**PODCAST TRANSCRIPT**

### 360 Degrees Reliability and Safety by Design:

### What Does 360 Degrees of Reliability and Safety Mean?

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**Podcast Episode:**

**Marcus Schmidt:** Welcome to the Podcast Series 360 Degrees of Safety and Reliability. Reliability and safety are some of the most important aspects of a hearing implant. Children and adults who are implanted with a hearing implant will wear this device for many, many years, so you want to have this confidence in the safety and reliability and you want to have that peace of mind. My name is Marcus Schmidt.

**Manfred Pieber:** And I'm Manfred Pieber.

**Marcus Schmidt:** And we will moderate this podcast series. Manfred is MED-EL’s expert on implant reliability. Manfred, what is your background?

**Manfred Pieber:** So, my background is in electrical engineering. I studied for a Master's degree at the Technical University in Graz. I got in touch with reliability there already. But really, I was drawn to this topic in my professional life later on.

**Marcus Schmidt:** So for how long have you been involved now with hearing implant reliability?

**Manfred Pieber:** With hearing implant reliability, actually, soon after I started with MED-EL. So for about 15 years now, that's how long I'm with the company already.

**Marcus Schmidt:** Ok. So you should know something about implant reliability. So what drives you? What motivates you?

**Manfred Pieber:** As you already mentioned, reliability is a very important topic for our patients and patients are very, very important for us. The patient is at the center of our company philosophy, of our company motivation, and we want to give the patient the best possible solution for really a whole lifetime. And this is what drives us as a company, and also motivates me very much. And you Marcus, you are the Director of Corporate Marketing and with MED-EL for many, many years. So what is your history?

**Marcus Schmidt:**  Yeah, I also studied electrical engineering at the Technical University of Munich. Actually, I started off in Research and Development at MED-EL and over the years I worked myself over to Marketing. So why do we do this podcast series? Why should people listen to it, Manfred?

**Manfred Pieber:** Reliability is a very important topic for our patients and also for the professionals who are counseling the patients and the more you know about this topic, the easier it becomes to make a decision for a cochlear implant system.

**Marcus Schmidt:**  And we'll also talk about the philosophy of MED-EL regarding safety and reliability. Right?

**Manfred Pieber:** Right.

**Marcus Schmidt:**  So, whenever there's talk about reliability and hearing implants, there's this one number that always comes up and that is the cumulative survival rate or CSR. Cumulative survival rate. What does that number say?

**Manfred Pieber:** This number is derived from observing the implants over time, from the start of the implantation. And every time an implant fails or a therapy with an implant fails, the relative percentage of surviving implants is reduced, of course. The cumulative survival rate would give a probability of an implant to survive for a specific period in time. One example from our own implant series would be the cumulative survival rate for the SYNCHRONY 2 is currently at 99.97% after four years.

**Marcus Schmidt:**  Ok. And the SYNCHRONY 2 is our latest implant series. So 99.97% that means that 99.97% of implants will still be working after four years.

**Manfred Pieber:** Right, that is correct.

**Marcus Schmidt:**  OK. 99.97. So, so that means out of 10.000 implants, 9.997 are still working. That sounds really high.

**Manfred Pieber:** Yeah, this is an excellent number and also is a good example of how far we have come with our technology and how well our implants are working and this is also best in the industry. So, we are very aware of our responsibility to our users and also to our professionals. This is a big motivation for us to improve our devices.

**Marcus Schmidt:**  With this number, we could actually close the podcast series, right? I mean, 99.97% everything is said, isn't it?

**Manfred Pieber:**  Yeah, it is a very important starting point to start a discussion. But I think, and this is also the common view in the company, there are more than just the cumulative survival rate numbers to the reliability of hearing implant systems.

**Marcus Schmidt:**  OK, I understand an implant should not fail. But what else could there be that is related to reliability and safety? Can you, can you give us an example?

