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MED⁹**EL**

ABOUT HEARING AND TELLING

SPECIAL REPORT Basic Information on Hearing



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Special Report No. 1

About Hearing and Telling – Basic Information About Hearing

- What Hearing Loss Really Means
- Why Cochlear Implants Can Help
- Benefits for Children and Adults

Second, revised edition 2018

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A note from Ingeborg Hochmair, CEO MED-EL

What images come to mind when you hear the phrase loss of hearing? A lot of people think of old age; hearing loss as a phenomenon that affects senior citizens. If this holds true for you, then you are both right – and wrong. Hearing loss is a problem that affects people as they get older – but also the very youngest: one to two in 1,000 children are born with a hearing impairment. Hearing loss continues to be an issue for children later on, given that 4 to 11 in 10,000 children of school age are affected by profound, early-onset deafness.

It is our task to help all people with hearing impairments. A cochlear implant (CI), for example, can give children the opportunity to learn to hear and speak like other children of the same age. This opens up social, economic and vocational opportunities that would be unattainable without an implant.

Counting among the pioneers in this field, at MED-EL we take our responsibility very seriously. In 1977, the first patient in the world was fitted with a micro-electronic multichannel cochlear implant developed by us. My husband Professor Erwin Hochmair and I developed the device after several years of intensive research.

Today MED-EL offers the widest range of implantable hearing solutions for people with hearing loss. It is our mission to overcome hearing loss and provide a world of hearing for people in all regions of the globe. It is possible to achieve this goal: MED-EL is continuously setting new standards in the development of innovative biomedical engineering for people with hearing loss. But technology is not everything: we want to draw the attention of as many people as possible to this topic and inform them about the meaning and implications of hearing and hearing loss.

This Special Report is one element in achieving this goal. It contains valuable information – things you need to know, useful facts and figures, background and context about the situation faced by people with hearing loss, especially children. It is a brief and clear overview giving a quick and an informative insight into this complex and crucial topic.

We hope you enjoy reading it!
Yours

Ingeborg Hochmair
CEO MED-EL Medical Electronics

INTRODUCTION

How relevant is hearing loss?

An estimated 466 million people worldwide are affected by impaired hearing.* 34 million of them are children.¹ That is roughly five per cent of the world's population. Eighty per cent of all people with impaired hearing live in low-income countries.²

A hearing impairment of 26 to 40dB means that it is difficult to follow a quiet conversation; talk amidst disruptive noise is a real problem. Children with a hearing impairment of more than 40dB have trouble understanding normal speaking volume – even if the conversation is right next to them.³

Hearing loss is one of the most controversial issues in current and future health policy. Experts are convinced that the number of people with impaired hearing will increase in years to come. Two of the main reasons for this are growing noise pollution and increasing life expectancy, which also means more cases of age-related hearing loss. Infections such as measles, meningitis or middle ear infection are common causes of hearing loss, above all in low-income countries – but are also a key concern in western Europe. No matter where, early diagnosis and prompt therapy are essential in preventing hearing loss.

Comparable data required

Despite the importance of hearing loss even today, there are currently hardly any up-to-date comparable data at a worldwide or European level. The World Health Organisation (WHO) also stressed this fact in a report from 2017. The reason, according to the WHO, is inadequate documentation.⁴ There are estimations and extrapolations, but no standardised methods for identifying the status quo. Each country defines its own thresholds for hearing loss and the methods of collecting data also differ: official surveys in Austria, for example, are based on a sample of the population. The data commonly used in Germany are obtained by means of surveys and by measuring people's hearing.

In light of the important role played by hearing loss, in the foreseeable future consistent and comparable data should be collected. With this Special Report we would like to take the first step in this direction, offering you an insight into the topic of "Hearing" and its importance for human communication.

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* **Adults (aged 15 or older):**
hearing loss greater than
40dB in the better ear

Children (aged 0 to 14):
hearing loss greater than
30dB in the better ear

30dB corresponds to the
volume of whispering, 40dB
to fridge buzzing
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Types of hearing loss

Our ears collect sound waves and forward them to the brain through the outer, middle and inner ear. Many components are needed to fulfill this complex task: the auditory canal, the ear drum, the ossicles, the cochlea and the auditory nerve. As soon as one of these parts stops functioning properly, the person affected will have a hearing impairment. There are several different types of hearing loss, depending on which part of the ear is affected:

Conductive hearing loss

Any problem in the outer or middle ear that prevents sound from being conducted to the inner ear. The result is usually mild or moderate hearing loss that is often only temporary and can be remedied with medication or surgery. If the hearing problem persists, hearing aids, middle ear implants or bone conduction implants can help.

Sensorineural hearing loss

affects the cochlea in the inner ear. This form of hearing loss results from missing or damaged hair cells in the cochlea. This usually results in permanent hearing loss that can deteriorate over time. The degree of impaired hearing ranges from mild to severe or even complete loss of hearing. Sensorineural hearing loss is often caused by the side-effects of certain antibiotics. Other possible causes are infectious diseases such as meningitis, congenital hearing impairments, and noise. Mild or moderate sensorineural hearing loss is treated with hearing aids or middle ear implants. A cochlear implant is often an effective solution for people with severe, profound or complete hearing loss.

Partial hearing loss

is when sensorineural hearing loss occurs only in the high-frequency range. With partial hearing loss, the hair cells at the base of the cochlea are damaged. They are responsible for high-frequency hearing. Hair cells in the apex, i.e. in the innermost part of the cochlea, which is responsible for low-frequency hearing, are not affected, however. Combined Electric Acoustic Stimulation (EAS) was developed especially for people with partial hearing loss. It involves stimulating the patient's hearing both electronically, as with an implant, and acoustically, as with a hearing aid.

