

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

IN RE: SULZER HIP PROSTHESIS : Case No.1:01-CV-9000  
AND KNEE PROSTHESIS : (MDL Docket No. 1401)  
LIABILITY LITIGATION :  
: JUDGE KATHLEEN M. O'MALLEY  
:  
:  
: (This Document Relates to All Cases)

**PRELIMINARY NOTICE OF  
CLASS ACTION AND PROPOSED SETTLEMENT**

**TO: ALL CITIZENS OR RESIDENTS OF THE UNITED STATES WHO HAVE HAD PLACED IN THEIR BODIES EITHER A SULZER INTER-OP™ ACETABULAR SHELL HIP IMPLANT OR A SULZER Natural Knee II® TIBIAL BASEPLATE KNEE IMPLANT.**

**Read this notice carefully. You may be entitled to share in the settlement proceeds of a class action lawsuit. Your rights to money and other benefits may be affected.**

**This is not a lawsuit against you. You are not being sued. This is a notice of proposed class action settlement. In the following notice, you are given important information that will help you decide whether you would like to participate in this class action settlement.**

**This is a Preliminary Notice discussing the claims in this litigation and the terms of the proposed settlement agreement. The settlement agreement provides for due diligence discovery. At the conclusion of this discovery, a Final Notice will be sent to you, which will provide you with additional information about the settlement and your options to participate in the settlement or**

**exclude yourself from the settlement.**

Pursuant to an Order of the United States District Court for the Northern District of Ohio (the “District Court” or “The Court”), you are being provided with this Preliminary Notice of: (1) the conditional certification of a Class Action of which you are a member, and the preliminary approval of a proposed settlement with Sulzer Orthopedics Inc., Sulzer Medica Ltd., and all affiliates in the case known as *In re Sulzer Hip Prosthesis and Knee Prosthesis Liability Litigation*, Case No. 1:01-CV-9000 (MDL Docket No. 1401), pending in the District Court (“*In re Sulzer Litigation*”); (2) a fairness hearing to be held on Tuesday, March 12, 2002, at 10:00 a.m. in the Howard M. Metzenbaum U.S. Courthouse, 201 Superior Avenue, Cleveland, Ohio, 44114; and (3) the March 2, 2002 deadline for a Class Member to: (i) exercise his/her right to opt-out of the Settlement; (ii) file a written objection to the Settlement; and (iii) submit a request to participate in the Fairness Hearing. You will receive a Final Notice in January 2002, which will provide you with additional information about the proposed settlement and will provide a further description of the procedure to “opt-out” (exclude yourself from the Settlement) or comment on the Settlement.

### **BACKGROUND**

On December 8, 2000, Sulzer Orthopedics Inc. announced the voluntary recall of certain Inter-Op™ Acetabular Shells [“Affected Inter-Op™ Acetabular Shells”] used to make hip implants. A subsequent “Special Notification” announced Sulzer’s removal from the market of certain Natural Knee II® Tibial Baseplates [“Affected Natural Knee II® Tibial Baseplates”], used to make knee implants. The two products were manufactured using the same process.

A number of individuals have filed lawsuits against Sulzer Orthopedics Inc., Sulzer Medica Ltd., Sulzer Orthopedics Ltd. and various affiliates (collectively “Sulzer” or “Defendants”) for defectively

designing, marketing and manufacturing both the Affected Inter-Op™ Acetabular Shells and the Affected Natural Knee II® Tibial Baseplates. Plaintiffs also alleged that Defendants breached express and implied warranties associated with both products. All federal cases filed regarding the Affected Inter-Op™ Acetabular Shells have been transferred by the Judicial Panel on Multidistrict Litigation to the Honorable Kathleen O'Malley of the United States District Court for the Northern District of Ohio (The "Court") for further proceedings. The Court has not taken a position on the merits of any claims or defenses asserted by the parties. You are being provided this Notice because records indicate that you were implanted with either an Affected Inter-Op™ Acetabular Shell or a Natural Knee II® Tibial Baseplate.

### **THE PARTIES**

The following is a brief description of the individuals representing the interests of the Class and Sulzer.

