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Global Field Actions
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Smith+Nephew

[Recipients Address]

July 22, 2020

URGENT FIELD SAFETY NOTICE:
Medical Device Field Safety Notice for Recall

Reference: R-2020-13
Concerned Devices: GENESIS II TIBIAL BASE PLATES

Product No.	Description	Batch No.
71420164	GENESIS II CMT TIB SIZE 3 LEFT	See appendix 1
71420166	GENESIS II CMT TIB SIZE 4 LEFT	
71420184	GENESIS II CMT TIB SIZE 4 RIGHT	

Dear Customer:

This letter is to inform you that Smith & Nephew, Inc. has initiated a field safety corrective 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.

Risks to Health	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.
Actions to be taken by the user	1. Locate and quarantine affected unused devices immediately. 2. Please provide a copy of the attached Physician Communication to the surgical staff. 3. Return quarantined product to your national Smith+Nephew agency/distributor. 4. Complete the return slip and e-mail it to your national Smith+Nephew agency/distributor. 5. Please make sure this safety information is passed on to all those who need to be aware of it within your organization. 6. Please maintain awareness on this notice and resulting action until the Field Safety Notice for Recall is terminated to ensure effectiveness of the action.

Smith+Nephew is committed to distribute only products of the highest quality standards and to provide any required support. We regret that this has occurred and any inconvenience it may cause or has caused you, your patients, or your staff.

If you have any questions please feel free to contact us under the following contact details:

Contact Details of Subsidiary / Distributor

Return Slip

Please complete and return this feedback information to the contact specified above to prevent repetitive enquires.

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

In our facility we have _____ *[Qty]* concerned devices which we will return.

_____ *[Qty]* concerned devices have been discarded in our facility.

Institution: _____ Reference: R-2020-13

Name: _____ Date / Signature: _____

Enclosure:

- Product number, Batch and Product Description List
- Physician Communication

Smith+Nephew

Appendix 1

List of affected batches – Tuttlingen

Material	Batch	Material Description
71420184	19MT31457	GNS II CMT TIB SIZE 4 {} RIGHT
71420184	19MT31458	GNS II CMT TIB SIZE 4 {} RIGHT
71420184	19MT31459	GNS II CMT TIB SIZE 4 {} 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 {} RIGHT
71420184	20AT33570	GNS II CMT TIB SIZE 4 {} RIGHT
71420184	20AT33571	GNS II CMT TIB SIZE 4 {} 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 {} RIGHT
71420184	20BT33879	GNS II CMT TIB SIZE 4 {} RIGHT
71420184	20BT33880	GNS II CMT TIB SIZE 4 {} RIGHT
71420184	20BT33881	GNS II CMT TIB SIZE 4 {} RIGHT
71420184	20BT33882	GNS II CMT TIB SIZE 4 {} RIGHT
71420184	20BT33883	GNS II CMT TIB SIZE 4 {} RIGHT
71420184	20BT33884	GNS II CMT TIB SIZE 4 {} RIGHT
71420184	20BT33885	GNS II CMT TIB SIZE 4 {} RIGHT
71420184	20BT33886	GNS II CMT TIB SIZE 4 {} RIGHT
71420184	20BT33887	GNS II CMT TIB SIZE 4 {} RIGHT
71420184	20BT33888	GNS II CMT TIB SIZE 4 {} RIGHT
71420184	20BT33889	GNS II CMT TIB SIZE 4 {} 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 {} RIGHT
71420184	20BT34380	GNS II CMT TIB SIZE 4 {} RIGHT
71420184	20BT34381	GNS II CMT TIB SIZE 4 {} RIGHT
71420184	20BT34382	GNS II CMT TIB SIZE 4 {} RIGHT
71420184	20BT34383	GNS II CMT TIB SIZE 4 {} RIGHT
71420184	20BT34384	GNS II CMT TIB SIZE 4 {} RIGHT
71420184	20BT34385	GNS II CMT TIB SIZE 4 {} RIGHT
71420184	20BT34386	GNS II CMT TIB SIZE 4 {} RIGHT

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 {} RIGHT	G1925106
71420184	GNS II CMT TIB SIZE 4 {} RIGHT	G1925107
71420184	GNS II CMT TIB SIZE 4 {} RIGHT	G1925108
71420184	GNS II CMT TIB SIZE 4 {} RIGHT	G1925109
71420184	GNS II CMT TIB SIZE 4 {} RIGHT	G1925137
71420184	GNS II CMT TIB SIZE 4 {} RIGHT	G1925138
71420184	GNS II CMT TIB SIZE 4 {} RIGHT	G1925139
71420184	GNS II CMT TIB SIZE 4 {} RIGHT	G1925140
71420184	GNS II CMT TIB SIZE 4 {} RIGHT	G1925165
71420184	GNS II CMT TIB SIZE 4 {} RIGHT	G1925166
71420184	GNS II CMT TIB SIZE 4 {} RIGHT	G1925167
71420184	GNS II CMT TIB SIZE 4 {} RIGHT	G1925168
71420184	GNS II CMT TIB SIZE 4 {} RIGHT	G1925194
71420184	GNS II CMT TIB SIZE 4 {} RIGHT	G1925195
71420184	GNS II CMT TIB SIZE 4 {} RIGHT	G1925622
71420184	GNS II CMT TIB SIZE 4 {} RIGHT	G1925623
71420184	GNS II CMT TIB SIZE 4 {} RIGHT	G1925624
71420184	GNS II CMT TIB SIZE 4 {} RIGHT	G1925625
71420184	GNS II CMT TIB SIZE 4 {} RIGHT	G1925651
71420184	GNS II CMT TIB SIZE 4 {} RIGHT	G1925652

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

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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,

xxx