Mixed hearing loss

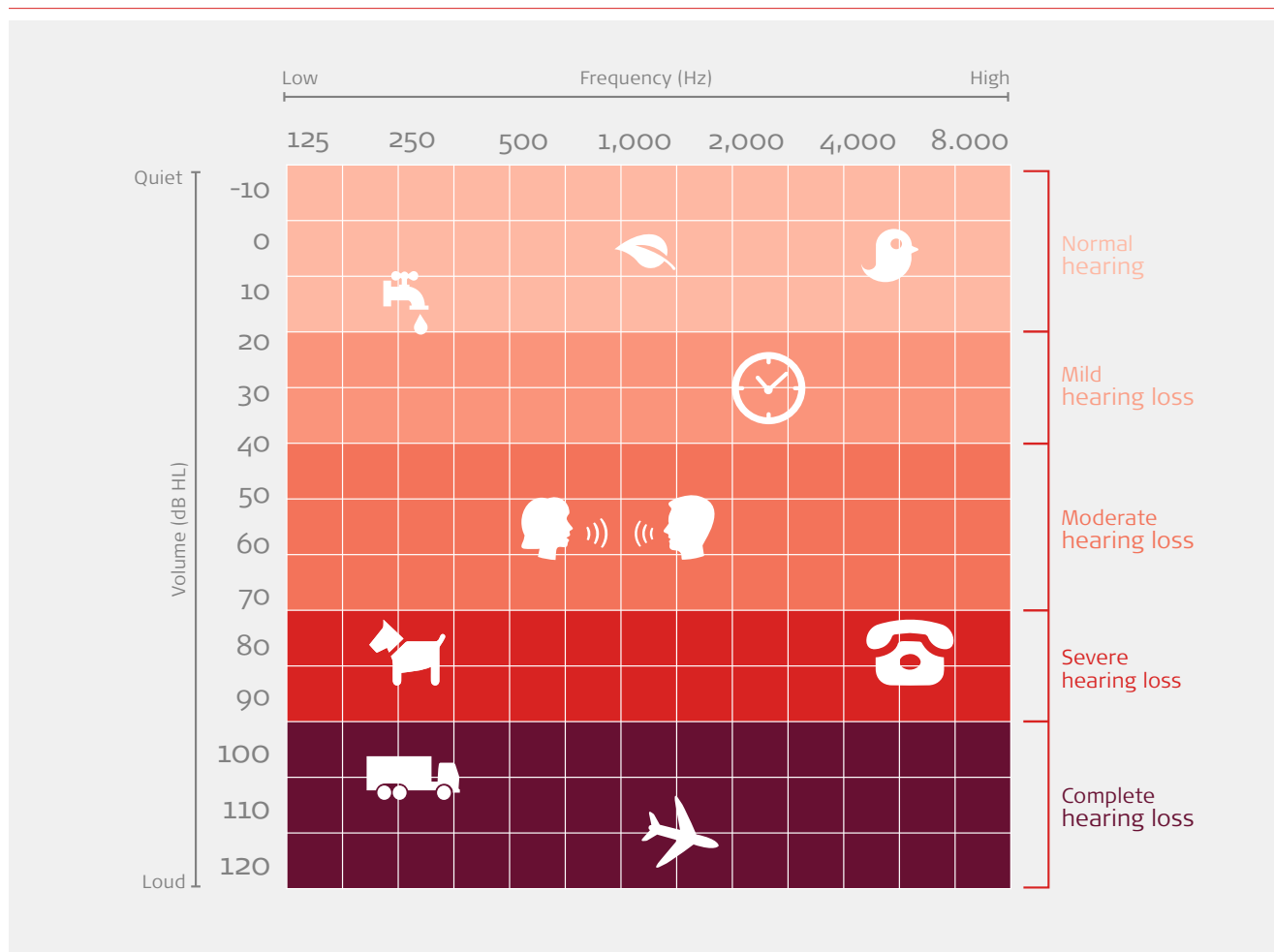
is a combination of conductive hearing loss and sensorineural hearing loss. Treatment options may include medication, surgery, hearing aids, middle ear implants or bone conduction implants.

Neural hearing loss

This form of hearing loss is caused by a missing or damaged hearing nerve, for example as a result of certain tumours. Neural hearing loss is profound and permanent; hearing aids or cochlear implants cannot help because the auditory nerve is not able to pass on sound information to the brain. In some cases, however, an auditory brainstem implant (ABI) may help.

Unilateral (single-sided) hearing loss

Impaired hearing in one ear and normal or almost normal hearing in the other. Unilateral hearing loss makes it difficult to identify the direction from which a sound is coming. Conversations in loud surroundings are also a major challenge. Hearing with just one ear is very tiring, which has a negative impact on performance at school, at university or at work. Suitable implant solutions for unilateral hearing loss are cochlear or bone conduction implants.



The audiogram

An audiogram is a “picture” of someone’s hearing. It shows – for each ear – how much your hearing varies from normal, i.e. indicates the degree of hearing loss. It also points to where the problem may lie and is therefore an indicator of the type of hearing loss involved.

The figures 125 to 8000 on the top axis of the audiogram indicate the frequency range, which in simplified terms corresponds to pitch.

Frequency is measured in hertz (Hz). The higher the frequency, the higher the tone. For example: the dripping of a tap has a frequency of roughly 250 hertz, i.e. creates a low sound; the ringing of a telephone goes up to around 8000 hertz and is therefore a high tone.

Volume is measured in decibels. Zero decibels (0 dB) does not mean that there is no sound, just that the sound is very quiet. A normal conversation takes place at a volume of around 65 decibels. 120 decibels is extremely loud – a jet taking off about 25 metres away is roughly that loud. The figures on the side of the diagram indicate volume in decibels.

In a hearing test, the audiologist plays one single sound after another at different pitches. The quietest sound that the person can hear at each frequency is recorded on the audiogram at the appropriate frequency and volume. This is referred to as the hearing threshold.

Hearing loss - a global issue

Hearing loss at adult age is the most common cause of disability, followed by refractive disorders and depressions.⁵ 1.4 per cent of children aged 5 to 14 are affected by a hearing impairment of 35 decibels (dB) or more. Among adults over fifteen, it is 12.2% of men and 9.8% of women over fifteen.⁶

What can people with hearing loss hear – and what can't they hear?

Hearing loss of 35 decibels sound pressure level means that the person can hear sounds at a volume of 35 decibels or more. For comparison: a gentle breeze, for example, has a sound pressure level of 20 decibels, whispering 30 decibels, a quiet conversation 50 decibels. Loud radio music comes to 80, a pneumatic hammer one metre away 90 decibels.⁹ So someone with a hearing loss of 90dB, can hardly hear the pneumatic hammer.

If we factor in all degrees of hearing loss (see diagram on p. 11), an estimated 15 per cent of the world's adult population is affected, with 25 per cent aged over 65. Around one third of all over-65s lives with impaired hearing.⁷

The frequency of hearing loss is intimately linked with income: the less people earn, the more likely they are to have to live with poor hearing – in other words: the lower the gross national income, the higher the frequency of hearing impairments in the particular country.⁸

Hearing loss in children: Facts and figures

Hearing loss has especially far-reaching consequences for children. Children affected by impaired hearing are unable or only partially able to understand words in their mother tongue, thus making them hard or impossible to learn. As a result, this leads to problems with grammar, word order – in short the whole spectrum of verbal communication. It is also possible that hearing loss may hamper the intellectual and psychosocial development of these children.^{10,11}

Having a hearing impairment also makes it hard for children to read: a Dutch study investigated reading comprehension in deaf children and teenagers between the ages of six and twenty. The authors came to the conclusion that reading comprehension in deaf children is well below that of hearing children – and is comparable to that of hearing children in year one.¹²

PREVALENCE OF IMPAIRED HEARING IN CHILDREN



32 Million
children suffer from
hearing loss

There is another interesting aspect that most people are not aware of: having a hearing impairment also hinders children when it comes to developing motor skills such as balance, and thus the way they interact with their environment, overall perception and learning the skills required to live together in society.¹³

Around 1 to 2 children in 1,000 are born with a hearing impairment.^{14,15} For Austria this means that 84 to 168 out of the 84,000 babies born each year have a hearing impairment.¹⁶ In Germany it is around 738 to 1,500 out of the total of approximately 738,000 newborns.¹⁷ Studies show that 4 to 11 in 10,000 school children are affected by severe hearing loss. In about 50% of these cases, the hearing impairment is genetic; other possible causes are serious diseases such as meningitis or the effects of certain medications.¹⁸

Hearing screening

Hearing is key for the development of speech and language. Babies first hear sounds and words and will form their own versions thereof. Cooing, gurgling, babbling will eventually develop into intelligible speech. For children with poor or no hearing it will be much harder – or even impossible – to learn to speak. It is therefore essential to discover hearing problems at a very early stage and take appropriate action.

