

# Reliability Report Autumn 2021

IMPLANTABLE COCHLEAR STIMULATORS  
AND SOUND PROCESSORS

# POWERFUL CONNECTIONS



# START HERE

Our Mission .....	4
Reporting on Reliability .....	5
Implantable Cochlear Stimulators .....	6
HiRes Ultra 3D (V2) cochlear implant .....	8
HiRes Ultra (V2) cochlear implant .....	10
HiRes Ultra 3D (V1) cochlear implant .....	12
HiRes Ultra (V1) cochlear implant .....	14
HiRes 90K Advantage cochlear implant .....	16
HiRes 90K cochlear implant .....	18
CII Bionic Ear cochlear implant .....	26
Clarion 1.2 cochlear implant .....	28
Clarion 1.0 cochlear implant .....	30
Sound Processor Stimulators .....	32
Naída CI M and Sky CI M sound processors .....	33
Naída CI Q90 sound processor .....	34
Chorus sound processor .....	34
Neptune sound processor .....	35
Harmony sound processor .....	35
Appendix .....	36

# OUR MISSION

At Advanced Bionics, we are dedicated to improving lives by developing implantable technologies and services that help our recipients achieve their full potential.

Our commitment to putting patients first and providing the best possible hearing performance remains at the forefront of all that we do. The trust patients place in us inspires us to act with integrity and transparency as we strive for excellence each and every day in all that we do.

This reliability report is an example of our commitment to an open and transparent communication to you.

# REPORTING ON RELIABILITY

Advanced Bionics remains dedicated to transparency and accuracy in reliability reporting.

To ensure that patients and professionals globally understand Advanced Bionics product performance, AB reports reliability data for each type, and significant variant of that type, of Cochlear Implant Stimulators (commonly referred to as implants) semi-annually.

Reporting utilizes methodologies recommended by both the International Organization for Standardization in **ISO 5841-2:2014**<sup>1</sup>, the principles outlined in the European Consensus on Cochlear Implant Failures and Explanations<sup>2</sup>; and **ANSI/AAMI CI86** - Cochlear Implant Systems: Requirements for Safety, Functional Verification, Labeling and Reliability Reporting<sup>3</sup>.

For each type of implant, the number of recipients and the Cumulative Survival Rate (CSR) is shared. The number of recipients using each implant is displayed as a table detailing adults and children, as well as a combination of both, in accordance with ISO 5841-2:2014 and ANSI/AAMI CI86. Separate graphs for each reporting standard exhibit the CSR.

Reliability of each currently-available sound processor is also reported utilizing methodologies that meet the recommendations of ANSI/AAMI CI86 - Cochlear Implant Systems: Requirements for Safety, Functional Verification, Labeling and Reliability Reporting<sup>3</sup>.

1. ISO 5841-2 (2014) Implants for Surgery – Cardiac Pacemakers. International Organization for Standardization (ISO), Geneva, Switzerland.

2. European Consensus Statement on Cochlear Implant Failures and Explanations. (2005) Otology and Neurology, 26(6): 1097-1099.

3. ANSI/AAMI CI86. Cochlear Implant Systems: Requirements for Safety, Functional Verification, Labeling and Reliability Reporting. (2017). Arlington, VA: American National Standards Institute.

## INTERPRETING TABLES AND GRAPHS

# IMPLANTABLE COCHLEAR STIMULATORS

### Number of registered HiRes 90K Advantage implants

As of September 30, 2021

Date of first commercial introduction<sup>a</sup>: 2012

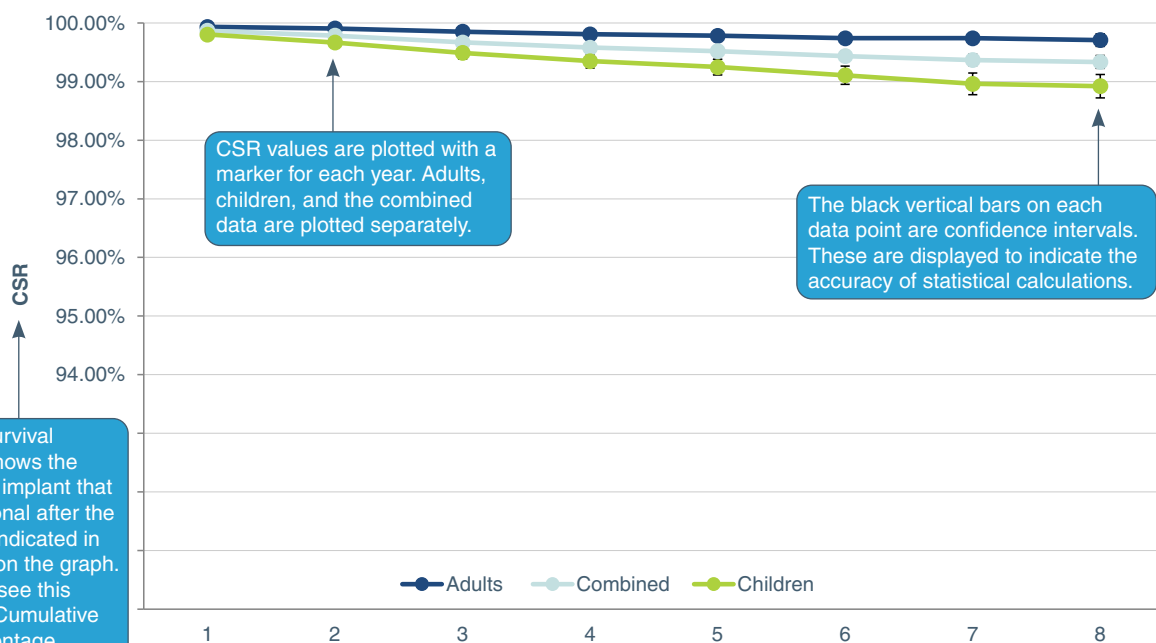
STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	15341	20190	37587 <sup>b</sup>
ANSI/AAMI CI86	19465 <sup>c</sup>	18122	37587

Number of registered users is detailed for adults, children and a combination of all ages in accordance with reporting methodologies.

- a. Dates provided are those for major markets covered by FDA and TUV regulation. Some implants may be pending approval in a subset of additional regions.  
 b. The combined number also includes any registered users for whom we do not have date of birth information.  
 c. The adult number also includes users whose personal information is not available or may not be obtainable due to certain privacy laws in certain countries.

Graph title shows the implant name and any additional identifying information.

### HiRes 90K Advantage ISO 5841-2:2014



### CUMULATIVE SURVIVAL PERCENTAGE

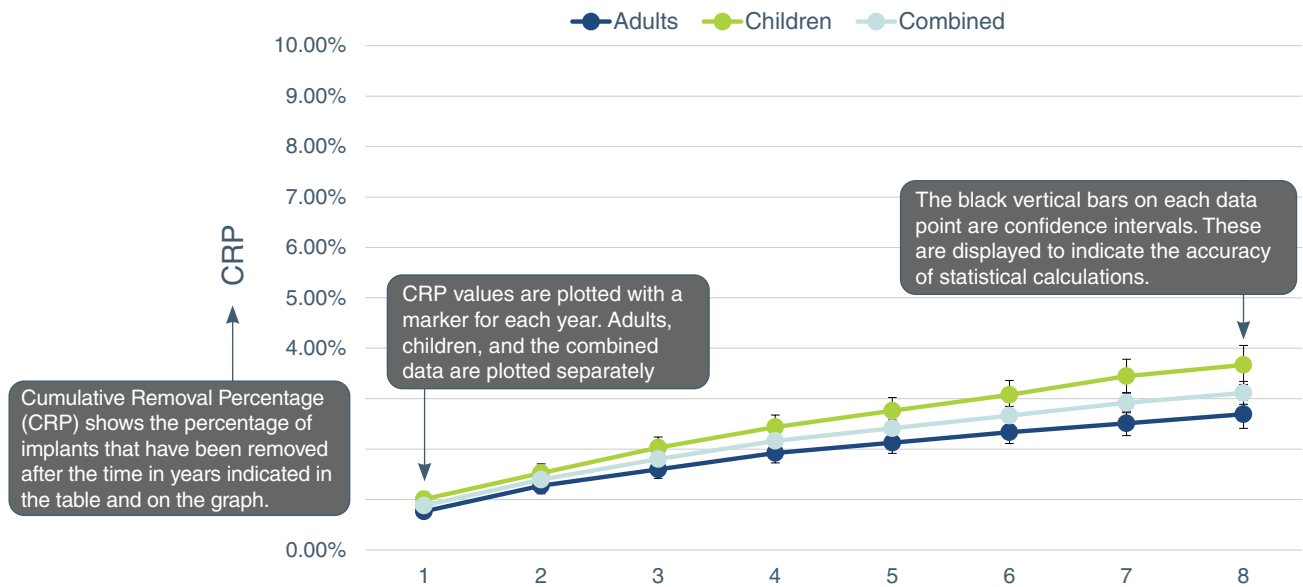
Years in use	1	2	3	4	5	6	7	8
ADULTS	99.93%	99.91%	99.85%	99.81%	99.78%	99.74%	99.74%	99.71%
COMBINED	99.87%	99.78%	99.67%	99.58%	99.52%	99.44%	99.37%	99.34%
CHILDREN	99.80%	99.67%	99.49%	99.35%	99.25%	99.11%	98.96%	98.92%

Detailed CSR percentages are shown for each year in the table. Results are broken up into adults, children, and shown as a combined total.

Graph title shows the implant name and any additional identifying information.

## HiRes 90K Advantage

### ANSI/AAMI CI86 STANDARD



The ANSI/AAMI CI86 Standard requires that all removed devices are classified into three categories, namely those related to device failure, to medical reasons for explant, or those whose reason for explant cannot be determined.

#### COMBINED ADULT AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
					CI Up	CI Down
1	0.73%	0.13%	0.02%	0.88%	0.98%	0.79%
2	1.13%	0.23%	0.04%	1.40%	1.52%	1.28%
3	1.41%	0.35%	0.04%	1.80%	1.94%	1.66%
4	1.66%	0.45%	0.07%	2.16%	2.32%	2.01%
5	1.82%	0.51%	0.10%	2.42%	2.58%	2.25%
6	1.98%	0.59%	0.11%	2.67%	2.85%	2.49%
7	2.13%	0.68%	0.12%	2.92%	3.12%	2.72%
8	2.26%	0.75%	0.12%	3.12%	3.34%	2.89%

Detailed CRP values are shown for each year in the table. Results are broken up into adults, children, and shown as a combined total.

Throughout the report, we will present the data and graphs to represent the conditions for: all analysis categories combined; by analysis category for adults and children; removal rates by analysis category for adults; and removal rates by analysis category for children.

Not all data may be shown alongside the graphs due to space limitations. Please see the appendix at the end of the report for a complete data set.

## CURRENT-GENERATION IMPLANT DATA

### HIRES ULTRA 3D V2

The HiRes™ Ultra 3D (V2) cochlear implant is an update to the previous HiRes Ultra 3D (V1) device. It includes reliability improvements resulting from the Corrective and Preventive Action undertaken by Advanced Bionics related to returned devices showing a common failure mode of fluid ingress into the external electrode pocket.

Based off the standard HiRes Ultra platform but featuring an innovative multi-magnet assembly, the HiRes Ultra 3D implant allows the use of clinical MRI at 1.5T and 3T without the need for magnet removal or head-bandaging. Due to the low torque, the user can be expected to have a hassle free and pain free experience.

The HiRes Ultra 3D (V2) device has now completed a 1.5-year reliability data, and the Cumulative Survival Rate (CSR) is 99.97%.



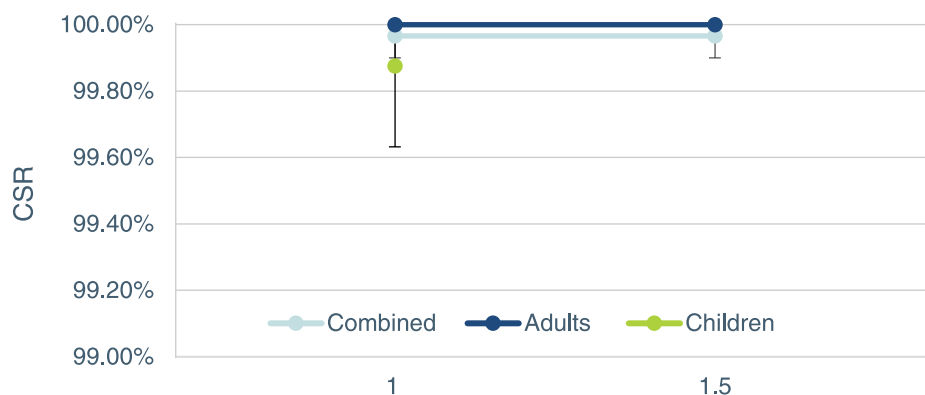
#### Number of registered HiRes Ultra 3D (V2) implants

As of September 30, 2021

Date of first commercial introduction<sup>a</sup>: 2019

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	4476	1834	6644 <sup>b</sup>
ANSI/AAMI CI86	5128 <sup>c</sup>	1517	6645

### ISO 5841-2:2014



#### CUMULATIVE SURVIVAL PERCENTAGE

Years in use	1	1.5
ADULTS	100.00%	100.00%
COMBINED	99.97%	99.97%
CHILDREN	99.88%	N/A <sup>d</sup>

a. Dates provided are those for major markets covered by FDA and TUV regulation. Some implants may be pending approval in a subset of additional regions.

b. The combined number also includes any registered users for whom we do not have date of birth information.

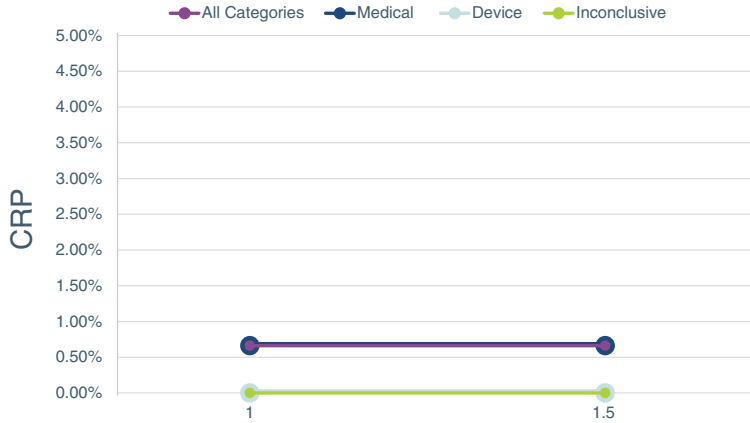
c. The adult number also includes users whose personal information is not available or may not be obtainable due to certain privacy laws in certain countries.

d. Sample size for children at 1.5 years is not large enough for reporting.

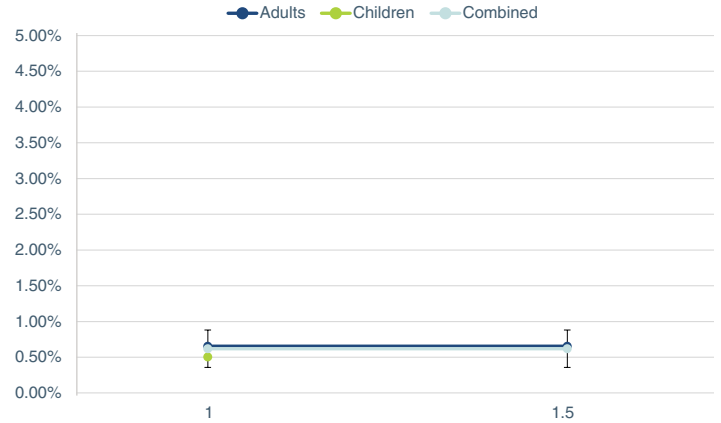


# ANSI/AAMI CI86

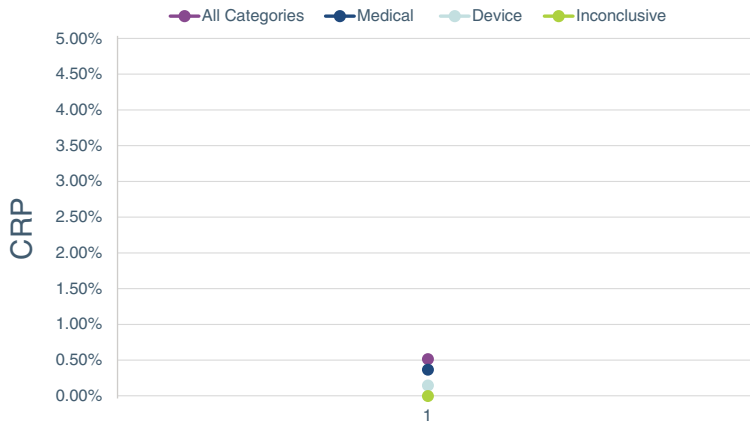
REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS



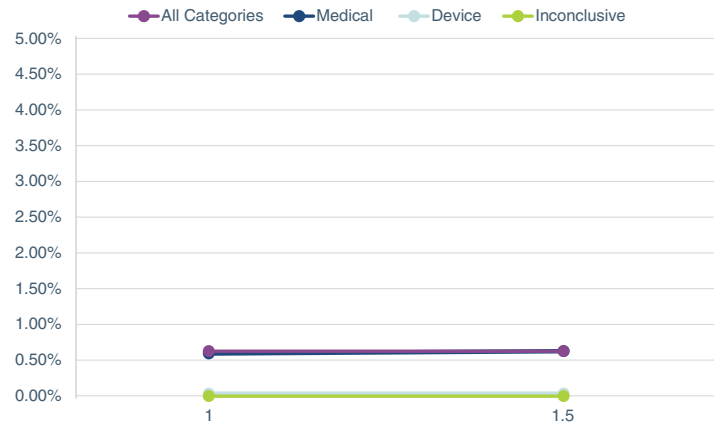
REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENTS POPULATION



REMOVAL RATES ANALYSIS CATEGORIES FOR CHILDREN



REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS AND CHILDREN



COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
					CI Up	CI Down
1	0.59%	0.03%	0.00%	0.63%	0.85%	0.40%
1.5	0.63%	0.03%	0.00%	0.63%	0.85%	0.40%

Not all data may be shown alongside the graphs due to space limitations. Please see the **Appendix** at the end of the report for a complete data set.

# HIRES ULTRA V2

The HiRes™ Ultra (V2) cochlear implant has the same reliability improvements as the HiRes Ultra 3D (V2) device.

Featuring the proven performance platform as the HiRes 90K™ Advantage, the HiRes Ultra (V2) offers a robust, thin, and discreet mechanical design that is suitable for adults and children.

The HiRes Ultra (V2) device has a limited number of devices that have completed the 1-year data point and the data presented may not reach statistical significance. There has not been a confirmed device-related failure to date.



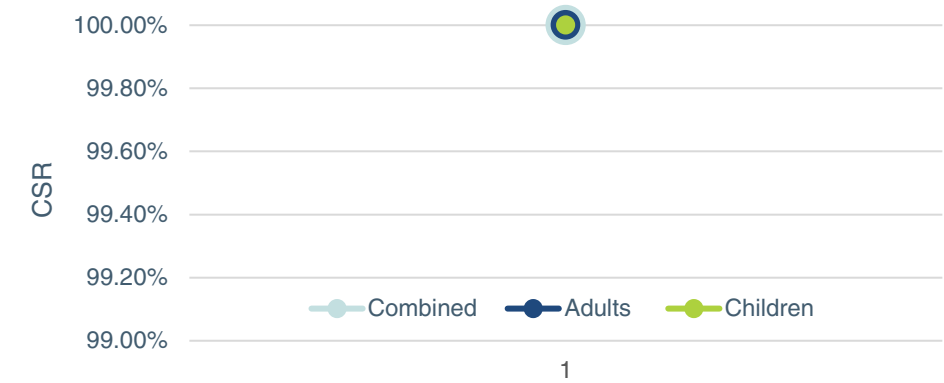
## Number of registered HiRes Ultra (V2) implants

As of September 30, 2021  
Date of first commercial introduction<sup>a</sup>: 2019

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	266	776	1312 <sup>b</sup>
ANSI/AAMI CI86	585 <sup>c</sup>	727	1312

- a. Dates provided are those for major markets covered by FDA and TUV regulation. Some implants may be pending approval in a subset of additional regions.  
b. The combined number also includes any registered users for whom we do not have date of birth information.  
c. The adult number also includes users whose personal information is not available or may not be obtainable due to certain privacy laws in certain countries.

