the direct system℠

Package Contents

Implant Assembly Set

CONTENTS STERILE
SINGLE USE ONLY
NON-PYROGENIC
DO NOT RESTERILIZE

Device Description

The SOUNDTEC® Direct System℠ is an electromagnetic, partially implanted, middle ear hearing device. The system consists of a permanent ossicular implant magnet, an external analog sound processor (in a behind-the-ear case), and an electromagnetic Earmold Coil Assembly that is worn in the external ear canal. The device is provided with specialized surgical instruments for the proper insertion and placement of the implant.

Indications for Use

The SOUNDTEC® Direct System℠ is indicated for use in adults, 18 years of age or older, who have a moderate to severe sensorineural hearing loss and desire an alternative to an acoustic hearing aid. Prior to receiving the device, it is recommended that an individual have experience with appropriately fit hearing aids.

Contraindications

The SOUNDTEC® Direct System℠ is contraindicated for subjects who have conductive hearing loss, retrochchlear or central auditory disorder, active middle ear infections, tympanic membrane perforations associated with recurrent middle ear infections, and disabling tinnitus.

Warnings Related to the Implant

1. Magnetic Resonance Imaging (MRI): Subjects implanted with the SOUNDTEC® Direct System℠ should not be subjected to MRI, and should not enter an MRI Suite or come into close proximity to other sources of strong magnetic fields.

2. Electrosurgery: Electrosurgical instruments are capable of producing radio frequency voltages that can directly couple the instrument tip and the implant. Monopolar electrosurgical instruments must not be used within the vicinity of the implant because the induced currents could cause damage to the implant or the subject's hearing.

3. Diathermy: Diathermy must never be applied over the implant because the high currents induced into the implant could cause damage to the implant or the subject's hearing.

4. Electroconvulsive therapy:
Electroconvulsive therapy must never be used on a subject with a SOUNDTEC® hearing implant because it may damage the implant or the subject's hearing.

5. The effect of cobalt treatment, PET scans, transcranial diagnostic ultrasound, and linear acceleration techniques on the implant are unknown.

Precautions Related to the Deep Earmold Impression Procedure

Proper fitting of this hearing device requires the taking of deep-canal impressions. Hearing health professionals should not attempt this type of fitting unless they have completed the SOUNDTEC®, Inc. training course and developed the necessary skills needed to safely make this type of impression. Only the impression material supplied by SOUNDTEC®, Inc. should be used for deep peritympanic impressions.

Precautions Related to the Sound Processor and Earmold Coil Assembly

1) Do not allow others to tamper with or wear any part of the Direct System℠. Each system is individually prescribed and use by others could result in bodily injury or damage to the device.

2) Do not swallow any part of the Direct System℠ or use in any manner other than that described in this manual. Doing so can result in illness, injury, or damage to the device.

3) Do not wear the Earmold Coil Assembly (ECA) when engaging in contact sports of any kind. This could result in damage to the ear canal and/or eardrum, as well as damage the device.

4) Do not get the SOUNDTEC® Direct System℠ wet. Doing so could cause intermittent performance or damage the device beyond repair. If the device does get wet, remove the battery and store the device in the dehumidifier overnight, leaving the battery door open. If the device still malfunctions, notify your Center.

5) Do not use hair care products, such as hairspray or gel, while wearing your Direct System℠. This may damage the device.

6) Do not allow any part of the device to be exposed to excessive heat, such as direct sunlight, blow dryer, or flame, or leave on the dashboard or inside of a car. Contact with a hot device may cause minor skin irritation or burns. Heat may also damage the device beyond repair.

7) Do not attempt to open the Sound Processor except to remove the battery. Exposing or tampering with the internal controls could seriously alter the device performance and output. Only trained professionals at your Center should make adjustments to the internal controls. Notify your Center if you feel adjustments are needed.

8) Do not ingest batteries; batteries are harmful if swallowed. The button cell batteries used to power the Direct System℠ are small and could be easily swallowed. Keep them away from children, pets, or anyone who might not understand the dangers associated with swallowing batteries.

