# The Influence of the 2020 COVID-19 Pandemic on the Implantation Rates of Cardiac Implantable Electronic Devices (CIEDs) in Germany

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# Changes between 2020 Q1-Q3 and 2019 Q1-Q3

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**ABSTRACT**

**Aim:** During the early phase of the COVID-19 pandemic, hospital admissions for several medical and surgical conditions have declined. Few data are available with respect to elective cardiac implantable electronic devices (CIEDs) implantation. The aim of the present study was to determine the impact of the COVID-19 pandemic on the monthly CIED implantation rates in Germany.

**Methods and Results:** The monthly rates of CIED implantation for the 2019 pre- and 2020 pandemic periods were retrieved from the "Institute für das Entgeltsystem im Krankenhaus" (InEK) using OPS codes to identify pacemakers (PMs), implantable cardioverter/defibrillators (ICDs) and cardiac resynchronisation therapy (CRT) systems. Compared with 2019, the COVID-19 pandemic was associated with an overall decline of CIED implantation rates of -2.6 %, reaching -22,9 % in April 2020. Stratified by device type, the patterns of implantation were similar between PMs and ICDs, with maximal declines of -24.3 % and -23.2 % in April, respectively. Thereafter, the implantation rates gradually increased before stabilizing to rates similar to those observed in 2019. CRT implantation rates also declined in the early pandemic wave, but the overall 2020 rates increased by +4.3% likely driven by an increase of +16.5% (June to September). All observed percentage differences of monthly device type related implantation rates demonstrated a statistical significance.

**Conclusions:** The COVID-19 pandemic had a significant impact on the implantation of CIEDs in Germany. A differential pattern of resource utilization was observed with a catch-up effect for PMs and ICDs. The implantation rates of CRT also declined, but they increased rapidly and remained higher than those of 2019.

**Keywords:** Cardiac Implantable Electronic Device, COVID-19, Cardiac Resynchronization Therapy, Implantable Cardioverter-Defibrillator, Implantation Rate, Pacemaker

## INTRODUCTION

Due to the increasing occupancy of intensive care units claiming, which surpassed their normal capacities during the outbreak of COVID-19 pandemic, the number of planned implantations of cardiac implantable electronic devices (CIEDs) decreased. This was mainly driven by the demand of the German Federal Ministry of Health and the German federal states to postpone planned in-hospital, non-emergent treatments such as replacement of medical devices or various surgeries such as hip implantations, but also CIED implantations. During this phase of reorganisation in the operating procedures, only emergent implantations of CIEDs were performed while many patients requiring non-emergent implantations, although planned, were put “on hold”.

The current investigation reports on the number of implantations of CIEDs performed in German hospitals during the mandatory lockdown of the COVID-19 pandemic. It also highlights the changes that occurred in the medical / hospital systems and the process undertaken to ensure all patients who had their procedures postponed were to receive appropriate treatments.

**METHODS**

Cardiac implantable electronic devices implantations are reimbursed by the German Diagnostic Related Groups (G-DRG) system. According to Section 21 of the Hospital Remuneration Act (short §21 KHEntG), it is mandatory for all German hospitals to transfer the activity and billing data related for these procedures to the "Institute für das Entgeltsystem im Krankenhaus" (InEK). Implantation procedures, which are performed in-hospital, are coded according to the German Operation and Procedure Classification (OPS) which provides unique OPS codes for different CIED systems. Moreover, it is possible to distinguish if the CIED implantations are performed as first-time device implantation, replacement, removal or revision.

For our analysis, we used the OPS code versions 2019 and 2020 (OPS code version 2019: https://www.dimdi.de/static/de/klassifikationen/ops/kode-suche/opshtml2019/; OPS code version 2020: https://www.dimdi.de/static/de/klassifikationen/ops/kode-suche/opshtml2020/; last accessed on May 31 2021). The classification of the relevant CIED systems and the corresponding OPS codes are displayed in Supplementary Tables 1S and 2S. Data for the following CIED systems were analyzed:

1) Pacemakers (PMs) comprising single-chamber pacemakers, dual-chamber pacemakers and implantable pulse generators (IPGs)
2) Implantable cardioverter/defibrillators (ICDs) comprising single-chamber, dual-chamber ICDs and subcutaneous ICDs (S-ICDs)
3) Cardiac resynchronization therapy (CRT) systems comprising CRT-D and CRT-P devices.