## ISO 5841-2:2014

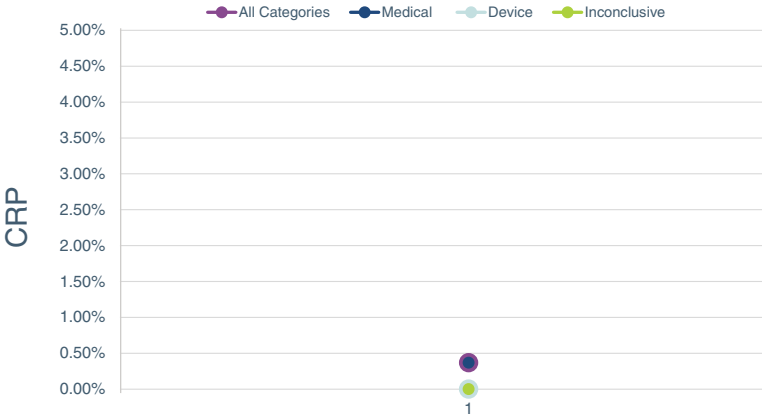


### CUMULATIVE SURVIVAL PERCENTAGE

Years in use	1
ADULTS	100.00%
COMBINED	100.00%
CHILDREN	100.00%

# ANSI/AAMI CI86

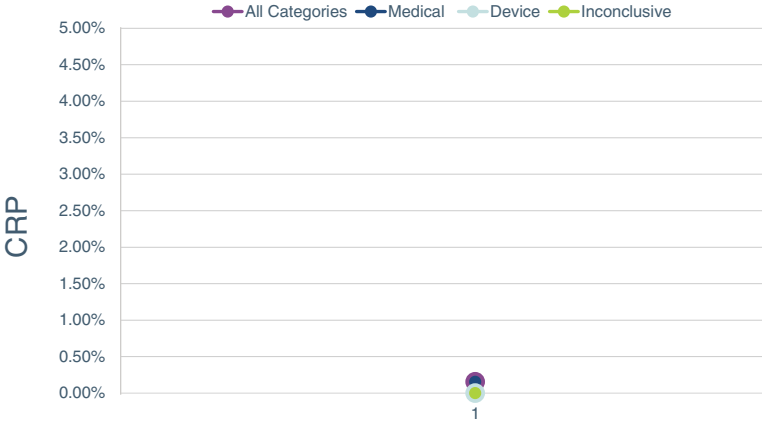
REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS



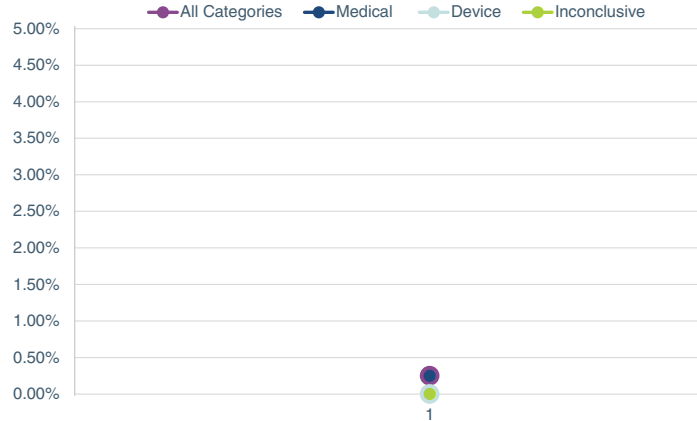
REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENTS POPULATION



REMOVAL RATES ANALYSIS CATEGORIES FOR CHILDREN



REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS AND CHILDREN



COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
					CI Up	CI Down
1	0.25%	0.00%	0.00%	0.25%	0.54%	0.00%

Not all data may be shown alongside the graphs due to space limitations. Please see the **Appendix** at the end of the report for a complete data set.

## PREVIOUS-GENERATION IMPLANT DATA

### HIRES ULTRA 3D V1

The HiRes™ Ultra 3D (V1) cochlear implant was subject to a Voluntary Field Action initiated by Advanced Bionics on February 18, 2020, and was withdrawn from sale worldwide. The Voluntary Field Action was due to recognition of a common failure mode for a small number of devices, resulting in loss of clinical benefit. Advanced Bionics will continue to provide regular reliability updates on the HiRes Ultra platform as new data and information becomes available.

#### Number of registered HiRes Ultra 3D (V1) implants

As of September 30, 2021

Last year of distribution<sup>a</sup>: subject to voluntary field action February 18, 2020

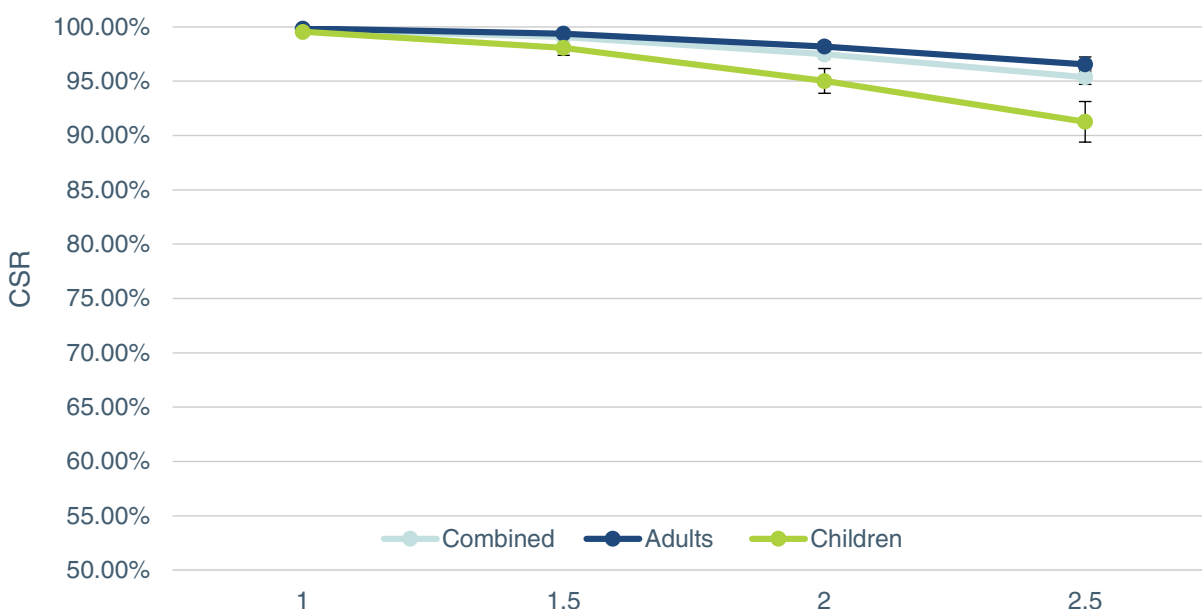
STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	4545	1583	6371 <sup>b</sup>
ANSI/AAMI CI86	5022 <sup>c</sup>	1349	6371

a. Dates provided are those for major markets covered by FDA and TUV regulation. Some implants may be pending approval in a subset of additional regions.

b. The combined number also includes any registered users for whom we do not have date of birth information.

c. The adult number also includes users whose personal information is not available or may not be obtainable due to certain privacy laws in certain countries.

#### ISO 5841-2:2014

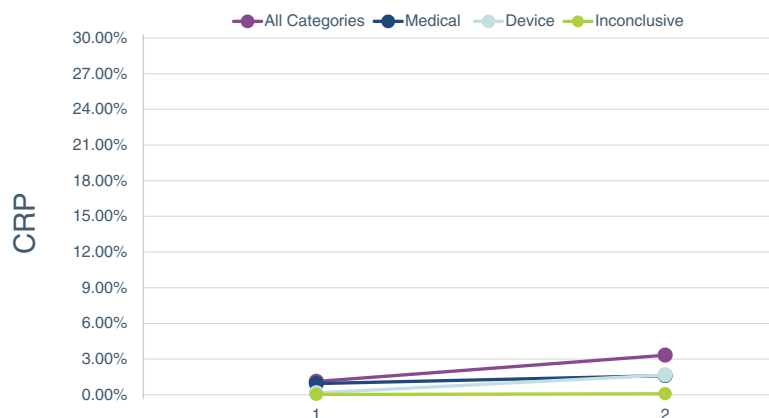


#### CUMULATIVE SURVIVAL PERCENTAGE

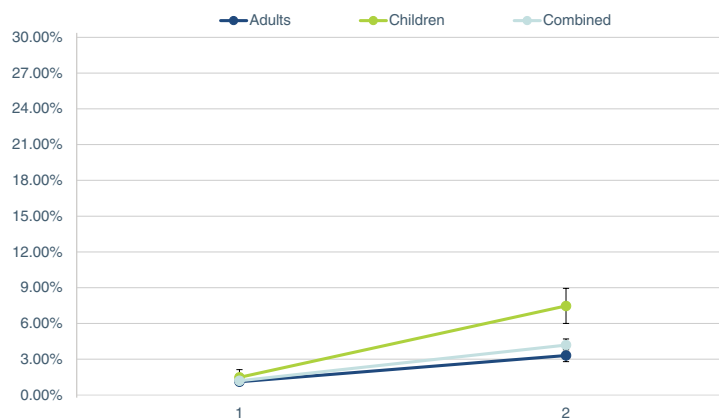
Years in use	1	1.5	2	2.5
ADULTS	99.84%	99.38%	98.20%	96.55%
COMBINED	99.78%	99.08%	97.48%	95.38%
CHILDREN	99.55%	98.08%	95.02%	91.27%

# ANSI/AAMI CI86

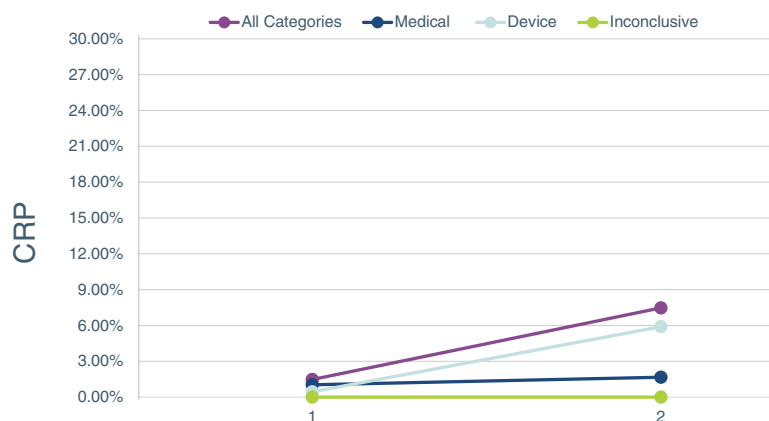
REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS



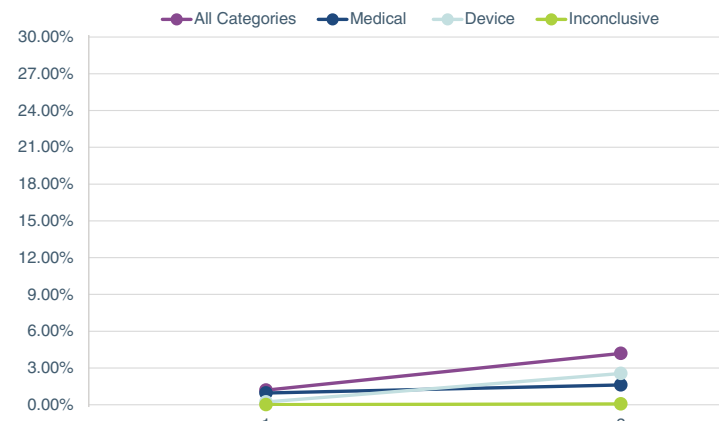
REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENTS POPULATION



REMOVAL RATES ANALYSIS CATEGORIES FOR CHILDREN



REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS AND CHILDREN



COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
					CI Up	CI Down
1	0.96%	0.22%	0.02%	1.19%	1.46%	0.93%
2	1.62%	2.56%	0.06%	4.19%	4.70%	3.68%

Not all data may be shown alongside the graphs due to space limitations. Please see the **Appendix** at the end of the report for a complete data set.

# HIRES ULTRA V1

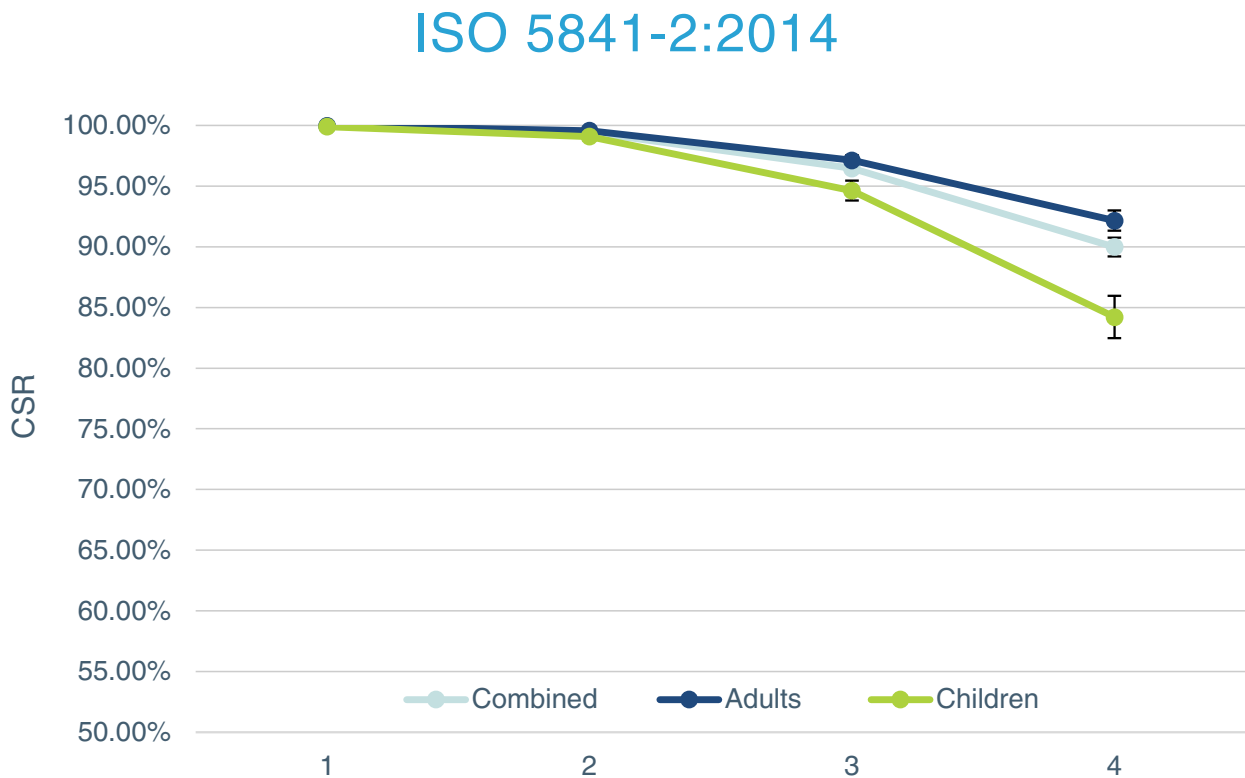
The HiRes™ Ultra (V1) cochlear implant was subject to a Voluntary Field Action initiated by Advanced Bionics on February 18, 2020, and was withdrawn from sale worldwide. This was due to recognition of a common failure mode for a small number of devices, resulting in loss of clinical benefit. Advanced Bionics will continue to provide regular reliability updates on the HiRes Ultra platform as new data and information becomes available.

## Number of registered HiRes Ultra (V1) implants

As of September 30, 2021  
 Last year of distribution<sup>a</sup>: subject to voluntary field action February 18, 2020

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	7087	4273	12135 <sup>b</sup>
ANSI/AAMI CI86	8363 <sup>c</sup>	3765	12128

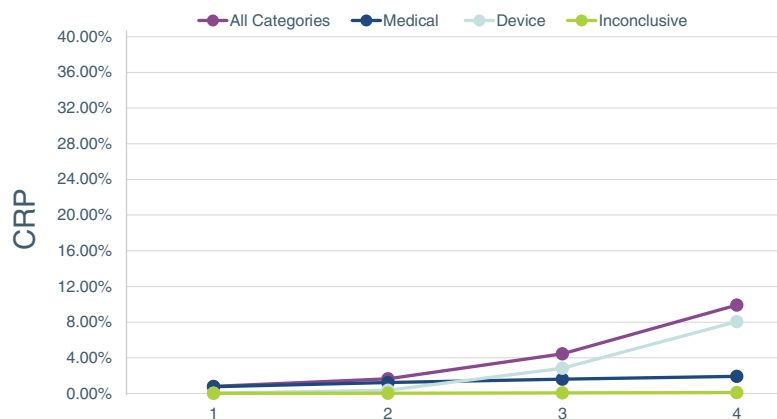
- a. Dates provided are those for major markets covered by FDA and TUV regulation. Some implants may be pending approval in a subset of additional regions.  
 b. The combined number also includes any registered users for whom we do not have date of birth information.  
 c. The adult number also includes users whose personal information is not available or may not be obtainable due to certain privacy laws in certain countries.



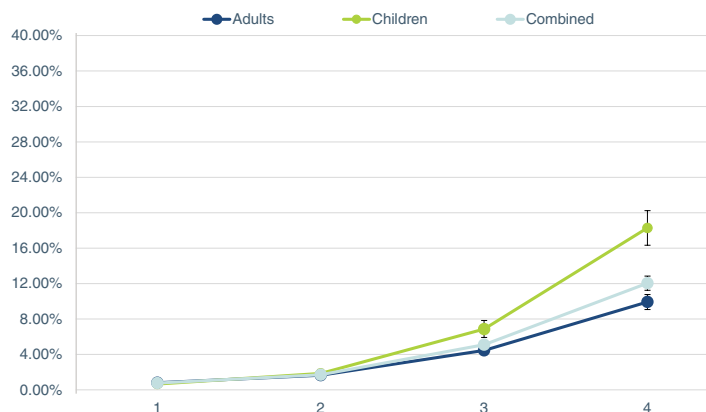
CUMULATIVE SURVIVAL PERCENTAGE				
Years in use	1	2	3	4
ADULTS	99.97%	99.56%	97.13%	92.15%
COMBINED	99.95%	99.42%	96.45%	89.98%
CHILDREN	99.91%	99.09%	94.62%	84.21%

# ANSI/AAMI CI86

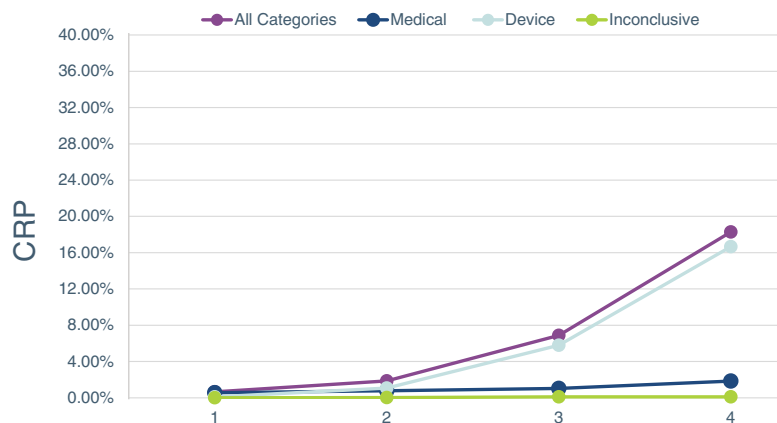
REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS



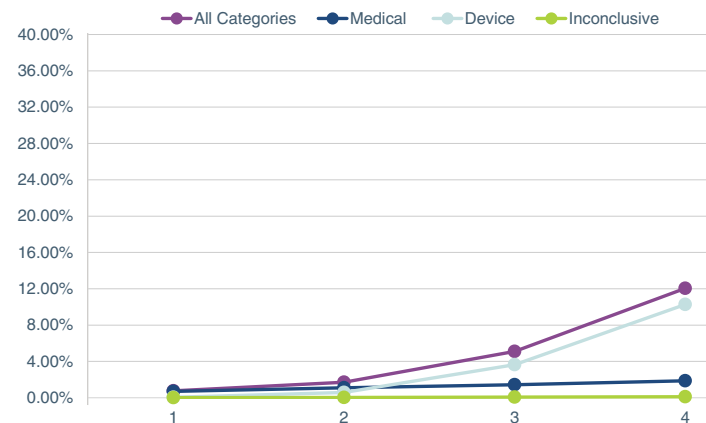
REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENTS POPULATION



REMOVAL RATES ANALYSIS CATEGORIES FOR CHILDREN



REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS AND CHILDREN



COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
					CI Up	CI Down
1	0.69%	0.05%	0.02%	0.76%	0.91%	0.60%
2	1.10%	0.59%	0.03%	1.71%	1.94%	1.47%
3	1.43%	3.65%	0.08%	5.10%	5.53%	4.67%
4	1.86%	10.28%	0.11%	12.04%	12.85%	11.24%

Not all data may be shown alongside the graphs due to space limitations. Please see the **Appendix** at the end of the report for a complete data set.