In case a battery is swallowed, immediately contact:

National Button Battery Hotline
1-202-625-3333

or your local physician.

Instructions For Use

BTE Sound Processor (P/N 300-0042-001) — The BTE is shipped non-sterile. Patients should refer to the SOUNDTEC® *Direct System℠ User's Guide* for specific instructions for use.

ECA (P/N 300-0057-001) – The ECA is shipped non-sterile. Patients should refer to the SOUNDTEC® *Direct System℠ User's Guide* for specific instructions for use.

Implant (P/N 300-0038-001 Left & 300-0039-001 Right) – The implant is a single use device, shipped sterile and Non-Pyrogenic. Surgeons should refer to the SOUNDTEC® Direct System℠ Surgeon's Manual for specific instructions for use.

Surgeon's Set (P/N 300-0046-001) – The Surgeon's Set is shipped non-sterile. Instruments should be sterilized prior to use. Surgeons should refer to the SOUNDTEC® Direct System℠ Surgeon's Manual for specific instructions for use.

Clinician's Set (P/N 300-0021-001) – Clinicians should refer to the SOUNDTEC® *Direct System℠ Clinician's Guide* for specific instructions for use.

Test Coupler Set (P/N 300-0066-001) – Clinicians should refer to the SOUNDTEC® *Direct System℠ Clinician's Guide* for specific instructions for use.

Search Coil Set (P/N 300-0067-001) – Clinicians should refer to the SOUNDTEC® *Direct System℠ Surgeon's Manual* for specific instructions for use.

CLINICAL CONSIDERATIONS

Evaluation procedures should include standard audiometric measures including air and bone-conduction thresholds, immittance measures, speech recognition, and hearing aid evaluation. Additionally, qualitative (subjective) questionnaires may help to determine if a candidate's lack of perceived benefit with an acoustic hearing aid may be addressed with an implantable middle ear hearing device. Care should be taken to ensure that the patient's perceived lack of benefit from the hearing aid(s) is not attributable to poor fit or lack of function.

The ear selected for implantation of the Direct System℠ should be equal to or worse than the non-implant ear.

The safety and effectiveness of bilateral implantation and implantation in pregnant women, nursing mothers, children, or those with unilateral hearing impairment has not been established.

Adverse Events

Summarized in Table 1 are the adverse events reported on a total of 103 subjects reported as of April 4, 2001.

Four (4) subjects were reported as having serious adverse events, all of which were determined by a physician to be "definitely" unrelated to the device. The events included a cardiovascular disorder, carcinoma, and two (2) deaths.

Table 1. Adverse Events Reported
(n=103 Subjects)

Description	No. Reported	No. Resolved
Abnormal Ear Sensation[1]	1	1
Device Noise/Electromagnetic Interference[2]	15	12
Ear Disorder[3]	1	1
Ear Mold Assembly Failure[4]	7	7
Ear Pain[5]	30	26
Increased Hearing Loss[6]	1	0
Hematoma Ear[7]	9	9
Infection[8]	4	4
Outer Ear Irritation[9]	14	14
Paresthesia[10]	1	1
Processor Failure[11]	13	12
Skin Irritation[12]	3	3
Taste Perversion[13]	3	2
Tinnitus[14]	1	0
Transient Balance Involvement[15]	5	5