For this investigation, only the number of first-time device implantations or device replacements (excluding device replacements in combination with lead replacements) were

analyzed. The number of monthly in-hospital CIED Implantations were retrieved by the InEK using the InEK Data Browser. The Data Browser represents an open-access, non-commercial database maintained by InEK and available at https://datenbrowser.inek.org/. The InEK Data Browser provides the Section 21 of the Hospital Remuneration Act data set. Each data set specifies a standardized data format for medical performance and resultant settlement data (DRG) for a patient-case, and each hospital performing CIED procedures is required to transmit the relevant information at pre-determined due dates. Further information regarding the definition of the data set according to Section 21 of the Hospital Remuneration Act is provided in the Supplementary Material.

***Investigation Period***

The months of January through September were analyzed for the years 2019 and 2020. The investigation period was chosen in order to reflect what became known as the first COVID-19 wave in 2020. To ensure the comparability of data, we have also analyzed the data set of the year 2019. The monthly data of both years were then compared to each other.

The respective data basis for the query from the InEK data browser was the "DRG 2019 data delivery grouped according to 2020" and the "In-year data delivery January through December 2020" (https://datenbrowser.inek.org/; last accessed on May 19, 2021).

***Query Procedure***

Data were retrieved via the InEK data browser (supplementary Figure 1S) using the following search criteria:

- Defined OPS codes for first-time implantation and replacement of CIEDs according to the 3 groups mentioned above

- Analysis of each month in the investigation periods of January through September 2019 and 2020 based on the admission date for in-patient treatment
- Admission period from the first day of the month until the last day of the month

Since this is a holistic analysis of all patients implanted during the investigation period, no further restrictions or search criteria were specified. With the upgraded list of the preliminary version of the OPS 2020 version (DIMDI, ops2020syst-aktualisierungsliste-20190809-vorab.pdf), it was ensured that the selected OPS codes for the procedures were identical for both data years and were thus comparable.

***Statistical Analyses***

All statistical analyses are based on a full survey of administrative data from InEK. The number of interventions was compared using absolute monthly frequencies for the years 2019 and 2020. The absolute differences between years were then considered per month. Additionally, monthly percentage changes with 95% confidence interval [CI] of interventions in 2020 related to 2019 (January until September) were evaluated and tested using a binomial test procedure (function binom test in R).

IBM SPSS Statistics 27 (SPSS Inc. an IBM Company, Chicago, IL) was used for the statistical calculations as well as R Core Team (2020). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria (https://www.R-project.org/).

**RESULTS**

The January to September 2020 time-course of the incidence of infections during the COVID-19 pandemic in combination with the policies undertaken by the German government is shown in Figure 1. The rise in the number of new infections is clearly observed with a first

peak occurring in March 2020. At that time, the German government decided to request all hospitals to postpone planned admissions and interventions.[1] At the end of the first peak, the government decided to allow the hospitals to gradually start scheduled interventions and admissions from May onwards.[2] Between March 16, 2020 and July 12, 2020, hospitals received financial support to provide financial planning security when postponing scheduled surgeries and interventions in the form of a uniform payment of a "free-bed" allowance of 560 euros per day and bed compared to the year 2019.[3] This approach was modified on July 13, 2020 to provide an incremental 5-category "free-bed" allowance for free beds per day (360, 460, 560, 660 and 760 euros).[4]

In addition to the above mentioned hospital treatment-related measures, the first lockdown in Germany came into effect on March 22, 2020 with further restriction on social contacts[5] and ended with the first easing of these restrictions on May 6, 2020 .[6] Furthermore, compared to 2019, urgent hospitalisations decreased during the first wave of COVID-19 pandemic presumably due ,among other things, to the fear of people getting infected with the Coronavirus at the hospital.[7,8] The fear of infection combined with the lockdown-related restrictive measures on social life could also have had an effect on the CIED implantation rates.