# HIRES 90K ADVANTAGE

The HiRes 90K™ Advantage cochlear implant offers mechanical improvements over its predecessor, the HiRes 90K cochlear implant. It has the capability to offer advanced sound coding strategies, together with the security of a deep bone bed.



## Number of registered HiRes 90K Advantage implants

As of September 30, 2021

Date of first commercial introduction<sup>a</sup>: 2012. Still available in selected markets

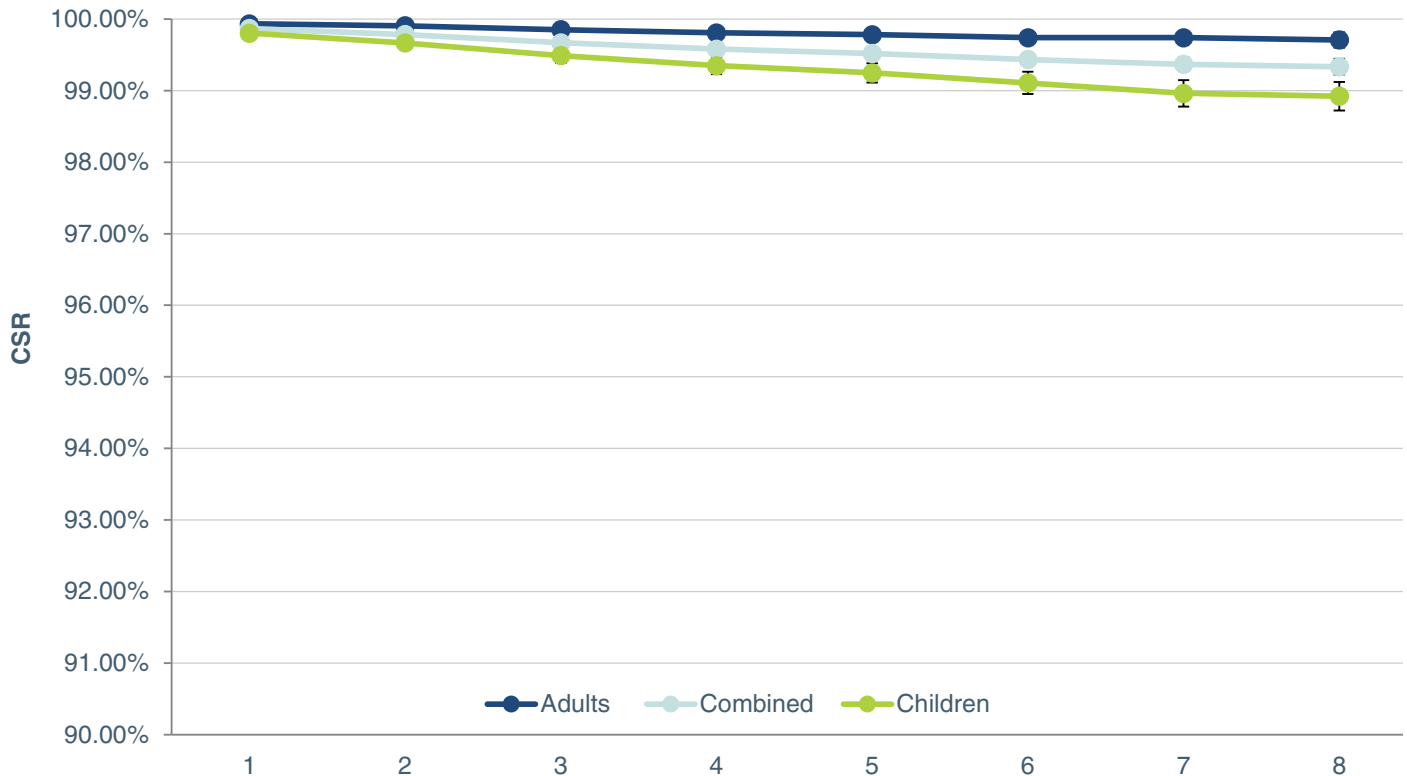
STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	15341	20190	37587 <sup>b</sup>
ANSI/AAMI C186	19465 <sup>c</sup>	18122	37587

a. Dates provided are those for major markets covered by FDA and TUV regulation. Some implants may be pending approval in a subset of additional regions.

b. The combined number also includes any registered users for whom we do not have date of birth information.

c. The adult number also includes users whose personal information is not available or may not be obtainable due to certain privacy laws in certain countries.

## ISO 5841-2:2014



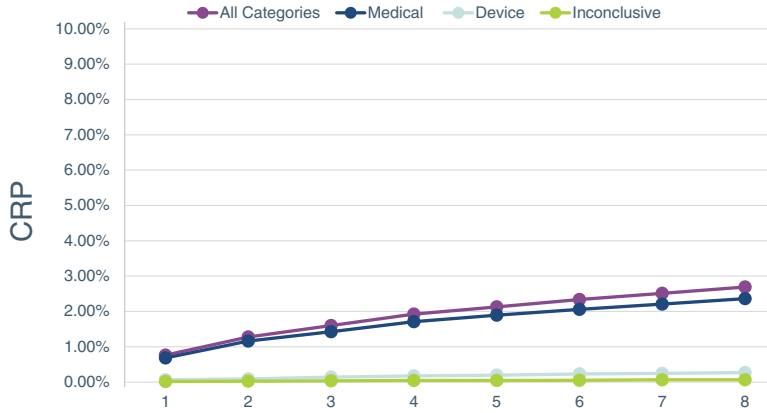
## CUMULATIVE SURVIVAL PERCENTAGE

Years in use	1	2	3	4	5	6	7	8
ADULTS	99.93%	99.91%	99.85%	99.81%	99.78%	99.74%	99.74%	99.71%
COMBINED	99.87%	99.78%	99.67%	99.58%	99.52%	99.44%	99.37%	99.34%
CHILDREN	99.80%	99.67%	99.49%	99.35%	99.25%	99.11%	98.96%	98.92%

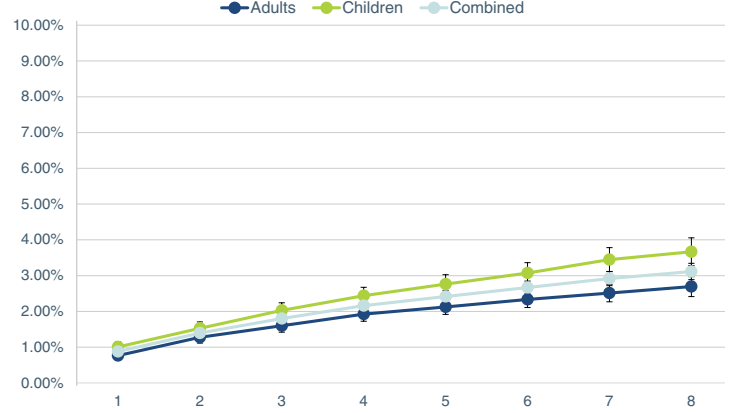


# ANSI/AAMI CI86

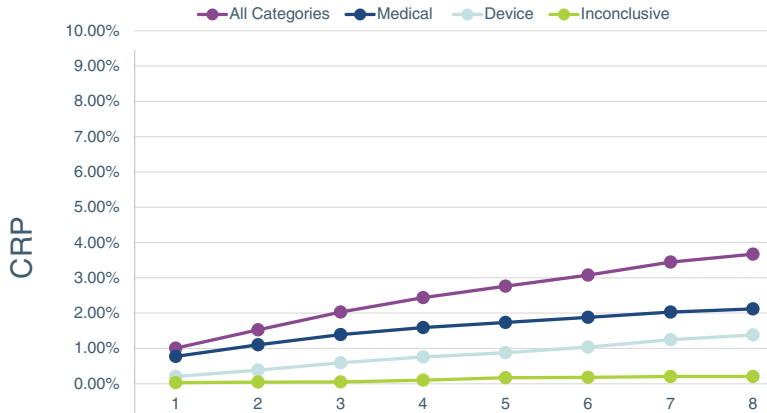
REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS



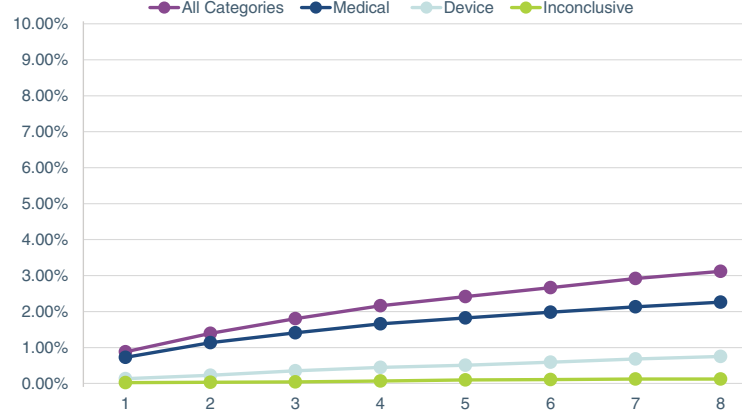
REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENTS POPULATION



REMOVAL RATES ANALYSIS CATEGORIES FOR CHILDREN



REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS AND CHILDREN



COMBINED ADULT AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
					CI Up	CI Down
1	0.73%	0.13%	0.02%	0.88%	0.98%	0.79%
2	1.13%	0.23%	0.04%	1.40%	1.52%	1.28%
3	1.41%	0.35%	0.04%	1.80%	1.94%	1.66%
4	1.66%	0.45%	0.07%	2.16%	2.32%	2.01%
5	1.82%	0.51%	0.10%	2.42%	2.58%	2.25%
6	1.98%	0.59%	0.11%	2.67%	2.85%	2.49%
7	2.13%	0.68%	0.12%	2.92%	3.12%	2.72%
8	2.26%	0.75%	0.12%	3.12%	3.34%	2.89%

Not all data may be shown alongside the graphs due to space limitations. Please see the **Appendix** at the end of the report for a complete data set.

# HIRES 90K vendor A post-mod

The HiRes 90K™ cochlear implant offers access to advanced sound coding technologies. It has undergone manufacturing modifications, with the version currently available being designated as the HiRes 90K (vendor A post-mod) implant.

## Number of registered HiRes 90K implants (vendor A post-mod)

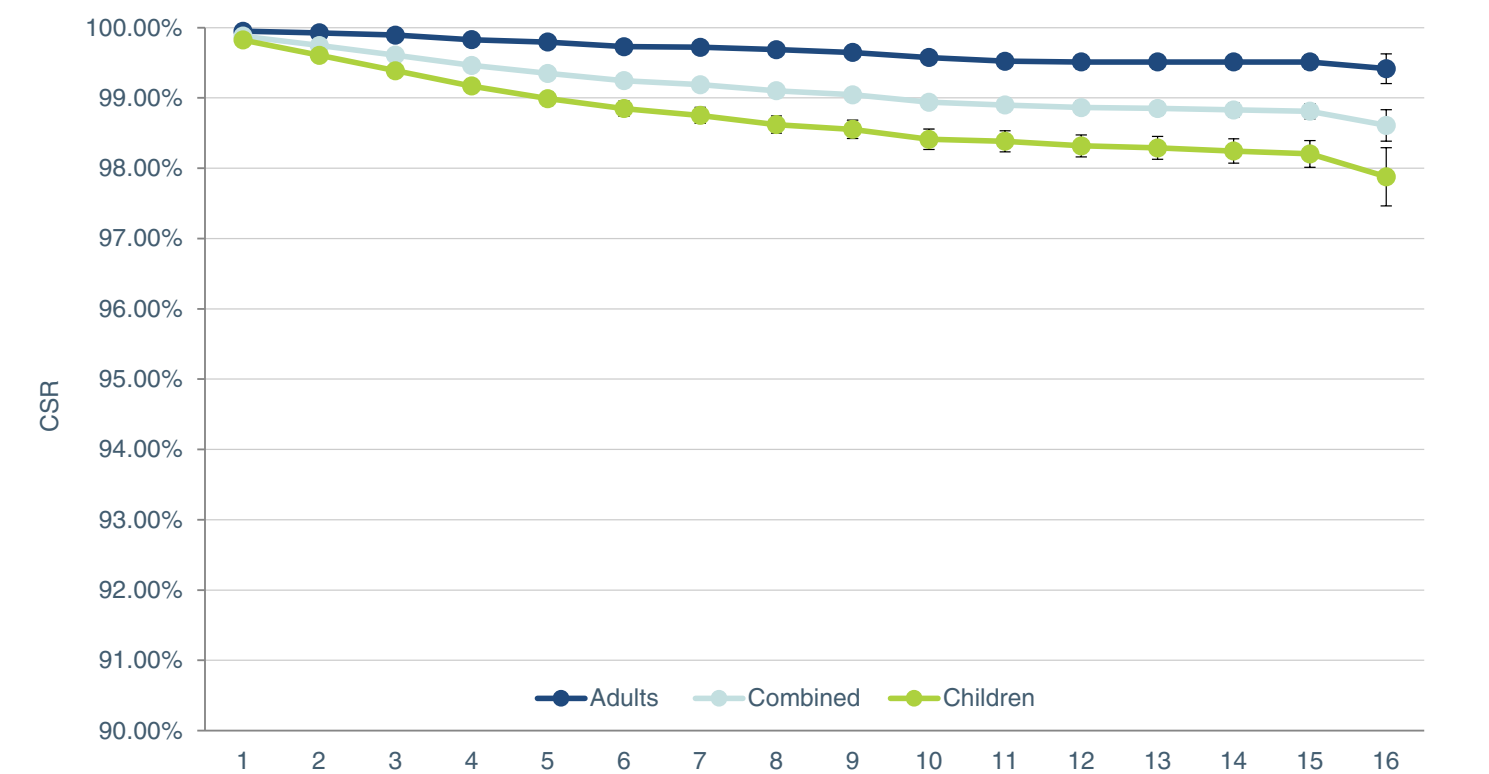
As of September 30, 2021  
Last year of distribution<sup>a</sup>. Still available in selected markets.

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	31468	44781	78785 <sup>b</sup>
ANSI/AAMI C186	39509 <sup>c</sup>	39366	78875

- a. Dates provided are those for major markets covered by FDA and TUV regulation. Some implants may be pending approval in a subset of additional regions.  
b. The combined number also includes any registered users for whom we do not have date of birth information.  
c. The adult number also includes users whose personal information is not available or may not be obtainable due to certain privacy laws in certain countries.



## ISO 5841-2:2014

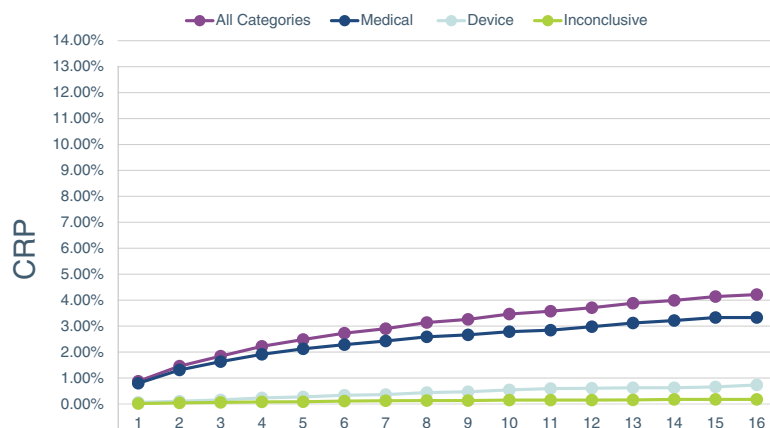


### CUMULATIVE SURVIVAL PERCENTAGE

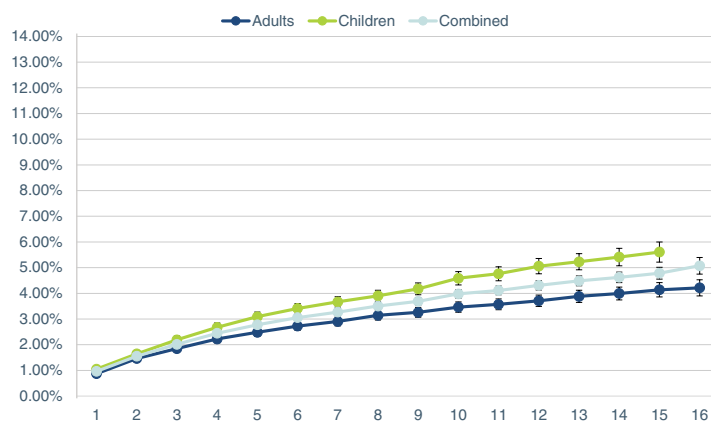
Years in use	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
ADULTS	99.95%	99.93%	99.89%	99.83%	99.79%	99.73%	99.72%	99.69%	99.65%	99.58%	99.52%	99.51%	99.51%	99.51%	99.51%	99.42%
COMBINED	99.88%	99.75%	99.61%	99.46%	99.35%	99.25%	99.19%	99.10%	99.05%	98.94%	98.90%	98.86%	98.85%	98.83%	98.81%	98.61%
CHILDREN	99.82%	99.61%	99.39%	99.17%	98.99%	98.85%	98.75%	98.62%	98.55%	98.41%	98.38%	98.32%	98.29%	98.25%	98.20%	97.88%

# ANSI/AAMI CI86

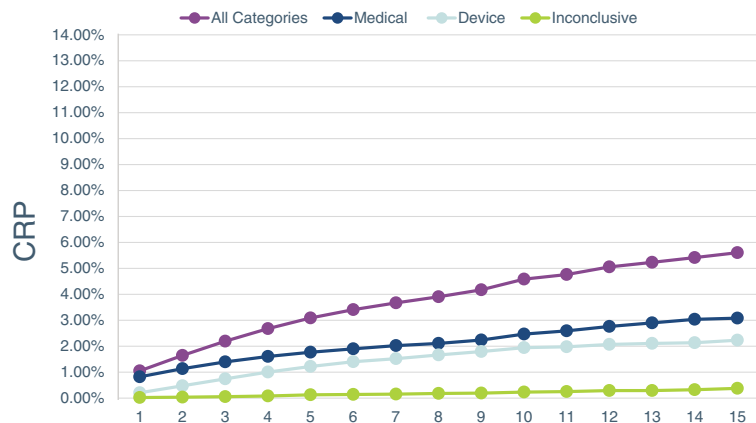
REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS



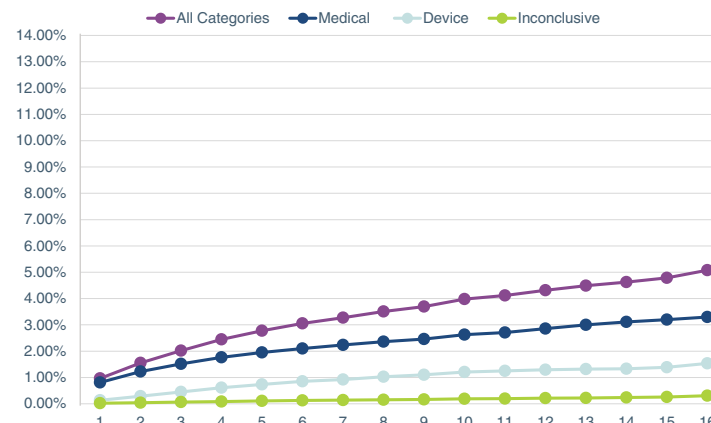
REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENTS POPULATION



REMOVAL RATES ANALYSIS CATEGORIES FOR CHILDREN



REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS AND CHILDREN



COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
					CI Up	CI Down
1	0.81%	0.14%	0.02%	0.96%	1.03%	0.90%
2	1.23%	0.29%	0.04%	1.55%	1.64%	1.47%
3	1.52%	0.45%	0.06%	2.02%	2.12%	1.92%
4	1.76%	0.61%	0.08%	2.45%	2.56%	2.34%
5	1.95%	0.73%	0.11%	2.78%	2.90%	2.66%
6	2.10%	0.85%	0.13%	3.06%	3.18%	2.93%
7	2.23%	0.92%	0.14%	3.27%	3.40%	3.14%
8	2.36%	1.03%	0.15%	3.51%	3.65%	3.37%
9	2.46%	1.10%	0.16%	3.69%	3.84%	3.54%
10	2.63%	1.21%	0.19%	3.98%	4.14%	3.82%
11	2.71%	1.25%	0.20%	4.11%	4.28%	3.95%
12	2.86%	1.29%	0.21%	4.31%	4.49%	4.14%
13	3.00%	1.32%	0.22%	4.49%	4.67%	4.30%
14	3.11%	1.33%	0.24%	4.62%	4.83%	4.42%
15	3.20%	1.39%	0.26%	4.79%	5.01%	4.56%
16	3.30%	1.54%	0.31%	5.08%	5.40%	4.75%

Not all data may be shown alongside the graphs due to space limitations. Please see the **Appendix** at the end of the report for a complete data set.

