



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Early detection of side effect of implants

Annual report 2022 and looking back at 5 years of reporting to MEBI



The Dutch Reporting Centre for Adverse Effects of Medical Implants (MEBI) is a facility where citizens¹ and healthcare professionals can report suspected side effects (undesired health effects) of implants². More information about MEBI's activities is available at the end of this report and on the MEBI website, www.rivm.nl/mebi.

Every year, MEBI publishes its annual report with an overview of reports received and activities undertaken in the preceding year. The present report concerns 2022, the year of MEBI's fifth anniversary. For that reason, this report also considers trends over the past five years.

The average age of the patients concerned in the reports was 43. The youngest was 19 years old, the oldest 92. In two cases the report concerned a man; all other reports concerned women.

In 63% of all reports, MEBI staff contacted the person who made the report for additional information, for example about the implant, the reported health problem(s) and/or the medical history.

Overview of reports received in 2022

Number of reports

In 2022, MEBI received reports about health problems from 193 persons.

Below, the reports from 2022 are broken down by type of person who made the report: citizen or healthcare professional.

Figure 1. Reports received, broken down by type of person who made the report

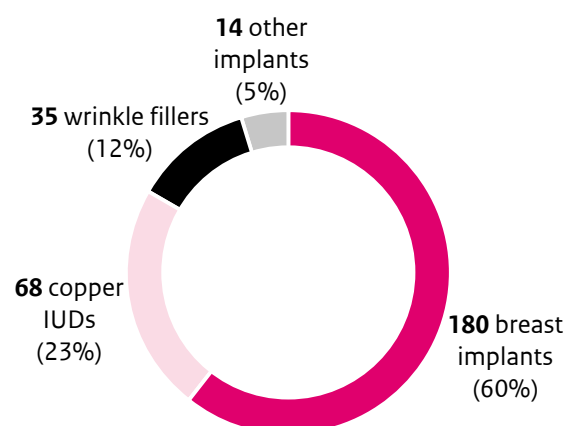


In 2022, MEBI received reports about health problems from **193 persons**

Types and numbers of implants

The 193 reports concerned a total of 297 implants. This means that a number of reports concerned multiple implants. Figure 2 presents the types of implants about which the reports were received.

Figure 2. Distribution of reports by type of implant in 2022 (in percentages and numbers)



¹ In this annual report, the term 'citizens' is used to refer to patients as well as persons making a report on behalf of a patient. Persons with one or more health problems are referred to as patients in this report, irrespective of whether they receive medical care.
² An implant is a medical aid placed inside the body for a prolonged period of time for medical or cosmetic reasons.

The 'Other implants' category covers a wide variety of implants. For example, this category contains reports about urinary incontinence tapes (TVT or TVT-O³), abdominal wall, pelvic floor or inguinal hernia meshes, female sterilisation devices, knee prostheses and pacemakers.

Most reports from citizens in 2022 concerned breast implants and copper IUDs. Reports from healthcare professionals mainly concerned copper IUDs. The higher number of reports about breast implants and copper IUDs can be attributed in part to the recurring media attention for these implants.

Types and numbers of health problems

The reports received described a total of 1,921 health problems. Most reports were about breast implants, copper IUDs and wrinkle fillers. Last year, wrinkle fillers reached the top three for the first time. Again, this can be explained by the attention – also in the media – for side effects of wrinkle fillers following a COVID-19 vaccination⁴ and a [notice](#) that we issued on the subject. Tables 1, 2 and 3 present the most frequently reported health problems attributed to breast implants, copper IUDs and wrinkle fillers.

The **193** reports concerned a total of **297** implants

Breast implants

Table 1. Most frequently reported health problems attributed to breast implants in 2022

Reported health problems	Numbers
Fatigue	109
Pain in one or both breasts	60
Concentration impairment	54

95% of all reports concerning breast implants included information about the impact on daily life. Approximately 67% of reporters said that the impact of the health problems on their daily life was serious to very serious.