To make this possible, health authorities in many countries have introduced Newborn Hearing Screening programmes. A quick and painless test, taken a few days after birth, is performed on the sleeping baby. If the screening delivers an unusual result, more tests are performed to confirm or rule out a potential hearing problem. Even when the Newborn Hearing Screening was normal, regular hearing checks are recommended to discover hearing loss that may have developed at a later stage.

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Please also read our Special Report No. 2: "About Hearing in Old Age".

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Prevalence of Hearing Loss in Selected Countries

Austria

According to the latest official survey from 2007, 2.5 per cent of the population have permanent hearing problems.¹⁹

This figure is very different to those in other countries, where the prevalence of hearing loss is considerably higher, see Germany. The reason for this substantial difference lies in the method of investigation: whereas German authors surveyed the degree of hearing loss by means of measurements, among other factors, statisticians in Austria asked subjects whether they had hearing problems despite a hearing aid or cochlear implant.

The actual number of cases in Austria is probably much higher: according to estimates, one to two per cent of all schoolchildren, 15 per cent of all 15 to 19-year-olds, 30 per cent of over-60s, and 50 per cent of over-65s live with impaired hearing.²⁰ So we can assume that a total of around 20 per cent of the population in Austria has impaired hearing. In absolute numbers, that equates to some 1.7 million people.²¹

This assumption is backed up by the German findings, but also by figures from other European countries: in the United Kingdom and Italy, for example, around seventeen per cent of the population live with hearing loss^{22,23}, with ten per cent in Denmark and Sweden.²³

Australia

In 2006, the business consulting firm Access Economics published the most frequently cited figures regarding hearing loss in Australia. According to this study, 16% of Australians have a hearing impairment. Every year, roughly one child in 1,000 is born with a hearing impairment in Australia.

The older the individuals, the more likely they are to be living with hearing loss: in children aged up to 15 the prevalence is less than one per cent, in the over-70s roughly 70%. In total, some 3.5 million Australians aged over fifteen live with hearing loss. Impaired hearing is a growing problem here too: by 2050, around 25% of Australians will be living with a hearing impairment.

In 2005, the real financial costs of hearing loss were estimated as \$11.75 billion, that is 1.4% of GDP in total. The biggest component here is productivity loss, accounting for 57% of total costs (\$6.7 bn).

Canada

Audiometry results from the 2012 to 2015 Canadian Health Measures Survey (CHMS) indicate that 40% of adults aged 20 to 79 have at least a mild hearing loss in one or both ears. Men are more likely to have hearing loss than women (47 vs. 32%).

Eight per cent of children and youth aged 6 to 19 have a hearing loss. Boys are affected as often as girls. Four per cent of children aged three to five live with a hearing impairment.

It is interesting to note that the majority of Canadians with a measurable hearing loss were not aware that they had any hearing problems before they had their hearing tested.

Awareness of noise in the workplace also seems low: of Canadians aged 16 to 79, 42% have worked or currently work in an environment where it was or is required to speak in a raised voice to communicate with someone standing an arm's length away. Among these employees, 24% always used hearing protection, while 41 per cent never did. The remaining 35% used hearing protection often, sometimes, or rarely.

Egypt

Unfortunately, there is hardly any way of obtaining reliable figures regarding the prevalence of hearing loss in Egypt.

In 2017, MED-EL Egypt conducted a survey among hearing professionals in order to discover how many children a year would benefit from cochlear implantation. The experts surveyed estimated that around 3,500 children a year needed a cochlear implant – and that the need will increase in years to come.

According to MED-EL's own statistics, around 1,120 individuals were fitted with a MED-EL implant in 2016; the vast majority were children. By mid-November 2017, the figure was slightly more than 1,000 implantations.

France

According to estimates of the European Federation of Hard of Hearing People (EFHOH), six million people in France live with hearing loss. This corresponds to around eight per cent of the total population.

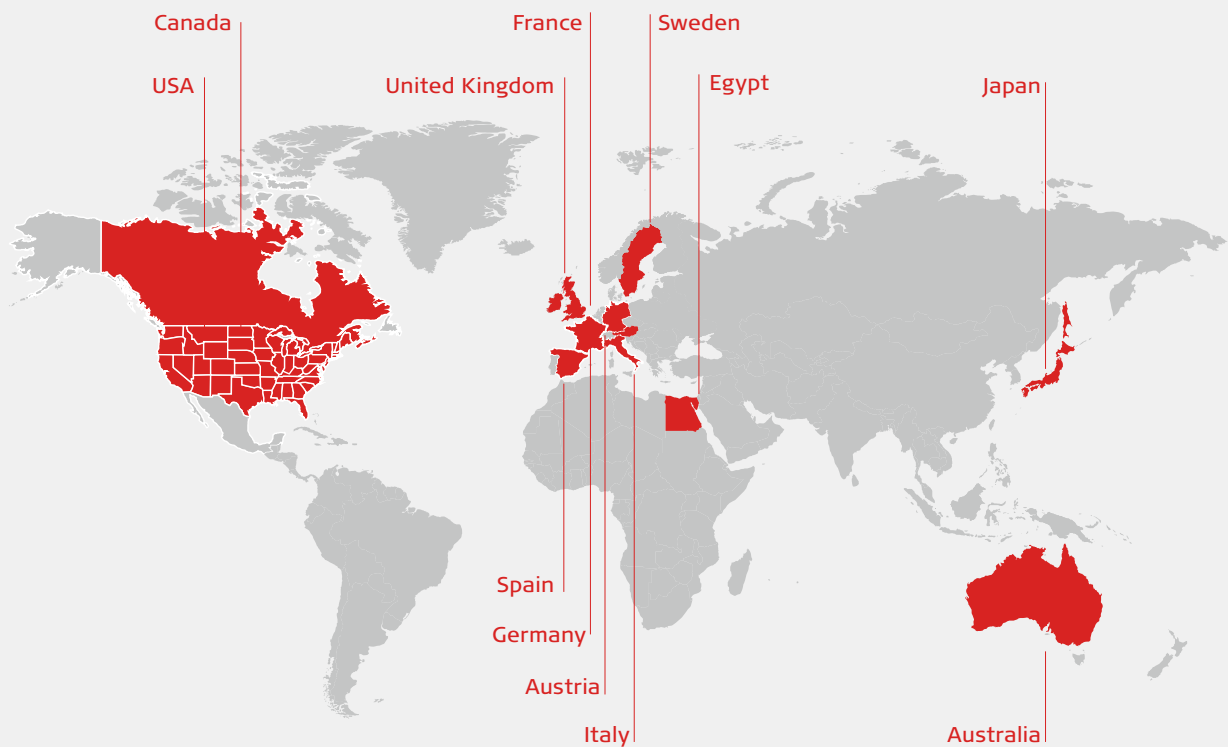
A survey commissioned by the European Hearing Instrument Manufacturers Association (EHIMA) produced similar results concerning hearing loss and the use of hearing aids. 14,800 people took part in the survey. The results were published in the "EuroTrak France 2015" report. According to the study, a total of 9.3% of the respondents live with hearing loss, with 11.4% of over-18s.