# HIRES 90K vendor A all

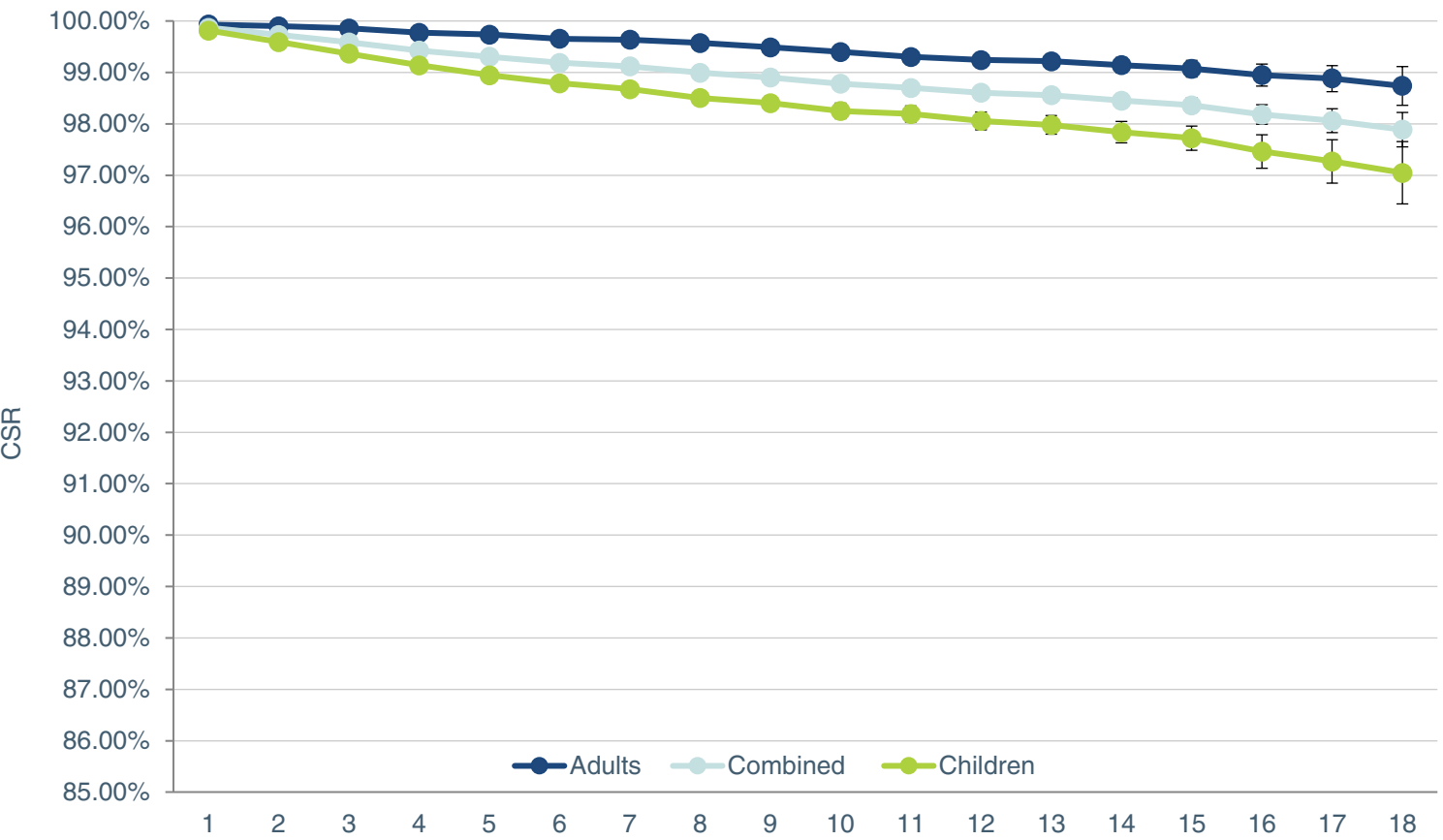
## Number of registered HiRes 90K implants (vendor A all)

As of September 30, 2021  
Last year of distribution<sup>a</sup>. Still available in selected markets.

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	33016	45944	81596 <sup>b</sup>
ANSI/AAMI C186	41270 <sup>c</sup>	40326	81596

- a. Dates provided are those for major markets covered by FDA and TUV regulation. Some implants may be pending approval in a subset of additional regions.  
b. The combined number also includes any registered users for whom we do not have date of birth information.  
c. The adult number also includes users whose personal information is not available or may not be obtainable due to certain privacy laws in certain countries.

## ISO 5841-2:2014

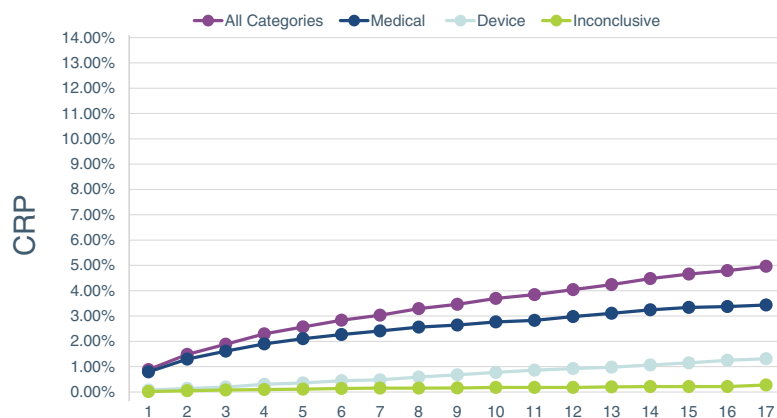


### CUMULATIVE SURVIVAL PERCENTAGE

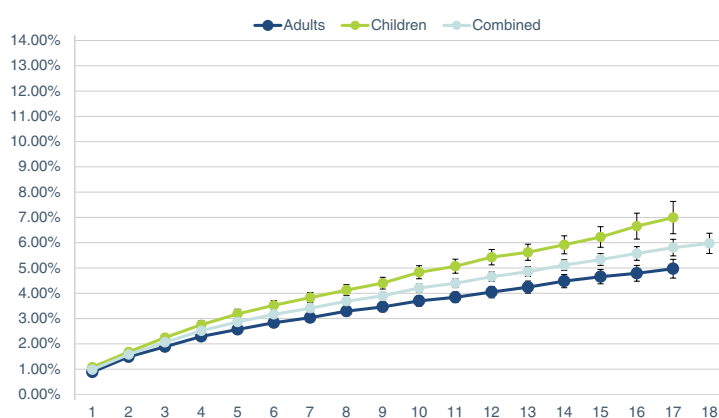
Years in use	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
ADULTS	99.93%	99.90%	99.86%	99.77%	99.74%	99.65%	99.64%	99.57%	99.49%	99.40%	99.30%	99.24%	99.22%	99.14%	99.07%	98.95%	98.88%	98.74%
COMBINED	99.87%	99.73%	99.59%	99.43%	99.30%	99.19%	99.12%	98.99%	98.90%	98.78%	98.70%	98.60%	98.56%	98.45%	98.36%	98.18%	98.06%	97.89%
CHILDREN	99.82%	99.59%	99.37%	99.14%	98.95%	98.79%	98.68%	98.50%	98.40%	98.25%	98.19%	98.06%	97.98%	97.84%	97.72%	97.46%	97.27%	97.05%

# ANSI/AAMI CI86

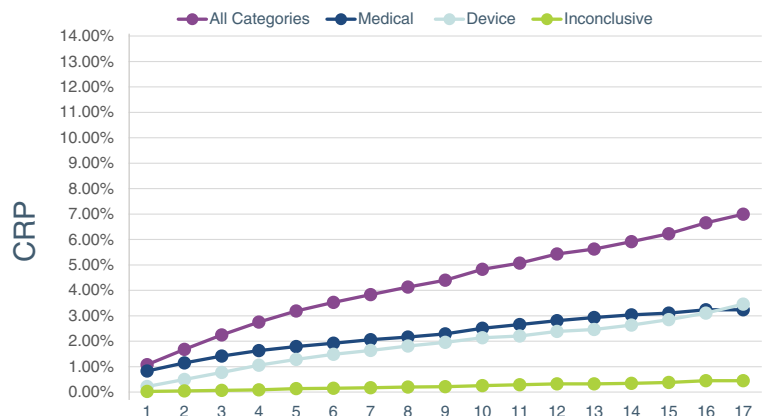
REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS



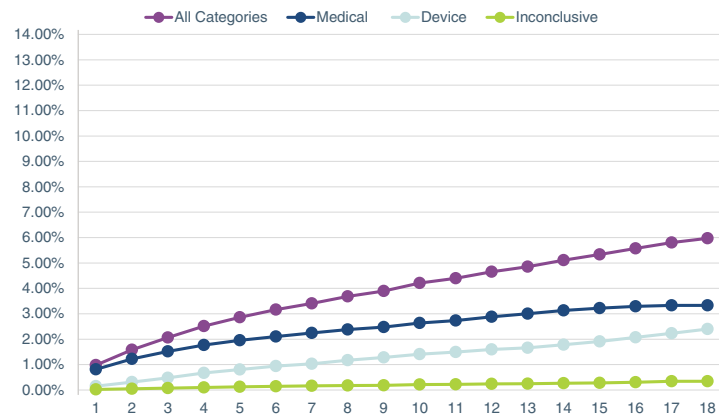
REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENTS POPULATION



REMOVAL RATES ANALYSIS CATEGORIES FOR CHILDREN



REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS AND CHILDREN



COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
					CI Up	CI Down
1	0.81%	0.15%	0.02%	0.98%	1.05%	0.91%
2	1.23%	0.31%	0.05%	1.58%	1.67%	1.49%
3	1.52%	0.48%	0.07%	2.06%	2.16%	1.96%
4	1.77%	0.67%	0.10%	2.52%	2.63%	2.41%
5	1.96%	0.80%	0.12%	2.86%	2.98%	2.75%
6	2.10%	0.94%	0.14%	3.16%	3.29%	3.04%
7	2.25%	1.03%	0.16%	3.41%	3.54%	3.28%
8	2.38%	1.17%	0.17%	3.69%	3.83%	3.55%
9	2.47%	1.28%	0.18%	3.90%	4.05%	3.75%
10	2.64%	1.41%	0.21%	4.21%	4.37%	4.05%
11	2.73%	1.49%	0.22%	4.40%	4.57%	4.23%
12	2.88%	1.60%	0.24%	4.66%	4.84%	4.48%
13	3.01%	1.66%	0.25%	4.85%	5.05%	4.66%
14	3.13%	1.78%	0.27%	5.11%	5.32%	4.90%
15	3.22%	1.91%	0.28%	5.34%	5.57%	5.10%
16	3.29%	2.07%	0.30%	5.58%	5.85%	5.30%
17	3.33%	2.23%	0.34%	5.81%	6.14%	5.48%
18	3.33%	2.40%	0.34%	5.97%	6.38%	5.57%

Not all data may be shown alongside the graphs due to space limitations. Please see the **Appendix** at the end of the report for a complete data set.

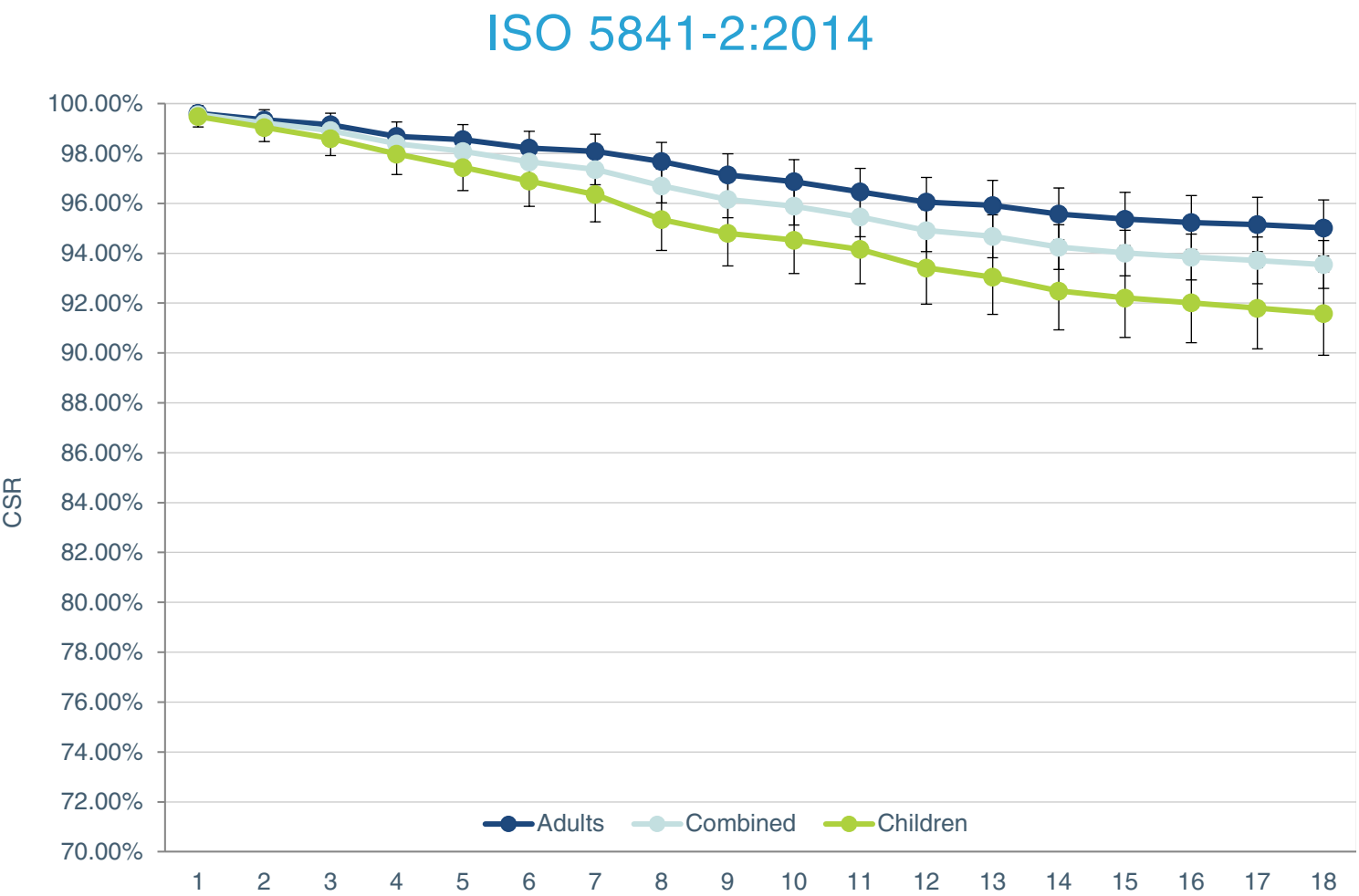
# HIRES 90K vendor A pre-mod

## Number of registered HiRes 90K implants (vendor A pre-mod)

As of September 30, 2021  
Last year of distribution<sup>a</sup>: 2005.

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	1548	1163	2721 <sup>b</sup>
ANSI/AAMI CI86	1661 <sup>c</sup>	894	2555

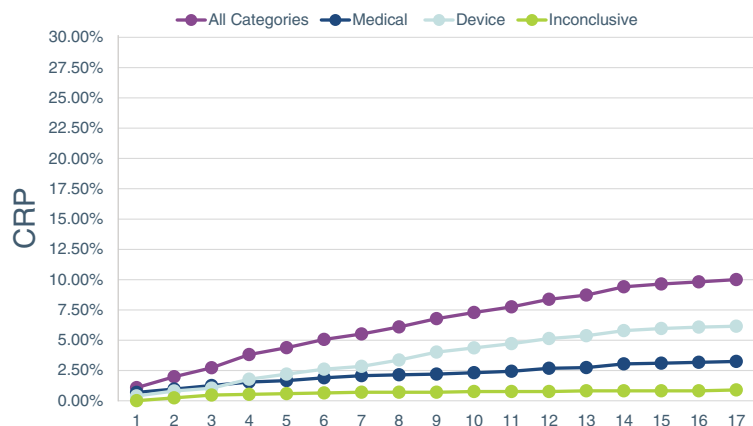
- a. Dates provided are those for major markets covered by FDA and TUV regulation. Some implants may be pending approval in a subset of additional regions.  
b. The combined number also includes any registered users for whom we do not have date of birth information.  
c. The adult number also includes users whose personal information is not available or may not be obtainable due to certain privacy laws in certain countries.



