

[Modtageradresse]

22. april 2020

VIGTIG PRODUKTINFORMATION: Information om tilbagekaldelse af medicinsk udstyr

Reference: R-2020-04
Berørte enheder: R3[◊] Acetabular Shells

Artikelnummer	Beskrivelse	Batchnummer
Se bilag 1	R3 Acetabular Shells	Se bilag 2

Kære kunde:

Med dette brev informeres du om, at Smith+Nephew har indledt en frivillig tilbagekaldelse for at fjerne bestemte partier af R3 Acetabular Shells på grund af en produktionsfejl. Brug af de berørte enheder, som muligvis ikke er fremstillet i henhold til deres designspecifikationer, kan medføre intraoperativ låsning.

Denne korrigerende handling er blevet indberettet til de relevante kompetente myndigheder.

Sundhedsrisici	I det mest sandsynlige scenarie vil enhederne fungere efter hensigten. Indtil dags dato har vi modtaget seks reklamationer vedrørende den intraoperative låsning. I værste fald kan en keramisk liner, der tilsyneladende låser fuldt ud intraoperativt med acetabular shell, brække efter operationen, hvilket vil kræve et revisionsindgreb. Der er ingen rapporter om et sådant værst tænkeligt tilfælde.
Foranstaltninger, som brugeren skal iværksætte	<ol style="list-style-type: none">1. Lokaliser og sæt omgående ubrugte berørte enheder i karantæne.2. Sørg venligst for, at det kirurgiske personale får en kopi af den vedhæftede Meddelelse til læger.3. Returner det karantæneramte produkt til din nationale Smith+Nephew agent/forhandler.4. Udfyld returfølgersedlen, og send den per e-mail, eller fax den til din nationale Smith+Nephew agent/forhandler.5. Sørg for, at denne sikkerhedsinformation videregives til alle, som skal have kendskab til den i din organisation.6. Vær opmærksom på denne information og den resulterende handling, indtil produktinformationen om tilbagekaldelse er afsluttet, for at sikre handlingens effektivitet.

Smith+Nephew er forpligtet til kun at levere produkter af den højeste kvalitet og til at yde enhver påkrævet support. Vi beklager, at dette er sket samt enhver ulejlighed, det kan forvolde eller har forvoldt dig, dine patienter eller dit personale.



Hvis du har spørgsmål, er du velkommen til at kontakte os i henhold til følgende kontaktoplysninger:

Smith & Nephew A/S
Slotsmarken 14
2970 Denmark
Tlf. 45 80 61 00, Email: CS.dk@smith-nephew.com

Returfølgeseddel

Udfyld og returner denne tilbagemeldingsinformation til den ovennævnte kontakt for at undgå gentagne forespørgsler.

Vi bekræfter hermed, at vi er opmærksomme på denne produktinformation om en korrigerende handling og at der er blevet informeret herom i vores organisation og til vores kirurgiske personale.

På vores institution har vi _____ [antal] berørte enheder, som vi vil returnere.

_____ [antal] berørte enheder er blevet bortskaffet på vores institution.

Institution: _____ Reference: R-2020-04

Navn: _____ Dato / underskrift: _____

Vedlæg:

- Liste over artikelnumre og produktbeskrivelser (Bilag 1)
- Liste over produkt- og partinumre (Bilag 2)
- Meddelelse til læger

Bilag 1: Liste over artikelnumre og produktbeskrivelser

Artikelnummer	Beskrivelse	Artikelnummer	Produktbeskrivelse
71331842	R3 0 HOLE ACETABULAR SHELL 42MM	71335540	R3 3 HOLE ACETABULAR SHELL 40MM
71331848	R3 0 HOLE ACETABULAR SHELL 48MM	71335542	R3 3 HOLE ACETABULAR SHELL 42MM
71331850	R3 0 HOLE ACETABULAR SHELL 50MM	71335544	R3 3 HOLE ACETABULAR SHELL 44MM
71331852	R3 0 HOLE ACETABULAR SHELL 52MM	71335546	R3 3 HOLE ACETABULAR SHELL 46MM
71331854	R3 0 HOLE ACETABULAR SHELL 54MM	71335548	R3 3 HOLE ACETABULAR SHELL 48MM
71331856	R3 0 HOLE ACETABULAR SHELL 56MM	71335550	R3 3 HOLE ACETABULAR SHELL 50MM
71331858	R3 0 HOLE ACETABULAR SHELL 58MM	71335552	R3 3 HOLE ACETABULAR SHELL 52MM
71331860	R3 0 HOLE ACETABULAR SHELL 60MM	71335553	R3 3 HOLE ACETABULAR SHELL 53MM
71331942	R3 3 HOLE HA COATED ACETABULAR SHELL 42MM	71335554	R3 3 HOLE ACETABULAR SHELL 54MM
71331946	R3 3 HOLE HA COATED ACETABULAR SHELL 46MM	71335556	R3 3 HOLE ACETABULAR SHELL 56MM
71331948	R3 3 HOLE HA COATED ACETABULAR SHELL 48MM	71335558	R3 3 HOLE ACETABULAR SHELL 58MM
71331950	R3 3 HOLE HA COATED ACETABULAR SHELL 50MM	71335560	R3 3 HOLE ACETABULAR SHELL 60MM
71331952	R3 3 HOLE HA COATED ACETABULAR SHELL 52MM	71338663	R3 MULTI HOLE ACET SHELL 48MM
71331954	R3 3 HOLE HA COATED ACETABULAR SHELL 54MM	71338664	R3 MULTI HOLE ACET SHELL 50MM
71331956	R3 3 HOLE HA COATED ACETABULAR SHELL 56MM	71338665	R3 MULTI HOLE ACET SHELL 52MM
71331958	R3 3 HOLE HA COATED ACETABULAR SHELL 58MM	71338666	R3 MULTI HOLE ACET SHELL 54MM
71331960	R3 3 HOLE HA COATED ACETABULAR SHELL 60MM	71338667	R3 MULTI HOLE ACET SHELL 56MM
71331962	R3 3 HOLE HA COATED ACETABULAR SHELL 62MM	71338668	R3 MULTI HOLE ACET SHELL 58MM
71331964	R3 3 HOLE HA COATED ACETABULAR SHELL 64MM	71338733	R3 HA MULTI-HOLE ACETABULAR SHELL 48MM
71331968	R3 3 HOLE HA COATED ACETABULAR SHELL 68MM	71338734	R3 HA MULTI-HOLE ACETABULAR SHELL 50MM
71332242	R3 0 HOLE HA COATED ACETABULAR SHELL 42MM	71338735	R3 HA MULTI-HOLE ACETABULAR SHELL 52MM
71332246	R3 0 HOLE HA COATED ACETABULAR SHELL 46MM	71338736	R3 HA MULTI-HOLE ACETABULAR SHELL 54MM
71332248	R3 0 HOLE HA COATED ACETABULAR SHELL 48MM	71338737	R3 HA MULTI-HOLE ACETABULAR SHELL 56MM
71332250	R3 0 HOLE HA COATED ACETABULAR SHELL 50MM	71338738	R3 HA MULTI-HOLE ACETABULAR SHELL 58MM
71332252	R3 0 HOLE HA COATED ACETABULAR SHELL 52MM	71338740	R3 HA MULTI-HOLE ACETABULAR SHELL 62MM
71332254	R3 0 HOLE HA COATED ACETABULAR SHELL 54MM	71338741	R3 HA MULTI-HOLE ACETABULAR SHELL 64MM
71332256	R3 0 HOLE HA COATED ACETABULAR SHELL 56MM		
71332258	R3 0 HOLE HA COATED ACETABULAR SHELL 58MM		
71332260	R3 0 HOLE HA COATED ACETABULAR SHELL 60MM		
71332262	R3 0 HOLE HA COATED ACETABULAR SHELL 62MM		
71332264	R3 0 HOLE HA COATED ACETABULAR SHELL 64MM		