Germany

The prevalence of hearing loss in Germany is assumed to be roughly 17 to 20 per cent.²⁴ That equates to as many as 16.4 million people.²⁵

According to statistics of the German Deaf Association (DSB), 56.5 per cent of the population is mildly, 35.2 per cent moderately, and 7.2 per cent profoundly hard of hearing. 1.6% of people in Germany are affected by a hearing impairment verging on deafness. Most people affected by a hearing impairment are found among the over-50s according to the DSB: while only 1% of the 14 to 19 age group have impaired hearing, the 50 to 59 age group amounts to 25%, the 60 to 69 age group accounts for 37% and the 70+ group makes up 54%.²⁶

PREVALENCE OF HEARING LOSS IN SELECTED COUNTRIES



Italy

According to the Italian statistics office, 16.5% of people aged fifteen and over live with moderate hearing loss, while 4.2% are affected by severe hearing loss. 35.6% of Italians aged over 65 have a moderate hearing loss, 12% a severe hearing loss.

In 2015 the Zürich-based market research institute Anovum was commissioned by the National Association of Pharmaceutical Industry of self medical treatment (ANIFA) to survey 15,600 people about their hearing. The results were published in the "EuroTrak Italy 2015" report. A total of 11.7% of respondents indicated that they had hearing problems, with 13.6% of over-18s.

Japan

The prevalence of hearing loss in Japan is 11.3%. 13.1% of people aged over eighteen are affected by some sort of hearing impairment.

This was revealed by the study "JapanTrak 2015" conducted by Anovum Zurich in 2015 by commission of the Japan Hearing Instruments Manufacturers Association (JHIMA) in which some 14,300 people were surveyed. Yoko Kobayashi and colleagues describe the (data) situation in a scientific study from 2015 as follows: "Evidence on the living and health conditions of people with hearing loss in Japan is scarce. A nationwide survey of people with disabilities, conducted in 2006, reported that 0.27% of the Japanese population (n = 350,000) had some degree of hearing loss." According to the experts, this number was restricted to those having a physical disability certificate, which requires an average hearing loss of greater than 70 decibels. Hearing loss of more than 70 decibels means that the person cannot hear anything quieter than a lawnmower.

We can therefore assume that the prevalence is higher. According to the authors, an estimated six million people (4.7% of the population) has a hearing aid although they do not have a physical disability certificate as their hearing loss is less than 70 decibels. The authors observe that the living arrangements of those who do not have this certificate have rarely been focused on or investigated in Japan.

Spain

Evidence on the prevalence of hearing loss is extremely limited in Spain. However, there are some official statistics – although they are much lower than those of other countries.

According to official figures, just over one million people (aged six or older) live with some form of hearing loss, which is 2.3% of the total population. Unofficial estimates assume a prevalence of 3.5 million people with a hearing impairment. Given a population of 47 million, that amounts to 7.4%.

According to statistics of the Commission for the Early Detection of Deafness, one in 1,000 newborns is diagnosed with profound bilateral hearing loss. Five in 1,000 have a different type and degree of hearing impairment. This means that every year one child in 2,000 families is born with a hearing impairment. 40% of children with severe to profound hearing loss are candidates for a hearing implant. A prevention programme for identifying hearing loss was launched on the Balearic Islands in 1986. Since then, almost 120,000 primary school children have been screened. Every tenth child was diagnosed with hearing loss. In 60% one ear is affected, in 40% both ears. The causes were not covered.

Sweden

The Swedish Association of Hard of Hearing People (HRF) estimates that 1.4 million people live with hearing loss in Sweden. That is around 13% of the total population.

A study of 590 adults aged between 20 and 80 in the Östergötland region from 2003 shows a prevalence of 16.9% with a mild hearing loss. 7.7% of participants had a moderate hearing loss, 3.3% a severe and 0.2% a profound hearing loss. For 7.7% a hearing aid would have made sense – but only 2.4% actually had one fitted.

In 2010 scientists studied the prevalence of hearing loss in working and non-working adults in Sweden. The data covered some 11,400 people. The main finding according to the authors of the study: 31% of working people and 36% of non-working people report either hearing loss or tinnitus or both. The prevalence of hearing problems increases with age, is higher among men and persons with low self-rated socio-economic status. Noise in the workplace is a key factor. Severe hearing problems are already present in people under 40 years of age who are exposed to work-related noise.

United Kingdom

Ten million people are estimated to live with hearing loss in the United Kingdom, the International Longevity Centre – UK (ILC-UK) states in a report from 2014. That is around 15% of the population. A total of 45,000 British children are affected by hearing loss.

Owing to the growing number of older people, the ILC-UK experts foresee that the issue will become even more urgent in the next decade: 14.1 million people will be affected by hearing loss in the United Kingdom by 2031, i.e. almost 20% of the total population. The World Health Organisation estimates that in the UK adult onset hearing loss will be in the top ten disease burdens by 2030, above diabetes and cataracts (clouding of the eye lens).

Compared with the overall population, people with hearing loss are significantly less likely to be employed. According to recent studies of the ILC-UK, the loss in productivity due to hearing loss costs the British economy almost £25 billion a year.

Experts estimate that out of six million people who would benefit from a hearing aid, only two million actually own one and that one third of these two million do not use their hearing aid.

The stigma of hearing loss still lingers. Hardly anyone admits to being hard of hearing. What is more, hearing loss often develops slowly. These are two of the reasons why it takes an average of ten years before someone with hearing loss seeks help.

One reason for the small number of people using hearing aids is difficult access to hearing aids, the ILC-UK experts write: anyone wanting to obtain a hearing aid from the NHS must take a hearing test. This test requires a referral from your GP. Data show that 45% of people seeking help because of their loss of hearing are not referred by their GP. This raises the question as to whether the system should be opened, thus facilitating access to hearing services, the authors from ILC-UK write.

