It’s major surgery that many consider a minor miracle, allowing thousands to walk again. But what if you had to go through the operation not once, not twice, but three times? That’s what happened to patients in this story, and “Dateline” has learned that it may not have had to happen at all. After months of pouring over documents, we’ve uncovered a story of corporate secrets, a company’s evasions and the devastating impact it has had on thousands of lives. NBC’s Chief Consumer Correspondent Lea Thompson reports.

Inside the operating room, a surgeon is implanting an artificial hip in one of his patients. It’s a long, invasive, traumatic surgery. You have to learn how to walk all over again, but it works. Hip replacement is one of the most successful surgical advances in the last 50 years. Once patients recover they usually have a new lease on life.

But imagine finding out the artificial hip already implanted in your body was defective, that it didn’t work. Imagine finding out you had to go through the operation all over again?

Susie Kuhn: “It was horrible. I couldn’t imagine anybody having a surgery like that.”

But it gets worse. Imagine finding out the company that made that hip implant knew it was defective before you ever went into the hospital.

Susie: “I don’t think companies out there should do what they did. They shouldn’t get away with it.”

It happened to Susie Kuhn and thousands more both here in the U.S. and around the world. Now, “Dateline NBC” has the results of a six-month investigation into a medical catastrophe. “Dateline” reviewed hundreds of documents, documents that show one of the largest manufacturers of medical devices was keeping information from the government, from doctors and from patients.

There are patients like Kuhn, a 37-year-old mother of two small children. For her, it all started with a bad fall.

Susie: “I slipped and that’s when I felt pain just go up my leg.”

Surgery was supposed to restore Susie’s active lifestyle.

Susie: “I used to play tennis. My husband would take me fishing. We would go hunting.”

Susie’s doctor chose an innovative, top of the line implant called the “Inter-Op” hip made by Sulzer Orthopedics of Austin, Texas.

Thompson: “You went into surgery worried? Apprehensive?”

Susie: “I was really excited because I was in so much pain.”

Her surgeon, Michael Britt, had used the Sulzer implant successfully, dozens of times.

Britt: I felt it was a trustworthy product.

Here’s how the hip works: A metal rod called a stem is inserted into the thigh bone. Then a metal ball, which replaces the old joint, goes onto the stem. And a titanium shell with a porous coating replaces the old hip socket.

Thompson: “The bone is supposed to literally grow into this rough surface?”

Britt: “I think probably grow onto it is a more accurate description.”
Dr. Britt told Susie her new hip was expected to last up to 30 years. But it only took a few weeks to figure out something wasn’t right — Susie wasn’t getting any better.

Susie: “Oh, I was in pain. Oh my gosh. I had a burning pain in my hip that you could not imagine. [crying] And I was just taking pills after pills.”

Realizing she was getting hooked on pain pills and thinking maybe she wasn’t working hard enough at her rehab, Susie, a former athlete, really kicked in on her physical therapy. But the pain only got worse.

Susie: “That’s the type of pain that could make, I guess you could say, somebody go crazy.”

Thompson: “Did you feel at times that you were going crazy?”

Susie: “Yes.”

Susie wasn’t alone. It turns out thousands of patients all over the country were going through the same torment.

Naomi: “It’s like someone stabbing you in the leg.”

Arthritis patients like Naomi, Lillian, Helen and Joel were all wondering the same thing.

Joel: “Why am I having all this pain? Why can’t I function?”

Thompson: “You knew pretty quickly that this hip wasn’t working.”

Lillian: “Yes I did. I couldn’t walk without pain.”

After months of torturous therapy, Naomi, like the others just couldn’t take it anymore.

Naomi: “I became so despondent. I told my daughter, I don’t care whether I live or not if I have to go through this.”

Joel, once an agile rancher thought a new hip would put him back in the saddle again. But after surgery, he felt it was hopeless.

Joel: “If they have to take my leg off, you know, then let’s take it off. Let’s get it done and get it over with. I want out of this pain.”

His doctor told him, while it almost never happened, his body must have rejected the implant. he’d have to go through the same surgery all over again.