[1] Investigator reported abnormal ear sensation consisting of fullness; event resolved during the normal healing period after implant.
[2] Engineering analysis determined these events to be associated with the Printed Circuit Board (PCB) assembly operation. The operation has been modified and validated. Low levels of EMI have been found to be dependent upon the location and strength of the electromagnetic source.
Three events reported as unresolved were due to their intermittent nature and will be monitored by the investigator at the subjects' next visits.
[3] Investigator reported middle ear effusion; event resolved during the normal healing period after implant.
[4] Engineering analysis of the ECAs resulted in improved manufacturing processes and controls that have been implemented to eliminate systematic failures.
[5] These events were related to the operative procedure or to the ECA fitting. In most of the cases these events resolved through longer healing periods post-implant or through ECA modifications. The investigator is continuing to monitor the 2 subjects whose events were reported as unresolved.
[6] Audiological data indicated that the hearing loss appears to be conductive. Investigator reported that he will continue to monitor the subject.
[7] Each of the reported hematomas resolved through normal healing.
[8] The infections also included Otitis Media (2) and Otitis Externa (2). Each of the reported events resolved through otologic management.
[9] Outer ear irritation consisted of ear irritation (7), ear canal abrasion (2), ear edema (2), ear inflammation (2), and ear abrasion external (1).
[10] The investigator reported this event as a transient neurological effect.
[11] Processor failures were determined to be associated with the PCB assembly operation. The operation has been modified and validated. Analysis of the unresolved processor failure was in-process at the submission of this data.
[12] Several observations of skin irritation were reported, including Eczema (2) and Pruritis (1). The investigators noted that each event was resolved.
[13] Taste perversion can be related to the severing or irritation of the chorda tympani nerve during the implantation procedure. Resolution occurred spontaneously without treatment or surgical intervention. One case remains unresolved and will be monitored by the investigator.
[14] Subject medical records noted a past history of tinnitus. This case will be monitored by the investigator.
[15] Transient balance involvement comprised of reports of dizziness (1), nausea (1), vertigo (2), and vomiting (1). Each event resolved spontaneously.
[16] Four reported events were resolved through surgical intervention and one event resolved without intervention. One event is not resolved and the investigator is monitoring the subject.

(Non-serious adverse events unrelated to the device are not included in Table 1. These events consisted of: Unconfirmed ECA/Sound Processor failures (16), broken ECAs due to user abuse, improper use, or adjustments that damaged the device (7), tooth disorder (1), and infection in the non-implant ear (1)).

Potential Adverse Events

Surgery of the middle ear requires manipulation of the ossicular bones (malleus, incus, and stapes) and exposes the inner ear to the risk of surgical trauma. Serious complications may arise either during or after surgery that may include, but are not limited to: sensorineural or conductive deafness due to trauma during surgery; granular inflammatory lesions; device displacement after surgery due to development of scar tissue; damage to the incus; non-functioning implant; and infection after surgery. Additional surgery may be required to correct these conditions, if possible.

There may also be nu[illegible]welling or discomfort around the ear, the pos[illegible]of facial paresis, and/or the disturbance of balance or taste, but they are usually transient and resolve within a few weeks after surgery.

Implant Device Failures and Replacements

There were no implant device failures, revisions or replacements reported in this study. Some failures of the external Sound Processor and Earmold Coil Assembly were noted and analyzed. Improved manufacturing processes and controls have been implemented to eliminate systematic failures.

Clinical Study Summary

One hundred-three (103) subjects underwent the implant procedure with the SOUNDTEC® Direct System℠. The following clinical study summary is based on ninety-five (95) subjects who had completed 20-week assessments. The assessment compared preoperative results with an optimally fit acoustic hearing aid in the ear to be implanted to post operative results with the SOUNDTEC® Direct System℠. "Optimally fit" as defined by the clinical study included insertion gain matching using National Acoustic Laboratories-Revised (NAL-R) prescriptive target ranges (±5 dB for 500, 1000, and 2000 Hz and ± 12 dB for 3000 and 4000 Hz) and evidence of improvement in aided benefit.

Subjects were tested to find hearing thresholds, sound field thresholds, speech testing in quiet and noise, aided benefit, and subject perceptions.

All items showing improvements were determined to be statistically significant. For more detailed information about the SOUNDTEC Direct Drive Hearing System (DDHS) / Direct System℠ please refer to the Clinical Study Results.

1. For most subjects, the change in residual hearing was not significant. Average decrease in air conduction thresholds at 20 weeks was 4.2 dB across the frequency range of 250 to 8000 Hz. Average bone conduction thresholds decreased by 1.1 dB. Few subjects (10/95 or 10.5%) had greater than 10 dB of change by air conduction. Few subjects (4/95 or 4%) had greater than 10 dB of change by bone conduction.