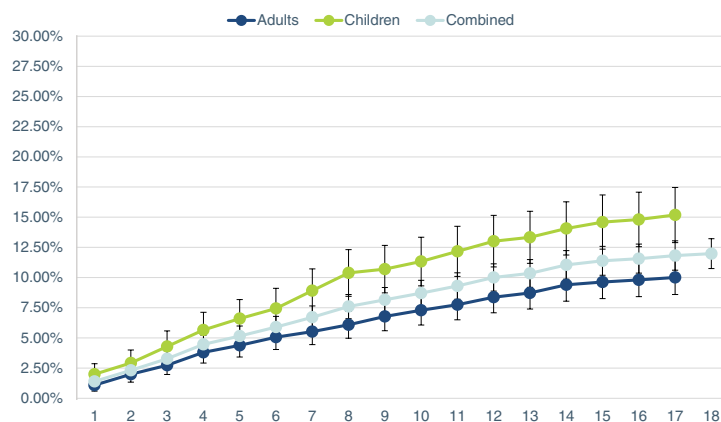
CUMULATIVE SURVIVAL PERCENTAGE																		
Years in use	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
ADULTS	99.61%	99.35%	99.15%	98.69%	98.56%	98.22%	98.09%	97.68%	97.14%	96.87%	96.46%	96.05%	95.92%	95.57%	95.37%	95.23%	95.15%	95.01%
COMBINED	99.56%	99.22%	98.92%	98.39%	98.09%	97.66%	97.36%	96.70%	96.16%	95.89%	95.46%	94.91%	94.68%	94.24%	94.01%	93.85%	93.71%	93.55%
CHILDREN	99.48%	99.04%	98.60%	97.98%	97.44%	96.90%	96.35%	95.35%	94.80%	94.52%	94.15%	93.41%	93.04%	92.48%	92.20%	92.02%	91.80%	91.59%

# ANSI/AAMI CI86

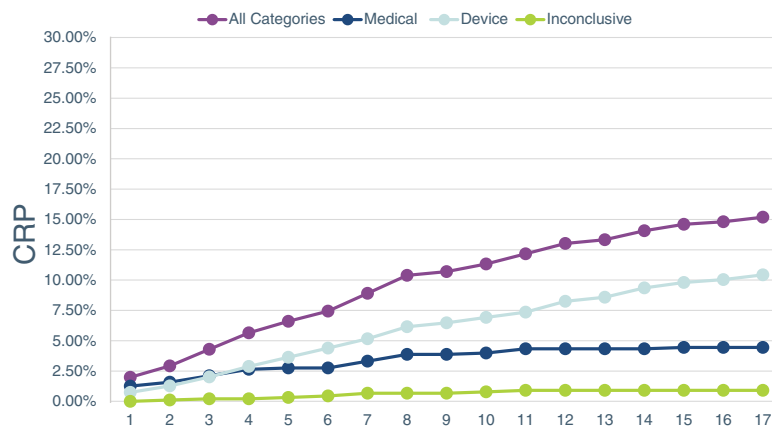
REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS



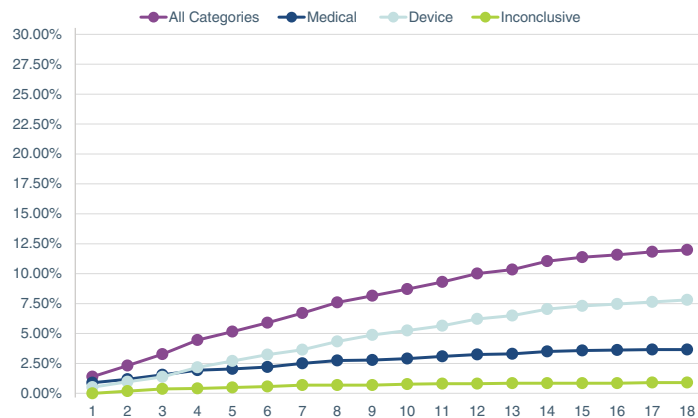
REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENTS POPULATION



REMOVAL RATES ANALYSIS CATEGORIES FOR CHILDREN



REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS AND CHILDREN



COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	CI Up	CI Down
1	0.88%	0.52%	0.00%	1.40%	1.84%	0.96%
2	1.18%	0.96%	0.19%	2.32%	2.88%	1.75%
3	1.56%	1.38%	0.38%	3.28%	3.95%	2.61%
4	1.93%	2.17%	0.41%	4.46%	5.23%	3.68%
5	2.05%	2.70%	0.49%	5.16%	5.99%	4.33%
6	2.20%	3.23%	0.57%	5.90%	6.78%	5.01%
7	2.51%	3.65%	0.69%	6.71%	7.65%	5.77%
8	2.74%	4.34%	0.69%	7.60%	8.60%	6.60%
9	2.78%	4.87%	0.69%	8.15%	9.18%	7.12%
10	2.90%	5.26%	0.77%	8.71%	9.77%	7.65%
11	3.10%	5.64%	0.81%	9.30%	10.40%	8.21%
12	3.25%	6.22%	0.81%	10.01%	11.14%	8.88%
13	3.29%	6.49%	0.85%	10.34%	11.49%	9.19%
14	3.50%	7.03%	0.85%	11.05%	12.23%	9.87%
15	3.58%	7.31%	0.85%	11.38%	12.58%	10.18%
16	3.62%	7.46%	0.85%	11.57%	12.77%	10.36%
17	3.66%	7.64%	0.90%	11.82%	13.04%	10.61%
18	3.66%	7.81%	0.90%	11.98%	13.22%	10.74%

Not all data may be shown alongside the graphs due to space limitations. Please see the **Appendix** at the end of the report for a complete data set.

# HIRES 90K vendor B

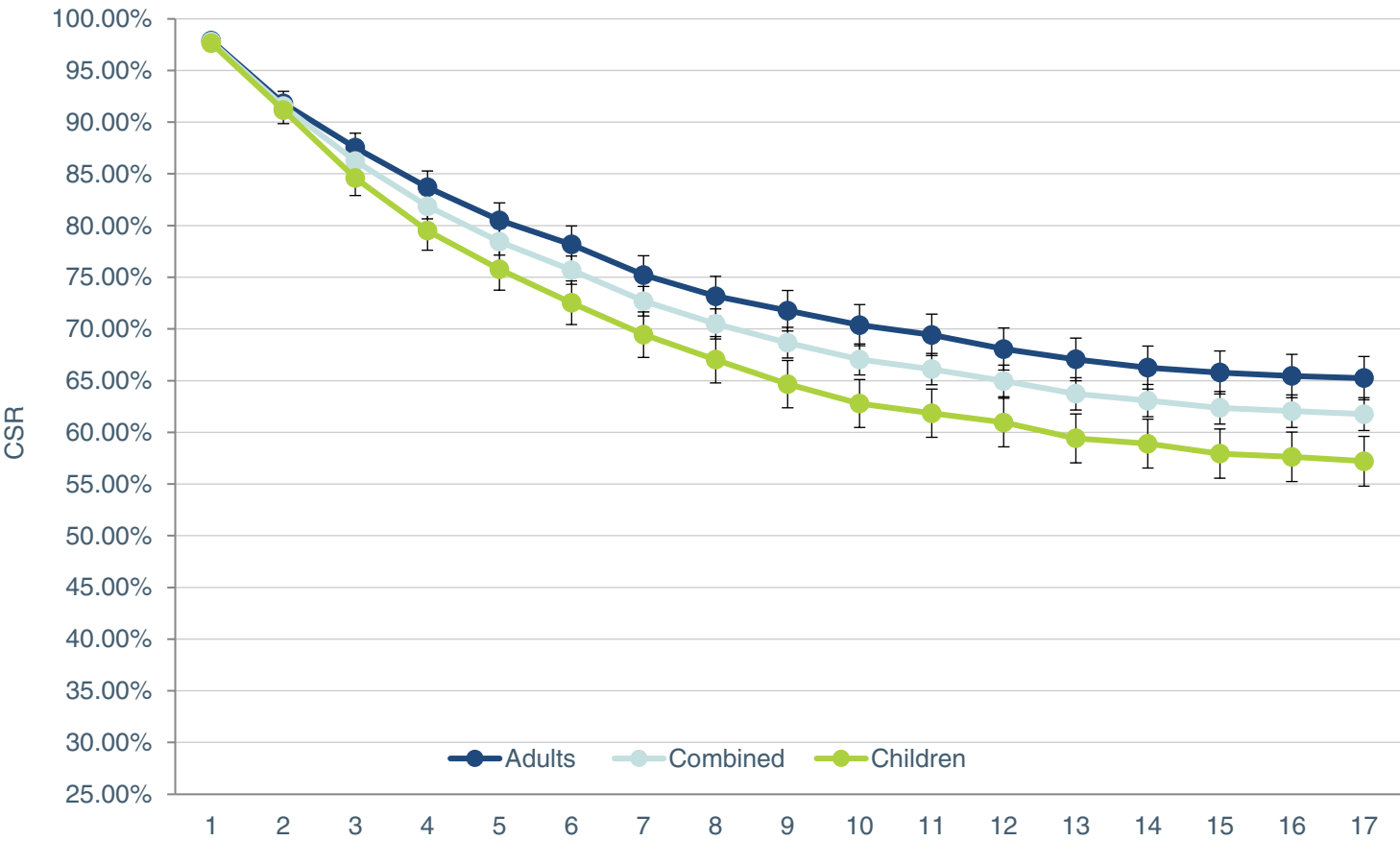
## Number of registered HiRes 90K implants (vendor B)

As of September 30, 2021.  
Last year of distribution<sup>a</sup>. Subject to voluntary recall in 2006.

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	2204	1837	4065 <sup>b</sup>
ANSI/AAMI C186	2561 <sup>c</sup>	1504	4065

- a. Dates provided are those for major markets covered by FDA and TUV regulation. Some implants may be pending approval in a subset of additional regions.  
b. The combined number also includes any registered users for whom we do not have date of birth information.  
c. The adult number also includes users whose personal information is not available or may not be obtainable due to certain privacy laws in certain countries.

## ISO 5841-2:2014



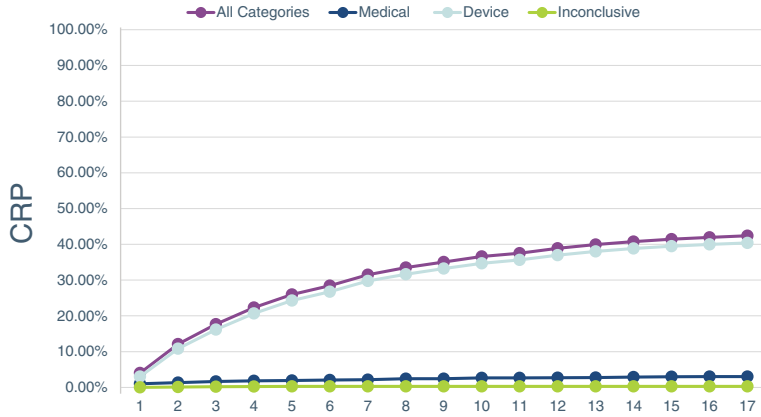
### CUMULATIVE SURVIVAL PERCENTAGE

Years in use	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
ADULTS	97.89%	91.83%	87.54%	83.70%	80.50%	78.17%	75.22%	73.16%	71.77%	70.36%	69.42%	68.06%	67.05%	66.26%	65.78%	65.46%	65.24%
COMBINED	97.79%	91.55%	86.24%	81.86%	78.44%	75.69%	72.69%	70.49%	68.66%	67.05%	66.11%	64.97%	63.73%	63.07%	62.37%	62.05%	61.75%
CHILDREN	97.64%	91.17%	84.59%	79.50%	75.77%	72.53%	69.45%	67.03%	64.67%	62.79%	61.84%	60.95%	59.42%	58.90%	57.94%	57.62%	57.20%

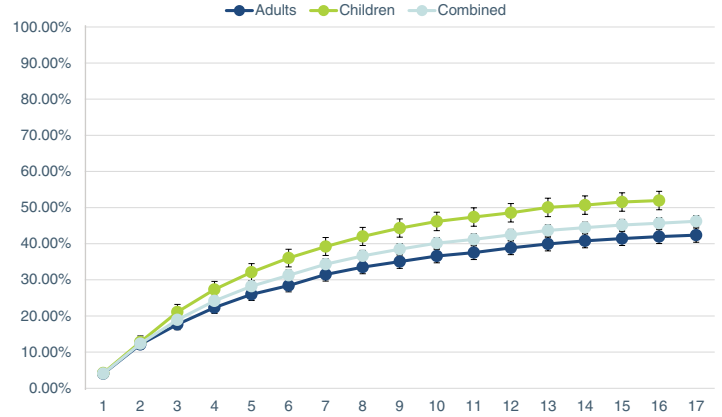


# ANSI/AAMI CI86

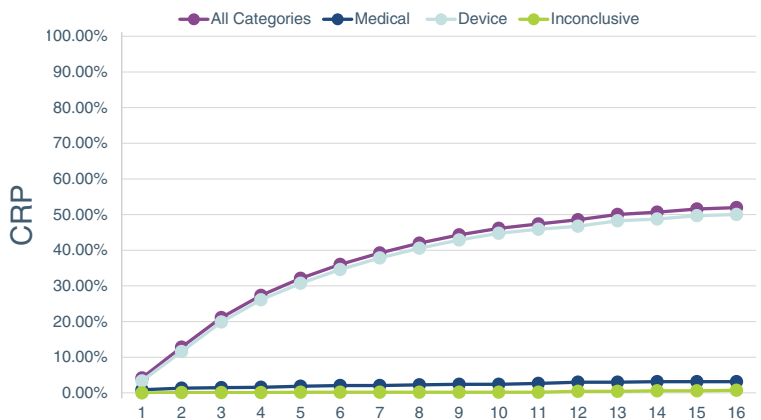
REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS



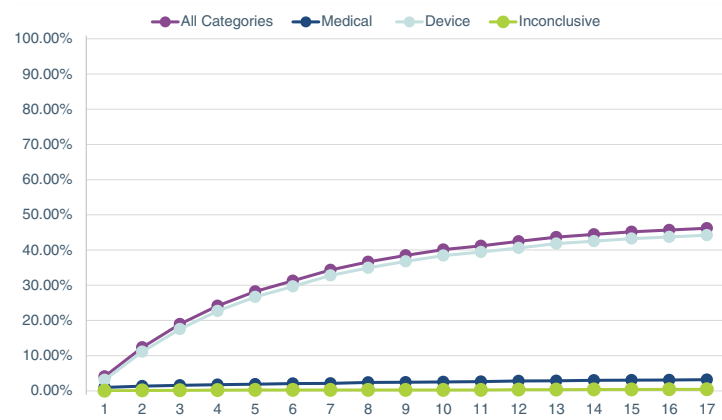
REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENTS POPULATION



REMOVAL RATES ANALYSIS CATEGORIES FOR CHILDREN



REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS AND CHILDREN



COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
					CI Up	CI Down
1	0.98%	3.14%	0.00%	4.09%	4.70%	3.48%
2	1.32%	11.11%	0.08%	12.36%	13.37%	11.35%
3	1.58%	17.53%	0.14%	18.95%	20.16%	17.75%
4	1.74%	22.69%	0.17%	24.16%	25.48%	22.84%
5	1.90%	26.67%	0.24%	28.24%	29.63%	26.85%
6	2.04%	29.65%	0.24%	31.25%	32.68%	29.82%
7	2.12%	32.76%	0.24%	34.34%	35.81%	32.87%
8	2.39%	34.95%	0.24%	36.66%	38.15%	35.17%
9	2.42%	36.79%	0.24%	38.47%	39.98%	36.97%
10	2.55%	38.43%	0.24%	40.14%	41.66%	38.62%
11	2.63%	39.44%	0.24%	41.18%	42.70%	39.65%
12	2.80%	40.60%	0.33%	42.45%	43.98%	40.92%
13	2.84%	41.83%	0.33%	43.67%	45.21%	42.13%
14	2.98%	42.52%	0.37%	44.44%	45.98%	42.89%
15	3.02%	43.26%	0.37%	45.18%	46.72%	43.63%
16	3.07%	43.70%	0.43%	45.67%	47.22%	44.12%
17	3.17%	44.20%	0.43%	46.20%	47.77%	44.63%

Not all data may be shown alongside the graphs due to space limitations. Please see the **Appendix** at the end of the report for a complete data set.

# CII BIONIC EAR

The CII Bionic Ear cochlear implant is the base for the advanced technology found in Advanced Bionics implants today. The platform can still take advantage of the latest innovations today. It benefited from the mechanical improvement made to the earlier C1.2 implants.



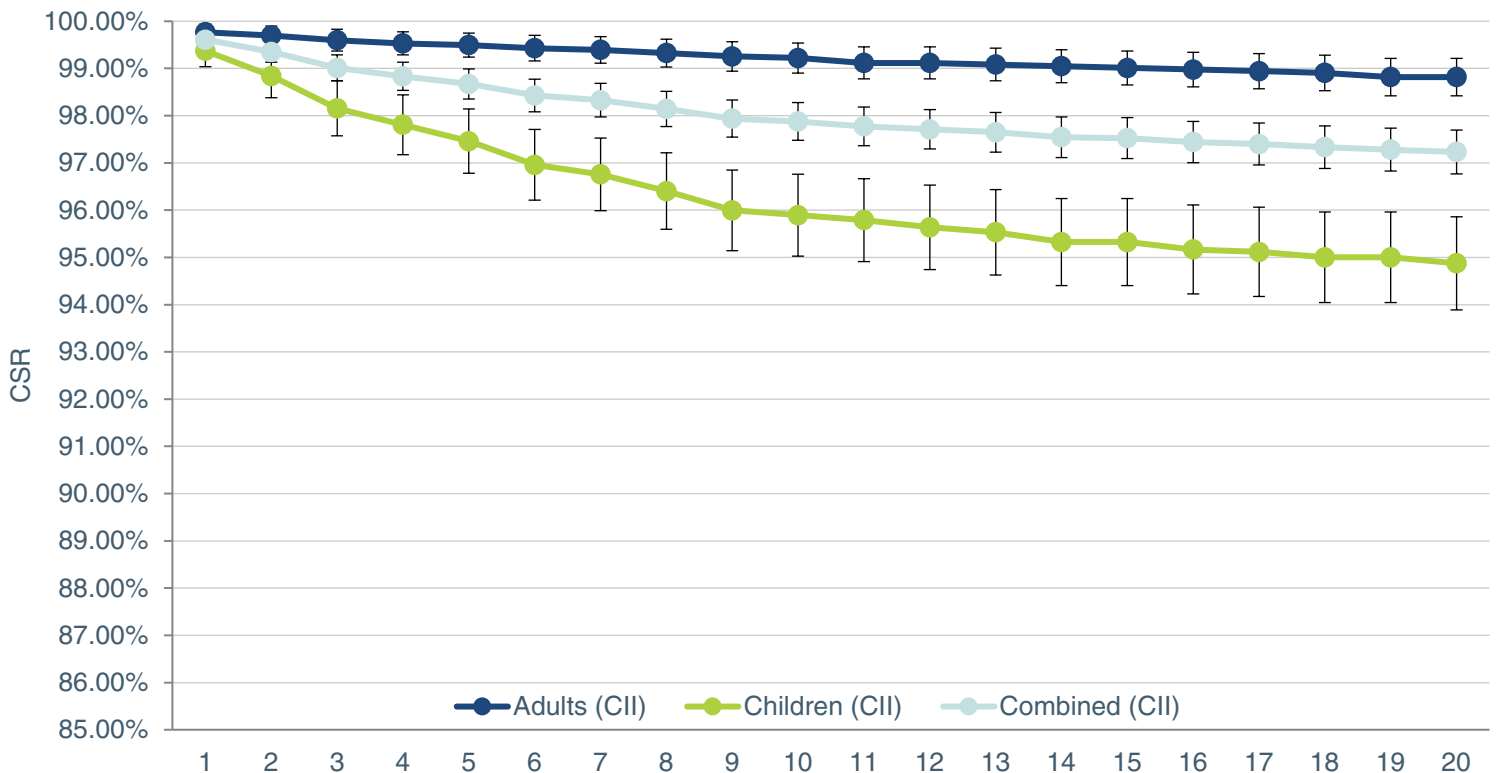
## Number of registered CII implants

As of September 30, 2021  
Last year of distribution<sup>a</sup>: 2004

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	3000	2084	5108 <sup>b</sup>
ANSI/AAMI CI86	3381 <sup>c</sup>	1727	5108

- a. Dates provided are those for major markets covered by FDA and TUV regulation. Some implants may be pending approval in a subset of additional regions.  
b. The combined number also includes any registered users for whom we do not have date of birth information.  
c. The adult number also includes users whose personal information is not available or may not be obtainable due to certain privacy laws in certain countries.