Joel: “He took an X-ray and said, ‘Joel, its loose.’ I said, ‘loose?’ And he said, ‘yes.’ He said we’re going to have to do a revision.”

So Joel went in for a second surgery.

Joel: “And I’m saying you know was there an error in surgery? Did the doctor make a mistake?”

Living on pain pills, resigned to a life of misery, Joel and the others were soon stunned by a startling announcement. Seemingly out of the blue, Sulzer, the maker of all those hip implants, said, it was not the doctors’ or patients’ fault — the implants were defective.

Sulzer Tape: “I’m Gary Sabins, president of Sulzer Orthopedics... On December 5, 2000, our company began a voluntary recall of specific lots of our Inter-Op acetabular shells used in hip implants.”

So 40,000 artificial hips were recalled. But the problem was that 17,500 of them were already inside patients. When she got the news from her doctor, Susie was horrified.
Susie: “And then I panicked on the phone and he said, no, no, no, wait a minute. Don’t worry, Susie.”

Some patients were simply in denial.

Naomi: “I said, no way Jose. I don’t have one. I’m just not going to have it.”

Helen: “Don’t let me think that you’re going to tell me this has to be done again. He said, yes it does.”

Lillian was still in the hospital recovering from her first hip surgery when the doctor gave her the bad news.

Lillian: “Dr. Britt had tears in his eyes and I felt so bad for him that I couldn’t think about myself.”

That’s because Dr. Britt was shocked to find out why the Sulzer hip wasn’t working in many of his 64 patients who received them.

Britt: “The Interface between the bone and the prosthesis never matured and the bone never grew into the prosthesis.”

Thompson: “So this surface was rubbing on somebody’s raw bone?”

Britt: “Yes.”

But the patient’s tears would soon turn to anger as some of them began to hear whispers that Sulzer had known about problems with its hip implants long before it told anybody. What they heard was right. While Sulzer was telling patients in this video release it took action as soon as it saw a problem, “Dateline” has put together a timeline that shows the company knew far more than it let on publicly, months before it announced the recall.

In the summer of 2000, at least seven months before the recall, Sulzer started getting reports from doctors that its Inter-Op hips were failing. One doctor, an actual designer of the hip said, “something strange” was going on.

By late September, seven doctors were reporting 21 failed implants, but the company didn’t say anything — so surgeons were replacing defective Sulzer implants in people like Joel with, incredibly enough, another Sulzer hip made in exactly the same way.

Joel: “How do you explain that. How can you justify that?”

More than a month and a half before the recall, that same designer was telling the company, “I have a bit of an epidemic here.” And a month before the recall, 14 doctors were reporting hip failures. But still, there no warning bulletins to doctors. Instead, the company was writing memos to sales agents giving them kudos on hitting an all time sales record, “1500” implants sold in the past month.

Two weeks before the recall, 29 doctors were reporting problems, and internal documents reveal the company suspected a “cleaning problem” with the implants. But doctors were still putting them inside people’s bodies.

Naomi: “They knew what was wrong inside, they just didn’t reveal it.”

In fact, just days before the recall, “Dateline” has discovered that a Sulzer supervisor was still contending ,”I don’t feel that the hip investigation needs to be discussed with the FDA.” That’s the Food and Drug Administration, the government agency responsible for regulating medical devices.

By the time of the December recall, seven months after the first complaint, Sulzer knew of 110 hip failures, including 61 cases where the implant had to be removed. This woman is outraged by that. Dr. Suzanne Parisien is the former chief medical officer for the FDA’s Medical Device Section, who now does consulting work for medical device manufacturing companies but sometimes testifies against them in court.
Parisien: “They were concerned about the competition, about their impression with the physicians, but not about the patients... If you’re not selling a safe and effective product, then you’re not in compliance with the law.”

And what is the law? The law says if a company gets a serious complaint about a medical device, it must investigate and report the problem to the FDA. If a company knows a product puts patients at risk, the law says it must stop selling the device, even if it doesn’t know why it’s failing.

But former FDA medical officer Parisien says based on her reading of the documents in this case, that is not what Sulzer did.

