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Products
Surgical Support
Services
Education
About Us
Careers
Sales Force
Site Map
Search
Events
What's New

Inter-Op Voluntary Recall

Sulzer Orthopedics Worldwide

Inter-Op Voluntary Recall
A Message from the President | Press Release 12/6/00 | Press Release 1/18/01
Patient Letter | Frequently Asked Questions | About Total Hip Replacement

Frequently Asked Questions

(Updated January 11, 2001)

- **What specific product was recalled by Sulzer Orthopedics?**

Sulzer Orthopedics has recalled its Inter-Op acetabular shell manufactured in the United States. Most of the recalled shells were produced October 1999 and after. A limited number of recalled shells were produced as early as June 1997.

The products affected by this voluntary recall are listed below:

Catalog Numbers	Product	Lot Numbers Beginning #	Lot Numbers Ending #
4360-00-039/065	Hemispherical Shells	1307848	1465372
4361-00-039/071	Rim Flare Shells	1398234	1465247
4362-00-043/081	Revision Shells	1397531	1465242
4363-00-053/081	Protrusio Shells	1403576	1453540

- **What caused the recall of the Inter-Op shell?**

Some of these implants had an unacceptable level of mineral oil-based lubricant on the product. Based on the expertise of some independent scientists, this residue may cause adverse reactions in the body that can lead to loosening of the shell.

- **What are the components of the lubricant residue?**

There are five mineral oil based lubricants used in the machines to manufacture these parts. These include Mobil DTE 24, Mobil Velocite Oil No. 8, Mobil Velocite Oil No. 6, Mobil Vactra Oil No. 2, and Mobil Vactra Oil Heavy

- **Where can I find more data or Material Safety Data Sheets (MSDS) on the lubricants?**

We use 5 mineral-oil based lubricants in the machines to manufacture the Inter-Op shells. All five are made by Mobil.

Mobil has a searchable database containing the MSDS sheets for its products. The database can be found at: http://emmsds.ihsgsl.com/msds/search.html

EXHIBIT 2

The Mobil products are:

- DTE 24
- Velocite Oil No. 8
- Velocite Oil No. 6
- Vactra Oil No. 2
- Vactra Oil Heavy

To find information on these lubricants, enter part of the name in the TRADE NAME field (ex velocite), you will be able to select and print out the MSDS you want. All the lubricants have a similar base (approximately 95% mineral oil) and, therefore, the MSDS sheets are almost identical.

- **How could this happen in your manufacturing process?**

Our investigation indicated that a small amount of mineral oil-based lubricant leaked into the machine coolant and residual amounts of this lubricant remained on the shell after the cleaning process.

- **How many shells have been implanted? How many of those have been recalled?**

The actual affected product lots included approximately 25,000 parts. 17,500 of the affected products were implanted. All remaining affected products were pulled back.

- **Why didn't you recall all hip implant products?**

No other implants produced by Sulzer are manufactured by the same process as the Inter-Op shell. There have been no reports from the field of other products exhibiting a similar response. After a thorough investigation, we can state, without reservation, that no other products are affected, and we can unequivocally state that each of our products is safe and clean.

- **Did you manufacture the Inter-Op shell using different processes than for your other products?**

Yes. Parts not included in the recall are manufactured by a different process.

- **How did you conduct the investigation to determine what caused the problem with the Inter-Op shell?**

We extensively reviewed all material available, such as patient and lot histories, manufacturing processes, product design and instrumentation, retrievals, etc, until we identified the residue as the cause of the loosening. Specifically we:

- Reviewed patient histories.

- Reviewed product lot histories.
- Reviewed manufacturing processes.
- Reviewed surgical techniques.
- Reviewed design requirements for implants and instrumentation (reamers).
- Inspected production parts (implants and reamers) for adherence to current inspection and design requirements.
- Reviewed inspection procedures.
- Reviewed process parameters and changes to processes.
- Conducted fact finding surgeon visits.
- Inspected explants internally and at independent laboratory.
- Reviewed histology/pathology reports.
- Reviewed biological test reports.
- Repeated Cytotoxicity tests in independent labs.
- Conducted chemical analyses

- **Has the problem been solved and is there proof that it has been solved?**

Yes. We have completely eliminated one of the two machining steps unique to the Inter-Op process. We modified the remaining step to reflect the original process that gave us good clinical results. We also implemented in-process controls to ensure the cleanliness of the product. We also convened a panel of internationally recognized experts and scientists to confirm our findings.

