



Italian Medicines Agency
Via del Tritone
181 00187 Roma
Italy

3rd February 2016

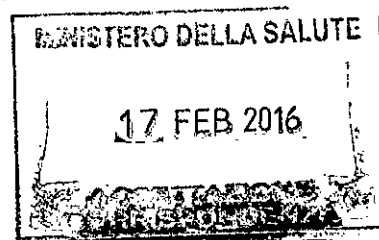
Ministero della Salute
DGDMF
0008587-A-18/02/2016

SALA POSTA
Agenzia Italiana del Farmaco



- 5 FEB. 2016

Firma per ACCETTAZIONE



Reference: Field Corrective Action of Bi-Manual Irrigating Handpieces

Dear Sir/Madam

You will have received notification last year (NCA report ref. no.: UK-2015-02-26-048) via the MHRA regarding a field corrective action concerning the Steriseal Bi-Manual Irrigating/Aspirating Handpieces (sterile and non-sterile variants) which are class IIa devices. This activity was internally identified as ASPENR1. I have summarised the details of this action below.

This action was filed as a precautionary removal of product. At the present time we have received no notice of any injuries over the past 5 years, which represents the shelf life of the product. Since its introduction 17 years ago, over 226,500 handpieces have been shipped.

Description of issue:

Potential for the cannula to rotate on the eye during introduction and for the metal tip to become dislodged from the Irrigating Handpiece, resulting in possible injury to the patient. It was identified through investigations that the Aspirating Handpiece involves the same manufacturing process as the Irrigating Handpiece and therefore these products were also recalled as a precautionary measure.

This Field Action was safety related:

All Bi-Manual Irrigating and Aspirating Handpieces shipped by Aspen Medical Europe, Redditch from the 1st January 2010 to 31st December 2014.

Action plan and resolution:

Aspen Medical Europe, Redditch sent out a Field Safety Notice to advise customers:

- To immediately stop using the product.
- Place the product into quarantine to be returned or destroyed.

- To return product via the Returned Materials Authorisation system or return a completed certificate of destruction/response form.
- Customers would receive either credit or replacement product at no cost.

Number of consignees notified of the recall, and date and method of notification:

Italy	The initial customer letter was e- mailed with delivery confirmation to 2 Consignees beginning February, 2015 and completed
RoW	E-mail and mailing with delivery confirmation beginning February, 2015. Level 2 communication (the second communication) commenced in February, Level 3 communication (the third communication) commenced July and finalized in October for five consignees who did not respond.

Number of consignees responding to the recall communication and quantity of product on hand at the time it was received:

Location	Consignees contacted	Consignees responded	Confirmation of product destruction (return)
Italy	2	2	1 complete
Italy + RoW	38	33	33 complete

Number of consignees that did not respond:

Five (5) consignees did not respond. Italy consignees have all been accounted for.

Number of products returned or corrected by each consignee:

Please see the attached database ASPENR1 Reconciliation Data Dec 2015.

No. Units Destroyed	No. of Units Returned	No. of Units Used
564	615	69,113



Total quantity of product accounted for:

Please see the attached database ASPENR1 Reconciliation Data Dec 2015.

Total No of Units Dispatched	Total Units Accounted for
70,832	70,292

Number and results or effectiveness checks that were made:

Communication for the removal is completed. For the five customers who did not provide proof of receipt or who do not respond, we attempted to contact customers a second and third time and no reply was received. If any customer is identified or replies in the future, the information will be provided along with certificate of use or destruction forms and credit supplied. Please see the attached database ASPENR1 Reconciliation Data Dec2015. The customers in Italy is accounted for. Reconciliation is now complete.

Final disposition of returned recalled devices:

Reconciliation entailed product destruction, acknowledgement that no affected product is in inventory and has been used or was returned for credit.

Root cause:

The Root Cause was identified due to an error on the part of the initiator of an incorrect tolerance change (0.2mm instead of 0.02mm). This value was assigned to the inner core pin diameter of the hand piece, which resulted in a loose fitting of the cannula to the plastic hand piece when recording the tolerance on the drawing.