Parisien: “They were doing everything they could to try to hide that there was an issue going on with their device. They were trying to sell more hips.”

Thompson: "Irresponsible?"

Parisien: “I believe it was.”

She’s angry, but not as angry as the patients.

Susie: “If this would have been corrected, my life would be a whole different story today.”

Joel: “And if they were aware that there may be a problem with this, then for goodness sakes, let’s don’t put it into somebody’s body!”

So how could a company allow this to happen? What went wrong? For years, Sulzer hips were made by a subcontractor who had a good track record. That may explain why so many doctors were later caught off guard. After all, why would a part that was for years reliable, suddenly become defective? But what the doctors didn’t know, was that in order to cut costs, Sulzer decided to change the manufacturing process.

First, it decided to make all the hips in house, no more subcontractor. Then, to save money, Sulzer cut out a key step on the assembly line — a key step in the cleaning process that would have removed lubricating oil, used in the machining of parts, from the surface of the implants. And how much did that save the company?

Ironically, dropping that procedure only saved one dollar 15 cents per implant on a device for which patients are billed more than $9,000.

Michael Froehlich: “They were never satisfied with what their profits were.”

Froehlich worked as an inspector for Sulzer at the time.

Froehlich: “It was an ineffective process. They used the wrong cleaning process from the beginning.”

“Dateline” has discovered Sulzer never did any testing for oil contamination after it dropped the cleaning step, a clear violation of FDA rules. And Froehlich says a company engineer told him oil contamination on the implants might have also come from another source.

Froehlich: “They were handled improperly by machinists who were handling these parts with contaminated dirty, oily, gloves.”

An internal Sulzer report confirms workers “dropped implants on the floor,” “got oil on their hands” and “did not use gloves while handling parts.”

Britt: “In the manufacturing process, it’s left on the backside of this cup.”

Wherever it came from, once inside the patients, that oil residue kept the pelvic bone from properly bonding to the hip implant leaving thousands of people limping and in excruciating pain.
Susie: “It was like a nightmare.”

As a result of this medical disaster, people like Susie Kuhn would have to have their failed hip implants removed and go through more, nightmarish surgery. And what brand of new hip was likely to be implanted? Believe it or not, another Sulzer. That’s because Sulzer brought back all those contaminated hips, not yet implanted in patients, re-cleaned them and promised doctors a safe product. No more oil, no more problems. Guess again.

Thompson: “What did you eventually find out about that second hip implant?”

Susie: “I could no longer walk.”

ANOTHER ROUND

It was a medical disaster of enormous proportion. Who would ever think that a medical device implanted in thousands of people would be contaminated and have to come out? For anguished patients like Susie Kuhn, it meant more hellish surgery, more unbearable pain, and another heart-wrenching talk with her doctor.

Susie: “I told him I just couldn’t, I’d rather be dead an buried than have to go through a surgery like the first surgery, you know. And then he said, he got real upset, too, and I asked him if I was going to die. I was so scared.”

Thompson: “Did you really think you would die?”

Susie: “I think these days, you just never know when a complication or something could happen.”

Susie’s fears were not unfounded. “Dateline” has uncovered several cases where patients did die of complications as a result of having defective Sulzer implants removed. The company, meanwhile was trying to cut its losses. Rather than destroying the recalled hips, Sulzer had those not yet implanted in patients returned to the plant. It announced it could re-clean them with a new, improved process that would get rid of the oil. Michael Froehlich worked as a parts inspector at the Sulzer plant.

Froehlich: “If we could just get all of the parts from the field that may have been contaminated back into the plant and enough volunteers to come in during their Christmas vacation to re-clean the parts, and repackage them, we would get them all out and no one would know the difference.”

And that’s exactly what Sulzer did, assuring doctors the recalled hips were now clean and safe.

Dr. Michael Britt, Susie Kuhn’s doctor, believed if the hip was now clean, it was still the best choice for his patient.

Thompson: “Doctor, why would you put in a hip that had been recalled and reprocessed?”

Britt: “At that time, you’d have faith in what you’re being told.”

Susie: “I just looked at him and I said, I trust you and you’re my doctor so do what you think we need to do.”