USA

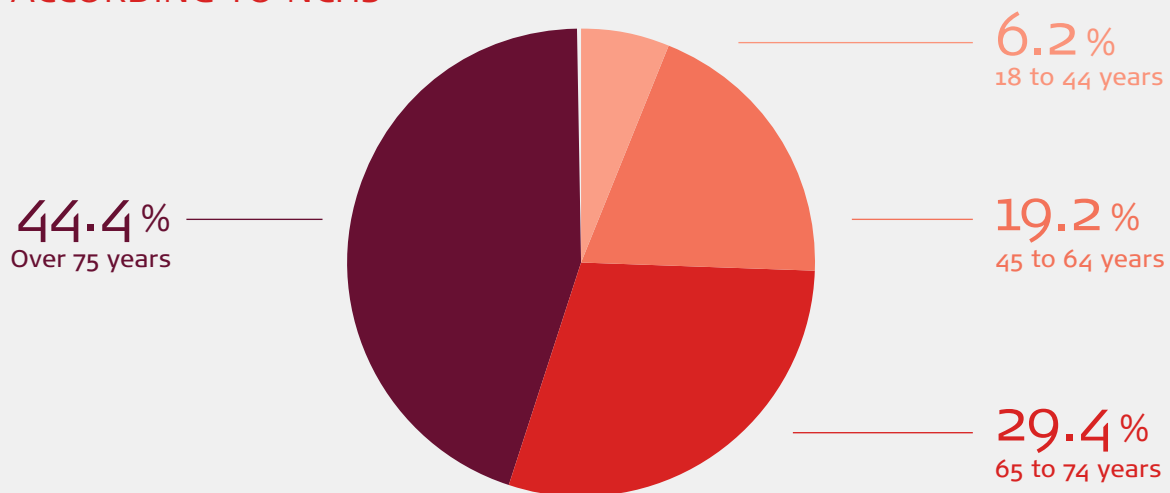
According to the National Center for Health Statistics (NCHS), 15% of the total U.S. population over eighteen live with some form of hearing impairment. Men are more likely to be affected than women (18.4% vs. 12.4%).

Loss of hearing is the third most common chronic physical condition in adults, following high blood pressure and arthritis. 1.6 of 1,000 newborns subjected to a hearing screening were diagnosed with a hearing impairment.

In a study published in 2017, scientists examined leisure and occupational noise exposures of people in the USA. The study was based on data from just under 240 million Americans from the National Health Interview Series (Hearing Survey Module) conducted in 2014. Loud and very loud occupational noise exposures were reported by 5.3% and 21.7%, respectively. 38.2% (1.9 million) of those with very loud occupational exposures never used hearing protection. Exposure to firearm noise was reported by 36.6% of respondents. Of those, 21.4% (7.4 million) never used hearing protection.

An online survey on hearing awareness among 2,200 adults aged over eighteen was conducted by Harris Poll on behalf of MED-EL USA in June 2017. The survey shows that one person in two knows someone with hearing loss or difficulty and 64% have had a conversation with that person about it. Results suggest that the awareness of hearing problems is growing and that people are becoming more open about hearing loss: the majority (78%) would not be offended or ashamed if someone they knew approached them because they thought they were experiencing hearing loss or difficulty hearing.

AGE DISTRIBUTION OF HEARING IMPAIRMENT IN THE US, ACCORDING TO NCHS



Hearing implants: Types and application

Hearing implants can be used by people of all ages, including infants from as young as just a few months.

Children with complete bilateral sensorineural hearing loss benefit from an implant. Adults with severe to complete bilateral sensorineural hearing loss can be fitted with a cochlear implant. Children and adults with mild to moderate sensorineural, conductive or profound hearing loss can benefit from middle ear implants. Experts advise implantation in cases where hearing aids are not effective or tolerated. (For types of hearing loss see "Types of hearing loss", p. 6.)

Implantation is a routine procedure

Today, cochlear implantation is considered a routine procedure. In most cases, the surgery is minimally invasive, which means that the surgeon performs only small incisions behind the ear. As a result, patients report hardly any pain and the wound heals faster. Surgery typically takes one to three hours and most patients are up and about on the same day and leave hospital a few days later.

Prior to surgery a medical team assesses a candidate's general health status to determine whether he or she is fit for surgery and is able to wear the external system parts. Before implantation, the team also ensures that the electrode can be inserted into the individual's cochlea.

If there are no medical contraindications, the decision to have a cochlear implant is up to the patient and/or their family. They must also be aware of how important it is for them to work together with the medical team after implantation. Intensive auditory training is usually required to familiarise the wearer with the device and the new hearing sensation.