## ISO 5841-2:2014

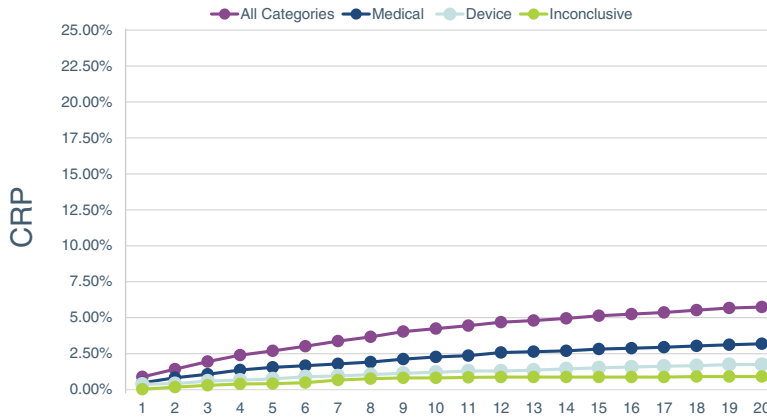


## CUMULATIVE SURVIVAL PERCENTAGE

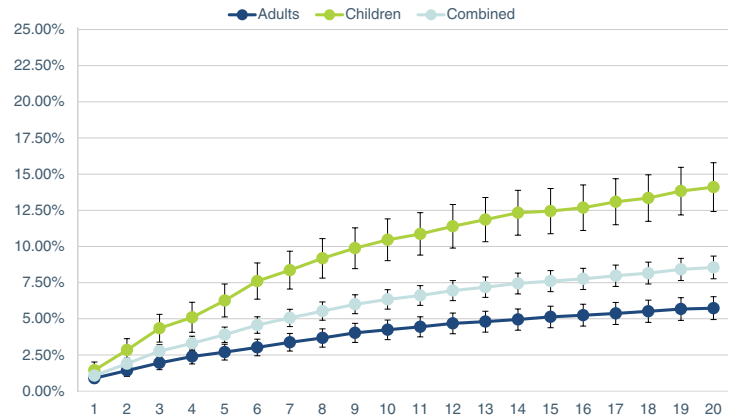
Years in use	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
ADULTS	99.77%	99.70%	99.60%	99.53%	99.50%	99.43%	99.39%	99.32%	99.25%	99.22%	99.12%	99.12%	99.08%	99.05%	99.01%	98.98%	98.94%	98.90%	98.82%	98.82%
COMBINED	99.61%	99.35%	99.01%	98.83%	98.67%	98.43%	98.33%	98.14%	97.94%	97.88%	97.77%	97.71%	97.65%	97.55%	97.52%	97.44%	97.40%	97.33%	97.28%	97.23%
CHILDREN	99.37%	98.84%	98.15%	97.81%	97.46%	96.96%	96.76%	96.40%	96.00%	95.89%	95.79%	95.64%	95.53%	95.32%	95.32%	95.17%	95.12%	95.00%	95.00%	94.88%

# ANSI/AAMI CI86

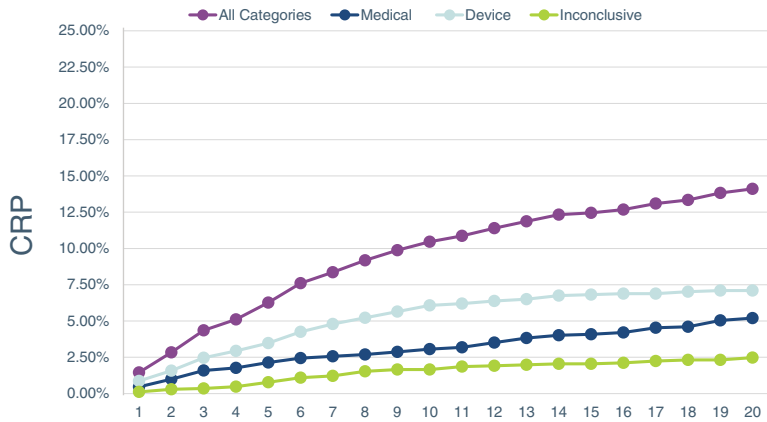
REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS



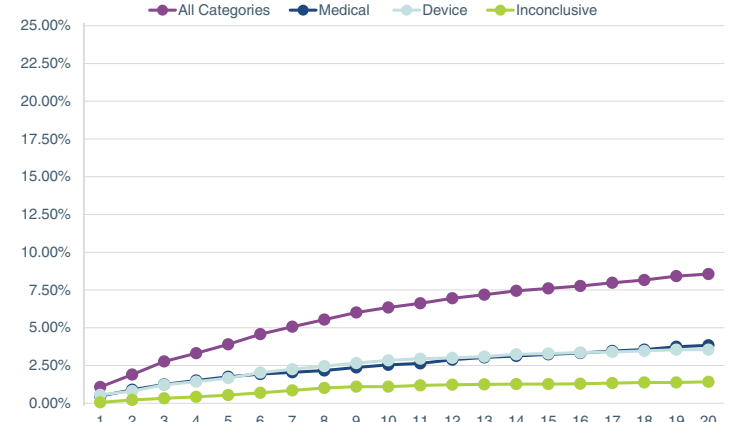
REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENTS POPULATION



REMOVAL RATES ANALYSIS CATEGORIES FOR CHILDREN



REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS AND CHILDREN



COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total CI Up	Total CI Down
1	0.47%	0.55%	0.06%	1.08%	1.36%	0.79%
2	0.89%	0.81%	0.22%	1.90%	2.27%	1.52%
3	1.24%	1.22%	0.32%	2.76%	3.21%	2.31%
4	1.50%	1.42%	0.42%	3.31%	3.80%	2.82%
5	1.74%	1.66%	0.54%	3.90%	4.43%	3.37%
6	1.92%	2.03%	0.68%	4.57%	5.14%	4.00%
7	2.05%	2.25%	0.85%	5.06%	5.66%	4.46%
8	2.17%	2.45%	1.01%	5.53%	6.16%	4.91%
9	2.37%	2.66%	1.09%	6.01%	6.66%	5.35%
10	2.54%	2.84%	1.09%	6.34%	7.01%	5.67%
11	2.64%	2.94%	1.18%	6.62%	7.30%	5.93%
12	2.89%	3.00%	1.22%	6.95%	7.65%	6.25%
13	3.03%	3.09%	1.24%	7.19%	7.90%	6.48%
14	3.13%	3.23%	1.26%	7.44%	8.16%	6.72%
15	3.24%	3.29%	1.26%	7.60%	8.33%	6.87%
16	3.32%	3.35%	1.28%	7.76%	8.49%	7.02%
17	3.46%	3.39%	1.33%	7.98%	8.72%	7.23%
18	3.55%	3.46%	1.37%	8.16%	8.91%	7.41%
19	3.74%	3.54%	1.37%	8.42%	9.18%	7.65%
20	3.83%	3.54%	1.42%	8.55%	9.33%	7.77%

Not all data may be shown alongside the graphs due to space limitations. Please see the **Appendix** at the end of the report for a complete data set.

# CLARION 1.2

The Clarion 1.2 (C1.2) implant offers mechanical improvements over its predecessor the C1.0 implant, which first introduced independent current-sources, a key technology differentiator for Advanced Bionics implants.



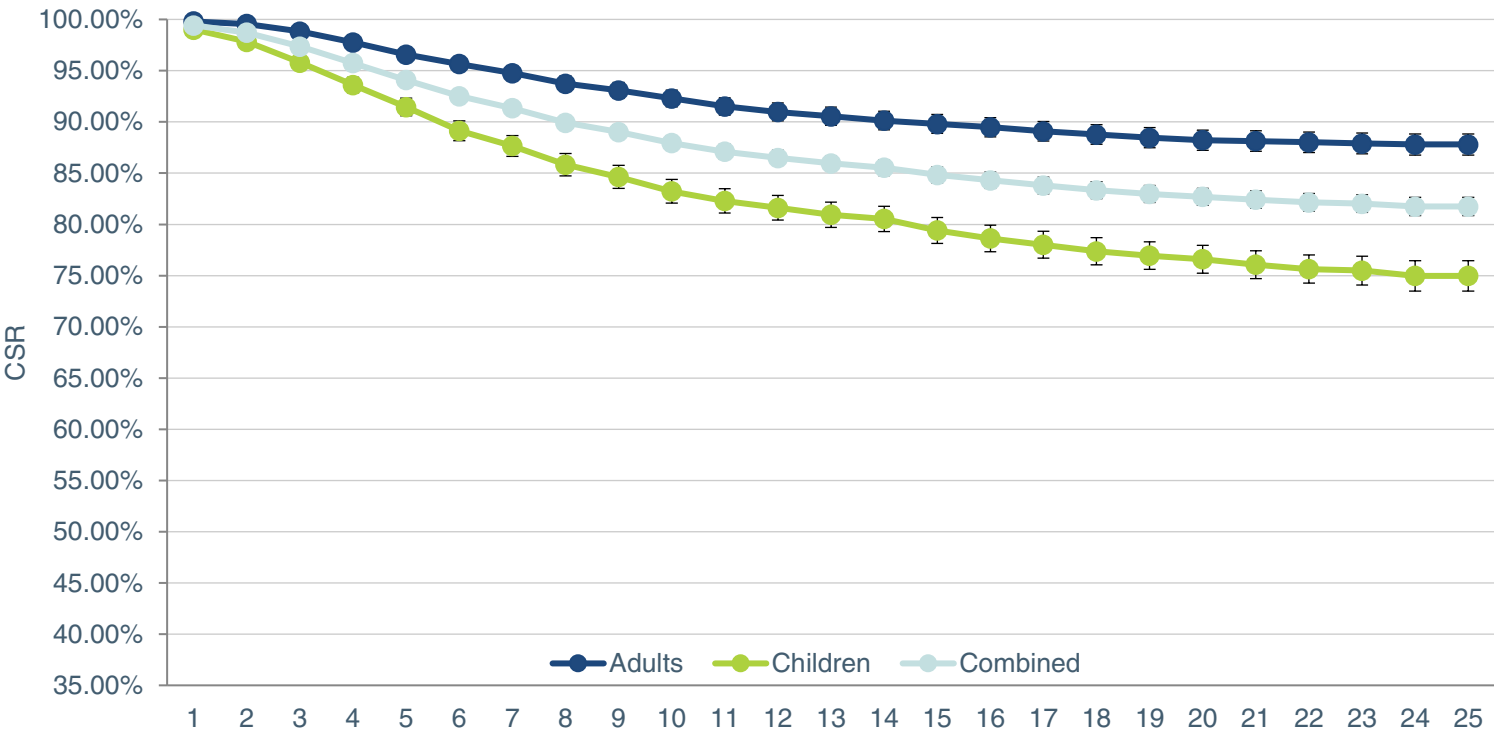
## Number of registered C1.2 implants

As of September 30, 2021  
Last year of distribution<sup>a</sup>: 2004

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	4315	4149	8501 <sup>b</sup>
ANSI/AAMI C186	4964 <sup>c</sup>	3537	8501

- a. Dates provided are those for major markets covered by FDA and TUV regulation. Some implants may be pending approval in a subset of additional regions.  
b. The combined number also includes any registered users for whom we do not have date of birth information.  
c. The adult number also includes users whose personal information is not available or may not be obtainable due to certain privacy laws in certain countries.

## ISO 5841-2:2014



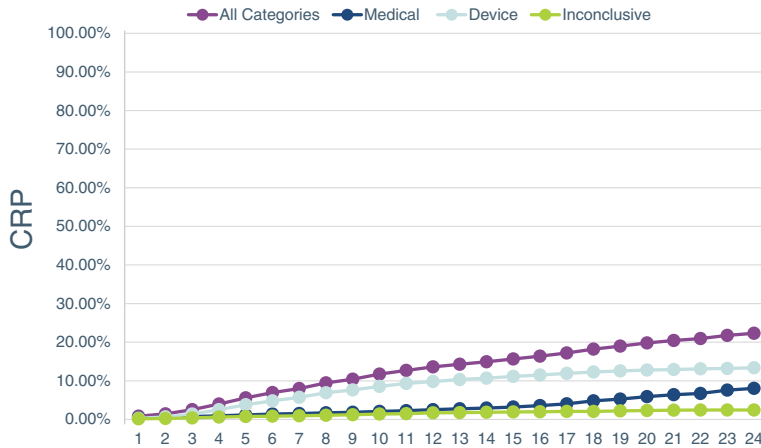
### CUMULATIVE SURVIVAL PERCENTAGE

Years in use	1	2	3	4	5	6	7	8	9	10	11	12	13
ADULTS	99.81%	99.56%	98.83%	97.76%	96.57%	95.66%	94.77%	93.73%	93.08%	92.30%	91.51%	90.97%	90.55%
COMBINED	99.42%	98.72%	97.36%	95.75%	94.10%	92.51%	91.34%	89.93%	89.01%	87.94%	87.09%	86.49%	85.95%
CHILDREN	99.00%	97.83%	95.80%	93.61%	91.46%	89.14%	87.66%	85.83%	84.63%	83.23%	82.30%	81.62%	80.95%

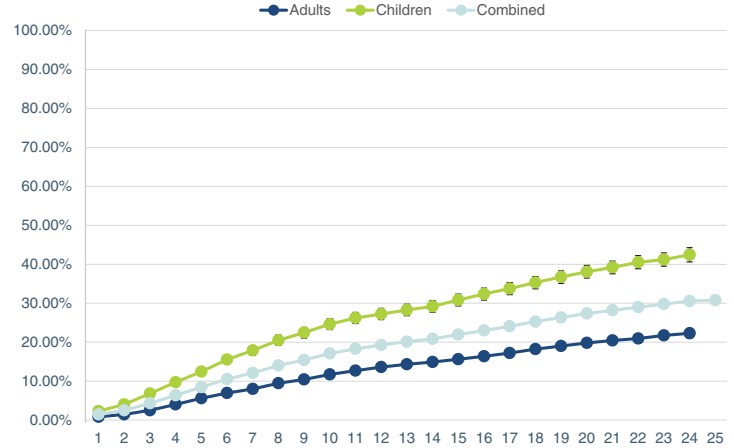
Years in use	14	15	16	17	18	19	20	21	22	23	24	25
ADULTS	90.13%	89.81%	89.48%	89.08%	88.77%	88.46%	88.22%	88.13%	88.01%	87.89%	87.79%	87.79%
COMBINED	85.54%	84.84%	84.30%	83.80%	83.34%	82.98%	82.69%	82.41%	82.15%	82.02%	81.74%	81.74%
CHILDREN	80.54%	79.41%	78.63%	78.01%	77.37%	76.95%	76.60%	76.08%	75.64%	75.49%	74.98%	74.98%

# ANSI/AAMI CI86

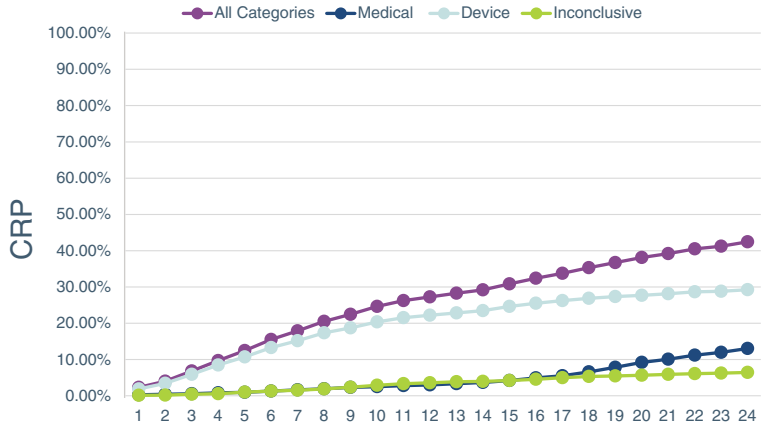
REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS



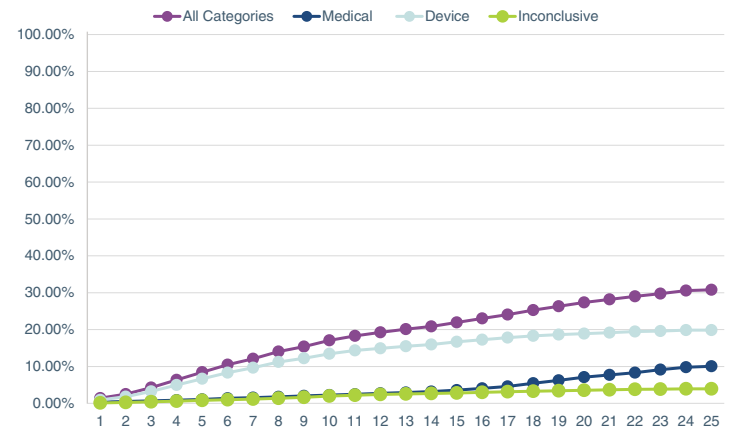
REMOVAL RATES ANALYSIS FOR ALL ANALYSIS CATEGORIES AND DIFFERENT PATIENTS POPULATION



REMOVAL RATES ANALYSIS CATEGORIES FOR CHILDREN



REMOVAL RATES ANALYSIS CATEGORIES FOR ADULTS AND CHILDREN



COMBINED ADULTS AND CHILDREN

Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total CI Up	Total CI Down
1	0.36%	0.97%	0.13%	1.45%	1.70%	1.19%
2	0.50%	1.80%	0.24%	2.52%	2.86%	2.19%
3	0.68%	3.26%	0.41%	4.31%	4.74%	3.88%
4	0.88%	4.98%	0.58%	6.37%	6.89%	5.85%
5	1.07%	6.67%	0.84%	8.45%	9.04%	7.85%
6	1.37%	8.35%	1.01%	10.51%	11.16%	9.86%
7	1.57%	9.65%	1.17%	12.10%	12.80%	11.41%
8	1.80%	11.24%	1.38%	14.04%	14.78%	13.30%
9	2.01%	12.22%	1.66%	15.41%	16.18%	14.64%
10	2.25%	13.46%	1.99%	17.09%	17.90%	16.29%
11	2.46%	14.36%	2.21%	18.31%	19.14%	17.49%
12	2.72%	14.94%	2.44%	19.27%	20.11%	18.43%
13	2.97%	15.49%	2.57%	20.11%	20.96%	19.25%
14	3.22%	15.97%	2.67%	20.85%	21.72%	19.98%
15	3.59%	16.70%	2.80%	21.94%	22.83%	21.06%
16	4.08%	17.28%	2.97%	23.01%	23.91%	22.11%
17	4.57%	17.83%	3.18%	24.08%	25.00%	23.17%
18	5.46%	18.29%	3.31%	25.30%	26.23%	24.37%
19	6.23%	18.65%	3.44%	26.34%	27.28%	25.40%
20	7.10%	18.93%	3.57%	27.37%	28.33%	26.41%
21	7.74%	19.18%	3.70%	28.20%	29.17%	27.23%
22	8.33%	19.47%	3.83%	29.01%	30.00%	28.02%
23	9.13%	19.60%	3.87%	29.77%	30.79%	28.75%
24	9.81%	19.88%	3.93%	30.58%	31.66%	29.50%
25	10.07%	19.88%	3.93%	30.78%	31.89%	29.67%

Not all data may be shown alongside the graphs due to space limitations. Please see the **Appendix** at the end of the report for a complete data set.

# CLARION 1.0

The Clarion 1.0 (C1.0) implant was Advanced Bionics first device, the start of a technology-forward lineage that continues today. As the number of children implanted with the C1.0 is below the level required for statistical analysis, the data is included with the adult data.