When looking at the total implant rate of PMs, ICDs and CRT systems, Figure 2 provides detailed information on the time-course between 2020 and the 2019 rates. The decline of CIED implantations is clearly seen during the first pandemic wave from March 2020 to May 2020. In April 2020, the maximal implant rate decrease reached -22,9 %. The % changes (2020 versus 2019) of monthly implantation rates differentiated according to the three device types (PM, ICD and CRT) as well as the % change over the entire observation period (January to September 2020 versus 2019) are shown in Table 1. All monthly % differences for each device

types were statistically significant ($p < 0.001$). Figure 3 compares the progress of PM implantation between January 2019– September 2019 and January 2020– September 2020. Compared with 2019, the implantation rates started to decline in March, reaching a maximal reduction of -24.3 % in April followed by an increase starting in May. Between May and June, the rates of PM implantation surpassed those observed for the same 2019 time period. During June and July, there was a catch-up of the postponed procedures. Between June and July 2020, the implantation rates showed a rise of +13.9% and +14%, respectively.

Similar to the implantation of PMs, the implantation rates of ICDs reached a maximum reduction in April (-23.2%) followed by an increase starting in June. Between June and July, the rates of ICD implantation surpassed those observed for the same 2019 time period. During June and July, there was a catch-up of the postponed procedures. Between June and July 2020, the implantation rates showed a rise of +7.8% and +10.4%, respectively. By August, the implantation rate was similar to that of 2019 (Figure 4).

Finally, CRT showed a similar decline in its rate of implantation starting in March. However and, in contrast to PMs and ICDs, the increase in implantation observed in June remained stable throughout the study period and continued to exceed the rates in 2019 (Figure 5). Compared with 2019, the CRT implantation rates were +16.5% higher during the period from June to September 2020.

The data retrieved and analysed revealed a decrease in the implantations of ICDs and PMs of -4.5% and -3.3% during January to September 2020, respectively. On the other hand, more CRT systems (+4.3%) were implanted in the period from January to September 2020 compared to 2019. The increase in implanted CRT systems was higher for CRT-P (+13.4%) compared to CRT-D (+1.4%). Overall, there was a decline in CIED implantation of -2.6 % in the period from January 2020 to September 2020 compared to the previous year.

## DISCUSSION

The current investigation compares the nationwide rate of CIED implantation in Germany during the first three quarters of the COVID-19 pandemic with the same time period in 2019. The main findings consist of a significant decrease in the number of CIED implantations beginning in March 2020 and reaching a nadir in April 2020 at nearly -23%. During the summer period, i.e. starting in June 2020, the number of implantations exceeded the year 2019 with over 14% in June and July 2020. When looking specifically at device type, the number of CRT implants "cross the line" of the prior year and, at the end of the time period compared, they still exceeded the number of CRT implants in 2019. To the best of our knowledge, our investigation is the first nationwide analysis of CIED implantation in Germany using an official database focusing on OPS codes and DRGs. Our results are therefore representative of the true German reality in terms of CIEDs implantation during the pandemic first three quarter of 2020.

### *Comparison with Other CIEDs Analysis in Germany*

König and colleagues from the private HELIOS-group in Germany reported on their HELIOS hospital based findings recently[9]. They analyzed the frequency of cardiac intervention during the time period from mid-March 2020 to mid-September 2020. Results of their analysis showed that the number of CIED implantations was significantly reduced (-7%, $p < 0.001$).

In our German-wide analysis, the reduction in the number of implantations during the same seven-month time period reached an average of -4.3% for pacemakers and -3.6% for ICDs whereas, CRT devices increased by +5.7%. The reasons for this discrepancy may be due to the fact we analyzed the number of implantations and device replacements for the entire German hospitals compared to the 80 HELIOS hospitals analyzed by König and colleagues.

Furthermore, because the authors did not provide the number of different CIED types, their analysis likely differs from ours as we excluded some implant types such as insertable cardiac monitors/implantable loop recorders.

Another report of the HELIOS group analyzed the number of acute hospital admissions between March and April 2020 compared to the same 2019 time period[10]. They found a reduction of overall CIEDs implantation of approximately -15% which is consistent with -19% - 14% and -6% for pacemakers, ICDs and CRT, respectively during the same time period. However, because of the short observation period, the authors could not quantify the amount of the catch-up effect during the first wave of the pandemic.

