From:	Hendrickson, Amy [DPYUS]
To:	Cary, Polly [DPYUS]
CC:	Reimink, Matt [DPYUS]
Sent:	12/19/2008 3:21:21 PM
Subject:	FW: ASR™ XL metal bearings demonstrated 99.2% survivorship at 3 years does NOT match our results!!!

Hi Polly,

Please see the email below from Dr. Sampson. Our department will take care of the complaint reporting; however, we feel it would be best if someone on your end contacts the surgeon. If this is not your product responsibility, please make sure this gets forwarded to the appropriate person so that they can contact the doctor as he has requested.

Thank you,

Amy Hendrickson Complaint/MDR Administrator DePuy Johnson & Johnson Phone: 800-473-3789 x 7179 Fax: 574-372-7490

From: Ask DePuy [DPYUS]
Sent: Friday, December 19, 2008 8:30 AM
To: Product Complaint/Warsaw [DPYUS]
Subject: FW: ASR™ XL metal bearings demonstrated 99.2% survivorship at 3 years does NOT match our results!!!

Please find below a product complaint email we received late yesterday in the Ask DePuy mailbox.

Thank you,

Lisa Mahan

From: Thomas Sampson [mailto:tgsampsonmd@msn.com]
Sent: Thursday, December 18, 2008 11:59 PM
To: Ask DePuy [DPYUS]
Subject: ASR<sup>™</sup> XL metal bearings demonstrated 99.2% survivorship at 3 years does NOT match our results!!!

Dear Sir:

We have abandoned the use of the ASR cup due to 15-20% failures due to to fibrous ingrowth. We have met with Drs. Schmaltzreid and Vail at AAOS 2008 and were left feeling it was our surgical technique. We have done thousands of THR's in the past and have never had such a high failure rate. Please contact me to discuss this as I have never had so many patients have early failure and I has affected my reputation. Sincerely,

Thomas G. Sampson M.D.

Medical Director: Total Joint Center Saint Francis Memorial Hospital, Medical Director of Hip Arthroscopy at Post Street Surgery Center

Office: Post Street Orthopaedics and Sports Medicine 2299 Post Street Suite 107 San Francisco, California 94115-3443 (Phone) 415-345-9400

## From: AskDepuy@dpyus.jnj.com To: tgsampsonmd@msn.com Subject: DePuy Orthopaedics Update: Winter Surgeon eNewsletter Date: Thu, 18 Dec 2008 08:45:46 -0600

To view this email as a web page, go here.

	l					
A	Message from	David Floyd				
ha inn	What a difference a year makes. In 2008, DePuy Orthopaedics, Inc. (DePuy) has made significant progress in advancing orthopaedic care through product innovation, professional education and patient education. As you'll see in this issue of					
<i>In-The-Know</i> ™, DePuy ends the year looking back on several successful product launches, and poised to do more of the same in 2009.						
DePuy also continues to motivate osteoarthritis sufferers to learn more about joint replacement and seek the care of an orthopaedic surgeon through our direct-to-patient education campaign, <i>Never Stop Moving</i> ™. DePuy's recent print ad captures the story of DePuy Knee Patient Jane Armstrong, who was able to compete in the 2008 Cycling Paralympics in Beijing. Jane's accomplishments remind us of why we are proud to be in this business.						
It's gratifying to see what's been accomplished in 2008, and we're looking forward to working with you in 2009 to further advance orthopaedic care for patients.						
All the best,						
David						
New A.L.P.S. Anatomic, Locked Plating Systems for Hand and Fibula fractures						
This month DePuy launches the A.L.P.S. Hand and Fibula Fracture System, which provides increased intra-operative fixation options for fractures of the metacarpal and phalangeal bones.						
The A.L.P.S. Hand Fracture System uses low-profile titanium plates that can be contoured directly to the anatomy, while the A.L.P.S. Fibula System features two plate designs that offer surgeons hybrid technology with locking and non-locking capabilities in the same plate for a						

stable construct in degraded bone tissue. For more information, please contact your DePuy Sales Representative.

# New High Stability, Low Wear Solutions

With the introduction of AltrX<sup>™</sup> LD large diameter polyethylene liners and matching BIOLOX® delta TS femoral heads, DePuy has enhanced its portfolio of high stability, low wear solutions for hip replacement. With 40 and 44mm inner diameter (ID) sizes, this new bearing combination offers improved

range of motion, may increase the distance needed to dislocate, and improve wear resistance. In fact, volumetric wear from a 48mm AltrX LD liner is as low as previous generation 28mm polyethylene liners (Data on file with DePuy Orthopaedics, Inc.).