Corrective action(s) taken to prevent similar problems in the future:

Internal CAPA number C02199 - All corrective actions relating to the modification of the inner core pin diameter have been successfully implemented, documented, approved including validation activities with Risk management file updated.

Please find attached all documentation for your records. This recall which was closed out by the MHRA on 3rd December 2015.

Please can you let us know if this closure by the MHRA is sufficient or if you require us to do anything in addition to meet your requirements.



Please do not hesitate to contact me at lynda.mcconaghy@aspenmedicaleurope.com should you require any further information regarding this field correction closure request. If we do not hear anything further from you by the 15th March, we will accept this as your confirmation of closure of this field action.

We sincerely apologise for not informing you directly of this recall which was an oversight on our behalf.

Yours faithfully

A handwritten signature in black ink, appearing to read 'L McConaghy'.

Lynda McConaghy
QARA Manager

Telephone: +44 (0)1527 587716

Email: Lynda.mcconaghy@aspenmedicaleurope.com

NATIONAL COMPETENT AUTHORITY REPORT

This form should be used for the exchange of medical device information between national Competent Authorities and European Commission only.
Completed forms should not be released to the public:

1. Is this report confidential? ☐ Yes. ☒ No

Reference and Reporter Data

2. NCA report ref. no.: UK-2015-02-26-048 INC-GB-15-02-000048	3. Local NCA reference no.: 2015/002/004/081/012	4. Related NCA report nos.:
5. Manufacturer Ref/FSCA no.: ASPENR1	6. Sent by Adverse Incident Centre Medicines & Healthcare products Regulatory Agency	7. Contact person: Sara Vincent
8. Tel: +44 20 3080 7080	9. Fax: +44 20 3118 9814	10. E-mail: aic@mhra.gsi.gov.uk

Device Data

11a. Generic name/ kind of device: Handpiece	11b Device Category (GMDN):	20. CAB/Notified Body no.: 086
12. Nomenclature id: GMDN	13. GMDN No.: 60793	
14. Trade name and make and model: Bi-Manual Irrigating / Aspiring Handpieces Catalogue Numbers: 157500, 257500, 157400, 257400		
15. Software version:		21a. Device approval status: CE Mark Y
16. Serial no.:	17. Lot/batch no.: See FSN	21b. Risk Class: MDD Class IIa
18. Manufacturer: Aspen Medical Europe Ltd Country: UK Full Address: 27 Thornhill Road B98 9NL Contact: Lynda McConaghy Tel: 01527 587 716 Fax: 01527 592 111 E-mail: Lynda.McConaghy@aspenmedicaleurope.com	19. Authorised rep: Country: Full Address: Contact: Tel: Fax: E-mail:	22. Action taken: Field Safety Corrective Action [] None [x] Field Safety Corrective Action [] Safeguard Action [] Other (specify)

Event Data

23a. Background information and reason for this report: See attached FSN
23b. Is the investigation of the report complete? <input type="checkbox"/> Yes. <input checked="" type="checkbox"/> No
24a. Conclusions: See attached FSN
24b. Have the manufacturer actions been made public in a Field Safety Notice? <input checked="" type="checkbox"/> Yes. <input type="checkbox"/> No
24c. The originator of this NCAR will take the lead and co-ordinate the investigation <input checked="" type="checkbox"/> Yes. <input type="checkbox"/> No
25a. Recommendation to receivers of this report: Establish if you are affected by this issue and take appropriate action - See attached FSN.
25b. Device known to be in the market in (Distribution confirmation from manufacturer / authorized rep attached): BE, CZ, ES, GB, IT, TR, , Lebanon, USA
25c. Device also marketed as (trade name):
Report Distribution
26a. This report is being distributed to: [X] IMDRF NCAR Secretariat for further distribution to all non EEA IMDRF FULL NCAR participants [X] EEA states, EC, Switzerland and Turkey [] The following targeted NCAs: [X] The manufacturer / authorised rep:
26b. The last GHTF-NCAR distributed by this NCA was: UK-2015-02-26-047

3rd 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	



A Hill-Rom Company

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.