Bilag 2: Liste over artikel- og partinumre

Artikelnummer	Partinummer
71331842	18HM20691, 18KM15724, 18LM09819
71331848	18HM01685, 19AM15804, 19AM15805, 19AM15809, 19AM15828, 19AM15829
71331850	18LM00667, 18LM00668, 18LM00668A, 18LM00670, 18LM00671, 18LM00671A, 18LM00702
71331852	18KM00744, 18KM00775, 18KM00779, 18KM00833, 18KM06667, 18KM06675, 18KM06676, 18KM06680, 18KM06681, 18KM06682, 18KM13594, 18KM13632, 18KM15736, 18KM15736A, 18KM15737, 18KM15738, 18KM15739, 18KM20281, 18KM20281A, 18KM20284, 18KM20289, 18KM20291, 18KM20292, 18KM20293A, 18KM20315, 18KM24785, 18KM24785A, 18KM24792, 18KM24795, 18KM24805, 18LM02315, 18LM02317, 18LM02337, 18LM07653, 18LM14077, 18LM17941, 18LM17942, 18LM17946, 19EM10292
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Meddelelse til læger

Smith+Nephew-handling	Frivillig tilbagekaldelse
Reference for tilbagekaldelse	R-2020-04
Berørt produkt	R3 Acetabular Shells
Oplysninger om det berørte produkt	Se vedhæftede

Kære læge

Med dette brev vil vi informere dig om en frivillig tilbagekaldelse for specifikke partier af R3 Acetabular Shells fremstillet af Smith+Nephew, Inc. USA.

Baggrund

Smith+Nephew har modtaget seks reklamationer relateret til intraoperativ fejl i låsningen af R3 Acetabular Shells. En gennemgang af fremstillingsprocessen har vist, at specifikke partier muligvis ikke er fremstillet i henhold til deres designspecifikationer. Selvom kun nogle af enhederne i de angivne partier potentielt er uden for specifikationen, udfører Smith+Nephew en frivillig tilbagekaldelse af alle enheder fra de angivne partier.

Handlinger

I det mest sandsynlige scenarie vil enhederne fungere efter hensigten. I alle seks reklamationer modtaget for fejl i låsningen blev der anvendt en erstatningsenhed, og indgrebet blev gennemført. I værste fald kan en keramisk liner, der tilsyneladende låser fuldt ud intraoperativt med acetabular shell, brække efter operationen, hvilket vil kræve et revisionsindgreb. Der har imidlertid ikke været nogen rapporter om dette.

Smith+Nephew anbefaler lægerne at fastholde deres rutinemæssige protokol for opfølgning af patienter med implanterede R3 Acetabular Shells, der identificeres som værende inden for rammerne af denne frivillige tilbagekaldelse.

Som en del af udførelsen af den frivillige tilbagekaldelse bedes lederen af din institution bekræfte modtagelsen og distributionen af dette brev i henhold til relevans. Derudover bliver lederen bedt om at håndtere berørte enheder i henhold til den tilhørende Sikkerhedsrelateret tilbagekaldelse for medicinsk udstyr.

Smith+Nephew forpligter sig til kun at levere produkter af den højeste kvalitet, der er sikre og effektive, og til at yde support til kirurger, der anvender disse produkter.

Hvis du har spørgsmål, er du velkommen til at kontakte mig på følgende e-mail fieldactions@smith-nephew.com.

Med venlig hilsen



Dr. Luca Orlandini MD
Vice President Medical Affairs