Copper IUDs

Table 2. Most frequently reported health problems attributed to copper IUDs in 2022

Reported health problems	Numbers
Severe blood loss during menstruation	25
Dislocation of the copper IUD into the uterus	13
Copper IUD breakage during removal	12

In 80% of all reports concerning copper IUDs, the person who made the report included information about the impact of the problems on daily life. Nearly one quarter (23%) of reporters said that the impact of the health problems on their daily life was serious to very serious.

Wrinkle fillers

Table 3. Most frequently reported health problems attributed to wrinkle fillers in 2022

Reported health problems	Numbers
Immune response	33
Wrinkle filler response	13
Swelling around the implant	11

These three health problems are closely related. They concern immune responses to a vaccine and to the wrinkle filler. These responses can be systemic (immune response) and/or local (wrinkle filler response) and may cause swelling around the implant.

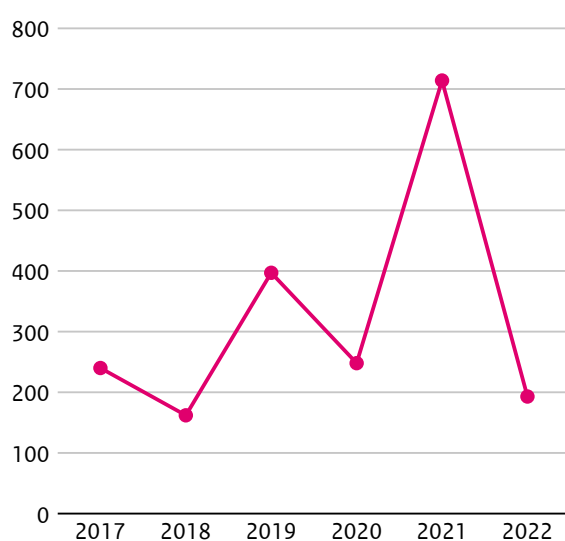
³ TVT stands for Tension-free Vaginal Tape and TVT-O for Tension-free Vaginal Tape Obturator.

⁴ *Tientallen fillerreacties na vaccinatie COVID-19* (Dozens of filler reactions following COVID-19 vaccination), *Pharmaceutisch Weekblad*, January 2022

Reports received over the past five years

MEBI was launched in July 2017. This means that it has existed for over five years now. Figure 3 presents the number of reports received per year. The number of reports varies notably from year to year.

Figure 3. Number of reports made per year



Thus far MEBI receives reports primarily from women and citizens, less from men and healthcare professionals

Table 4 gives a detailed picture of the similarities and differences between reports made over the past five years. Note that many reports are about implants mainly received by women. Another notable fact is that the number of reports made by healthcare professionals is consistently low compared with the number of reports made by citizens. In 2022, the number of reports made by healthcare professionals and the average age of the patient concerned in the report were in line with the years before 2021. In that year, there was a peak in the number of reports made by healthcare professionals about copper IUDs.

Table 4. Overview of reports made in previous years

	Reports made by healthcare professionals	% women	Average age	Top three types of implants reported on
2017 (July-Dec)	2	85	55	1. Breast implants 2. Pelvic mesh implants 3. Hip prostheses
2018	11	86	51	1. Breast implants 2. Knee prostheses 3. Hip prostheses
2019	25	93	48	1. Breast implants 2. Copper IUDs 3. Pelvic mesh implants
2020	46	98	42	1. Breast implants 2. Copper IUDs 3. Pelvic mesh implants
2021	139	98	37	1. Copper IUDs 2. Breast implants 3. Pelvic mesh implants
2022	28	99	43	1. Breast implants 2. Copper IUDs 3. Wrinkle fillers

There has been little variation in the top three implant types reported on over the past five years.

The variation in both the number of reports and the types of implants concerned has two main causes: publications by MEBI itself (such as notices and fact sheets) on the one hand, and publications by other organisations and media attention on the other. There is a clear correlation between attention (in the media or otherwise) and the numbers and types of implants reported upon. This is shown in Figure 4 for two types of implants: breast implants and copper IUDs. The number of copper IUDs placed far exceeds that of breast implants. This difference is also clearly reflected in the numbers of reports that MEBI received.