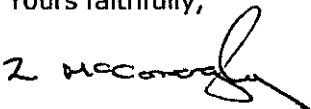
If there are any questions or concerns, please contact:

Lynda McConaghy	or Linda Philip
Head of QA/RA	Regulatory Affairs Specialist
+44(0)1527 587716	+44(0)1527 587752
Lynda.McConaghy@AspenMedicalEurope.com	Linda.Philip@AspenMedicalEurope.com

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

Report Form
Field Safety Corrective Action
Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 7)

new case, keep base data

Version 2.7en
2012-12-03

1 Administrative information
To which NCA(s) is this report being sent? MHRA
Type of report <input type="radio"/> Initial report <input type="radio"/> Follow-up report <input checked="" type="radio"/> Final report
Date of this report 2015-11-26
Reference number assigned by the manufacturer ASPENR1
FSCA reference number assigned by NCA 2015/002/004/081/012
Incidence reference number assigned by NCA 2015/002/004/081/012
Name of the co-ordinating NCA Competent Authority (if applicable) MHRA

2 Information on submitter of the report
Status of submitter <input checked="" type="radio"/> Manufacturer <input type="radio"/> Authorised Representative within EEA and Switzerland <input type="radio"/> Others: (identify the role)

3 Manufacturer information	new
Name Aspen Medical Europe Limited	
Contact Name Lynda McConaghy	
Address Thornhill Road, Worcestershire	
Postcode B98 9NL	City Redditch
Phone +44 (0)1527 587700	Fax
E-mail lynda.mcconaghy@apenmedicaleurope.com	Country GB - Great Britain

4 Authorised Representative Information

new

Name	
Contact Name	
Address	
Postcode	City
Phone	Fax
E-mail	Country DE - Germany

5 National contact point information

new

National contact point name Aspen Medical Europe Limited	
Name of the contact person Lynda McConaghy	
Address Thornhill Road, Worcestershire	
Postcode B98 9NL	City Redditch
Phone +44 (0)1527 587700	Fax
E-mail lynda.mcconaghy@apsenmedicaleurope.com	Country GB - Great Britain

6 Medical device information

new

Class☐ AIMD Active implants☐ MDD Class III☐ MDD Class IIb☒ MDD Class IIa☐ MDD Class I☐ IVD Annex II List A☐ IVD Annex II List B☐ IVD Devices for self-testing☐ IVD General**Nomenclature system (preferable GMDN)**

GMDN

Nomenclature code

46705

Nomenclature text

Ophthalmic irrigation/aspiration cannula

Commercial name/ brand name / make

Steriseal

Model number

157400, 157500, 257400, 257500

Catalogue number

157400, 157500, 257400, 257500

Serial number(s)

N/A

Lot/batch number(s)

010240 045220 040845 011845 045351 041232 012392 045511
041959 013259 046013 042357 014081 046541 042598
014817 046964 043627 018033 047408 043809 020819 047623
044282 021350 047758 044525 023650 048384 044945
024230 048587 053488 025440 048713 053968 026647 049535
054190 028623 049927 054579 030008 050189 054930 031997
050304 056263 033214 050711 056415 034257 050882 056525
035548 051185 036780 051399 037538 052413 038469 052699
038946 052833 039767 053332 010593
041573 050754 011581 042071 051032 012948 042358 051340
013260 042681 052132 013714 043705 052355 014689 044130
052460 018034 044424 052834 020820 044775 053015
021276 045142 053015 023455 045352 053711 024106 045770
054015 024889 046123 054191 026648 046565 054666
028134 046965 054889 029337 047229 056007 030160 047636
056264 032332 047759 056526 033983 048286 056596
034527 048714 036130 048846 037233 049164 037816 049536
038793 049974 039768 050242 041045 050542 10246 17772
33055 11095 22129 33989 11869 28141 34265 11977 29346
38269

Device Mfr Date

2013-12-01

Expiry date

2018-12-01

Notified Body (NB) ID-number

0086

Accessories / associated devices (if applicable)

N/A

Software version number (if applicable)