***Comparison with Other Medical Procedures/Treatments in Germany***

An analysis of health insurance billing data of the large German health insurance AOK (Allgemeine Ortskrankenkasse) examined the changes of hospital treatment cases for AOK-insured persons between the COVID-19 pandemic in 2020 and the pre-COVID-19 period in 2019.[7] For predictable and less urgent cases, there was a relatively strong decline in the number of cases in the first pandemic wave (March to May). Typical of these interventions are osteoarthritis-related hip prosthesis implantation (-44.4%) and hysterectomy in the case of benign neoplasm or leiomyoma of the uterus (-40.4%). During the immediate period after the first pandemic wave (June to September), a stabilization of the hospital cases was observed but the case numbers remained below the level of 2019. The only exception was the osteoarthritis-related hip prosthesis implantation with an increase of treatment cases of 12.1% during June to September 2020 compared to 2019, suggesting a catch-up effect. In the case of urgent interventions, there was also a decline in the number of cases during the first wave of COVID-19 pandemic. In contrast to the predictable interventions, the decline in urgent treatment tended to be relatively small with myocardial infarction and stroke

treatment cases decreasing by -16.0% and -11.5%, respectively. With respect to urgent procedures, there also was a stabilization phase after the first wave of pandemic with the number of cases below the 2019 level. Between June and September, the decrease in hospital case numbers for myocardial infarction and stroke were -0.4% and -1.9%, respectively.

The catch-up effect we observed with CIED implantations was only detected in the AOK analysis for osteoarthritis-related hip prosthesis implantations. In our investigation, the catch-up effect was seen for all types of CIED systems. The highest increase was observed for CRT systems with 16.5% more implantations in the period June to September 2020. Due to this catch-up effect, the overall decline in CIED implantations during the complete observation period (January to September 2020) was relatively low at -2.6%. In contrast, the number of treatment cases billed according to DRG decline by over -12% during the same time period.[11]

***Comparison with Other CIEDs Analysis in Europe***

When looking at other European countries, Arbelo and colleagues reported their finding in Catalonia (reflecting approximately 16 % of the Spanish population).[12] They analyzed a period of 7 weeks, from March 16 to April 30, 2020, and compared their findings of new CIED implantation with the preceding 7 weeks (from February 1 to March 15). They found a dramatic reduction of -54.5% for PM and approximately -63.7% for ICD implantations which suggest these procedures were likely postponed as an emergency preventive measure.

Another Spanish study analyzed the impact of the first wave of COVID-19 on preferential/emergent PM implantations.[13] They compared preferential/urgent PM implantations performed between March 15 and May 15, 2019 with the same dates in 2020. This study showed a total decrease in the number of preferential/urgent PM implantations by -32.5%.

Compared to our findings, no data of the progress of the ongoing process was reported.

In Italy, few studies were published on the handling CIED implantation during the first pandemic wave. Migliore and colleagues reported their findings on urgent PM implantations performed in the Veneto region (7.1% of the Italian population) 6 weeks before and after the first COVID-19 wave in Italy (February 21, 2020).[14] They found a significant reduction of -29% of all urgent PM implantations after the first COVID-19 wave compared with the corresponding 6-week period in 2019. Although their observation is similar to ours (-24%), it has to be interpreted with caution as we included all PM implantations in our analysis of the following month after the start of lockdown.

Another Italian study, a survey conducted by the Italian Association of Arrhythmology and Cardiac Pacing, revealed that PM and ICD implantations for primary and secondary prevention decreased by over -50% during the early phase of the pandemic (March and April 2020).[15] Interventional electrophysiologist found this high decline of CIED implantations very concerning as it appears the COVID-19 pandemic disrupted the entire health care system with a massive impact on the activities and procedures related to arrhythmia management.

In Campania, data from 14 implantations centers were collected for the time between March 10th and May 4th 2020.[16] Compared to 2019, Russo and co-workers found a heterogeneous pattern of CIED implantations. The reduction of new implantation was -30 % for pacemakers up to -48 % for CRT. Of note, device replacements were not affected significantly.