So Dr. Britt and surgeons all around the world went back to the operating room. But soon after her second Sulzer implant, Susie knew something was wrong. Her hip began to fail, just as the first one had.

Susie: “And I couldn’t sleep at night. It just seemed like I was just miserable all day and all night.”

Unbelievable as it may sound, Susie’s supposedly oil-free hip implant failed in exactly the same way as the first hip.

Michael Froehlich isn’t surprised. He says the company, at least initially, never changed the cleaning process on the recalled hips, a process it knew by then was faulty.

Froehlich: “When they did bring in all the parts and tried to re-clean them, they immediately encountered problems.
The plan that they set out to re-clean the parts failed.”

In fact, there have been at least 138 cases in which the supposedly fixed hips had to be removed from patients.

Susie: “When I found out this part was bad, I just couldn’t understand how you know, they promised my doctor a good part and they let him down and they let me down.”

Sulzer says it never skipped any of the cleaning steps on the reprocessed hips and disputes there was ever any problem with them. The company says the initial results of a study it sponsored show the failure rate with those reprocessed hips was no greater than would be expected with any hip implant.

Froehlich: “These people hadn’t learned any lessons.”

But, former Sulzer employee Michael Froehlich differs with Sulzer’s account. He says, for instance, he was told by a supervisor to lie on company records.

Froehlich: “We falsified records, we falsified test results.”

Thompson: “Falsifying records is illegal.”

Froehlich: “It probably is, at the time I wasn’t informed of that. I understand it is now.”

Thompson: “Why did you do it?”

Froehlich: “I did it because the environment there in the plant was so pervasive with this kind of behavior, there just wasn’t any dissent. They assured me the shortcuts that we were taking would not affect the quality of the part.”

Froehlich says he finally went over the heads of his supervisors to top company management and told them what was going on, and he was fired. Sulzer says its investigation found Froehlich violated company procedures and falsified records on his own, not at the direction of supervisors.

But who falsified what doesn’t much matter to Susie Kuhn. As unimaginable as it seems, she had to go in for a third surgery to remove that second bad hip implant, all in less than a year.

Thompson: “As they wheeled you in a third time, what was going through your mind?”

Susie: “I was real scared, and I need to make it through this.”

Today, just looking through a mountain of medical records and bills is enough to relive the agony all over again.

But wait, there’s even more. Sulzer also made artificial knees at that Austin plant. But at the time of the hip recall the company said the oil problem did not extend to any of its other products and told the government it was confident in the safety of its knees. Right on its Web site it said, “no other Sulzer Orthopedics products are suspect. Our other products do not go through the same manufacturing process.” But as “Dateline” has discovered, the company knew that wasn’t true.

Roger: “When I came out of the Navy I went to work on the river.”

Roger Porter was a commercial fisherman for 50 years. It took a physical toll on his body. Just two months after Sulzer recalled it’s hips, Roger entered the hospital for a double knee implant. He remembers talking to his doctor.

Roger: “He said, oh, are you scared? I said, yeah, yeah I’m scared.”

It was a gruesome ordeal.

Roger: “They cut it open and then they cut off this knee cap and lay it down, then they have a machine that fits on
the lower part and then they trim the bone off square.”

What Roger didn’t know was that months before his implant, a Sulzer vice president was telling his staff that “Word is beginning to spread” of loose knee implants. And e-mails from doctors were alerting Sulzer that failed knee implants “appeared to have the same symptoms” as the recalled hips.

Thompson: “When Sulzer recognized that it had a problem with hip implants did it also by definition have a problem with knee implants?”

Froehlich: “The knee implants which were produced in the same way as the hip implants, they should have definitely known that there would be a contamination risk with those lots of knees.”

Roger’s knees weren’t healing — and then came the call from his doctor.

Roger: “He says you got oil in ‘em. You got to come right back, he says, I got to take those knees out and put new ones in, period.”

Roger’s verdict?

Roger: “That’s really criminal.”

What really makes him furious is that just a month after his first surgery, the company abruptly stopped selling that knee implant, yet never called his doctor.

