

[Recipients Address]

November 16, 2016

URGENT FIELD SAFETY NOTICE: Medical Device Field Safety Corrective Action / Recall

Reference: R-2016-40

Concerned Devices: REFLECTION® Dead Blow Mallet

Product No.	Description	Product No.
71362106	Reflection Dead Blow Mallet	See attached

Dear Dr.

This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary field safety corrective action of its DEAD BLOW MALLET ('the Mallet'). A number of complaints have been received in relation to cracking of the welds on the head of the Mallet. In a small number of reported cases, the cracks in the welding resulted in some lead beads escaping from the head of the Mallet.

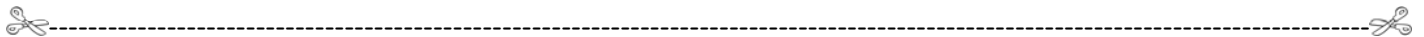
Context

The Mallet is a standard surgical instrument used mostly in hip replacement surgery for general impaction of broaches and of hip implants. It was first placed on the market by Smith & Nephew in 1995.

This field action has been reported to the relevant competent authorities.

Risks to Health	Smith & Nephew has received a small number of complaints reporting cracks the welds located on the head of the mallet which is filled with lead beads. In the reported cases some of the lead beads and particles escaped from the mallet into the surgical wound. As these failures occurred intraoperatively and appropriate actions were taken to remove the lead beads from the wound during surgery, no further adverse effects were reported. Smith & Nephew is recalling the mallets as the risk of lead escaping from the mallet and the potential adverse effects associated with lead exposure were previously unidentified risks. Based on the low occurrence (0.03%) of the worst case failure mode defined above and the high detectability should any lead beads escape into the surgical wound, no proactive follow-up is recommended.
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Actions to be taken by the user	1. Locate and quarantine affected devices immediately. 2. Return quarantined product to your national Smith & Nephew agency/distributor. 3. Complete the return slip and fax it to your national Smith & Nephew agency/distributor. 4. Please make sure this safety information is passed on to all those who need to be aware of it within your organization. 5. Please maintain awareness on this notice and resulting action until the Field Safety Corrective Action is terminated to ensure effectiveness of the action.
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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 Notice concerning the REFLECTION Dead Blow Mallet. The Field Safety Notice was communicated within our organisation.

Please mark accordingly:

- ☐ In our facility we do not have any of the affected product in stock
 or
☐ We will return the following products:

Product	Description	Lot Number	Number Returned
71362106	Reflection Dead Blow Mallet		