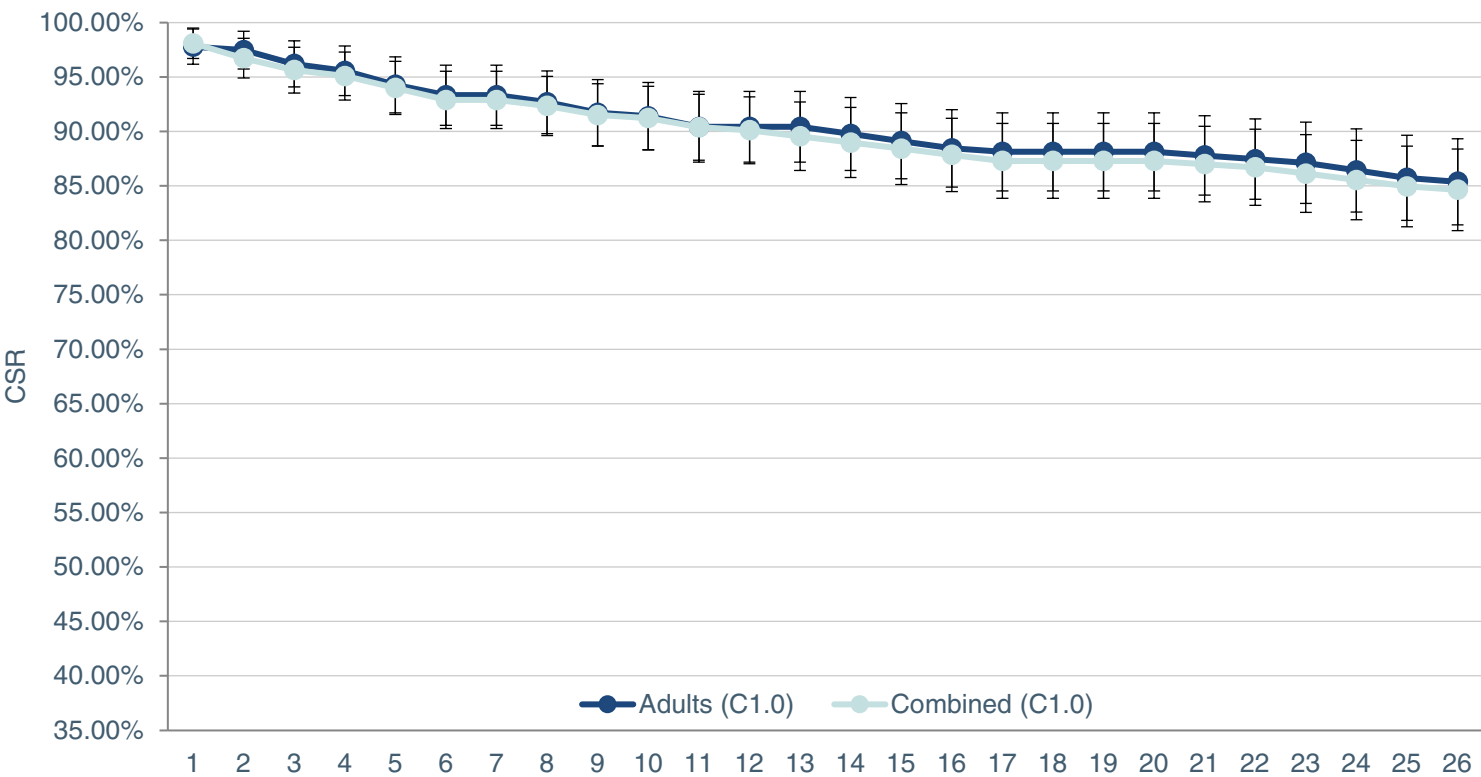
## Number of registered C1.0 implants

As of September 30, 2021  
Last year of distribution<sup>a</sup>: 2004

STANDARD	ADULTS	CHILDREN	COMBINED
ISO 5841-2:2014	316	49	367 <sup>b</sup>
ANSI/AAMI C186	-	-	-

a. Dates provided are those for major markets covered by FDA and TUV regulation. Some implants may be pending approval in a subset of additional regions.  
b. The combined number also includes any registered users for whom we do not have date of birth information.

## ISO 5841-2:2014



### CUMULATIVE SURVIVAL PERCENTAGE

Years in use	1	2	3	4	5	6	7	8	9	10	11	12	13
ADULTS	97.78%	97.47%	96.19%	95.56%	94.28%	93.32%	93.32%	92.68%	91.72%	91.39%	90.42%	90.42%	90.42%
COMBINED	98.09%	96.73%	95.63%	95.08%	93.99%	92.89%	92.89%	92.34%	91.50%	91.23%	90.39%	90.11%	89.55%

Years in use	14	15	16	17	18	19	20	21	22	23	24	25	26
ADULTS	89.77%	89.11%	88.45%	88.12%	88.12%	88.12%	88.12%	87.78%	87.44%	87.11%	86.42%	85.73%	85.37%
COMBINED	88.98%	88.42%	87.85%	87.28%	87.28%	87.28%	87.28%	87.00%	86.71%	86.13%	85.54%	84.95%	84.64%

# ANSI/AAMI CI86

The ANSI/AAMI CI86 Standard does not require reporting for devices older than 20 years after the last implantation of that device type. Please refer to the ISO data for information.

## SOUND PROCESSOR STIMULATORS

For each currently-available sound processor, there will be a simple measure of reliability based on the average global yearly return rate and graphical data in compliance with ANSI/AAMI CI86 Standard that shows the monthly failure rate.

Where possible this monthly data is further categorized into failure mechanisms, if known, to include mechanical, electronic, moisture damage, and other. In specification processors, commonly referred to as no-fault-found, are also included. Where available, the number of registered users is shown, categorized into adult, children, and combined.



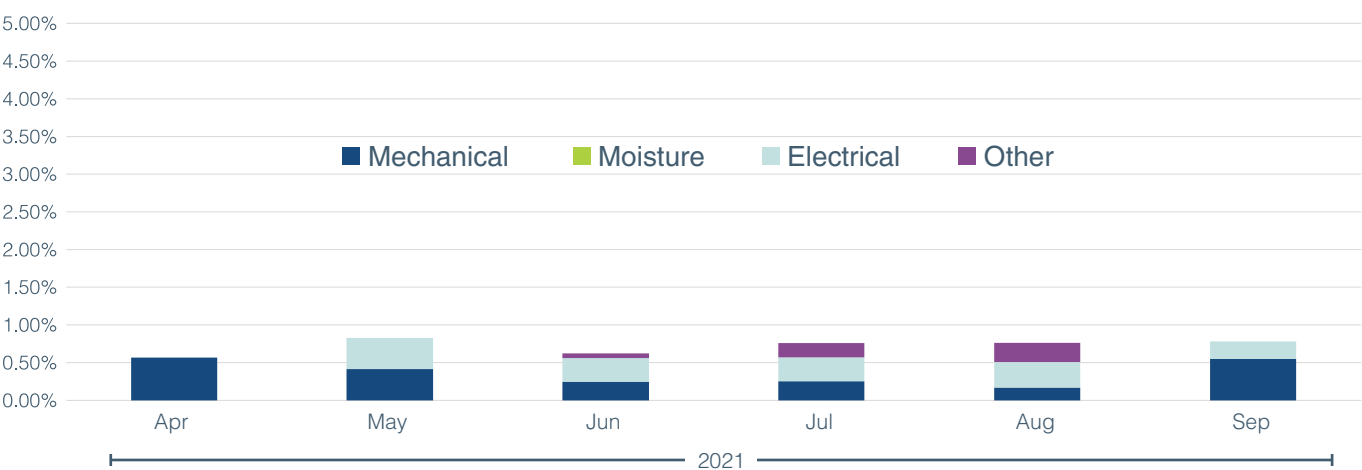


# NAÍDA CI M AND SKY CI M

The Naída™ CI M sound processor for adults and Sky CI™ M sound processor for children are the newest Advanced Bionics products integrated with the latest advancements from Phonak, the Marvel platform. With built-in connectivity solutions and the ability to automatically sense and adapt to every situation, the Naída CI M and Sky CI M processors are designed to give you the best hearing experience.

Reliability of the Naída CI M and Sky CI M sound processors are combined at this time due to the limited number of devices in use. As field data becomes available globally, we will present the reliability metrics as separate products in future reports.

## RELIABILITY: 99.09%<sup>a</sup>



FAILED COMPONENT RETURN RATE<sup>b</sup>

Cause	Apr 2021	May 2021	Jun 2021	Jul 2021	Aug 2021	Sep 2021
Mechanical	0.57%	0.41%	0.25%	0.25%	0.17%	0.55%
Moisture	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Electrical	0.00%	0.41%	0.31%	0.32%	0.34%	0.23%
Other	0.00%	0.00%	0.06%	0.19%	0.25%	0.00%

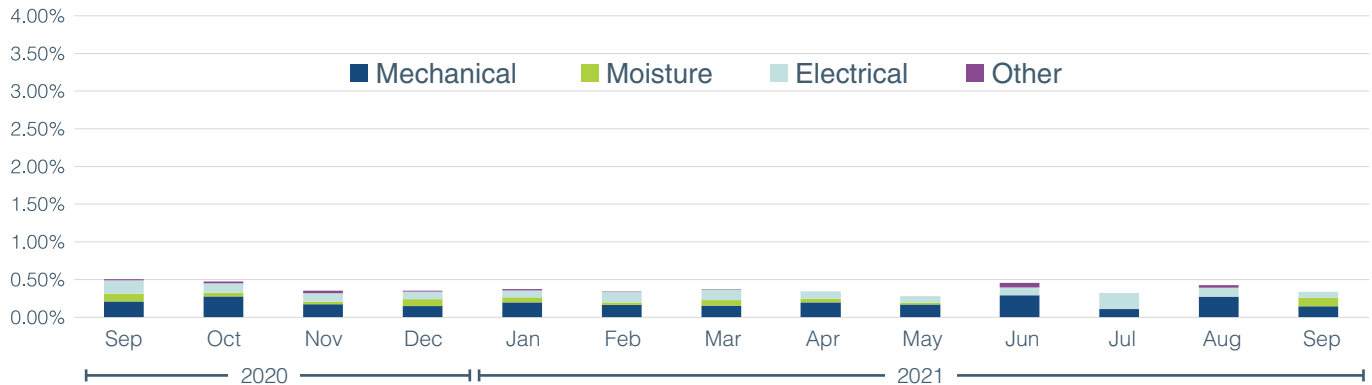
a. Reliability is 1 minus the return rate. The return rate is the average global monthly return rate April 2021 to September 2021.  
b. The number per month represent the unit that complete failure analysis in that month.



# NAÍDA CI Q90

The Naída™ CI Q90 sound processor features state-of-the-art technologies exclusively available from Advanced Bionics and Phonak for the best possible hearing experience.

**RELIABILITY: 99.64%<sup>a</sup>**



FAILED COMPONENT RETURN RATE<sup>b</sup>

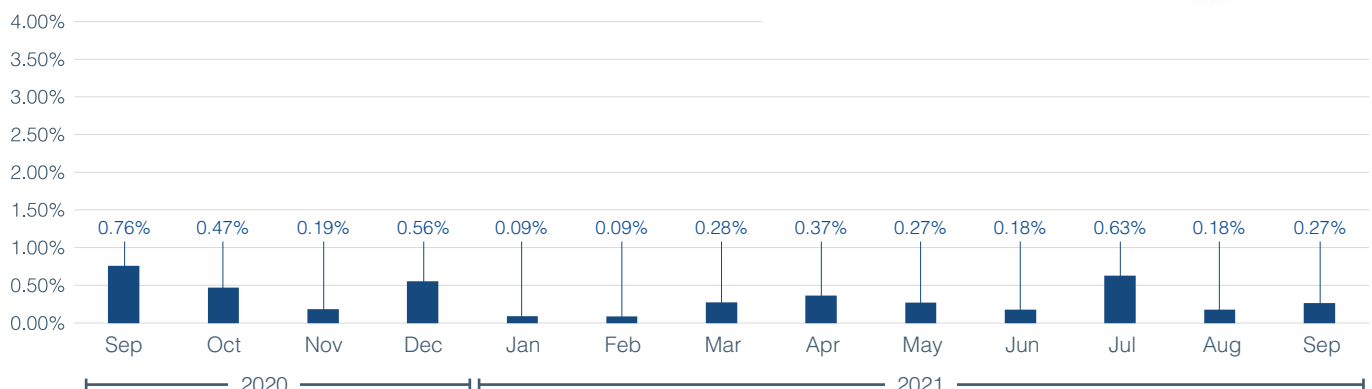
Cause	Sep 2020	Oct 2020	Nov 2020	Dec 2020	Jan 2021	Feb 2021	Mar 2021	Apr 2021	May 2021	Jun 2021	Jul 2021	Aug 2021	Sep 2021
Mechanical	0.21%	0.27%	0.17%	0.14%	0.19%	0.16%	0.15%	0.19%	0.17%	0.29%	0.11%	0.27%	0.14%
Moisture	0.10%	0.05%	0.03%	0.09%	0.07%	0.03%	0.07%	0.05%	0.02%	0.00%	0.00%	0.00%	0.11%
Electrical	0.18%	0.12%	0.11%	0.10%	0.09%	0.14%	0.14%	0.10%	0.08%	0.10%	0.21%	0.12%	0.08%
Other	0.01%	0.02%	0.03%	0.01%	0.02%	0.01%	0.01%	0.00%	0.00%	0.06%	0.00%	0.03%	0.00%

# CHORUS

The Chorus™ sound processor is compatible with C1.0 and C1.2 cochlear implants, and offers integrated Roger™ technology for connectivity and performance.

Data set too limited for detailed analysis.

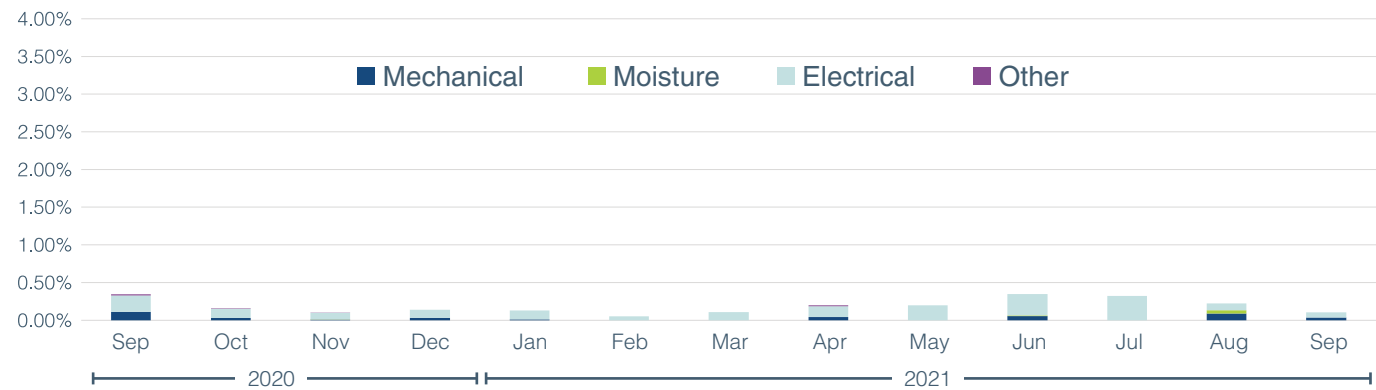
**RELIABILITY: 99.73%<sup>a</sup>**



# NEPTUNE

The Neptune™ sound processor is the first and only swimmable sound processor.

RELIABILITY: 99.83%<sup>a</sup>



FAILED COMPONENT RETURN RATE<sup>b</sup>

Cause	Sep 2020	Oct 2020	Nov 2020	Dec 2020	Jan 2021	Feb 2021	Mar 2021	Apr 2021	May 2021	Jun 2021	Jul 2021	Aug 2021	Sep 2021
Mechanical	0.11%	0.03%	0.01%	0.03%	0.01%	0.00%	0.00%	0.04%	0.00%	0.05%	0.00%	0.09%	0.03%
Moisture	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.00%	0.04%	0.00%
Electrical	0.22%	0.12%	0.09%	0.11%	0.12%	0.05%	0.11%	0.15%	0.20%	0.28%	0.32%	0.09%	0.07%
Other	0.01%	0.01%	0.00%	0.00%	0.00%	0.00%	0.00%	0.01%	0.00%	0.00%	0.00%	0.00%	0.00%

a. Reliability is 1 minus the return rate. The return rate is the average global monthly return rate over a 12-month period from September 2020 to September 2021.  
b. The number per month represent the unit that complete failure analysis in that month.

## HIRES ULTRA 3D V2

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
						CI Up	CI Down
ADULTS	1	0.66%	0.00%	0.00%	0.66%	0.92%	0.40%
	1.5	0.66%	0.00%	0.00%	0.66%	0.92%	0.40%
CHILDREN	1	0.37%	0.15%	0.00%	0.51%	0.94%	0.08%
	1.5 <sup>a</sup>	NA	NA	NA	NA	NA	NA

a. Sample size for children at 1.5 years is not large enough for reporting

## HIRES ULTRA V2

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
						CI Up	CI Down
ADULTS	1 <sup>a</sup>	0.37%	0.00%	0.00%	0.37%	0.88%	0.00%
CHILDREN	1 <sup>b</sup>	0.15%	0.00%	0.00%	0.15%	0.45%	0.00%

b. Sufficient data to report adults at 11 months

c. Sufficient data to report children at 10 months

## HIRES ULTRA 3D V1

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
						CI Up	CI Down
ADULTS	1	0.94%	0.16%	0.02%	1.12%	1.41%	0.83%
	2	1.60%	1.66%	0.08%	3.32%	3.83%	2.81%
CHILDREN	1	1.04%	0.45%	0.00%	1.48%	2.13%	0.84%
	2	1.67%	5.89%	0.00%	7.47%	8.94%	6.00%

## HIRES ULTRA V1

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
						CI Up	CI Down
ADULTS	1	0.75%	0.02%	0.02%	0.80%	0.99%	0.61%
	2	1.24%	0.37%	0.04%	1.64%	1.92%	1.37%
	3	1.60%	2.83%	0.06%	4.45%	4.93%	3.98%
	4	1.91%	8.06%	0.11%	9.92%	10.76%	9.07%
CHILDREN	1	0.56%	0.11%	0.00%	0.66%	0.92%	0.40%
	2	0.78%	1.07%	0.03%	1.86%	2.30%	1.42%
	3	1.03%	5.80%	0.11%	6.87%	7.83%	5.91%
	4	1.84%	16.66%	0.11%	18.29%	20.24%	16.33%

# HIRES 90K ADVANTAGE

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
						CI Up	CI Down
ADULTS	1	0.68%	0.07%	0.02%	0.76%	0.89%	0.64%
	2	1.16%	0.09%	0.03%	1.27%	1.43%	1.12%
	3	1.42%	0.14%	0.04%	1.60%	1.78%	1.42%
	4	1.71%	0.17%	0.04%	1.92%	2.12%	1.73%
	5	1.89%	0.20%	0.04%	2.13%	2.34%	1.92%
	6	2.06%	0.23%	0.05%	2.34%	2.56%	2.11%
	7	2.21%	0.24%	0.07%	2.51%	2.76%	2.27%
	8	2.36%	0.27%	0.07%	2.69%	2.97%	2.41%
CHILDREN	1	0.77%	0.21%	0.03%	1.01%	1.15%	0.86%
	2	1.10%	0.38%	0.05%	1.53%	1.71%	1.35%
	3	1.39%	0.60%	0.05%	2.03%	2.24%	1.82%
	4	1.59%	0.76%	0.10%	2.44%	2.68%	2.20%
	5	1.74%	0.88%	0.17%	2.76%	3.02%	2.50%
	6	1.88%	1.04%	0.18%	3.08%	3.36%	2.79%
	7	2.03%	1.25%	0.20%	3.45%	3.78%	3.11%
	8	2.12%	1.38%	0.20%	3.67%	4.05%	3.28%