#### **Representative Plaintiffs**

The persons named as class representatives in this product liability action are citizens or residents of the United States who have had placed in their bodies either a hip implant or knee implant, manufactured by Sulzer, and containing either an Affected Inter-Op™ Acetabular Shell or Natural Knee II® Tibial Baseplate.

#### **Sulzer Medica Ltd.**

Defendant Sulzer Medica Ltd. is a publicly traded company which designs, manufactures and markets implantable medical devices and biological products for cardiovascular and orthopedic markets worldwide. Defendant Sulzer Medica Ltd. is the parent company of Defendants Sulzer Orthopedics Ltd. and Sulzer Orthopedics Inc. Its principal place of business is in Winterthur, Switzerland.

**Sulzer Orthopedics Inc.**

Defendant Sulzer Orthopedics Inc. is a company in the business of designing, manufacturing and distributing orthopedic devices, and its principal place of business is Austin, Texas.

**Sulzer Orthopedics Ltd.**

Defendant Sulzer Orthopedics Ltd. is a company in the business of designing, manufacturing and distributing orthopedic devices, and its principal place of business is Baar, Switzerland.

Defendants, at all times relevant to the claims in this action, designed and/or manufactured and/or distributed and/or sold and/or otherwise placed into the stream of worldwide trade or commerce hip and knee implants containing Affected Inter-Op™ Acetabular Shells and Affected Natural Knee II® Tibial Baseplates.

**CONDITIONAL CERTIFICATION OF A CLASS ACTION  
AND PRELIMINARY APPROVAL OF SETTLEMENT**

On \_\_\_\_\_, 2001, the District Court conditionally certified, pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2) and 23(b)(3), a class action composed of four subclasses. Subclass I consists of those Class members who have an unsatisfied claim arising out of a hip revision surgery performed prior to the Final Judicial Approval Date; Subclass II consists of Class members who have an unsatisfied claim arising out of hip revision surgery that will be performed on or after the Final Judicial Approval Date; Subclass III consists of those Class members who have an unsatisfied claim arising out of a knee revision surgery performed prior to the Final Judicial Approval Date; and Subclass IV consists of Class members who have an unsatisfied claim arising out of knee revision surgery that will be performed on or after the Final Judicial Approval Date. In the same Order, the Court preliminarily approved the proposed settlement.

Several Objectors have filed motions requesting permission to appeal the District Court's class certification decision under Federal Rules of Civil Procedure 23(f) in the United States Court of Appeals for the Sixth Circuit. No decision has been rendered by the Court of Appeals.

Counsel for the parties have begun the due diligence discovery in connection with the Settlement. This discovery should be completed by the end of December 2001. When this due diligence discovery is completed, the parties will send out a Final Notice providing additional information, including your rights and duties by which you will have to decide whether you desire to remain in the Class and the procedures to file any comments with the Court relating to the Proposed Settlement.

March 2, 2002 will be the last day for Class members to: (a) exercise their right to opt-out of the Settlement; (b) file a written objection to the Settlement; and (c) submit a written request to participate in the Fairness Hearing. If you opt-out of the class, you will no longer be bound by the terms of the Settlement. This means that you will no longer be represented by Class Counsel, and will not be able to recover anything under the terms of the Settlement Agreement. Should the Court grant final approval of the proposed Settlement, all remaining members of the class will be bound by these and all other orders and judgments entered by the Court.

### **SUMMARY OF THE SETTLEMENT TERMS**

The terms and conditions of the proposed settlement are contained in the Class Action Settlement Agreement between Defendants and Representative Plaintiffs (Amended and Restated as of October 12, 2001). You may view the entire agreement by visiting the website [www.sulzerimplantsettlement.com](http://www.sulzerimplantsettlement.com) This Preliminary Notice is intended as a summary only.

To resolve this litigation, the parties will create a Settlement Trust, which will administer four funds:

a Research Fund, Medical Monitoring Fund, Patient Benefit Fund, and an Extraordinary Injury Fund.

- The defendants will put \$4 million in cash into the Research Fund, which will be used for “medical research relating to reconstructive orthopedic implants . . . for the benefit of Class Members.”