Institution: _____ Reference: R-2016-40

Name: _____ Date / Signature: _____

Appendix 1 – Affected Batch Numbers

Item 71362106-Reflection Dead Blow Mallet Affected Batches				
606861	606862	606863	606864	701432
701433	808421	808422	1200840	50903653
60708545	60806634	61005467	70704991	70907344
71002434	71106654	71106655	80603593	80603594
80609278	80610026	80807064	81007463	81108699
81202445	90309401	90309402	90309937	90309941
90309943	7136210699	00701432A	01BM13815	01BM13816
01GM03498	01GM03503	01GM03504	01GM03506	01JM01382
02DM06721	02DM06722	02EM06595	02FM01963	02LM00998
02LM01099	02LM01100	02MM02211	02MM02211A	03CM01191
03EM04694	03HM11994	03KM13414	04AM06979	04BM09860
04DM13907	04DM17920	04DM17921	04EM07129	04EM07132
04GM03326	04GM03327	04GM03328	04GM03329	04GM03330
04KM01861	04KM13683	04KM13684	04MM02700	04MM02701
05AM14642	05AM14643	05AM14644	05AM14645	05AM14646
05AM14646A	05EM08660	05EM08661	05FM07198	05FM07199
05GM00620	05GM00621	05GM00622	05GM01203	05GM01204
05GM01205	05GM02670	05GM02671	05GM05689	05GM05690
05GM05692	05GM08285	05GM08286	05GM08287	05HM03895
05HM03896	05HM07787	05HM07788	05HM07789	05HM07790
05HM07791	05HM08138	05HM08139	05HM08140	05HM12179
05HM12180	05JM02349	05JM02350	05LM11363	05LM11364
05LM11365	05MM07114	05MM07115	05MM07116	06AM12304
05MM07114	06DM06240	06FM08915	07AM04686	07EM23206
05MM07115	06DM08506	06GM03246	07AM04687	07EM23207
05MM07116	06DM08507	06GM03247	07AM04688	07EM23207A
06AM12304	06DM08508	06GM04389	07AM04689	07EM23208
06AM12306	06DM08510	06GM04390	07BM11025	07FM13912
06AM12307	06DM08511	06HM04336	07BM11027	07FM22176
06BM06458	06DM08513	06HM04337	07BM11028	07FM22177
06BM06459	06DM14258	06HM13309	07CM20766	07FM22177R
06BM06460	06EM07997	06HM13310	07CM20767	07FM22179
06DM03707	06EM07998	06HM13311	07CM20769	07FM22180
06DM03709	06EM07999	06HM13312	07CM20770	07FM22180R
06DM03710	06EM08000	06KM05142	07CM20772	07FM22181
06DM04641	06EM08001	06KM05143	07CM20773	07FM22181R
06DM04642	06EM08913	06KM05144	07DM20507	07GM15214
06DM04643	06EM08914	06KM09904	07DM20511	07JM08242
06DM04644	06EM08915	06KM09905	07DM20512	07JM08244
06DM04645	06EM08916	06LM07300	07DM20513	07JM08246
06DM04646	06EM08917	06LM07302	07DM20517	07JM08248
06DM06236	06EM15667	06MM06711	07EM17133	07JM08253
06DM06237	06EM15668	06MM06712	07EM17134	07JM08254
06DM06238	06EM18051	07AM04684	07EM17135	07JM08254R
06DM06239	06FM05947	07AM04685	07EM17139	07JM08256

07KM02873	08GM15339	09EM01236	10MM09446	11MM06903
07KM02875	08GM15340	09EM01237	10MM09448	12BM07223
07KM02876	08GM15341	09EM01238	10MM09450	12BM10723
07KM02877	08GM15342	09EM01239	11AM08358	12BM10724
07KM17062	08HC08114	09EYW0009	11AM08358A	12BM17244
07KM17063	08HM08096	09EYW0009A	11AM08359	12BM17245
07KM23733	08HM08100	09EYW0009B	11AM08359A	12BM18966
07KM23734	08HM08101	09EYW0009C	11AM08360	12CM17458
07KM23735	08HM08104	09EYW0009D	11AM08361	12DM05835
07LM10125	08HM08105	09EYW0009E	11AM08364	12DM05835A
07LM10126	08HM08106	09EYW0010	11AM10562	12DM05836
07LM10127	08HM08107	09EYW0010A	11AM10564	12DM05836A
07LM10128	08HM08108	09EYW0010B	11AM10566	12DM10416
07LM10129	08HM08109	09EYW0010C	11AM10566A	12DM10417
07LM13415	08HM08110	09EYW0011	11AM11219	12DM10420
07LM13416	08HM08111	09EYW0011A	11AM11221	12DM10420A
07LM13417	08HM08113	09EYW0011B	11CM04420	12EM00715
07LM13418	08HM08114	09EYW0011C	11CM06074	12EM00717
07LM13419	08HM08115	09EYW0011D	11CM15011	12EM00717A
07LM13420	08HM08116	09EYW0011E	11DM02748	12EM04424
07MM13910	08MM15605	09EYW0011F	11EM14498	12EM04425
07MM13911	08MM15605A	09EYW0012	11EM16916	12EM07109
07MM13911R	08MM15606	09EYW0012A	11FM04754	12EM07110
07MM13912	08MM15608	09EYW0012B	11FM04759	12EM07111
07MM13912R	08MM15609	09EYW0012C	11FM04761	12GM06808
07MM13914	08MM15611	09EYW0012D	11FM04767	12GM11585
07MM13915	09AM19274	09EYW0013	11GM05674	12HM06211
07MM13917	09AM19276	09EYW0013A	11GM05675	12HM06213
07MM13917R	09BM09445	09EYW0013B	11GM05676	12HM06213A
08AM04897	09BM09447	09EYW0013C	11GM10213	12HM06215
08EM13465	09BM09449	09MM09122	11HM09823	12HM06216
08EM19975	09BM09450	10GM03167	11HM11556	12HM10408
08FM09824	09BM15217	10GM05180	11HM15618	12HM11856
08FM09826	09BM15219	10HM00478	11HM15619	12HM11857
08FM09827	09BM15220	10HM00480	11HM15620	12HM11857R
08FM09829	09BM15217	10HM01652	11HM15620A	12JM00568
08FM11005	09BM15219	10HM08505	11JM06646	12JM00569
08FM11006	09BM15220	10HM08505R	11KM03092	12JM00569A
08FM16340	09BMO9445	10HM11149	11KM03094	12JM00570
08FM16341	09BMO9450	10HM11149R	11KM03095	12JM00571
08FM16342	09CM18713	10HM16824	11KM03096	12JM00572
08FM16343	09CM18715	10HM16824R	11KM03097	12JM00573
08FM16344	09CM18717	10HM16824S	11MM06746	12JM04979
08FM16345	09CM18715	10LM01590	11MM06746A	12JM04981
08GM15336	09DM13396	10MM09443	11MM06894	12JM04983
08GM15337	09DM13399	10MM09444	11MM06898	12KM16512
08GM15338	09DM13400	10MM09445	11MM06901	12KM16513