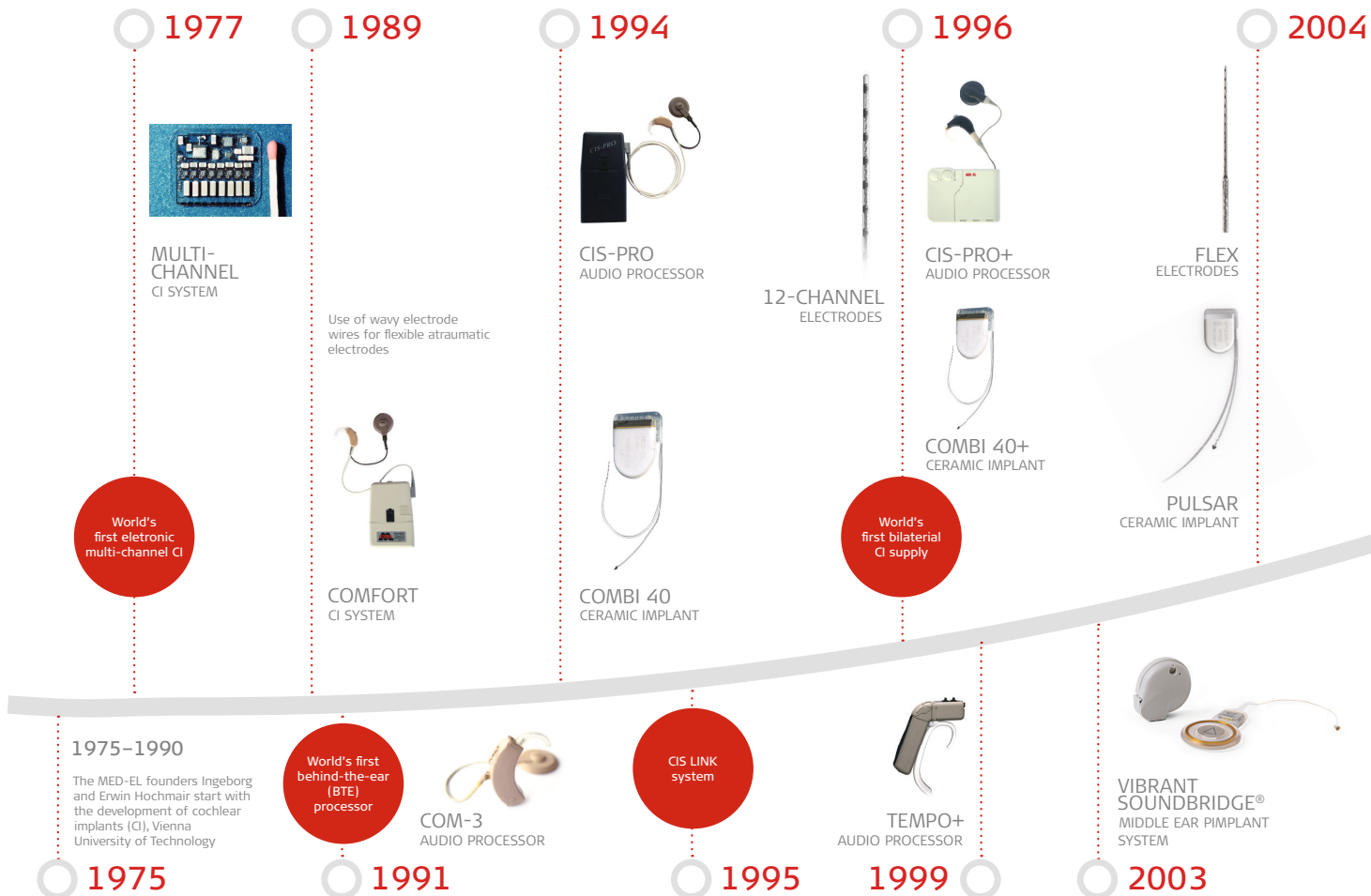
Auditory training after surgery

The period of auditory training begins after the operation. People who have received a cochlear implant therefore need support from their families, clinic staff and speech therapists/audiologists. The auditory training should begin as soon as possible after successful initial fitting.

Practising hearing is particularly important for children. They depend on assistance from their parents. In the course of undergoing speech therapy after surgery, parents are therefore advised about how best to support their children: by drawing their attention to noises, singing and making music with them, and playfully making hearing a part of day-to-day life.

Individual solutions

Various MED-EL technologies help people with different kinds of hearing loss: among the products available are cochlear implants, systems for Electric Acoustic Stimulation, middle ear implants, bone conduction implants and auditory brainstem implants. MED-EL's electrode arrays feature wave-shaped wires, making them especially soft and flexible and therefore ideal for preserving residual hearing.



Cochlear Implant

MED-EL's cochlear implant system consists of two components: the audio processor, which is worn behind the ear, and the implant. The surgeon can choose from the combination of system components that best match the clinical requirements and the patient's individual needs.

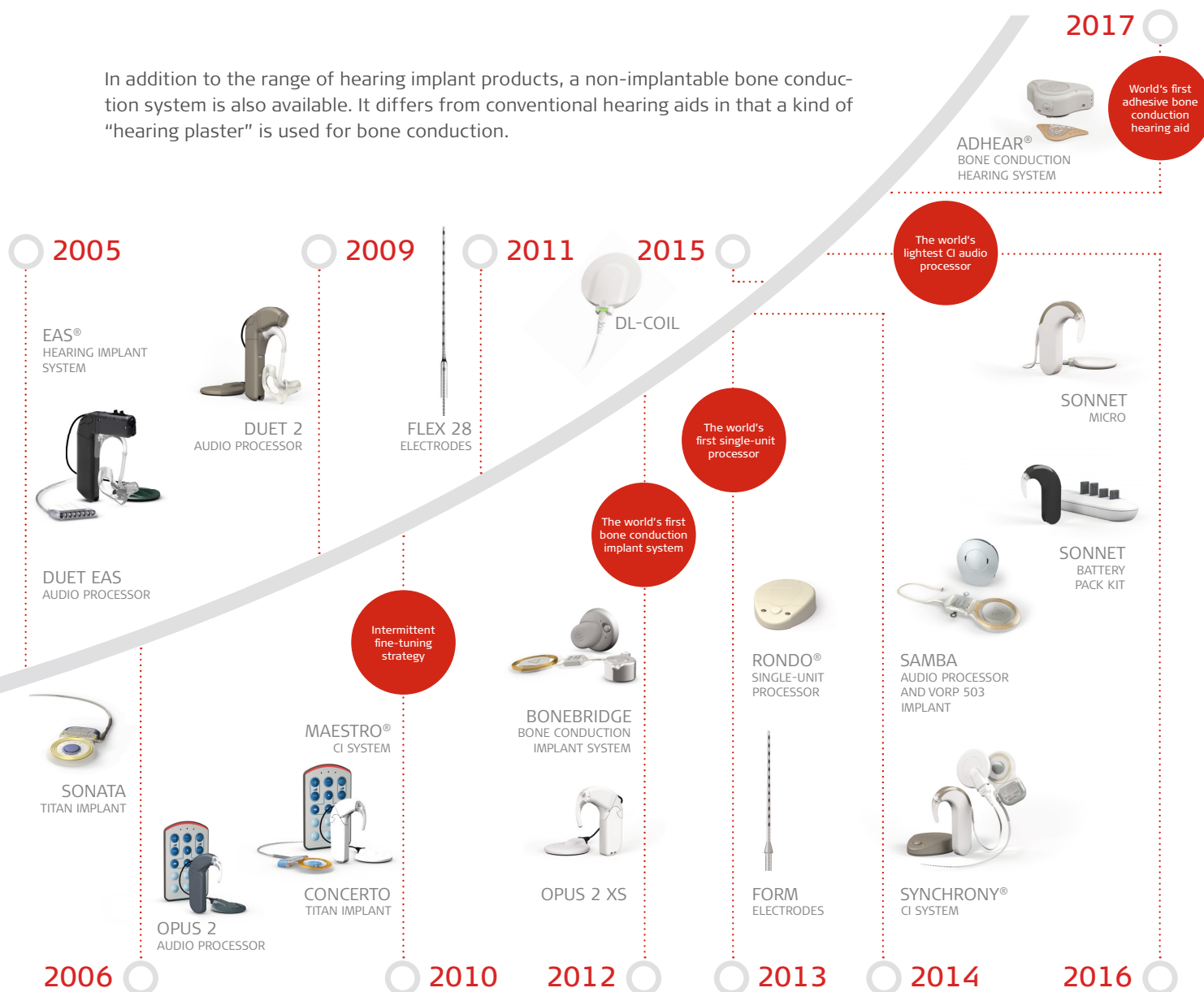
Electric Acoustic Stimulation (EAS)

Individuals with partial hearing loss are able to hear low-frequency sounds to a certain extent, but are unable to hear higher frequencies. MED-EL's EAS hearing implant system for electric acoustic stimulation combines the technology of cochlear implants and digital hearing aids. The inner ear receives both acoustic and electronic stimulation in parallel. Similar to natural hearing, it can thus process high and low frequencies simultaneously.

VIBRANT SOUNDBRIDGE Middle Ear Implant System

The middle ear implant system VIBRANT SOUNDBRIDGE represents an alternative to conventional hearing aids. It converts sound into mechanical vibrations that directly stimulate the middle ear structures. Middle ear implant systems are used for individuals with mild to severe sensorineural hearing loss as well as for conductive and mixed hearing loss.

In addition to the range of hearing implant products, a non-implantable bone conduction system is also available. It differs from conventional hearing aids in that a kind of "hearing plaster" is used for bone conduction.