MEBI is a reporting centre for all types of implants, but it receives few reports about implants other than breast implants and copper IUDs. Below are examples of implants that MEBI has received few reports about over the past five years.

Figure 4. Number of reports made per day associated with media attention for breast implants (red) and copper IUDs (black) over a two-month period. The reports about breast implants were made in response to the consumer television programme Radar of broadcaster AVRO/TROS in November 2018 (red triangle). The reports about copper IUD were made in response to a notice issued by MEBI and the associated media attention it received in March 2021 (open triangle).

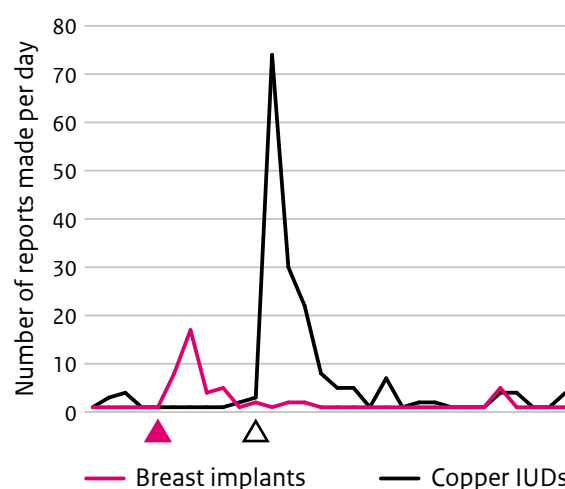


Table 5. Number of reports <10

Implant type	Example
Hearing implant	Bone-anchored hearing aid, cochlear implant
Implant to measure glucose or administer insulin (implant for diabetics to measure blood sugar levels or administer insulin)	Insulin pump, blood sugar sensor
Airway implant	Airway stent, lung valve
Stomach, bowel or liver implant	Adjustable gastric band, gastric balloon, bile duct stent
Visual implant (eye implant)	Lens

Table 6. Number of reports 10–50

Implant type	Example
Active heart implant (stimulating heart implant)	Pacemaker
Cardiovascular implant (heart or vascular implant)	Stent, artificial heart valve
Jaw implant	Dental implant
Urological implant (urinary tract implant)	Urethral band, urethral stent
Neurological implant (implant in the nervous system)	Electric brain stimulator, neurostimulator

Table 7. Number of reports >50

Implant type	Example
Orthopaedic implant	Intervertebral disc prosthesis, hip or knee prosthesis

The relatively small number of reports that MEBI receives about certain implants can have several causes. For example, the implants concerned may be highly effective and cause very few health problems. It is also possible, however, that the people who have such implants and the healthcare professionals who place them are not aware of the existence of MEBI. In other cases, they might not make a report because they consider the health problem associated with the implant to be 'known'. It is important that these groups know where to find MEBI and what purpose it serves. For that reason, MEBI will also focus on the users of these implants in campaign activities in the period ahead.

Campaign activities in 2022

MEBI developed a series of campaign activities to promote awareness and continued them in 2022. Examples include activities on social media (e.g. banners on Facebook, Instagram and Twitter) and informative video clips to be shown in GP waiting rooms.

The purpose of MEBI is to detect possible side effects of implants at an early stage

In addition, MEBI created an [e-magazine](#) to mark its fifth anniversary in 2022. The magazine explains why MEBI is important and gives readers a glimpse behind the scenes. It also features interviews with people about their experiences when making a report to MEBI. The e-magazine was published in January 2023.

Why does MEBI exist?

The purpose of MEBI is to detect possible side effects of implants at an early stage. An implant is a medical aid placed inside the body for a prolonged period of time for medical or cosmetic purposes. There are many different types of implants. For example, there are cardiovascular implants (such as heart valves, pacemakers and stents), breast implants, knee and hip prostheses, gastric balloons, pelvic floor, hernia and scar meshes, wrinkle fillers, dental implants, hearing implants and lens implants.

