From: Donny_Shapiro/HQ/Corp/OAI
Sent: Wednesday, February 6, 2013 9:17 AM
To: Laura_Storms-Tyler/HQ/Corp/OAI%OAI
Subject: Re: Fw: Duodenoscope safety recall ??

Thanks, however as discussed how can this get resolved? We continue to have these issues for products and responses. Any discussion at your level how leadership at OMSC can change?

Donny Shapiro
Director, Regulatory Affairs & Quality Assurance
Olympus Corporation of the Americas
Medical Systems Group
2400 Ringwood Ave.
San Jose, CA 95131
408.935.5161
408.621.2040 (cell)

Laura Storms-Tyler---02/06/2013 08:56:53 AM---Hi Donny I will send you by separate e-mail the communication between myself and OEH on this topic.

From: Laura Storms-Tyler/HQ/Corp/OAI
To: Donny Shapiro/HQ/Corp/OAI@OAI
Date: 02/06/2013 08:56 AM
Subject: Re: Fw: Duodenoscope safety recall ??

Hi Donny

I will send you by separate e-mail the communication between myself and OEH on this topic.

I was pushing OMSC to take a position on this EU action, but as you can see from my communications with OMSC, they feel that no universal communication is required. Therefore, it places us in an awkward position. However, this is part of the bigger problem, in my viewpoint, of lack of leadership and direction from OMSC.

Regards,

Laura
Laura Storms-Tyler
V.P., Regulatory/Clinical Affairs & Quality Assurance
Olympus Corporation of the Americas
3500 Corporate Parkway
Center Valley PA 18034
Phone (484) 896-5688
Cell (631) 871-1724
laura.storms-tyler@olympus.com

Donny Shapiro---02/06/2013 11:44:16 AM---Hi Laura, For my own understanding, is the issuance of safety alerts communicated to notified bodies

From: Donny Shapiro/HQ/Corp/OAI
To: Laura Storms-Tyler/HQ/Corp/OAI@OAI
Date: 02/06/2013 11:44 AM
Subject: Fw: Duodenoscope safety recall ??

Hi Laura,
For my own understanding, is the issuance of safety alerts communicated to notified bodies?
If an alert is issued in Europe only, with a statement that its not needed worldwide, what is the implications if the alert then gets forwarded and sent out in the US?

Thanks

Donny Shapiro
Director, Regulatory Affairs & Quality Assurance
Olympus Corporation of the Americas
Medical Systems Group
2400 Ringwood Ave.
San Jose, CA 95131
408.935.5161
408.621.2040 (cell)

----- Forwarded by Donny Shapiro/HQ/Corp/OAI on 02/06/2013 08:41 AM -----

From: Neal Walther/Central/Medical/OAI
To: Mary Ann Drosnock/HQ/Medical/OAI
Cc: James Kovacic/HQ/Medical/OAI, Philip Doyle/HQ/Medical/OAI, Laura Storms-Tyler/HQ/Corp/OAI, Donny Shapiro/HQ/Corp/OAI, Steve Thomas/HQ/Medical/OAI, Tom McNutt/HQ/Medical/OAI, Erin McClain/East/Medical/OAI, "Complaints" <Complaints@Olympus.com>
Date: 02/06/2013 08:20 AM
Subject: Re: Duodenoscope safety recall ??

Thank you Mary Ann.

Is it ok to forward your message to my concerned customer?

I assume that this safety alert issued in Europe is not necessary to communicate to customers in the US, other than to possibly reinforce our already published reprocessing instructions from our manual?

Thank you,

.....
Neal Walther
Endoscopy Account Manager
Olympus America
317-376-0561
neal.walther@olympus.com

Sent from my iPhone

On Feb 6, 2013, at 11:12 AM, "Mary Ann Drosnock" <MaryAnn.Drosnock@olympus.com> wrote:

Good morning everyone,

The aforementioned safety alert was issued in Europe due to a complaint related to improper reprocessing of the TJF-Q180V. Olympus Europa had sent out a safety alert to their customers and created a quick reference guide which reminding them of the proper reprocessing method for the TJF-Q180V as it differs from previous generations. The reprocessing issues that were stressed in the quick reference guide reminded customers that this model of endoscope has a fixed distal cap and sealed elevator wire channel that is not brushed. However, there is a requirement during manual cleaning to brush the front and rear of forceps elevator at the distal tip using the brush MAJ-1339 (channel opening cleaning brush) as instructed in the reprocessing manual. Additionally, the quick reference guide reminded customers to raise the forceps elevator to the intermediate position (approximately 45 degrees) prior to placing the endoscope into the AER to be sufficiently cleaned and disinfected.