**Manfred Pieber:** For example, what is not directly related to a failed implant is the structure preservation, hearing preservation in the inner ear. This is something which is very important for us as a company, I think which is also very important to most of the professionals and should also be very important to the patients. One of the topics which influences this structure preservation is of course the electrode design. But another very important topic is the stimulation. And stimulation with electrical current has to be done in such a way that the tissue and the cell structure in the inner ear is not damaged, especially not damaged in the long run.

**Marcus Schmidt:**  So how is that done?

**Manfred Pieber:** In our implants we are, for example, using safety capacitors at each of the active electrode channels in order to block direct current from entering the inner ear.

**Marcus Schmidt:**  OK. I understand, we don't want direct current, what would happen if direct current is not blocked?

**Manfred Pieber:** Direct current is dangerous in that in the atmosphere of the inner ear, the electrode contacts would start to dissolve. And so this must be avoided at any cost. And therefore we have these safety capacitors which safely block the direct current from each of the electrodes.

**Marcus Schmidt:**  And actually these safety capacitors take up, I think, about half of the electronic space in the implant. And that kind of shows how important that is to us, right?

**Manfred Pieber:** Right.

**Marcus Schmidt** Often, when I think about reliability and quality, and I think that OK, there has to be a well-defined manufacturing process, that there is a lot of testing. But from what you tell me, it seems that there’re also a lot of design aspects that play a big role in in safety and reliability.

**Manfred Pieber:** That is absolutely correct. The reliability of a device is determined already with the design. So we need smart design and reliability and safety by design. That's how we call it also in our R&D Department. The engineers are very aware of this and so they are doing all the best to learn from the experience in the field and also to use the latest technologies that are available.

**Marcus Schmidt:**  So there is a lot of know-how, a lot of technology and design aspects that add to safety and reliability. And this is why we call our reliability and safety philosophy, the 360 Degree View.

**Manfred Pieber:** Right. So for the 360 Degree View, there are several different topics that we included in this. Apart from the implant reliability and the cumulative survival rate numbers, we are also looking into electrode safety, stimulation safety, as we mentioned with the safety capacitors. Also, MRI is a big topic and MRI safety and of course, the audio processors which are part of the cochlear implant systems, they must also be designed in such a way that they are reliable over time.

**Marcus Schmidt:**  Ok. And we have developed this 360 Degree View for our cochlear implant systems, but also for our bone conduction implant system. For the BONEBRIDGE, there will be a separate episode. But let's talk about what episodes will be in this podcast series.

**Manfred Pieber:** We will start with looking into the design and also the manufacturing aspects of our hearing implants and what makes them reliable there. And we will also be talking about the reporting of the reliability because this is something which is done by the manufacturers, also by us, and done also by the clinics. And it's important to understand all the differences and all the similarities there.

**Marcus Schmidt:** One episode will be, and this is what you mentioned, Manfred, will be on how MED-EL electrodes of a cochlear implant add to safety and reliability of a cochlear implant. And there will be an episode that has a special view on children.

**Manfred Pieber:** Yeah. And as you mentioned, we will have episodes that look into the reliability and safety aspects of our bone conduction implants, the BONEBRIDGE, and also our active middle ear implants, the VIBRANT SOUNDBRIDGE. And another episode will be on MRI safety.

**Marcus Schmidt:**  Of course, we will have one episode on audio processor reliability. And that will also cover what's called the audio processor retention, meaning that the coil or the button processor should stay reliably on the head.

**Manfred Pieber:** And finally, there will be an episode on reliability and safety aspects of our support processes for the clinical engineers which are supporting the clinics in counseling and also in troubleshooting.

**Marcus Schmidt:**  And that is I think an interesting view because it goes beyond, you know, the product. So in most of our episodes, we will invite specialists from the field, clinicians, and I think that should make it very interesting. In the meanwhile, if you are interested, you can of course get information on reliability and safety on our websites. This is [www.medel.com](http://www.medel.com) and for professionals [www.medel.pro](http://www.medel.pro), and there you can also download our latest reliability report.

**Manfred Pieber:** And I hope that you will join us for our next episodes.

**Marcus Schmidt:**  Thank you very much for listening.