Marini and co-workers found in their regional referral center analysis that urgent PM implantation rates during COVID-19 outbreak (March and April 2020) were similar to those

during the comparison period (March and April 2019).[17] A major limitation of this single center study is the small sample size (61 patients with PM implantations).

Compared to Italy, the management of the COVID-19 pandemic in Germany was significantly different as there was only a reduction of approximately a quarter of CIED procedures. The reasons for this difference remains speculative since the government actions as well as the impact of the COVID 19 pandemic on the health care providers show distinct discrepancies.

Mohamed and colleagues highlighted the situation in England during the period from January to the end of May 2020.[18] They divided this period into the first two months of 2020 and March to May, and compared these time periods to the preceding years 2018 and 2019. In their investigation, they analysed not only the changes of CIEDs implantations but also the changes of the overall cardiac procedure activities. In addition, catheter interventions as well as surgical procedures such as CABG and valve operations were also studied. In their analysis of over 350 000 cardiac procedures, the highest decrease in terms of percentage was detected for the surgical procedures (-67.6 % for CABG and -70.6 % for mitral valve procedures). When focussing on cardiac device procedures, the total deficit accounted for 43.1 %. When comparing the current investigation with the numbers reported in Germany, the CIEDs implantations were reduced by -9.7 % in the months January to May 2020 compared to 2019. Of note, the total numbers of all CIEDs implantation during January to May 2020 was 47758 in Germany compared to 28595 in England.

In Greece, Bechlioulis reported on a single centre experience during the first wave of the COVID-19 pandemic (February to April 2020) and found a significant decline of the number of new implantations of CIEDs.[19] In agreement with the other studies we have

discussed, the number of replacements or even new CRT implantations did not show a significant difference.

***Comparison with Other CIEDs Analysis:***

Gonzales-Luna and colleagues found a significant reduction of over 73 % of new pacemaker implantations in Peru.[20] However, they did not report on a potential catch-up effect.

**Limitations**

***Advantages and Disadvantages of the InEK Database Query Procedure***

The analysis or query procedure with the admission date in the respective month as the only temporal search criterion has the advantage that patients who remained in-hospital from the previous month and also from the previous year (2018 to 2019 and 2019 to 2020) were not included in the study. The data years can be separately analyzed and compared. However, the analysis or query procedure has the disadvantage that the admission date may not equal the implantation date. This means that for patients who have been hospitalized at the end of a month, it is possible that the implantation or replacement of the active cardiac device only took place at the beginning of the following month. As a result, the procedures are allocated to the month of hospital admission.

Since the data query was performed for both the 2019 and 2020 years, there is no systematic bias of the results as the advantages and disadvantages of the query procedure, and the allocation of the admission date are valid for both data years. Furthermore, the changes of CIED implantation and replacement rates (January to September 2020 versus 2019) were not only influenced by the COVID-19 pandemic. There are also known long-term

trends for the different device types which showed an annual increase for CRT pacemakers or decrease for single and dual chamber ICDs implantation and replacement rates.[21,22,23] The reasons being these differences are numerous such as new therapeutic or treatment guidelines, further product developments (longevity of battery) or introduction of new medical devices innovations.

**Conclusions and Clinical Implications/Future Perspectives**

Our study is the first to highlight nationwide German data on the impact of the COVID-19 pandemic on CIED implantation during the first COVID-19 pandemic wave. In contrast to other European countries or small investigations in Germany, our results clearly show, an increase of the number of device implantations in the months following the first pandemic wave. Moreover, with respect to CRT, the number of implantations performed in 2020 exceeded that of 2019.

This German scenario provides information about the rapid response of electrophysiologist-guided device therapy after the government decided to re-start usual medical care. This shows a reduced idleness of this system. For future and unexpected events, it would be desirable and necessary to provide the population with a nearly continuous high level medical therapy. Hence, changes in the health care system are necessary:

1. Routine follow-up care for patients already carrying CIEDs should be conducted mainly by remote monitoring.
2. The proportion of implantations and care for CIED patients should be shifted to an ambulatory setting (in or out of hospital) with the help of the national cardiology societies. Therefore, the framework conditions for procedures, appropriate reimbursement of corresponding medical measures and for the ambulatory environment (in and out of hospital) have to improve.