Thank you,

Mary Ann Drosnock, MS, CIC, CFER
Associate Manager, Infection Control
Medical Systems Group
Olympus America Inc.
3500 Corporate Parkway
Center Valley, PA 18034

Phone: (484) 896-3059
Cell: (610) 704-9817
Fax: (484) 896-7157
maryann.drosnock@olympus.com

www.olympusamerica.com

----- Forwarded by Mary Ann Drosnock/HQ/Medical/OAI on 02/06/2013 11:08 AM -----

From: Philip Doyle/HQ/Medical/OAI
To: Mary Ann Drosnock/HQ/Medical/OAI@OAI, Laura Storms-Tyler/HQ/Corp/OAI@OAI
Date: 02/06/2013 05:38 AM
Subject: Fw: Duodenoscope safety recall ??

Good morning,
Are you familiar with a safety alert that we supposedly sent out recently about duodenoscope reprocessing?
Thanks,
Phil

Philip Doyle
Director of Marketing, Core GI

MSG Endoscopy Marketing
Olympus America Inc.
3500 Corporate Parkway
Center Valley, PA 18034

Phone: (484) 896-5670
Cell: (484) 538-6251
philip.doyle@olympus.com

www.olympusamerica.com

----- Forwarded by Philip Doyle/HQ/Medical/OAI on 02/06/2013 05:36 AM -----

From: Neal Walther/Central/Medical/OAI
To: Philip Doyle/HQ/Medical/OAI@OAI, James Kovacic/HQ/Medical/OAI@OAI, Complaints@OAI
Cc: Tom McNutt/HQ/Medical/OAI@OAI, Erin McClain/East/Medical/OAI@OAI
Date: 02/06/2013 12:04 AM
Subject: Fw: Duodenoscope safety recall ??

Phil or Jim,

Could either of you please confirm if there has been a recent safety alert sent out by Olympus , concerning the reprocessing of our Duodenoscopes? TJF or possibly JF?

Our customer below stated that she received information from ECRI, a group that provides a database and alerts of MDSR's.

Please confirm and send me any information that I may need to pass on to my customers.

Thank you,

Neal K. Walther
Endoscopy Account Manager
Medical Systems Group
Olympus Corporation of the Americas
Indianapolis, Indiana

Cell: (317) 376-0561
neal.walther@olympus.com

*** Please ask about the new Olympus EVIS EXERA III Endoscopy System, and "190 Series" endoscopes:**
http://www.olympusamerica.com/msg_section/msg_evis_exera_iii.asp

----- Forwarded by Neal Walther/Central/Medical/OAI on 02/05/2013 11:58 PM -----

From: "Selking, Susan" <SSelking@ecommunity.com>

To: "'erin.mcclain@olympus.com'" <erin.mcclain@olympus.com>, "neal.walther@olympus.com" <neal.walther@olympus.com>
Date: 02/05/2013 07:58 AM
Subject: RE: Fwd: Duodenoscope safety recall

It came through ECRI.

Susan Selking BSN RN CGRN
Team Leader Community North Endoscopy
Phone: 317.621.5424
sselking@eCommunity.com

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From: Erin.McClain@Olympus.com [mailto:Erin.McClain@Olympus.com]
Sent: Tuesday, February 05, 2013 7:34 AM
To: Neal.Walther@Olympus.com
Cc: Selking, Susan
Subject: Re: Fwd: Duodenoscope safety recall

Susan,
Neal and I are not aware of this but we are checking with corporate to see. I will let you know when I find out something definite. Did you get the safety alert from Olympus?
Thanks

Erin M McClain
Endoscopy Support Specialist
Regional Service & Repair - Midwest
Medical Systems Group
Olympus America Inc.

Cell Phone: (317) 448-0793
Regional Office: 877-430-5481
National Service Hotline: 800-848-9024
E-Mail: erin.mcclain@olympus.com
Web: http://www.olympusamerica.com/serviceportal

From: "Selking, Susan" <SSelking@ecommunity.com>
Date: February 4, 2013, 11:05:55 AM EST
To: "neal.walther@olympus.com" <neal.walther@olympus.com>
Subject: Duodenoscope safety recall

Neal,

I received a ECRI safety alert stating that duodenoscopes may not be cleaned properly. It said I should have received a safety advice letter in January, reply form, and cleaning instructions from Olympus. I have not received any of these items. Can you verify this for me, and send me what I was supposed to receive so that I can respond to this safety alert?

Thanks!

Susan Selking BSN RN CGRN
Team Leader Community North Endoscopy
Phone: 317.621.5424
sselking@eCommunity.com

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