BONEBRIDGE Bone Conduction Implant System

MED-EL developed BONEBRIDGE as the world's first active bone conduction implant with transcutaneous intact-skin technology. The system is suitable for people suffering from conductive and mixed hearing loss or single-sided deafness. By means of bone conduction, sound is conducted directly to the inner ear, thus bypassing problems in the inner or middle ear.

ADHEAR Bone Conduction System

ADHEAR is an alternative for people with conductive hearing loss who cannot undergo surgery. Bone conduction stimulation involves conducting sound waves through the skull bone directly to the inner ear. The system consists of two external components: an adhesive adapter and an audio processor. The audio processor collects sound waves, converts them into vibrations, and sends them through the adhesive adapter behind the ear (a kind of "hearing plaster") to the skin and the bone below. The bone conducts the vibrations through the skull to the inner ear, where the sound is processed naturally.

Auditory Brainstem Implant

The Auditory Brainstem Implant (ABI) is a hearing implant system for individuals with hearing loss due to a non-functional auditory nerve.

Please refer to www.medel.com for detailed product information on all implants

Provision of hearing implants: Facts and figures

As of April 2018, an estimated 570,000 devices have been implanted worldwide. Currently, between 45,000 to 49,000 CIs are sold worldwide each year.^{27,28,29} Two thirds of cochlear implant recipients are children. Based on a global population of 7.5 billion people, six cochlear implants per million inhabitants are used.

Hearing implants help people understand speech better, increase career opportunities and thus the national income of the particular country (see "Hearing implants increase income and reduce costs, p. 20). However, the majority of people who would benefit from an implant do not have one.

Majority of people with impaired hearing do not have implants

The criteria for cochlear implantation differ internationally, but potential candidates for implantation generally have a profound bilateral hearing loss of more than 85 to 90 dB, a functioning auditory nerve, and generally good health status.³⁰

Only five per cent of adults in the United Kingdom with the appropriate indication are fitted with a cochlear implant.³¹ In the Netherlands, the figure is seven per cent. The situation is similar in the USA.³² We can assume that the figures in Austria and Germany are similar or slightly higher, as the situation in Austria and Germany is good compared with the rest of Europe. But even these top rankers presumably only fit a fraction of those people who would benefit from cochlear implantation.

In most Western European countries, around 200 in one million people are fitted with cochlear implants. In Austria the figure is roughly 300, in Germany 340 per one million inhabitants; in Hungary and Slovakia, in contrast, only slightly more than fifty. This discrepancy may be due to the mode of financing or the fact that cochlear implantation only became available later in Eastern Europe compared with other countries. In some of these countries, cochlear implants for adults are not paid for by the state, or only partly. In the vast majority of countries, the costs of implantation in children are paid for by the state. Some countries such as Estonia, Slovakia, Hungary or Italy place a special emphasis on fitting children with implants.³²

Emphasis: Children

In Western countries, around 80 to 95 per cent of all deaf-born children are fitted with a cochlear implant. In Austria, the figure is around nine in 10,000, in Germany around fourteen in 10,000 newborns a year.³²

The implantation figure in most Western European countries is 5.5 to 8.5 in 10,000 births. Although not all of these children are born deaf. 3 to 4 in 10,000 are implanted relatively soon after birth, while 3 to 4 in 10,000 children are only diagnosed later or become deaf during childhood. Data from the United Kingdom show that 40 to 50 per cent of young candidates aged under three are implanted, 50 to 60 per cent at the age of three to seventeen. Reasons for this relatively later implantation are a progressive deterioration in hearing or one that is only manifested in later years.³²

Benefits of hearing implants: Study results

For hearing people, everyday sounds are a matter of course: the peeping of an oven when the cake is done or the pattering of children's bare feet on the floor. Deaf people live without them, and without the useful pointers they give us. Hearing means participating in the world, deafness prevents us from taking part in most of the acoustic world. Hearing implants can change people's lives.

A cochlear implant improves the wearer's hearing and their quality of life significantly, as numerous studies with both children and adults show.^{33, 34, 35, 36, 37, 38, 39}

Children benefit in both hearing and speaking

Many studies show that children with a profound hearing impairment who have a CI learn language in the same way as children with normal hearing and that, compared with children without a CI or with a hearing aid, they achieve significantly better results when it comes to perception, comprehension and production of meaningful language and reading skills. The best results are when children are implanted in their first year of life.^{40, 41, 42, 43} Children with bilateral implants achieve better results in written and spoken language compared with children with a unilateral implant. The more the family supports their children with reading and learning, the better the results.⁴⁴

If children are fitted with a cochlear implant at an early age, they do not display any significant differences in their hearing and speaking abilities compared to their peers. On the contrary, studies showed that hearing in children with a cochlear implant develops faster than in their hearing peers.⁴⁵

Another long-term study evaluated the development of auditory skills in children who were fitted with a cochlear implant before the age of 24 months. The results were astonishing: the hearing behaviour of the implanted patients developed in the same way as with their normal hearing peers – albeit in a shorter period. With the cochlear implant system, infants with impaired hearing achieved the same level as those with normal hearing in less time.⁴⁵ Speaking on the phone, listening to music, and making music is possible for children with a cochlear implant.^{47,48,49,50}

Enhanced quality of life for adults

Studies show that cochlear implants also allow adults to identify sounds and understand spoken words again. The important thing is to perform implantation as soon as possible after hearing loss has been diagnosed.

In addition to understanding speech, cochlear implant wearers also enjoy distinct improvements in social situations: People who can hear feel more secure when dealing with other people, feel accepted and at ease. It is not just about a sensory organ working properly, it is about quality of life.

In a subjective evaluation of quality of life, researchers surveyed cochlear implant users about their hearing, speech production, changes in self-esteem, and social activities. Users reached significantly improved levels in all categories within the first month after implantation. What is more, the CI-wearer's self-esteem increased with their activities and social interactions.⁵¹

Hearing implants increase income and reduce costs

Studies show that a hearing impairment has a negative effect on a person's financial situation – and thus also influences a country's overall economic performance. Additionally, there is the positive effect on their financial situation: people with a cochlear implant generally earn more than prior to implantation and thus contribute to the national income.

The World Health Organisation (WHO) conservatively estimates that the annual global cost of unaddressed hearing loss is in the range of 750 to 790 billion International Dollars. The most recent WHO report on "Global costs of unaddressed hearing loss and cost-effectiveness of interventions" takes no account of certain aspects of hearing loss, the costs of which are not well documented in literature, such as the costs of providing informal care, or preschool learning and higher education for people with unaddressed hearing loss. Therefore, the real economic costs are likely to be even higher.⁵⁵

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Two ears are better than one

This is the key idea behind bilateral implantation, whereby individuals receive an implant in both ears. This is done either during a single operation (simultaneous) or in two procedures (sequential).