3. As a consequence, the reaction time to unexpected events, such as pandemics, will be reduced dramatically as no large hospital would have to change its routing. This would result in a more flexible health care system.

**ACKNOWLEDGEMENTS**

We thank Ulrike von Hehn (medistat GmbH) for performing the statistical calculations.

We thank Danielle Libersan, PhD for reviewing the manuscript.

We also thank Paul Korb for supporting our own calculations of the data from Robert-Koch-Institut.

**FUNDING**

The study was supported by BIOTRONIK, Berlin, Germany

**Conflict of Interest:** J.O.S has no conflict to declare. T.H and J.W. are employees of BIOTRONIK.

**DATA AVAILABILITY**

The data underlying this article were accessed from "Institute für das Entgeltsystem im Krankenhaus" (InEK), https://datenbrowser.inek.org/. The derived data generated in this research will be shared on reasonable request to the corresponding author.

**DECLARATION OF TRANSPARENCY**

J.O.S., affirms as principal author that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as originally planned have been explained.

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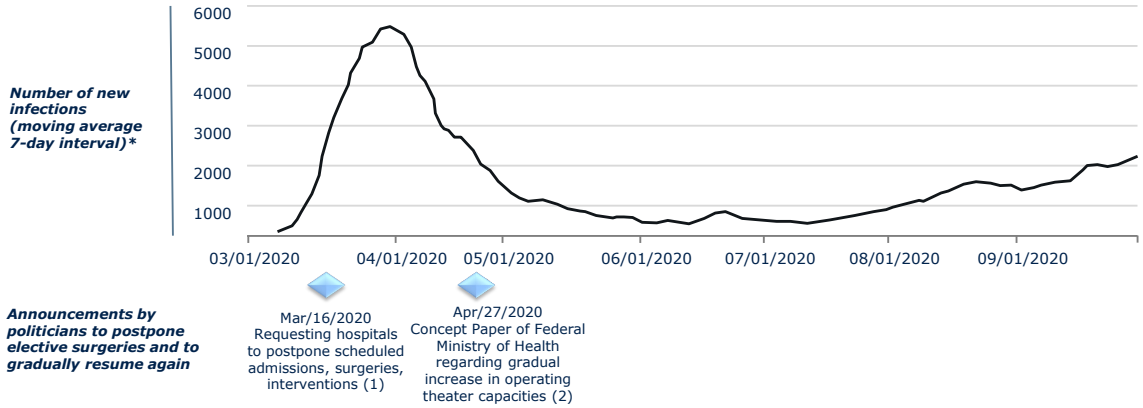
**Table 1:** Monthly percentage changes of PM, ICD and CRT implantations in 2020 compared to 2019

| | PM | | | | ICD | | | | CRT | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Period** | % change* | 95% CI | | p | % change* | 95% CI | | p | % change* | 95% CI | | p |
| **Jan** | -0,18 | -0,1 | -0,3 | <0.001 | -5,25 | -4,32 | -6,3 | <0.001 | 4,14 | 3,18 | 5,28 | <0.001 |
| **Feb** | 0,89 | 0,68 | 1,13 | <0.001 | -9,47 | -8,12 | -10,95 | <0.001 | -4,64 | -3,56 | -5,91 | <0.001 |
| **Mar** | -14,18 | -13,39 | -14,99 | <0.001 | -5,9 | -4,82 | -7,13 | <0.001 | 1,71 | 1,07 | 2,57 | <0.001 |
| **Apr** | -24,34 | -23,34 | -25,35 | <0.001 | -23,17 | -21,15 | -25,29 | <0.001 | -14,54 | -12,61 | -16,65 | <0.001 |
| **Mai** | -14,29 | -13,52 | -15,1 | <0.001 | -14,99 | -13,39 | -16,71 | <0.001 | -8,71 | -7,28 | -10,31 | <0.001 |
| **June** | 13,87 | 13,06 | 14,71 | <0.001 | 7,83 | 6,53 | 9,3 | <0.001 | 27,54 | 24,91 | 30,29 | <0.001 |
| **Jul** | 14,03 | 13,21 | 14,88 | <0.001 | 10,39 | 8,91 | 12,04 | <0.001 | 21,13 | 18,75 | 23,68 | <0.001 |
| **Aug** | -3,68 | -3,26 | -4,13 | <0.001 | -1,09 | -0,64 | -1,74 | <0.001 | 11,41 | 9,62 | 13,4 | <0.001 |
| **Sep** | 0,76 | 0,57 | 0,98 | <0.001 | 5,13 | 4,1 | 6,33 | <0.001 | 7,88 | 6,47 | 9,49 | <0.001 |
| **Sum (Jan-Sep)** | -3,28 | -3,14 | -3,41 | | -4,52 | -4,19 | -4,86 | | 4,3 | 3,94 | 4,69 | |