Roger: “The big word is, why? Why would you do something like this? You know, because this is affecting people all over the country.”

According to court records, of the over 1,300 Sulzer knees implanted after it changed its cleaning process, at least 600 had to be removed. Still, there has never been any recall. The company says for business reasons — not safety — it pulled them off the market so there were no knees left to recall. And that is what Sulzer also told the FDA. But internal documents obtained by “Dateline” show at about the time Sulzer stopped selling knees, it knew of at least 20 failed knee implants already removed from patients and knew of more than 35 other suspect cases.

Dr. Suzanne Parisian used to be chief medical officer for the medical devices section at the FDA.

Lea: “Surely nobody in this company wanted to hurt anybody... that’s not what this is about?”

Parisian: “I don’t think you would take anyone from Sulzer and they would want to go out and hurt people like this. But, it’s so easy when you make a product to forget that there is a human being involved.”

And you have to wonder, where was the FDA during all of this? It is supposed to regulate medical devices. We asked the head of the FDA’s Medical Device section for an on-camera interview. He declined. But he told us he felt Sulzer acted in a responsible and timely manner in recalling its hips. Based on the stories you just heard, how could he say that?

Well it appears the FDA’s file in this case, obtained by “Dateline,” simply doesn’t contain much of the information in our report. Typical of cases involving a voluntarily recall, the government relied heavily on information supplied by the company.

Thompson: “Was Sulzer honest with the FDA?”

Parisien: “Not from the documentation I’ve seen. They were not.”

Thompson: “You believe there was a cover up here?”

Parisien: “Yes, there was a cover-up by Sulzer to keep the information from the physician, and the public and the
One reason Dr. Parisian believes there was a cover-up was because the company told the FDA it only heard about hip failures two and a half months before the recall, not seven months as “Dateline” has found.

And why didn’t Sulzer notify doctors and the FDA sooner? Sulzer contends it needed time to figure out the problem and until it knew the cause, alerting the public and the medical community would have been irresponsible and caused widespread panic. Dr. Parisien says that’s no excuse.

Parisien: “And the minute they knew this product was not performing the way it was supposed to, that’s when they should have said, stop using this product, we’re doing a recall. The law doesn’t say you have to have the fix.”

Joel: “It was a hideous two years. It hurt physically, it hurt emotionally.”

Lillian: “It makes you sick, just sick to think that you’ve gone through all of this.”

At least some people agreed. In August 2001, in Corpus Christi, Texas, a jury awarded these three women, Lillian, Naomi, and Helen, damages of $15 million, asserting Sulzer was guilty of manufacturing a defective product, guilty of malice, and that it knowingly caused injury to elderly patients. They later settled.

Its hard to imagine, but between them, this small group of patients has undergone more than a dozen hip surgeries in just the last two years. Susie and Joel endured three surgeries each.

Thompson: “Have any of you ever gotten a letter of apology from Sulzer?”

Group: “No.”

Thompson: “Have you ever gotten a phone call?”

Group: “No.”

The company says in letters to “Dateline” it “deeply regrets the pain and discomfort our implants caused some of our patients. That the well being of patients who receive our products is of the highest priority to us. And we have done our best to be proactive in supporting everyone affected by the recall.”

As for those manufacturing changes which led to the defective hips, the company says in addition to being a cost cutting move, it removed steps from the cleaning process because at the time, it didn’t think they were necessary. Sulzer also says it was trying to cut down on the use of hazardous chemicals in the plant.

So far, almost 4,000 defective implants have been removed from patients. Sulzer, which has since changed its name to Centerpulse, tells “Dateline” in the two years since the problems occurred, a new management team has taken aggressive action to make sure nothing like this happens again. The company says its products are now clean and safe.

Thompson: “Are you in pain?”

Susie: “I still have pain.”

And as I look back/at all the time I missed out with my kids and my family. You can’t bring it back to me.”

Susie is one of 4000 patients who recently reached a financial settlement with the company. Because of the repeated surgeries, Susie’s tennis days are over, and sadly, her recovery may be a lifelong struggle.

Susie: “I only hope that this doesn’t happen to anybody else in the future.”

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