

Date: 11 April 2017

FOLLOW-UP NOTICE:
PRODUCT AVAILABILITY FOR
Product Removal 515379- Impactor for PFNA Blade

In December 2016, Synthes GmbH initiated a medical device removal of the Impactor for PFNA Blade. The PFNA impactor part number and affected lot are listed below and are part of the PFNA and PFNA-II systems.

Part Number(s)	Part Description	Lot Numbers
03.010.410	Impactor for PFNA Blade	See Attachment 1 for affected parts. NOTE: Replacement units will begin with lot # L341786 and above.

You are receiving this follow-up because you have acknowledged receipt of the original notification and chose to continue to use of the Impactor for PFNA Blade until replacement availability.

This notice is to inform your facility that replacement parts are now becoming available. If you have questions regarding the return and recovery of the part, we ask that you contact your local DePuy Synthes representative.

IMPORTANT NOTE: Due to the potential risks to public health of complete unavailability of a treatment option, Facilities may continue use of the affected Impactors until the replacement device is provided.

Thank you for your attention and cooperation.

DePuy Synthes



Anne Brisson
Senior Quality Assurance Manager,
Product Safety and Performance

Attachment 1

Part Number 03.010.410					
Lot Numbers:					
2140549	2779287	8242870	8904786	9419710	9908203
2544605	2786995	8316329	8938264	9430395	9925480
2554071	2795687	8333012	8938267	9443295	9947458
2568798	2804428	8346409	8954624	9464849	9956732
2569597	2814599	8365683	8954626	9478510	17500681
2569601	2818271	8365684	8979224	9481941	L007710
2618058	2825644	8392887	8979485	9515028	L021644
2618059	7720394	8412005	8989365	9527707	L036242
2663077	7727718	8422158	9052185	9544077	L045816
2663082	7739491	8435439	9068166	9555825	L057687
2663271	7775137	8454497	9078126	9571249	L066979
2679071	7808156	8472076	9092324	9596712	L075568
2679100	7808157	8482400	9120066	9610603	L096182
2688407	7834849	8536990	9143829	9633972	L111682
2698274	7841822	8545304	9143830	9649644	L118869
2714248	7842977	8562547	9173004	9669777	L120492
2720817	7860373	8584178	9173008	9685132	L171370
2720818	7901706	8615985	9173011	9707765	L179837
2720819	7931718	8639579	9182435	9708805	L189000
2724732	7965914	8660612	9182436	9727517	L203780
2732773	7995645	8683004	9208653	9745984	L212043
2734301	8000118	8708138	9221060	9761309	L236940
2740007	8029208	8731352	9248843	9775292	L236941
2747016	8067486	8755180	9251276	9785974	L245797
2748823	8109643	8769609	9269007	9802595	L245801
2752742	8135485	8783044	9291155	9802597	L257656
2757876	8165189	8838421	9311832	9811063	L257659
2761817	8198345	8838425	9319845	9827325	L257660
2765046	8222972	8853040	9349629	9829662	L257662
2772062	8227807	8883922	9360646	9853115	
2777268	8227812	8883923	9387458	9868300	
2778506	8227813	8883924	9406100	9883613	