N/A

7 Description of the FSCA	
Background information and reason for the FSCA	
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. Identified through investigations that as the Aspiring Handpiece involved the same manufacturing process as the Irrigating Handpiece and therefore these products were also recalled as a precautionary measure.	
Description and justification of the action (corrective / preventive)	
Investigation:	
<p>1. Product Specification tolerance found to be incorrect (typo error) for both the Irrigation and Aspiration Handle: On the 7th November 2006 the original specification for the diameter holding the steel tube was changed from 0.70 +0.02/-0 to 0.70 +0.2/-0 and sent to supplier for manufacturing. Tolerances should have read +0.02/-0</p> <p>2. Goods Inwards: Diameter of the Core pin within the hand piece is measured using gauges, acceptance criteria measures 0.7 min/+0.02, however QC Inspector accepted 0.073 if gauge went part way in.</p>	
Root cause:	
<ul style="list-style-type: none"> • Error on part of initiator when recording tolerance, in addition, Approvers failed to conduct a thorough review of product specification. • Goods Inwards Inspection: Misinterpretation of the Quality control specification, QC personnel failed to understand if diameter was greater than 0.72, this would be deemed as a fail, regardless if the 0.73 gauge could go part way in. 	
Corrective and preventive actions:	
<p>1. Update product specification (drawing no. B214/08/5056, B214/08/5057) to reduce the core pin diameter and tolerances to ensure an interference fit and complete protocol activities assigned to this correction.</p> <p>2. Establish and conduct training of change management process to ensure changes are documented and verified by cross functional team prior to implementation.</p> <p>3. Review of all change notes vs product drawings from January 2010 to January 2015 (Product shelf life) to ensure implementation of changes align with change requests.</p> <p>4. Initiate and seek approval for a Field Safety Action plan (ASPENR1) for Medical Device reporting of the Irrigation Hand piece, providing objective evidence and approval. Completion will be addressed via Complaint Number C-0000224718 in on-line complaints management system.</p> <p>5. Establish via validation activities new product specification and conduct training of all personnel impacted.</p>	
Advice on actions to be taken by the distributor and the user	
<p>1. To immediately stop using the product.</p> <p>2. To place the product in quarantine to be returned or destroyed.</p> <p>3. Aspen customers received either credit or replacement product at no cost, for returned product or a returned completed Certificate of Destruction.</p>	
Progress of FSCA , together with reconciliation data (Mandatory for a Final FSCA)	
FSCA completed. See attached table with reconciliation data.	
Time schedule for the implementation of the different actions	
FSCA completed. CAPA actions completed and in effectiveness phase; due for closure January 25th 2016.	
Attached please find	FSN Status
<input type="checkbox"/> Field Safety Notice (FSN) in English	<input type="radio"/> Draft FSN
<input type="checkbox"/> FSN in national language	<input checked="" type="radio"/> Final FSN
<input type="checkbox"/> Others (please specify)	
N/A	

The medical device has been distributed to the following countries:

within the EEA and Switzerland

- | | | | | | | | |
|-----------------------------|--|-----------------------------|--|--|--|-----------------------------|--|
| <input type="checkbox"/> AT | <input checked="" type="checkbox"/> BE | <input type="checkbox"/> BG | <input type="checkbox"/> CH | <input type="checkbox"/> CY | <input type="checkbox"/> CZ | <input type="checkbox"/> DE | <input type="checkbox"/> DK |
| <input type="checkbox"/> EE | <input checked="" type="checkbox"/> ES | <input type="checkbox"/> FI | <input checked="" type="checkbox"/> FR | <input checked="" type="checkbox"/> GB | <input checked="" type="checkbox"/> GR | <input type="checkbox"/> HU | <input type="checkbox"/> IE |
| <input type="checkbox"/> IS | <input checked="" type="checkbox"/> IT | <input type="checkbox"/> LI | <input type="checkbox"/> LT | <input type="checkbox"/> LU | <input type="checkbox"/> LV | <input type="checkbox"/> MT | <input type="checkbox"/> NL |
| <input type="checkbox"/> NO | <input type="checkbox"/> PL | <input type="checkbox"/> PT | <input type="checkbox"/> RO | <input type="checkbox"/> SE | <input type="checkbox"/> SI | <input type="checkbox"/> SK | <input checked="" type="checkbox"/> TR |

Candidate Countries

- ☐ HR

- ☐ All EEA, candidate countries and Switzerland

Others:

USA, Lebanon, Czech Republic

8 Comments

This Field Action was safety related and covered all Bi-Manual Irrigating and Aspirating Handpieces shipped by AME, Redditch from the 1st January 2010 to 31st December 2014.

