

3<sup>rd</sup> February 2015

Dear Customer,



**RE: FIELD SAFETY NOTICE (FSN)**

**FSN No: ASPENR1**  
**Device: Bi-Manual Irrigating / Aspirating Handpieces**

Please be advised that we are notifying you of an issue related to the potential for the cannula to rotate on the eye during introduction and for the metal tip to become dislodged from irrigating handpiece, resulting in possible injury to the patient.

It has been identified through our investigations that as the Aspirating Handpiece involves the same manufacturing process as the Irrigating Handpiece we are recalling these products as a precautionary measure. The Products affected are listed below:

Product Name	Product Code (Sterile)	Lot Numbers		
Bi-Manual Aspirating Handpiece	157400	010240	045220	040845
Bi-Manual Aspirating Handpiece	157400	011845	045351	041232
Bi-Manual Aspirating Handpiece	157400	012392	045511	041959
Bi-Manual Aspirating Handpiece	157400	013259	046013	042357
Bi-Manual Aspirating Handpiece	157400	014081	046541	042598
Bi-Manual Aspirating Handpiece	157400	014817	046964	043627
Bi-Manual Aspirating Handpiece	157400	018033	047408	043809
Bi-Manual Aspirating Handpiece	157400	020819	047623	044282
Bi-Manual Aspirating Handpiece	157400	021350	047758	044525
Bi-Manual Aspirating Handpiece	157400	023650	048384	044945
Bi-Manual Aspirating Handpiece	157400	024230	048587	053488
Bi-Manual Aspirating Handpiece	157400	025440	048713	053968
Bi-Manual Aspirating Handpiece	157400	026647	049535	054190
Bi-Manual Aspirating Handpiece	157400	028623	049927	054579
Bi-Manual Aspirating Handpiece	157400	030008	050189	054930
Bi-Manual Aspirating Handpiece	157400	031997	050304	056263
Bi-Manual Aspirating Handpiece	157400	033214	050711	056415
Bi-Manual Aspirating Handpiece	157400	034257	050882	056525
Bi-Manual Aspirating Handpiece	157400	035548	051185	
Bi-Manual Aspirating Handpiece	157400	036780	051399	
Bi-Manual Aspirating Handpiece	157400	037538	052413	
Bi-Manual Aspirating Handpiece	157400	038469	052699	
Bi-Manual Aspirating Handpiece	157400	038946	052833	
Bi-Manual Aspirating Handpiece	157400	039767	053332	

Product Name	Product Code (Sterile)	Lot Numbers		
Bi-Manual Irrigating Handpiece	157500	010593	041573	050754
Bi-Manual Irrigating Handpiece	157500	011581	042071	051032
Bi-Manual Irrigating Handpiece	157500	012948	042358	051340
Bi-Manual Irrigating Handpiece	157500	013260	042681	052132
Bi-Manual Irrigating Handpiece	157500	013714	043705	052355
Bi-Manual Irrigating Handpiece	157500	014689	044130	052460
Bi-Manual Irrigating Handpiece	157500	018034	044424	052834
Bi-Manual Irrigating Handpiece	157500	020820	044775	053015
Bi-Manual Irrigating Handpiece	157500	021276	045142	053015
Bi-Manual Irrigating Handpiece	157500	023455	045352	053711
Bi-Manual Irrigating Handpiece	157500	024106	045770	054015
Bi-Manual Irrigating Handpiece	157500	024889	046123	054191
Bi-Manual Irrigating Handpiece	157500	026648	046565	054666
Bi-Manual Irrigating Handpiece	157500	028134	046965	054889
Bi-Manual Irrigating Handpiece	157500	029337	047229	056007
Bi-Manual Irrigating Handpiece	157500	030160	047636	056264
Bi-Manual Irrigating Handpiece	157500	032332	047759	056526
Bi-Manual Irrigating Handpiece	157500	033983	048286	056596
Bi-Manual Irrigating Handpiece	157500	034527	048714	
Bi-Manual Irrigating Handpiece	157500	036130	048846	
Bi-Manual Irrigating Handpiece	157500	037233	049164	
Bi-Manual Irrigating Handpiece	157500	037816	049536	
Bi-Manual Irrigating Handpiece	157500	038793	049974	
Bi-Manual Irrigating Handpiece	157500	039768	050242	
Bi-Manual Irrigating Handpiece	157500	041045	050542	

Product Name	Product Code (Non-Sterile)	Lot Numbers		
Bi-Manual Aspirating Handpiece	257400	10246	17772	33055
Bi-Manual Aspirating Handpiece	257400	11095	22129	33989
Bi-Manual Aspirating Handpiece	257400	11869	28141	34265
Bi-Manual Aspirating Handpiece	257400	11977	29346	38269

Product Name	Product Code (Non-Sterile)	Lot Numbers		
Bi-Manual Irrigating Handpiece	257500	10248	26083	34266
Bi-Manual Irrigating Handpiece	257400	11978	26091	38058
Bi-Manual Irrigating Handpiece	257400	12862	31734	
Bi-Manual Irrigating Handpiece	257400	21120	33990	

**Customer Actions:**

1. Please immediately stop using the product.
2. Place the product in quarantine to be returned or destroyed.
3. Aspen customers will receive either credit or replacement product at no cost, for returned product or a returned completed Certificate of Destruction. Please use Return Authorization Number ASPENR1 when returning the product.

Product to be returned should be sent to the following address:

QA/RA Department  
 Aspen Medical Europe Ltd  
 A Hill-Rom Company  
 Thornhill Road, North Moons Moat,  
 Redditch, Worcestershire  
 B98 9NL, UK

This Field Safety Notice advises you of the situation together with action to take. Please review the Field Safety Notice and complete the applicable form.

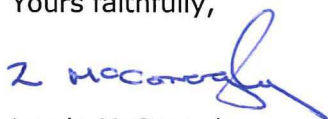
If there are any questions or concerns, please contact:

Lynda McConaghy Head of QA/RA +44(0)1527 587716 Lynda.McConaghy@AspenMedicalEurope.com	or Linda Philip Regulatory Affairs Specialist +44(0)1527 587752 Linda.Philip@AspenMedicalEurope.com
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Your help and support is much appreciated.

Please accept our sincere apologies for the inconvenience this situation may have caused.

Yours faithfully,



Lynda McConaghy  
Head of QA/RA