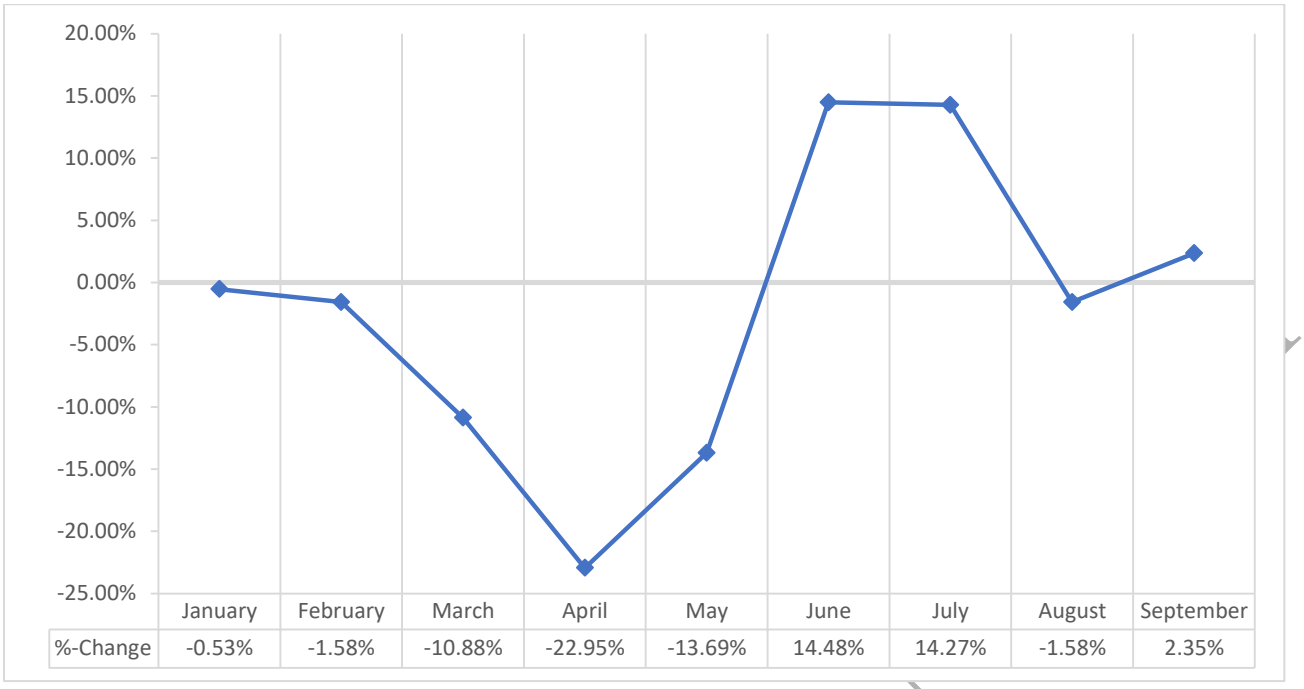
*monthly % change 2020 versus 2019; CRT, cardiac resynchronization therapy; ICD, implantable cardiac defibrillator; PM, pacemaker; CI, confidence interval

**Figure 1:** Infection rate during the beginning of the COVID-19 pandemic in 2020. Number of new infections is shown at a 7-day interval. Public health measures are displayed in relation to the temporal course of the infection rates.