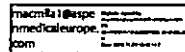
This Field Action was initiated on 3rd February 2015, and completed in November 2015. Good faith efforts were made to contact customers up to a maximum of 3 times where necessary, between 4th February 2015 and 1st July 2015.

43 accounts were identified in the field action plan, with 93,753 potentially affected handpieces. All accounts have been notified. At the completion of this action, a total of 93,213 handpieces were identified. See reconciliation data for details. The variance of 540 handpieces relates to being unable to elicit a response from the relevant customer, despite 3 attempts to do so.

CAPA 02199 was raised on 20th January 2015 to document the corrective and preventive actions. It is currently in the effectiveness phase, with a planned closure date of 25th January, 2016. All actions from the CAPA have been implemented.

Submission of this report does not, in itself, represent a conclusion by the manufacturer and/or authorised representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.

Signature



I affirm that the information given above is correct to the best of my knowledge

print

check

sent on Sunday, November
29, 2015 13:15:11

Anne Macmillan

From: Laura.Magnan@mhra.gsi.gov.uk
Sent: 03 December 2015 11:10
To: Linda Philip
Subject: Closing Letter MHRA Ref: 2015/002/004/081/012

03/12/2015

Your Ref: ASPENR1
MHRA Ref: 2015/002/004/081/012

Dear Sir/Madam

Thank you for your report.

So far as we are concerned, the file on this report is now closed. However, we shall continue to monitor the situation and would welcome details of any additional or similar incidents.

Many thanks for your help in bringing this matter to a conclusion.

Yours sincerely
Adverse Incident Centre

Note

Use this email address aic@mhra.gsi.gov.uk to contact us. We check it regularly.

This email and any files transmitted with it are **confidential**. If you are not the intended recipient, any reading, printing, storage, disclosure, copying or any other action taken in respect of this email is prohibited and may be unlawful.

If you are not the intended recipient, please notify the sender immediately by using the reply function and then permanently delete what you have received. Incoming and outgoing email messages are routinely monitored for compliance with the Department of Health's policy on the use of electronic communications.

For more information on the Department of Health's email policy, click

DHTermsAndConditions

The original of this email was scanned for viruses by the Government Secure Intranet virus scanning service supplied by Vodafone in partnership with Symantec. (CCTM Certificate Number 2009/09/0052.) This email has been certified virus free.

Communications via the GSi may be automatically logged, monitored and/or recorded for legal purposes.

CERTIFICATE OF DESTRUCTION

*I certify that I have destroyed the following product according to recall letter, dated
xxxxxxx.*

Part Number: _____

Quantity: _____

Lot Number: _____

Date of Destruction: _____

Method of Destruction: _____

Witness

Date

Signature

Date

Printed Name: _____

Title: _____

Telephone number: _____

Company Name: _____

Address: _____

Post Code: _____

Please return this form to Aspen Medical Europe Ltd, using any one of the following:

Address: Aspen Medical Europe Ltd

Thornhill Road, North Moons Moat, Redditch, Worcestershire, B98 9NL, UK

Fax: +44(0)1527 592111

Email: Linda.Philip@AspenMedicalEurope.com

ASPENR1

	Customer	Complete	Outbound Communication			Customer Response				Paperwork Received			Units Numbers			
			Level 1	Level 2	Level 3	Acknowledged	Destroyed	Returned	Used	CofD Received	Email Confirm Destruction	Response Form	No of Units Despatched	No. Units Destroyed	No. of Units Returned	No. of Units Used
1	Al Mourad Est		04.02.15	17.02.15	06.05.15	17.02.15							300	184	0	116
2	Alcon Belgium		04.02.15	18.02.15									3,650	153	0	3,497
3	ALDER HEY CHILDRENS NHS Foundation Trust		04.02.15	18.02.15	06.05.15								80	60	0	20
4	Aneurin Bevan Local Health Board		04.02.15	18.02.15	01.07.15								20	0	0	0
USA	Aspen Surgical Products		04.02.15							N/A			200	0	0	200
5	Barts and The London NHS Trust		04.02.15	18.02.15	01.07.15								520	0	0	0
6	BMI Blackheath Hospital									N/A			110	0	0	110
COMBINED	BMI Bury St Edmunds Hospital		04.02.15	18.02.15	15.04.05	18.02.15										
COMBINED	BMI Carrick Glen Hospital															
COMBINED	BMI Clementine Churchill Hospital															
7	BP S R L		04.02.15	18.02.15									960	0	0	960
8	Bradford Hospitals NHS Trust		05.02.15	18.02.15									40	0	20	20
9	Bunzl Healthcare		04.02.15	18.02.15	01.07.15	05.03.15							15,380	0	129	15,251
10	Cambridge University Hospitals NHS Foundation Trust		05.02.15			13.02.15				N/A			10,500	0	0	10,500
11	Cash Sales		04.02.15	18.02.15	01.07.15								40	0	0	40
12	Cash Sales (Export)		04.02.15			19.02.15							80	0	0	80
13	Compagnia Italiana Oftalmologica SRL		04.02.15	17.02.15		23.02.15							1,780	0	110	1,670
14	E Janach S.R.L.		04.02.15			18.02.15							160	0	0	160
15	East and North Hertfordshire NHS Trust		05.02.15	18.02.15	01.07.15	18.02.15							40	0	0	40
16	John Tranter - South Ophthalmics (Bob)		05.02.15			05.02.15							240	0	0	240
17	Julie Adams - Aspen		05.02.15			05.02.15							120	0	40	80
18	Mark Underwood		05.02.15	01.07.15		05.02.15							20	0	0	20
19	Medical-Mix S.L.		05.02.15			05.03.15							810	99	0	711
20	Mid Yorkshire Hospitals NHS Trust		05.02.15	18.02.15	01.07.15								130	0	0	130
USA	Moria		04.02.15			30.04.15							60	20	0	40
21	Network Medical Products Ltd		04.02.15	15.04.15	01.07.15	18.02.15							800	0	0	800
22	NHS Supply Chain		04.02.15	17.02.15		23.03.15							21,653	0	0	21,653
23	Northern Devon Healthcare NHS Trust		05.02.15	18.02.15		18.02.15							80	8	0	72
24	Nuffield Health		05.02.15	01.07.15		10.02.15							60	0	0	60
25	Odakmed Tibbi Malzemeler Ltd.Sti		04.02.15	18.02.15	01.07.15								590	0	0	590
26	Omma Lite S.A.		04.02.15			05.02.15							3,090	0	90	3,000
27	Paul Rose Ophthalmic (Bob)		05.02.15			05.02.15							90	0	0	90
28	Peterborough and Stamford Hospitals NHS Foundation Trust		05.02.15	18.02.15	01.07.15								500	0	0	500
29	Rachel Willetts - Aspen		05.02.15			05.02.15							10	0	0	10
30	Robert Bennett - Aspen		05.02.15			05.02.15							19	0	0	19
31	Royal Liverpool Childrens NHS Trust		05.02.15	18.02.15	01.07.15	20.02.15							190	0	0	190
32	Royal Surrey County Hospital NHS Trust		05.02.15	18.02.15									270	40	0	230
33	Sancta Maria Hospital		04.02.15	18.02.15		18.02.15							1,860	0	0	1,860
34	Sinead North - Aspen		05.02.15			05.02.15							70	0	0	70
35	Squadron Medical Limited		04.02.15	18.02.15		04.02.15							2,840	0	0	2,840
36	T.P.Whelehan Son and Co. Ltd.		04.02.15			05.03.15							3,110	0	226	2,884
37	Warrington and Halton NHS Foundation Trust		05.02.15	18.02.15		20.02.15							60	0	0	60
38	Whipps Cross University Hospital NHS Trust		05.02.15	18.02.15	01.07.15								300	0	0	300
Totals													70,832	564	615	69,113

70,292