Hearing with two ears has clear advantages: sound can be localised better than with one ear alone, and speech discrimination in noise improves considerably. In addition, binaural hearing is less strenuous than hearing with only one ear. Parents of children with implants report that their children have better levels of attentiveness and concentration after implantation of a second CI than with a single device. The reason is obvious: children learn language more easily and do not need to concentrate as much when listening. Studies with adults show that hearing with a second cochlear implant works much better.^{52,53,54}

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The cost estimated by the WHO comprise:

- the cost to the health-care sector, for adults and children, estimated to be in the range of \$67–107 billion. This does not include the cost of providing hearing devices such as hearing aids and cochlear implants.
- a conservative estimate of the cost to the education sector of providing support to children (5–14 years) with unaddressed hearing loss is \$3.9 billion.
- loss of productivity, due to unemployment and premature retirement among people with hearing loss, estimated to cost \$105 billion annually.
- societal costs – the result of social isolation, communication difficulties and stigma – add a further \$573 billion each year. These costs are calculated on the basis of the monetary value attached to avoidance of a year lived with disability and draw upon disability-adjusted life years (DALYs) attributed to hearing loss.

Cochlear implants increase income

Economically, cochlear implants pay off over a person's lifetime – and what is more: the return on investment for every US dollar invested comes to US\$2.07 (equivalent to €1.90).⁵⁶ Cochlear implants are cost-effective over the entire life-span both with adults and children.⁵⁷

In 2012, a research team investigated the effect of cochlear implants on the implantees' income and were able to show that they earned roughly US\$12,000 (equivalent to approx. €11,000) a year more than before implantation.⁵⁸ A study carried out in 2015 yielded similar results: Implantation enabled some probands to participate in working life for the first time. Whereas 40 of the 65 participants had a paid job prior to implantation, afterwards it was 49.⁵⁹ While this is a small study, it nevertheless shows the positive effect of hearing on working life.

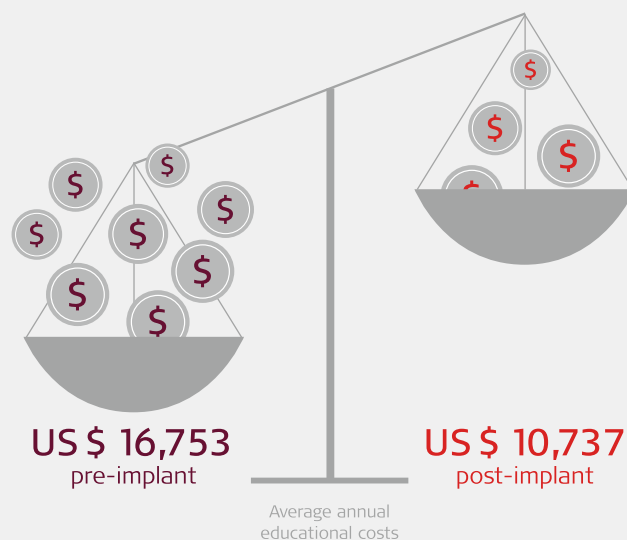
Implants reduce costs of education

The type of school that a child attends also has an effect on a country's overall economic situation. Nine years of standard compulsory schooling in Austria, for example, cost roughly €57,000, nine years of special-needs schooling, in contrast, around €400,000.⁶⁰

being fitted with a cochlear implant above all boosts the wearer's quality of life – among other things thanks to improved education and thus higher income. If hearing impaired children are fitted with cochlear implants, they not only benefit from a positive psychosocial development; implantation also has a positive impact on health and educational costs.

The earlier implantation is performed, the better: a study from 2013 showed that 81 per cent of children implanted before the age of eighteen months were able to attend a standard school full time. With children implanted at age 36 months or later, the figure was 63 per cent. The scientists came to the conclusion that in the course of a 77.5-year lifetime, cochlear implantation brings net savings of US\$31,252 (equivalent to approx. €29,000) for each child implanted before the age of 18 months.⁶¹

LOWER EDUCATIONAL COSTS AFTER COCHLEAR IMPLANTATION



Source: Cheng A.; Rubin H.; Powe N.; Mellon N.; Francis H.; Niparko J.
Cost-utility analysis of the cochlear implant in children JAMA, 284(7), 2000



Helena wears a MED-EL cochlear implant system on both sides

From the life of a young patient

Helena was born in Vienna in January 2015. The pregnancy and birth were what all parents hope for: unremarkable and normal. Four days after birth, a hearing test displayed negative results. The doctors suspected waters in the ear canal and referred the parents to an ENT specialist. Three weeks passed, with one test after another. In the end, it became clear: Helena was deaf in both ears. The hair cells in the inner ear were not conducting the sound signals to the auditory nerve. The doctors suspected a genetic cause.

"We had no experience with hearing loss. Nor did we know that cochlear implants existed", says Helena's mother Christine Petrovic. "My first thought was: she'll never be able to speak, she'll never sing, never say 'Mummy'." But things turned out differently because the doctor in charge told them about the possibility of cochlear implantation. "And we were so relieved. Right away we were determined to have the implantation done", says Christine today. Their daughter was implanted at the age of ten months.

Today Helena wears a MED-EL cochlear implant system on both sides, she enjoys playing her keyboard and the xylophone. She receives regular support from a speech therapist and early supporter and is developing wonderfully: she is speaking her first words and chats away like children do.

"She likes wearing her CIs", says mum Christine and recalls the first Christmas after implantation: "The implant was switched on for the first time on 17 December. Our family always rings a little bell on Christmas Eve. Helena reacted to this ringing and even 'sang along' with the Christmas carols. That was the loveliest moment. It was the best decision for us. It lets us allow our daughter to live in the world of the hearing too", says Christine. "I would advise anyone in the same situation to have the implantation done."

SUMMARY

There's still a lot to do

Around two in 1,000 infants cannot hear their mums say "You can do it!", encouraging them in their first attempts to crawl; they cannot hear their dads wish them good night. Every fifth person in industrialized countries cannot follow a quiet conversation among colleagues.

Although the present data on hearing loss are not complete, they show a clear trend: Hearing loss is a phenomenon affecting millions of people across Europe and the world, restricting their daily lives.

However, it is not only the individual person, but society in general, that plays a vital role: society has to devote the amount of attention to hearing loss that it deserves. After all, it is not just the individual person who has to deal with the consequences of an untreated hearing loss, but also his or her children, parents, friends, employers, colleagues – in short: society. People who cannot hear often earn less than people with normal hearing – and can therefore not contribute as much to a country's joint income.

We at MED-EL encourage a broader discussion of hearing loss. Every single person is invited to get involved, after all hearing loss not only affects our families, but society as a whole.

In Europe and industrialized countries, we are on the right track: an increasing number of children have been provided with hearing implants or hearing aids. So our children are already well cared. However in some markets there is still a high unmet need resulting in major negative impact on the individuals and their families. A challenge in years to come will be the level of care for individuals of all ages, especially older people with hearing loss. Increasing noise pollution and its effects on everyone's ears in later years is a key concern.

MED-EL's corporate goal is to overcome hearing loss as a barrier to communication and quality of life. We will therefore continue to use every effort to provide the best possible support to people with impaired hearing. Regardless of origin and age. After all, hearing affects all of us.

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