[redacted] [redacted] [redacted]

ZEISS CARL ZEISS MEDITEC

Carl Zeiss Meditec SAS BP 5 - 17053 La Rochelle Cedex 9 - France

Carl Zeiss Meditec SAS
Avenue Paul Langevin
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Phone: +33 (0) 5 46 44 85 50
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Division/Dept.:
Your contact: Materiovigilance / Regulatory Affairs
P. Bernard / M. Fournier

Your ref.:
Yours of:
Our ref.: [redacted]
Date: 08/10/07

RE: VOLUNTARY PRODUCT RECALL – Carl Zeiss Meditec SAS (former IOLTECH) Hydrophobic acrylic lens HYDROMAX of batches 6500 and 6271
COMPLEMENTARY INFORMATION

Dear Sir or Madam,

You have recently received notification for batch recall of 2 specific batches of the hydrophobic acrylic lenses designed for cataract surgery Hydromax (batches 6500 and 6271), following one case notification of early post-operative opalescence.

To date, we have on file the following information on this only case reported:
The lens was implanted 17/07/07; post-operative examination was performed 06/08/07. The case was reported to us 30/08/07.
During a preliminary phone conversation, the surgeon reported a slight haze. Visual acuity before development of cataract was 7/10.
After cataract surgery, visual acuity was identical at 7/10 & no visual consequence on the acuity of the patient was observed.

No explantation is expected for this patient.
Additional examination of the patient is planned in October. Additional information has been requested 30/08/07, including details on patient medical history (the surgeon reported that this patient had venous thrombosis treated by laser before cataract surgery) & details on cataract surgery. This surgeon implanted other Hydromax lenses the same day without problem.

[redacted]

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Recall and additional testing on extended samples have been decided as a very precautious measure.
Therefore, no specific recommendation for already implanted patients is anticipated. Patients already implanted and for whom no early post-operative event has been observed should not have any additional risk.

Should it be the case, we kindly remind you to report any abnormal finding during routine post-operative examination.
Yours sincerely,

[redacted]

Advanced Research Director
Adverse Event correspondent

[redacted]

Head of Regulatory Affairs

Contacts: P. Bernard / M. Fournier - czmlr.survey@meditec.zeiss.com
Tel. +33 5 46 44 08 17 - Fax +33 5 46 44 85 60

ZEISS CARL ZEISS MEDITEC

Ioltech® S.A.
A company of Carl Zeiss Meditec AG
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IOLTECH S.A. BP5 – 17053 La Rochelle Cedex 9 – France

Ref. : [redacted]
Division : Materiovigilance / Regulatory Affairs
Contact : P. Bernard/ M. Fournier
Date : 05.09.07

RE: VOLUNTARY PRODUCT RECALL - Hydrophobic acrylic lens HYDROMAX of batches 6500 and 6271
ACTION REQUIRED

Dear Sir or Madame,

Carl Zeiss Meditec SAS (former Ioltech SAS) sets highest standards when it comes to the quality of our products. We are following strict quality guidelines and procedures to ensure the safe use of our products. In accordance with our standards, we are proceeding a voluntary recall of the following hydrophobic acrylic lenses designed for cataract surgery:

Reference	Batch no.	Serial no
HYDROMAX	6271	ALL
HYDROMAX	6500	all marketed at 05.09.07 except: from HM0811379266 to HM0811379289
		from HM0811379290 to HM0811379304
		from HM0812379758 to HM0812379774
		from HM0812380137 to HM0812380158
		from HM0812380321 to HM0812380325
		from HM0812380349 to HM0812380374
		from HM0812380443 to HM0812380460
		from HM0812380974 to HM0812380986
		from HM0812381031 to HM0812381048
		from HM0812381179 to HM0812381198
		from HM0812381373 to HM0812381394
		from HM0812381645 to HM0812381666

This voluntary recall has been decided following only one complaint of early post-operative opalescence. As we would like to analyze more in detail the cause of this opacification, we would like to ask you to send back the Hydromax lenses of these two specific batches. Please send us back your entire stock of these two batches – it is our intend to replace it with either the re-released lenses or new, thoroughly tested Hydromax lenses. There might be, however, a certain delay in delivery.

Please immediately examine your inventory and quarantine the products subject to this voluntary action.
In addition, please identify your customers and notify them at once of this recall (you may use this notification letter).

Once identified, return all products by fedex to IOLTECH/CARL ZEISS MEDITEC SAS using the FedEx account number 163301628 and referencing BRP/0807 including the enclosed response form as soon as possible to the following address:
IOLTECH/CARL ZEISS MEDITEC SAS
Avenue Paul Langevin BP5
17053 La Rochelle cedex 9
France

We take this precautious and voluntary activity as we would like to guarantee the highest quality standards – now and in the future.

Your assistance is highly appreciated and necessary.
Yours sincerely,

[redacted]
Advanced Research Director
Adverse Event correspondent

[redacted]
Head of Regulatory Affairs

Contacts: M. Fournier / P. Bernard - czmlr.survey@meditec.zeiss.com
Tel. +33 5 46 44 08 17 - Fax +33 5 46 44 85 60

BRP/0807
RETURN RESPONSE FORM

Reference	Batch no.	Serial no
HYDROMAX	6271	ALL
HYDROMAX	6500	all marketed at 05.09.07 except: from HM0811379266 to HM0811379289
		from HM0811379290 to HM0811379304
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		from HM0812381179 to HM0812381198
		from HM0812381373 to HM0812381394
		from HM0812381645 to HM0812381666

Please tick as appropriate :

0 I have read and understand the recall instruction provided in the 03.09.07 letter

0 I have checked my stock and have quarantined inventory consisting of _____ units

0 disposition of recalled products : 0 returned _____(qty, date)

0 held for return _____(qty, date)

0 I have identified and notified my customers that were shipped _____(date of notification)

Any adverse events associated to recalled product ? 0 yes _____

0 no

Name _____

Title _____

Company_____

to be returned to :

IOLTECH/CARL ZEISS MEDITEC SAS

Avenue Paul Langevin BP5

17053 La Rochelle cedex 9

France

Tel: +33 5 46 44 08 17 - Fax : +33 5 46 44 85 60 - to the attention of M. Fournier / P. Bernard