*Based on own calculation of data from Robert-Koch-Institut (https://npgeo-corona-npgeo-de.hub.arcgis.com/search?collection=Dataset&type=table , last accessed on May 27 2021)

**Figure 2:** Comparison of the monthly percentage changes of CIED implantations in 2020 compared to 2019.




| | January | February | March | April | May | June | July | August | September |
|---|---|---|---|---|---|---|---|---|---|
| %-Change | -0.53% | -1.58% | -10.88% | -22.95% | -13.69% | 14.48% | 14.27% | -1.58% | 2.35% |

**Figure 3:** Implantation numbers of cardiac pacemakers between 2019 (blue line) and 2020 (red line).

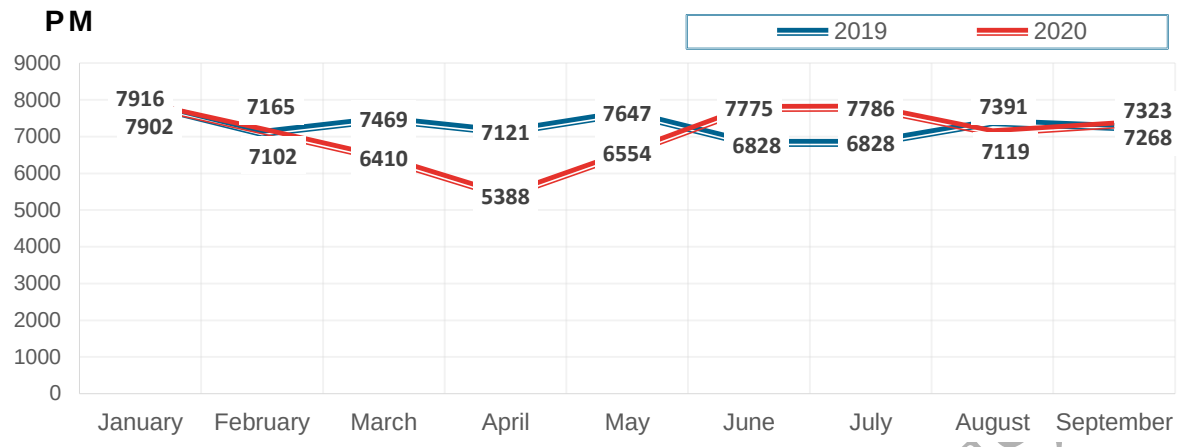


**Figure 4:** Implantation numbers of implantable cardioverter/defibrillators between 2019 (blue line) and 2020 (red line).

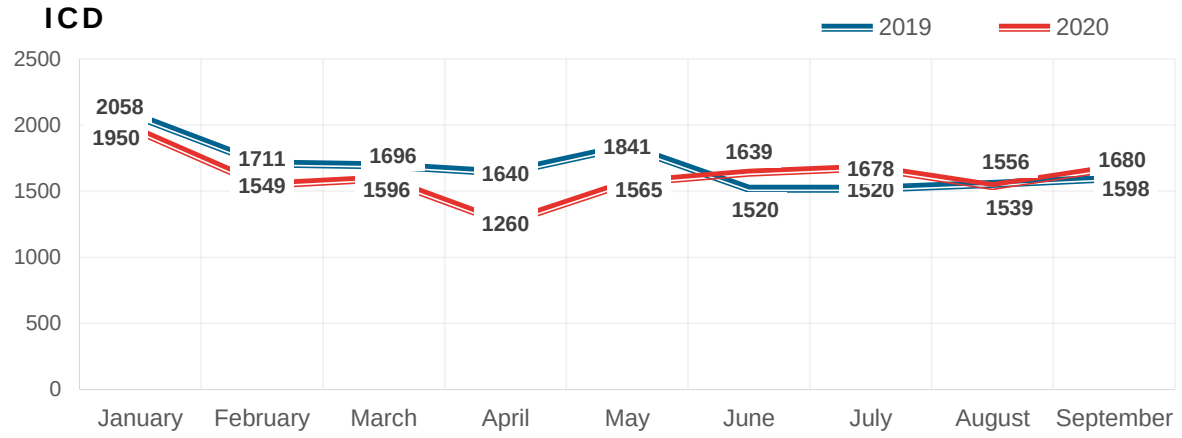


**Figure 5:** Implantation numbers of CRT-D and CRT-P Systems between 2019 (blue line) and 2020 (red line).