12KM16514	14BM01667	14MM09041	16BM15809
12KM16515	14BM01668	14MM13547	16BM15810
12KM17287	14BM01669	15AM02615	16BM15811
12LM02029	14BM01670	15AM08843	16BM20892
12LM02109	14BM01671	15CM15790	16CM00513
12LM07522	14BM01672	15DM07667	16CM01482
13BM15733	14BM01673	15DM08587	16CM01483
13CM12241	14BM04157	15DM10613	16CM08603
13CM12244	14BM04158	15DM12768	16EM01010
13DM05887	14BM04159	15DM13536	16EM01012
13DM05888	14BM04160	15DM13537	16EM13209
13DM09094	14BM04160R	15DM20374	16EM13210
13DM11253	14CM16664	15EM03979	16EM13211
13DM19796	14CM17194	15FM16705	16EM18044
13DM20982	14DM00236	15FM16706	16EM18046
13DM20982A	14DM08760	15JM03486	16FM01913
13EM09454	14DM08761	15JM03487	16FM03541
13EM09455	14DM13479	15JM03488	16FM11256
13FM02852	14EM05451	15JM05522	16FM11257
13FM18101	14EM06451	15JM05523	16FM11258
13FM18102	14EM11507	15JM05524	16FM15697
13FM18102A	14EM18730	15JM05525	16FM15698
13GM09614	14EM22863	15JM05526	16FM15699
13GM09615	14EM22864	15JM14855	16FM15700
13GM10866	14FM01204	15JM14999	16GM14186
13GM20305	14FM01205	15JM15003	16GM14187
13HM01391	14FM17260	15JM15004	16GM18830
13HM04334	14GM01262	15JM15005	61005467A
13HM20062	14GM03572	15JM15006	70907344A
13JM09524	14GM10619	15JM15008	71106654A
13JM09525	14GM12600	15JM15788	71106655A
13JM09526	14GM14974	15JM15789	80603594A
13JM10159	14GM18996	15JM15790	80609278A
13KM08048	14HM04314	15JM15791	
13KM08052	14HM18762	15LM09208	
13KM10776	14JM06466	15LM10375	
13KM22390	14JM09489	15LM10376	
13KM22391	14JM10770	15LM11432	
13LM07967	14LM01406	15LM11433	
13LM20117	14LM01406R	15LM19635	
13MM07087	14LM09219	15MM11292	
13MM07510	14LM09227	15MM11295	
13MM16218	14LM09235	15MM11296	
14AM09464	14LM09245	16AM00592	
14BM00550	14LM09247	16AM01881	
14BM00551	14LM10680	16BM15807	
14BM01666	14MM03602	16BM15808	