## Two Studies Demonstrate DePuy Metal Bearings Survivorship

According to two separate studies, Pinnacle® metal-on-metal bearings from DePuy Orthopaedics optimize wear resistance and durability, resulting in favorable patient outcomes. In a multi-center prospective study, Pinnacle metal bearings demonstrated 5-year midterm survival of 99.8%. These findings are based on

data presented at the 2007 American Academy of Orthopaedic Surgeons meeting.\* Separately, according to the Joint Registry of England and Wales (unpublished data), ASR™ XL metal bearings demonstrated 99.2% survivorship at 3 years. Over 1,500 ASR™ XL implants were included in the Joint Registry analysis.

\*Note: These findings are based on a review of metal-on-metal bearings data provided in the original study. Reference: Kindsfater, K., W.P. Barrett, J.E. Dowd, C.B. Southworth and M.J. Cassell. "99.9% Midterm survival of the Pinnacle Multi-Liner Acetabular Cup in a Prospective Multi-Center Study," Poster Presentation #P077, AAOS, San Diego, CA. February 14 -18, 2007 - MoM cohort at 5 yrs.

# Large-Scale Study Shows 97.2% Survivorship for Sigma® Knee System at 10 Years

As patient demand for total knee replacement (TKR) increases, especially among younger and more active patients, implant durability remains a major concern. Survivorship analysis quantifies implant success over time, thus, addressing this durability concern. According to a study published in the December issue of the *Journal of Bone and Joint Surgery* (British edition), the Sigma® Knee System yielded a 10-year survivorship of 97.2% excluding infection-related revisions and a 95.6% overall survivorship at 10 years.\* The study examined a notably large population: 1,512 patients and 1,970 knees.

\*Reference: *Journal of Bone and Joint Surgery* - British Volume, Vol. 90-B, Issue 12, 1594-1596.

DePuy Knee Patient Featured in *Never Stop Moving*™

# Campaign

# The *Never Stop Moving*™

direct-to-patient education campaign is continuing to raise awareness of DePuy's Hip and Knee Solutions. Since August 8, more than 225,000 patients have visited our patient web sites, with 48,000 using DePuy's Surgeon Locator to find a local surgeon who uses DePuy products.

# Update about AllAboutMyDoc.com Services

If you currently have a DePuy-hosted practice web site through AllAboutMyDoc.com, please note that this service will no longer be available as of December 31, 2008. For surgeons who don't currently have an independent practice web site, DePuy will continue to support AllAboutMyDoc.com sites until the end of the year to provide time for transitioning to a new service. As of December 31, if you have surgeon-specific URLs associated with AllAboutMyDoc.com, DePuy will re-direct patients to your web sites. For surgeons who do not currently have an independent practice site, the American Academy of Orthopaedic Surgeons (AAOS) offers a similar service. To learn more please visit: www.orthodoc.aaos.org/pows.cfm .

If you have any questions about AllAboutMyDoc.com, please contact your DePuy Sales Representative.

# Direct Anterior Approach Web Cast Available Online

Surgeons interested in the Anterior Approach to THA can view a recent web cast of the procedure using the Tri-Lock® Bone Preservation Hip Stem. The procedure was performed by Daniel Gannon, M.D., one of the designing surgeons of the system. The Tri-Lock Hip System is a new tapered-wedge titanium stem engineered to help preserve bone tissue. Surgeons may view the procedure for free on the Web at <u>www.OR-Live.com</u> by clicking on the "Previous Webcasts" option.

# **Upcoming Surgeon Training Opportunities**

Please contact your DePuy Sales Representative to learn more about these educational opportunities or visit the following section of DePuyOrthopaedics.com: <a href="http://www.depuyorthopaedics.com/HealthCare/Pages/EducationAndTraining.aspx">www.depuyorthopaedics.com</a>. Please note that course dates and locations are subject to change.

#### January 2009

January 29: Anterior Approach for Total Hip Arthroplasty (Phoenix, AZ) January 29-30: Agility LP Ankle Learning Center-DPM (Tucson, AZ)

#### February 2009

February 3-4: Advanced Total Ankle Replacement Learning Center-MD (Baltimore, MD) February 4-6: Signature Series Symposium-Trauma Course (Miami, FL) February 6: High Performance Approaches to Total Knee Arthroplasty Learning Center (Phoenix, AZ) February 12-13: CAS Surgeon Course (Las Vegas, NV) February 13: Masters Knee Revision (Sigma) Learning Center (Miami, FL) February 24: Pre-AAOS - Cadaver Lab (Henderson, NV)

### March 2009

March 11-12: Partial Knee Learning Center (Memphis, TN) March 13: High performance Learning Center (Memphis, TN) March 19: Anterior Approach Learning Center (Miami, FL) March 19-21: 4th & 5th Year Residents/Fellows Course (West Coast) - Cadaver Lab (San Francisco, CA) March 26-27: Partial Knee Learning Center (San Francisco, CA)

This email was sent to: tgsampsonmd@msn.com

This email was sent by: DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46580 USA

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