- The defendants will put \$20 million in cash into the Medical Monitoring Fund, which will be used to monitor the implants of claimants who have not yet had revision surgery, by paying for “the reasonable unreimbursed costs of one physician visit and one set of x-rays associated therewith during each of the annual periods ending on the second year, third year and fifth year following the date of” the original implantation.

- The defendants will put at least \$361.5 million in cash and stock into the Patient Benefit Fund (more if required), to pay compensation to implantees and their associated consortium claimants, as follows:

- to claimants who do not have revision surgery, \$750 in cash, [minimum of] \$2,000 in stock, and \$500 to their spouses.

- to claimants who have one revision surgery, \$37,500 in cash, [minimum of] \$20,000 in stock, and \$5,000 to their spouses.

- to claimants who have more than one revision surgery, \$63,500 in cash, [minimum of] \$34,000 in stock, and \$5,000 to their spouses.

- The defendants have committed to pay any claims against a Class Member or his/her attorney for reimbursement of medical expenses necessitated by an Affected Product. To the extent the total amount paid by defendants to medical providers for unreimbursed medical expenses is less than \$125 million, any unused funds shall be divided as follows: 80% to the Extraordinary Injury Fund; 20% shall revert back to the defendants. This is the only fund in which defendants have any right of reversion.

- The defendants will provide \$33.3 million in cash and stock as payment of attorney fees to

claimants' individual attorneys, at the rate of 1/3 of the claimants' compensation.

- The defendants will provide \$4.5 million in cash to cover the costs of administration of the Settlement Trust.

- The defendants will put a minimum of \$30 million in cash into the Extraordinary Injury Fund, to pay for additional compensation to implantees and their associated consortium claimants.

- Unless otherwise noted, any amounts not paid out of the other Funds will be transferred into the Extraordinary Injury Fund, so that this Fund may ultimately exceed \$100 million in cash and stock.

- Except where specifically noted, the money or stock placed into the Settlement Trust will not revert to the defendants; rather, it will all eventually be paid to participating class members.

- There will not be any reduction of the amounts that the defendants must pay into the Settlement Trust based on claimants who opt out of the class.

- The defendants have placed liens on all of their available assets in favor of the Settlement Trust, to secure all of their obligations; these liens will not be released until the defendants have met all of their obligations.

- To pay the amounts listed above, the defendants will: (a) put all available insurance proceeds into the Settlement Trust; (b) put all available cash into the Settlement Trust, except for one month's working capital; (c) put the required number of stock shares into the Settlement Trust; and (d) put 50% of their net annual income into the Settlement Trust.

- Additional insurance proceeds relating to claims arising out of the implantation of Affected Natural Knee II Tibial Baseplates may become available. If so, all of those proceeds will be placed into the Settlement Trust and allocated to the subclasses as agreed to by the parties and the insurers, subject to Court approval.

- Additional funds may be available from a related Sulzer entity. If so, those funds will be placed into the Settlement Trust and be allocated among the subclasses as agreed to by the parties, and subject to Court approval.

- If the defendants settle a case with an opt-out claimant on terms more favorable than are received under the Settlement Agreement by participating claimants, then the defendants agree to pay all participating claimants the increment.

Defendants have already provided the Settlement Trust with a security interest in all of Defendants' assets, the purpose of which is to insure Defendants' obligations under the Proposed Settlement Agreement. The Security interests terminate upon satisfaction of Defendants' obligations under the Settlement Agreement, or if the Court does not give final approval to the Settlement Agreement.

The Court will appoint a Claims Administrator for purposes of administering claims for Class benefits and making determinations under the Settlement Agreement.

### **RELEASE OF CLAIMS**

Final approval of the Settlement Agreement will mean that each individual Settlement Class Member forever releases any claims relating to either the Affected Inter-Op™ Acetabular Shell or Natural Knee II® Tibial Baseplate against Sulzer Orthopedics Inc., Sulzer Orthopedics Ltd., Sulzer AG, Sulzer Medica Ltd. and any other affiliated entities, as well as insurers of the Defendants and the Defendants' stockholders, directors, officers, attorneys, employees, agents, sales representatives, suppliers, vendors or sub-contractors. Settlement Class Members will also release all past, present and future claims by any person or entity for product warranty, medical care, injuries, or damages relating to either the Affected Inter-Op™ Acetabular Shell or Affected Natural Knee II® Tibial Baseplate.