2. There was an average increase in functional gain of 7.9 dB with the DDHS compared to their acoustic hearing aid. For the high frequencies of 2000, 3000, and 4000 Hz, there was an average increase in functional gain of 9.6 dB.

3. The Articulation Index score results showed an improvement of 11.9% with the DDHS. The Direct System℠ shows an improved audibility over acoustic hearing aids.

4. Speech recognition in quiet showed a 5.3% improvement with the DDHS when compared with the subjects' acoustic hearing aids.

5. Speech testing in noise results with the Speech Perception in Noise (SPIN) test showed no difference between the Direct System℠ and acoustic hearing aids.

6. The Abbreviated Profile of Hearing Aid Benefit (APHAB) scores showed an improvement of approximately 20% across three different sub-scales with the DDHS when compared to acoustic hearing aids.

7. When subjects compared their pre-implant acoustic hearing aid with the DDHS in the Hough Ear Institute Profile* (HEIP) test, the results showed that:
   a. Out of 94 subjects responding, 84 of those subjects (89%) preferred the DDHS in terms of overall satisfaction.
   b. Sixty-three of 94 subjects (67%) reported feedback with their acoustic hearing aids. Eight of 94 subjects (8.5%) reported feedback with the DDHS. Out of 94 subjects responding, 93 of them (99%) preferred the DDHS as having the least amount of feedback.
   c. Fifty of 92 subjects (54%) reported occlusion with their acoustic hearing aids. 21 of 92 subjects (23%) reported occlusion with the DDHS.
   d. Out of 94 subjects responding, 84 of those subjects (89%) responded that they preferred the DDHS over their acoustic hearing aids in the areas of sound quality.
   e. Twenty-one of 41 (51%) subjects reporting tinnitus pre-implant reported that their hearing aid decreased their perception of tinnitus.

   Twenty of 30 (67%) subjects reporting tinnitus post-implant reported that the Direct System℠ decreased their perception of tinnitus.

*HEIP is a validated but not standardized questionnaire addressing the subjects' perception of the presence of tinnitus, feedback, and occlusion as well as sound quality judgments and device preference.

Clinical Study Results

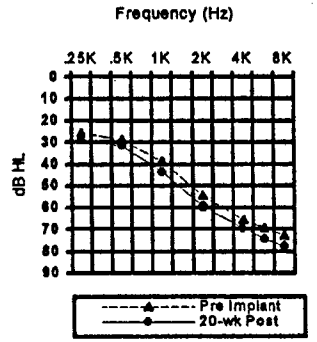
One hundred-three (103) subjects underwent the implant procedure with the SOUNDTEC® Direct System℠ implant. The following clinical study summary is based on ninety-five (95) subjects who had completed 20-week assessments. The assessment compared preoperative results with an optimally fit acoustic hearing aid in the ear to be implanted to post operative results with the SOUNDTEC® Direct System℠. "Optimally fit" as defined by the clinical study included insertion gain matching using National Acoustic Laboratories-Revised (NAL-R) prescriptive target ranges (±5 dB for 500, 1000, and 2000 Hz and ± 12 dB for 3000 and 4000 Hz) and evidence of improvement in aided benefit.

Subjects were tested to find hearing thresholds, sound field thresholds, speech testing in quiet and noise, aided benefit, and subject perceptions.

1. Residual Hearing

For most subjects (85 of 95 or 89.5%), residual hearing with the Direct System℠ was not significantly affected. Average decrease in air conduction thresholds at 20 weeks was 4.2 dB across the frequency range of 250 to 8000 Hz. Average bone conduction thresholds decreased by 1.1 dB. Few subjects (10 of 95 or 10.5%) had greater than 10 dB of change. Eight of 95 subjects (8%) experienced a change between 10 to 15 dB in hearing thresholds and 2 of 95 subjects (2%) experienced a change greater than 15 dB.
Refer to Figure 1.