- **Are other Sulzer Orthopedics products suspect? How does one know that?**

No other Sulzer Orthopedics products are suspect. Our other products do not go through the same manufacturing process. There have been no reports from the field of other products exhibiting a similar response. We have examined the processes of other products to ensure the highest quality products possible and determined that no other parts are affected.

- **What steps should surgeons take for patients with a recalled Inter-Op shell?**

The FDA does not require the surgeon to contact the patient. However, it is Sulzer's recommendation that surgeons contact patients that received Inter-Op

shells from an affected lot, if the surgeon deems appropriate. Sulzer is doing everything possible to deliver the appropriate information to relevant parties.

- **How can a patient or surgeon tell if there are problems with an Inter-Op shell implant?**

Be aware of symptoms:

Up to 6 weeks:

- The patient may be progressing well or reporting groin or anterior trochanteric pain.
- The patient may have increased thigh pain.
- Patient has significant startup pain with ambulation or, rising from a seated position, may have buttock pain.
- An x-ray may show possible component migration.

6 weeks to 3 months:

- Significant pain with weight bearing, may require cane or crutch.
- Patient cannot exert resistance in straight raised leg test and side-lying abduction test.

At 3 months:

- Sometimes only a Lauenstein lateral x-ray shows a nearly complete radiolucent line around the acetabular component 1mm or more in thickness and possible component migration – may not be seen on AP x-ray.
- No evidence of infection has been found preoperatively in sedimentation rate, c-reactive protein or aspiration. All cultures at surgery are negative; an arthrogram may not show dye around the shell.

- **Who is responsible for paying for revision surgery?**

Sulzer will reimburse patients for out-of-pocket expenses related to the revision surgery for costs not reimbursed by insurance or Medicare upon receipt of appropriate supporting documentation. It is our intent to treat all patients fairly and to make this as convenient as possible for both the surgeon and the patient. A toll free phone number, 800-888-4676 ext. 232, has been established for patients to call with questions and procedures related to reimbursement.

- **Will Sulzer provide retroactive compensation to patients who have already been revised?**

Yes. In the case of revision of an affected Inter-Op shell for aseptic loosening Sulzer Orthopedics will reimburse the patient for out-of-pocket expenses related to revision surgery for costs not reimbursed by insurance or Medicare. It is Sulzer's intent to treat all patients fairly and to make this as convenient as possible for both the surgeon and the patient. These patients should contact Sulzer Orthopedics using the toll free number: 800-888-4676, ext. 232.

- **Why doesn't Sulzer reimburse for insurance costs as well as out-of-pocket expenses?**

Medicare guidelines permit both physicians and hospitals providing services to patients associated with a product recall to bill the Medicare Program. It's our understanding that other payers also permit physicians and hospitals to bill for such services.

Billing Medicare or a private insurance company is the most efficient way of providing payment to the physician and hospital. In either case, the payer may choose to rebill Sulzer Orthopedics for these expenses, in which case, Sulzer Orthopedics may reimburse the payer, if deemed appropriate by both parties.

- **How does the recall affect the supply of the Inter-Op shell? When will it be available again?**

The voluntary recall virtually eliminated the supply of Inter-Op shells. Shipments of Inter-Op shells meeting the highest standards for patient safety are expected to resume in January 2001.

- **Has Sulzer notified surgeons and the patients yet of this recall? What steps have been taken to do this?**

Sulzer has notified surgeons and provided surgeons with the necessary information so they can properly notify patients. Continuous communication is critical to be sure that all parties are aware of the latest pertinent information. Sulzer began this process with a press release, establishment of toll-free phone lines for surgeon and patient use, formation of surgeon and scientific panels to use the best technical expertise available, creation of a web-site to make information available 24 hours a day and regular, updated communication to surgeons with the latest information as it becomes available. We will regularly communicate with surgeons to answer their questions and as new information becomes available.

- **How can I find out if I have an affected part?**

Your medical records contain the pertinent lot number information in your specific case and can be made available to you on request from the hospital or your surgeon. Our surgeons and representatives have been given the affected lot numbers. With the lot number, you can ask your surgeon or call the toll free patient hotline phone number (800-888-4676, extension 232) to check if your implant is in the recalled lot numbers.

Who should patients and surgeons contact for additional information?

We have established separate hotlines for surgeons and patients. Sulzer Orthopedics is dedicated to maintaining open and honest communications with our surgeons and patients. The hotline numbers are: (surgeon hotline) 800-888-4676, ext. 296 and (patient hotline) 800-888-4676, ext. 232. The Web site address is