### **HOW YOUR RIGHTS ARE AFFECTED**

This action has been conditionally certified as an opt-out class action. If you fall within the definition of the Class as set forth above, you are automatically a member of the Class. Should you wish to remain as a Class member, you need do nothing. Settlement Class members may, if they wish, comment on or object to the Settlement. If you remain in the Settlement Class, and the Settlement is approved, you will be bound by the Court's orders and judgment in *In re Sulzer Hip Prosthesis and Knee Prostheses Liability Litigation*.

If you do not wish to participate in the Settlement, you will be required to opt-out of, or exclude yourself from, the Settlement by March 2, 2002. The procedures for filing a claim to participate in the Settlement and the procedure for excluding yourself from the Settlement will be addressed in the second Notice, which you will receive on or before January 5, 2002.

**YOU DO NOT NEED TO DO ANYTHING AT THIS TIME TO OPT-OUT OF THE SETTLEMENT OR TO FILE A CLAIM TO RECEIVE ANY PAYMENTS PURSUANT TO THE TERMS OF THE SETTLEMENT.**

### **REPRESENTATION OF THE CLASS**

For purposes of this settlement, you are represented by Class Counsel, appointed by the Court in *In re Sulzer Hip Prosthesis and Knee Prosthesis Liability Litigation*. You may hire an individual attorney, at your own expense, to appear on your behalf for the purpose of commenting on the matters contained in this Notice, but you are not required to hire an attorney in order to appear, comment, or be heard at the fairness hearing, or to participate in the settlement, if it is approved.

### **ATTORNEYS' FEES AND EXPENSES**

Upon Final Approval of the Settlement, Class Counsel shall, as compensation for their services rendered, make an application for a Court award of fees and expenses. Class Counsel will also seek reimbursement of their expenses, including expert witness fees. The award of fees and expenses to Class Counsel shall be paid by Defendants.

### **FAIRNESS HEARING**

A fairness hearing will be held at the Howard M. Metzenbaum United States Courthouse, 201 Superior Avenue, Cleveland, Ohio 44114, at 10:00 a.m. on Tuesday, March 12, 2002, to determine whether class certification is proper, and whether the Settlement is fair, adequate, and reasonable and should be approved by the Court.

At the hearing, any Class member may appear in person, or through counsel, and may be heard in support of, or in opposition to, the fairness, reasonableness, and adequacy of the Settlement and on class certification. Your Notice to appear and comment on the Settlement must be filed with the Court by March 2, 2002. The procedure to be heard in support of, or in opposition to, the Settlement will be described more fully in the Final Notice which you should receive in January, 2002.

### **FURTHER INFORMATION AVAILABLE**

This Notice contains a summary of the proposed Settlement and class certification and is not intended, and should not be construed, as a complete statement of the proposed settlement or class certification. Any questions you may have about the matters addressed by this Notice should not be made to the Court, but should instead be directed to the Plaintiffs' Liaison Counsel:

Plaintiffs' Liaison Counsel  
*In re Sulzer Litigation*  
1600 Midland Building  
101 Prospect Avenue, W.  
Cleveland, OH 44115  
1-800-683-1861

Certain of the pleadings and other papers filed in this action are also available for inspection at the office of the Clerk of the Court, Howard M. Metzenbaum U.S. Courthouse, 201 Superior Avenue, Cleveland, Ohio 44114.

Class Counsel will also establish a website at [www.sulzerimplantsettlement.com](http://www.sulzerimplantsettlement.com). On the website, Class Counsel will post a copy of this Preliminary Notice, the Final Notice, the Class Action Settlement Agreement, and a copy of the Proof of Claim when it is completed.

By Order of The Honorable Kathleen M. O'Malley,  
Judge of the United States District Court for the  
Northern District of Ohio

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Clerk, United States District Court