# HIRES 90K vendor A post-mod

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
						CI Up	CI Down
ADULTS	1	0.80%	0.06%	0.02%	0.88%	0.97%	0.78%
	2	1.32%	0.11%	0.04%	1.46%	1.58%	1.34%
	3	1.63%	0.16%	0.06%	1.85%	1.98%	1.71%
	4	1.92%	0.23%	0.08%	2.22%	2.37%	2.08%
	5	2.13%	0.27%	0.09%	2.48%	2.64%	2.33%
	6	2.29%	0.34%	0.11%	2.73%	2.89%	2.56%
	7	2.43%	0.36%	0.13%	2.91%	3.08%	2.73%
	8	2.59%	0.44%	0.13%	3.14%	3.33%	2.96%
	9	2.67%	0.47%	0.14%	3.26%	3.45%	3.07%
	10	2.79%	0.55%	0.15%	3.47%	3.67%	3.26%
	11	2.85%	0.60%	0.15%	3.57%	3.78%	3.36%
	12	2.98%	0.61%	0.15%	3.71%	3.93%	3.49%
	13	3.12%	0.63%	0.16%	3.88%	4.12%	3.65%
	14	3.22%	0.63%	0.18%	4.00%	4.24%	3.75%
	15	3.33%	0.66%	0.18%	4.14%	4.42%	3.86%
	16	3.33%	0.74%	0.18%	4.22%	4.53%	3.90%
CHILDREN	1	0.82%	0.21%	0.03%	1.05%	1.15%	0.95%
	2	1.14%	0.47%	0.04%	1.65%	1.77%	1.52%
	3	1.40%	0.74%	0.06%	2.19%	2.34%	2.05%
	4	1.60%	1.01%	0.09%	2.68%	2.84%	2.51%
	5	1.77%	1.22%	0.13%	3.09%	3.27%	2.91%
	6	1.90%	1.40%	0.14%	3.41%	3.60%	3.22%
	7	2.02%	1.52%	0.16%	3.67%	3.87%	3.47%
	8	2.11%	1.66%	0.18%	3.91%	4.12%	3.69%
	9	2.24%	1.79%	0.19%	4.18%	4.41%	3.95%
	10	2.47%	1.95%	0.23%	4.59%	4.85%	4.33%
	11	2.59%	1.98%	0.26%	4.76%	5.04%	4.49%
	12	2.76%	2.07%	0.30%	5.06%	5.36%	4.76%
	13	2.90%	2.11%	0.30%	5.23%	5.55%	4.92%
	14	3.04%	2.14%	0.32%	5.41%	5.76%	5.07%
	15	3.09%	2.24%	0.38%	5.61%	6.00%	5.22%
	16	N/A	N/A	N/A	N/A	N/A	N/A

## HIRES 90K vendor A all

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
						CI Up	CI Down
ADULTS	1	0.79%	0.08%	0.01%	0.88%	0.97%	0.79%
	2	1.30%	0.14%	0.05%	1.49%	1.60%	1.37%
	3	1.61%	0.20%	0.08%	1.89%	2.02%	1.75%
	4	1.90%	0.30%	0.10%	2.29%	2.44%	2.15%
	5	2.11%	0.36%	0.11%	2.57%	2.72%	2.41%
	6	2.27%	0.44%	0.14%	2.84%	3.00%	2.67%
	7	2.42%	0.48%	0.15%	3.03%	3.21%	2.86%
	8	2.57%	0.59%	0.16%	3.29%	3.48%	3.11%
	9	2.65%	0.68%	0.16%	3.46%	3.65%	3.27%
	10	2.77%	0.78%	0.18%	3.70%	3.90%	3.49%
	11	2.83%	0.86%	0.18%	3.84%	4.06%	3.63%
	12	2.98%	0.92%	0.18%	4.05%	4.27%	3.82%
	13	3.11%	0.98%	0.20%	4.24%	4.48%	4.01%
	14	3.25%	1.07%	0.21%	4.48%	4.74%	4.22%
	15	3.34%	1.15%	0.21%	4.66%	4.94%	4.37%
	16	3.38%	1.26%	0.21%	4.79%	5.11%	4.48%
	17	3.44%	1.32%	0.27%	4.97%	5.34%	4.60%
	18	N/A	N/A	N/A	N/A	N/A	N/A
CHILDREN	1	0.83%	0.22%	0.03%	1.08%	1.18%	0.97%
	2	1.15%	0.49%	0.04%	1.68%	1.80%	1.55%
	3	1.42%	0.78%	0.06%	2.25%	2.39%	2.10%
	4	1.63%	1.06%	0.09%	2.76%	2.92%	2.59%
	5	1.79%	1.29%	0.13%	3.19%	3.36%	3.01%
	6	1.92%	1.49%	0.15%	3.52%	3.72%	3.33%
	7	2.06%	1.63%	0.17%	3.83%	4.03%	3.63%
	8	2.17%	1.81%	0.19%	4.13%	4.34%	3.91%
	9	2.29%	1.96%	0.21%	4.40%	4.63%	4.17%
	10	2.51%	2.13%	0.25%	4.83%	5.09%	4.57%
	11	2.65%	2.21%	0.29%	5.07%	5.35%	4.79%
	12	2.81%	2.38%	0.32%	5.43%	5.73%	5.13%
	13	2.93%	2.46%	0.32%	5.62%	5.94%	5.30%
	14	3.04%	2.64%	0.34%	5.92%	6.27%	5.56%
	15	3.11%	2.85%	0.38%	6.23%	6.63%	5.82%
	16	3.24%	3.10%	0.45%	6.65%	7.17%	6.14%
	17	3.24%	3.45%	0.45%	6.99%	7.63%	6.35%
	18	N/A	N/A	N/A	N/A	N/A	N/A

## HIRES 90K vendor A pre-mod

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
						CI Up	CI Down
ADULTS	1	0.68%	0.40%	0.00%	1.08%	1.56%	0.60%
	2	0.97%	0.80%	0.23%	1.99%	2.64%	1.34%
	3	1.26%	1.03%	0.46%	2.73%	3.49%	1.97%
	4	1.55%	1.78%	0.52%	3.81%	4.70%	2.91%
	5	1.66%	2.19%	0.58%	4.38%	5.33%	3.42%
	6	1.90%	2.60%	0.64%	5.06%	6.09%	4.04%
	7	2.08%	2.83%	0.70%	5.52%	6.58%	4.45%
	8	2.13%	3.36%	0.70%	6.09%	7.20%	4.97%
	9	2.19%	4.01%	0.70%	6.77%	7.95%	5.60%
	10	2.31%	4.36%	0.76%	7.29%	8.50%	6.07%
	11	2.44%	4.72%	0.76%	7.74%	8.99%	6.49%
	12	2.68%	5.13%	0.76%	8.37%	9.67%	7.08%
	13	2.74%	5.37%	0.82%	8.72%	10.04%	7.40%
	14	3.04%	5.79%	0.82%	9.41%	10.77%	8.04%
	15	3.11%	5.96%	0.82%	9.64%	11.02%	8.25%
	16	3.17%	6.08%	0.82%	9.81%	11.20%	8.42%
	17	3.24%	6.15%	0.89%	10.00%	11.41%	8.60%
	18	N/A	N/A	N/A	N/A	N/A	N/A

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
						CI Up	CI Down
CHILDREN	1	1.26%	0.74%	0.00%	1.98%	2.87%	1.10%
	2	1.57%	1.27%	0.11%	2.93%	3.99%	1.86%
	3	2.11%	2.02%	0.22%	4.29%	5.57%	3.01%
	4	2.65%	2.88%	0.22%	5.66%	7.12%	4.19%
	5	2.76%	3.64%	0.33%	6.60%	8.18%	5.03%
	6	2.76%	4.40%	0.44%	7.44%	9.11%	5.78%
	7	3.31%	5.16%	0.67%	8.91%	10.72%	7.10%
	8	3.87%	6.15%	0.67%	10.38%	12.32%	8.45%
	9	3.87%	6.48%	0.67%	10.70%	12.66%	8.74%
	10	3.99%	6.92%	0.79%	11.33%	13.34%	9.32%
	11	4.33%	7.36%	0.90%	12.17%	14.25%	10.10%
	12	4.33%	8.25%	0.90%	13.01%	15.15%	10.88%
	13	4.33%	8.58%	0.90%	13.33%	15.49%	11.17%
	14	4.33%	9.36%	0.90%	14.07%	16.28%	11.86%
	15	4.45%	9.81%	0.90%	14.60%	16.84%	12.36%
	16	4.45%	10.03%	0.90%	14.81%	17.07%	12.55%
	17	4.45%	10.43%	0.90%	15.18%	17.47%	12.90%
	18	N/A	N/A	N/A	N/A	N/A	N/A

## HIRES 90K vendor B

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
						CI Up	CI Down
ADULTS	1	1.03%	3.03%	0.00%	4.03%	4.79%	3.27%
	2	1.33%	10.84%	0.09%	12.10%	13.37%	10.84%
	3	1.65%	16.16%	0.18%	17.69%	19.17%	16.21%
	4	1.84%	20.68%	0.23%	22.31%	23.93%	20.70%
	5	1.94%	24.29%	0.28%	25.97%	27.67%	24.26%
	6	2.05%	26.73%	0.28%	28.44%	30.19%	26.68%
	7	2.16%	29.76%	0.28%	31.47%	33.28%	29.66%
	8	2.45%	31.65%	0.28%	33.51%	35.35%	31.67%
	9	2.45%	33.21%	0.28%	35.03%	36.89%	33.17%
	10	2.63%	34.70%	0.28%	36.60%	38.48%	34.72%
	11	2.63%	35.66%	0.28%	37.53%	39.42%	35.64%
	12	2.70%	36.99%	0.28%	38.86%	40.76%	36.96%
	13	2.76%	38.04%	0.28%	39.92%	41.83%	38.00%
	14	2.90%	38.83%	0.28%	40.77%	42.69%	38.85%
	15	2.96%	39.46%	0.28%	41.42%	43.35%	39.50%
	16	3.04%	39.97%	0.28%	41.96%	43.89%	40.03%
	17	3.04%	40.40%	0.28%	42.37%	44.33%	40.42%
CHILDREN	1	0.88%	3.34%	0.00%	4.19%	5.21%	3.18%
	2	1.31%	11.58%	0.07%	12.80%	14.49%	11.11%
	3	1.47%	19.87%	0.07%	21.11%	23.18%	19.04%
	4	1.56%	26.10%	0.07%	27.31%	29.57%	25.05%
	5	1.84%	30.72%	0.17%	32.11%	34.49%	29.74%
	6	2.04%	34.59%	0.17%	36.04%	38.48%	33.60%
	7	2.04%	37.85%	0.17%	39.23%	41.71%	36.75%
	8	2.27%	40.56%	0.17%	42.01%	44.52%	39.50%
	9	2.39%	42.86%	0.17%	44.32%	46.85%	41.80%
	10	2.39%	44.75%	0.17%	46.16%	48.70%	43.62%
	11	2.63%	45.87%	0.17%	47.39%	49.93%	44.85%
	12	3.02%	46.71%	0.43%	48.55%	51.09%	46.00%
	13	3.02%	48.27%	0.43%	50.05%	52.60%	47.50%
	14	3.15%	48.77%	0.57%	50.66%	53.21%	48.12%
	15	3.15%	49.69%	0.57%	51.56%	54.10%	49.01%
	16	3.15%	50.04%	0.74%	51.97%	54.52%	49.42%
	17	N/A	N/A	N/A	N/A	N/A	N/A

# CII BIONIC EAR

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
						CI Up	CI Down
ADULTS	1	0.47%	0.39%	0.03%	0.89%	1.20%	0.57%
	2	0.83%	0.42%	0.18%	1.42%	1.82%	1.02%
	3	1.07%	0.59%	0.30%	1.95%	2.42%	1.49%
	4	1.37%	0.66%	0.39%	2.40%	2.91%	1.88%
	5	1.55%	0.75%	0.42%	2.69%	3.24%	2.15%
	6	1.67%	0.90%	0.48%	3.02%	3.60%	2.44%
	7	1.79%	0.96%	0.66%	3.38%	3.99%	2.77%
	8	1.91%	1.05%	0.76%	3.67%	4.31%	3.04%
	9	2.12%	1.14%	0.82%	4.03%	4.69%	3.37%
	10	2.27%	1.20%	0.82%	4.24%	4.92%	3.56%
	11	2.36%	1.29%	0.85%	4.45%	5.14%	3.75%
	12	2.58%	1.29%	0.88%	4.68%	5.40%	3.97%
	13	2.64%	1.36%	0.88%	4.80%	5.52%	4.08%
	14	2.70%	1.45%	0.88%	4.95%	5.68%	4.22%
	15	2.82%	1.51%	0.88%	5.13%	5.88%	4.39%
	16	2.88%	1.57%	0.88%	5.25%	6.00%	4.50%
	17	2.94%	1.63%	0.88%	5.37%	6.13%	4.61%
	18	3.04%	1.67%	0.91%	5.52%	6.29%	4.75%
	19	3.11%	1.74%	0.91%	5.67%	6.45%	4.89%
	20	3.18%	1.74%	0.91%	5.74%	6.53%	4.94%
CHILDREN	1	0.47%	0.87%	0.12%	1.45%	2.01%	0.88%
	2	0.99%	1.57%	0.29%	2.84%	3.62%	2.06%
	3	1.59%	2.46%	0.35%	4.35%	5.31%	3.39%
	4	1.77%	2.93%	0.48%	5.10%	6.14%	4.07%
	5	2.13%	3.47%	0.78%	6.27%	7.41%	5.12%
	6	2.44%	4.25%	1.09%	7.61%	8.86%	6.35%
	7	2.56%	4.80%	1.22%	8.36%	9.67%	7.06%
	8	2.69%	5.22%	1.53%	9.18%	10.54%	7.81%
	9	2.87%	5.65%	1.66%	9.88%	11.29%	8.47%
	10	3.06%	6.08%	1.66%	10.46%	11.91%	9.02%
	11	3.19%	6.20%	1.85%	10.87%	12.34%	9.40%
	12	3.51%	6.38%	1.92%	11.40%	12.90%	9.89%
	13	3.82%	6.51%	1.98%	11.86%	13.39%	10.33%
	14	4.02%	6.75%	2.05%	12.33%	13.88%	10.78%
	15	4.08%	6.82%	2.05%	12.45%	14.01%	10.89%
	16	4.21%	6.88%	2.11%	12.68%	14.25%	11.11%
	17	4.53%	6.88%	2.24%	13.09%	14.69%	11.50%
	18	4.60%	7.01%	2.31%	13.34%	14.95%	11.73%
	19	5.04%	7.10%	2.31%	13.83%	15.47%	12.18%
	20	5.20%	7.10%	2.47%	14.11%	15.79%	12.42%



# CLARION 1.2

	Year	Medical CRP	Device CRP	Inconclusive CRP	Total All Categories	Total	
						CI Up	CI Down
ADULTS	1	0.40%	0.30%	0.14%	0.85%	1.10%	0.59%
	2	0.55%	0.65%	0.26%	1.45%	1.79%	1.12%
	3	0.75%	1.38%	0.41%	2.53%	2.96%	2.09%
	4	0.94%	2.51%	0.60%	4.00%	4.55%	3.46%
	5	1.15%	3.79%	0.74%	5.61%	6.25%	4.96%
	6	1.41%	4.83%	0.83%	6.94%	7.65%	6.23%
	7	1.51%	5.72%	0.92%	8.00%	8.76%	7.24%
	8	1.71%	6.91%	1.05%	9.46%	10.28%	8.64%
	9	1.84%	7.62%	1.20%	10.42%	11.27%	9.56%
	10	2.09%	8.57%	1.41%	11.74%	12.64%	10.84%
	11	2.27%	9.31%	1.50%	12.70%	13.63%	11.77%
	12	2.55%	9.82%	1.71%	13.62%	14.57%	12.66%
	13	2.76%	10.31%	1.75%	14.31%	15.29%	13.33%
	14	2.94%	10.69%	1.85%	14.92%	15.92%	13.93%
	15	3.22%	11.12%	1.92%	15.64%	16.65%	14.62%
	16	3.58%	11.51%	1.99%	16.38%	17.41%	15.34%
	17	4.03%	11.93%	2.06%	17.22%	18.27%	16.16%
	18	4.79%	12.28%	2.09%	18.23%	19.31%	17.15%
	19	5.28%	12.57%	2.19%	19.00%	20.10%	17.91%
	20	5.89%	12.78%	2.29%	19.80%	20.92%	18.68%
	21	6.42%	12.94%	2.38%	20.46%	21.60%	19.33%
	22	6.74%	13.11%	2.46%	20.95%	22.10%	19.80%
	23	7.57%	13.21%	2.46%	21.75%	22.95%	20.55%
	24	8.04%	13.39%	2.46%	22.31%	23.57%	21.05%
	25	N/A	N/A	N/A	N/A	N/A	N/A
CHILDREN	1	0.29%	1.90%	0.11%	2.30%	2.79%	1.80%
	2	0.43%	3.42%	0.20%	4.03%	4.68%	3.38%
	3	0.58%	5.89%	0.41%	6.82%	7.65%	5.99%
	4	0.80%	8.45%	0.57%	9.70%	10.68%	8.72%
	5	0.96%	10.72%	0.98%	12.44%	13.53%	11.35%
	6	1.32%	13.29%	1.28%	15.53%	16.73%	14.33%
	7	1.66%	15.18%	1.55%	17.88%	19.15%	16.61%
	8	1.94%	17.36%	1.90%	20.50%	21.83%	19.16%
	9	2.30%	18.71%	2.36%	22.45%	23.83%	21.07%
	10	2.52%	20.37%	2.91%	24.64%	26.07%	23.21%
	11	2.78%	21.51%	3.33%	26.23%	27.69%	24.77%
	12	3.01%	22.19%	3.59%	27.24%	28.72%	25.76%
	13	3.32%	22.84%	3.86%	28.28%	29.78%	26.79%
	14	3.67%	23.46%	3.98%	29.21%	30.72%	27.70%
	15	4.19%	24.63%	4.22%	30.84%	32.37%	29.30%
	16	4.92%	25.49%	4.55%	32.38%	33.93%	30.82%
	17	5.50%	26.23%	5.00%	33.78%	35.35%	32.21%
	18	6.60%	26.86%	5.30%	35.31%	36.89%	33.72%
	19	7.86%	27.34%	5.48%	36.72%	38.33%	35.12%
	20	9.22%	27.71%	5.67%	38.10%	39.72%	36.48%
	21	10.08%	28.14%	5.90%	39.19%	40.83%	37.55%
	22	11.20%	28.64%	6.12%	40.51%	42.19%	38.84%
	23	11.95%	28.82%	6.23%	41.23%	42.94%	39.51%
	24	13.03%	29.26%	6.42%	42.43%	44.26%	40.60%
	25	N/A	N/A	N/A	N/A	N/A	N/A

## CONTACT US

This report is intended to provide both professionals and our CI wearers with relevant information on the reliability of our products. If you have any questions, please contact us by emailing [hear@AdvancedBionics.com](mailto:hear@AdvancedBionics.com) or visit [AdvancedBionics.com](https://www.AdvancedBionics.com) for more general information.



🏢 ADVANCED BIONICS LLC – 28515 Westinghouse Place - Valencia, CA 91355, United States  
T: +1.877.829.0026 - T: +1.661.362.1400 - F: +1.661.362.1500 [info.us@advancedbionics.com](mailto:info.us@advancedbionics.com)

EC	REP
----	-----

 ADVANCED BIONICS GMBH - Feodor-Lynen-Strasse 35 – 30625 Hannover, Germany

For information on additional AB locations, please visit [advancedbionics.com/contact](https://advancedbionics.com/contact)

Advanced Bionics - A Sonova brand

Please contact your local AB representative for regulatory approval and availability in your region.