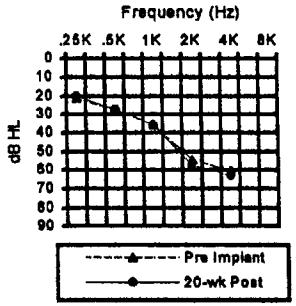
Figure 1
Air Conduction Thresholds



Bone Conduction Thresholds

Figure 2 shows the bone conduction thresholds over the audiometric frequency range (250-4000 Hz) for the pre-implant and 20 week post-implant conditions. The average changes across these frequencies post-implant compared to the pre-implant condition are 1.1 dB. Most subjects (91 of 95 or 96%) showed less than an average of 10 dB of change in bone conduction thresholds. Few (4 of 95 or 4%) showed an average decrease between 10-15 dB of change. No subjects showed greater than 15 dB of change for bone conduction thresholds.

Figure 2
Bone Conduction Thresholds



2. Increased Functional Gain and Aided Thresholds

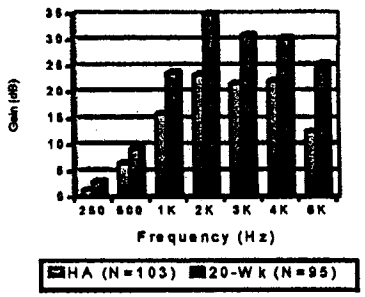
The SOUNDTEC® DDHS provided 7.9 dB additional functional gain when comparing the subject's acoustic hearing aid performance to that of the SOUNDTEC® Direct System℠ at the 20 week assessment. The DDHS demonstrated a statistically significant improvement in averaged aided sound field thresholds and functional gain from 500 – 4000 Hz.

At 36 and 52 weeks, the additional functional gain was 7.9 dB and 7.0 dB, respectively.

All three (3) time points, showed a statistically significant gain in average functional gain (each p-value < 0.05, Paired t-test).

Refer to Figure 3.

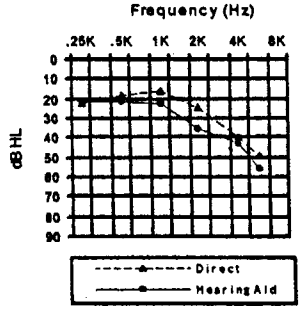
Figure 3
Functional Gain
for HA and 20-Wk Post-Implant



Additional functional gain is needed to compensate for the residual hearing threshold change. Aided thresholds are improved with the Direct System℠ regardless of the decrease in residual hearing. Individual results will vary.

Figure 4 shows aided thresholds comparing the DDHS to the acoustic hearing aid.

Figure 4
Aided Thresholds in Sound Field
25% Average Improvement for 500-4000 Hz



A similar analysis was performed for the high frequency average of 2000, 3000 and 4000 Hz (referred to in the protocol as the High Frequency Warble Tone Average-HFWTA of functional gain). The average improvement in the high frequency range at 20 weeks compared to performance with an acoustic hearing aid is 9.6 dB.

At 36 and 52 weeks, the average improvement in HFWTA is 9.2 dB and 10.8 dB, respectively.

At each of the three (3) time points, the improvement from performance with an acoustic hearing aid achieved

statistical significance -value < 0.05, Paired t-test).

3. Change in Articulation Index

A secondary outcome measuring audibility is the Articulation Index (AI) and was assessed at pre-implant and 20 weeks. The AI was used to calculate the level of audibility based on aided hearing thresholds. The average improvement in Articulation Index scores comparing performance with the DDHS to the acoustic hearing aid was 11.9%. The improvement was statistically significant (p-value < 0.05, Paired t-test).

4. Speech Perception Results

There are two (2) additional secondary efficacy measures of performance using audiometric speech tests. These consist of the NU-6 (50-item word list) and the Speech Perception in Noise (SPIN) test. Tables 2 and 3 show the results on the aided NU-6 test and the SPIN (aided, low predictability sentences-raw scores) test. The results indicate average improvements with the DDHS on the NU-6 performance of 5.3%, 5.0%, and 12.2% across the 20, 36, and 52-week assessments, respectively. The NU-6 improvement from the acoustic hearing aid to the DDHS was statistically significant at the 20 and 52-week follow-ups. On average, SPIN scores were similar pre-implant and post-implant at the 20 and 36 week assessments.

