNS II CMT TIB SIZE 4 LEFT	G1924545
71420166	GNS II CMT TIB SIZE 4 LEFT	G1924571
71420166	GNS II CMT TIB SIZE 4 LEFT	G1924572
71420166	GNS II CMT TIB SIZE 4 LEFT	G1924573
71420166	GNS II CMT TIB SIZE 4 LEFT	G1925072
71420166	GNS II CMT TIB SIZE 4 LEFT	G1925073
71420166	GNS II CMT TIB SIZE 4 LEFT	G1925074
71420166	GNS II CMT TIB SIZE 4 LEFT	G1925075
71420166	GNS II CMT TIB SIZE 4 LEFT	G1925102
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925106
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925107
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925108
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925109
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925137
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925138
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925139
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925140
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925165
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925166
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925167
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925168
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925194
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925195
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925622
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925623
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925624
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925625
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925651
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925652

1450 Brooks Road
Memphis, TN 38116
USA

1-901-396-2121
1-800-821-5700
www.smith-nehew.com

71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925653
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925654
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925682
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925683
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925684
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925685
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925712
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925713
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925714
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925715
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925741
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1925742
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1926271
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1926272
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1926273
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1926274
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1926301
71420184	GNS II CMT TIB SIZE 4 Ø RIGHT	G1926302

Physician Communication

Smith+Nephew Action: Voluntary Recall
Recall Reference: R-2020-13
Affected Product: GENESIS II Tibial Base Plates
Details of Affected Product: See attached

Dear Doctor,

This letter is to inform you of a voluntary recall for specific lots of GENESIS II Tibial Base Plates manufactured by Smith+Nephew, Inc. USA.

Background

Smith+Nephew identified non-homogeneous material irregularities during manufacturing of two devices. A review of the raw material manufacturing process identified that related lots may also contain units with internal, non-homogeneous material irregularities that were not detected during product inspections. While only some of the devices in the specified lots are potentially impacted, Smith+Nephew is performing a voluntary recall of all the units from the specified lots.

Actions

In the most likely scenario, the device is free of internal defects and performs as intended. In the worst-case scenario, the material defect is present in the tibia base plate which could lead to premature failure of the device resulting in fracture. A failure resulting in fracture would lead to a revision surgery. This worst case scenario has not been reported.

Smith+Nephew recommends that physicians maintain their routine patient follow-up protocol for implanted GENESIS II Tibial Base Plates identified in the scope of this voluntary recall.

As part of the execution of the voluntary recall, your facility manager is asked to acknowledge receipt and distribution of this letter, as applicable. In addition, they are asked to manage affected devices per the associated Urgent Medical Device Recall Notice.

Smith+Nephew is committed to distributing quality products that are safe and effective and providing support to surgeons who use those products.

If you have any questions, please contact me on the following email fieldactions@smith-nephew.com.

Yours sincerely,

Dr. Luca Orlandini MD
Vice President Medical Affairs

Smith+Nephew