Like medicines, implants can cause side effects. Side effects are undesirable effects on a person's health (health problems) caused by the implant, such as pain or difficulty when moving. For some implants, we know in advance what side effects they can cause. It is important for all health problems to be reported, as they can be side effects of the implant. The reports help to ensure that possible side effects are detected as soon as possible.

How MEBI works

Both healthcare professionals and citizens can report issues with one or more implants to MEBI. To do so, they can complete an online form at www.rivm.nl/mebi.

MEBI assesses every report it receives. If more information is needed, the person who made the report may be contacted with further questions. If necessary, MEBI will analyse a suspected side effect in connection with the implant. For example, it may conduct a literature review or interview care professionals and/or other experts. The analysis may concern a new (unknown) reaction, a new aspect of a known reaction or a sudden increase in the number of reports of a known reaction.

MEBI publishes information on the reports it receives on its [website](#). It does so in several ways:

- Every year, MEBI publishes an *annual report*. The annual report presents general information on which types of implants MEBI received reports about, and how many reports it received. The annual reports of previous years are available on the MEBI website (www.rivm.nl/mebi).
- MEBI also publishes *notices*. These are intended to spread knowledge about known risks of implants more widely among healthcare professionals and other interested parties. To date, MEBI has issued five notices. These were about a gastric band, a contraceptive device, IUDs (2x) and wrinkle fillers. The notices are available on the MEBI [website](#).

- In addition, MEBI publishes *fact sheets*. In its fact sheets, MEBI provides insights into the reports received about a particular type of implant. The purpose of these fact sheets is to show how many reports have been received about that type of implant and what kinds of health problems have been reported. So far, MEBI has published three fact sheets. Two of those concerned breast implants and one was about mesh⁵ implants. The fact sheets are available on the MEBI [website](#).
- Finally, MEBI issues *alerts* on the side effects that a particular implant can cause. Alerts describe side effects or risks that are unknown or have not previously been identified. Thus far, MEBI has not issued any alerts.

MEBI anonymises all information before publishing it. Once published, the information is available to anyone who is interested, including healthcare professionals, citizens and the Health and Youth Care Inspectorate (IGJ). MEBI actively disseminates its alerts, notices and fact sheets among relevant professional groups and/or patients' associations.

MEBI uses a reporting system for citizens and healthcare professionals to report health problems on their own initiative. It is important to ensure that healthcare professionals and citizens actually report suspected side effects of implants and do so as quickly as possible. Only side effects actually reported can be included, so the number of reports does not provide insights about the risk of a side effect or how often it occurs in connection with

a particular implant. In other words, the MEBI database cannot be used to calculate so-called incidence figures. Neither does the total number of suspected side effects give a comprehensive overview of all potential side effects to a particular type of implant. It is purely a representation of the number of suspected side effects reported to MEBI.

Impact of health problems on daily life

On the report form for health problems, MEBI also asks about the subjective impact of those problems on daily life. This is difficult to define. On the form, the person who makes the report can specify whether the side effect has a very serious, serious, moderate or low impact on daily life, or no impact at all. They can also give further details about this impact on daily life. For example, the extent to which it has affected their ability to work, do household jobs, look after the children or engage in hobbies.

The importance of MEBI and of reporting problems

It is important that implants are safe. Reporting to MEBI can help to make sure of this. Reporting possible side effects may help other patients. When many or unusual health problems are reported, MEBI will be able to detect potential connections between implants and problems at an early stage and inform healthcare professionals, patients and the government accordingly.

In 2023, MEBI will continue its efforts to increase awareness of its work among healthcare professionals and the general public.

When many or unusual health problems are reported, then MEBI can detect a possible relationship between implants and health complaints at an early stage

⁵ Mesh implants are sheets, bands or nets made of synthetic material and placed inside the body permanently. They are often made of thread of a synthetic material called polypropylene. Various types of mesh implants are available for the treatment of a variety of disorders, such as pelvic mesh implants, inguinal hernia meshes and abdominal wall meshes.

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