Table 2 - Summary of NU-6 Aided Word Test (mean±SD)

	NU-6 (% Correct)	Paired t-test p-value
Acoustic HA (N=103) Optimally Fit Hearing Aid	76.8±16.6	N/A
20 Weeks (N=95) DDHS	82.1±11.9	N/A
Improvement	5.3±16.6	0.0026 *
36 Weeks (N=33) DDHS	83.8±10.3	N/A
Improvement	5.0±15.4	0.0700
52 Weeks (N=12) DDHS	86.7±9.9	N/A
Improvement	12.2±12.6	0.0066 *

* Statistically Significant (Paired t-test, p-value < 0.05)

Reference: Clinical Report

The average change in SPIN aided, low predictability sentences at 20 weeks was –0.1 words. For the 36 and 52-week follow-ups, the average improvements were 0.1 words and 4.2 words. The SPIN improvement from the acoustic hearing aid to the 52-week follow-up was statistically significant (p-value = 0.0135, Paired t-test).

Table 3 - Summary of SPIN Aided, Low Predictability Test (mean±SD)

	SPIN Aided, Low Predictability (# Correct out of 20)	Paired t-test p-value
Acoustic HA (N=102) Optimally Fit Hearing Aid	9.8±5.4	N/A
20 Weeks (N=95) SOUNDTEC™ DDHS	10.0±5.0	N/A
Improvement	-0.1±5.9	0.8743
36 Weeks (N=22) SOUNDTEC™ DDHS	9.9±5.9	N/A
Improvement	0.1±8.2	0.9664
52 Weeks (N=12) SOUNDTEC™ DDHS	12.2±8.2	N/A
Improvement	4.2±5.0	0.0135 *

* Statistically Significant

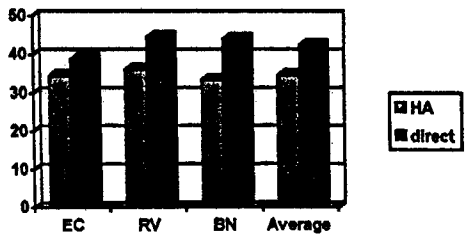
Reference: Clinical Report

6. Improvements in Perceived Aided Benefit in Various Listening Situations

The Abbreviated Profile of Hearing Aid Benefit (APHAB) is a questionnaire used to assess the subject's perceived performance benefit in three areas: Ease of Communication (EC), Reverberation (RV), and Background Noise (BN). These were reported at pre-implant using the subject's acoustic hearing aid and at 20 weeks using the SOUNDTEC® DDHS. On average, the hearing aid condition provided a score of 34.7 points of aided benefit and the DDHS 20 week condition provided a score of 42.2 points of aided benefit for the three subscales. While individual results varied, the average improvement across the three subscales is 7.2 ±19.9 points of improvement of aided benefit which is statistically significant.

Figure 5 shows the comparison between acoustic hearing aids and the Direct System℠ for each of the three areas.

Figure 5
Aided Benefit (APHAB)



7. Reduction in Feedback, Occlusion, and Distortion

A second questionnaire, the Hough Ear Institute Profile (HEIP), was used to examine the following areas: satisfaction, acoustic feedback, perception of speech quality, occlusion, and tinnitus. The 20 Week HEIP results with the SOUNDTEC® DDHS were compared to the subject's acoustic hearing aid values in 94 subjects (one subject of 95 completed all testing except the HEIP due to an error in test administration). All of these results were found to be statistically significant.

- Out of 94 subjects responding, 84 of those subjects (89%) preferred the DDHS in terms of overall satisfaction. Satisfaction was measured by a four point scale with four being very satisfied and one being not at all satisfied. Using this scoring method, satisfaction with the DDHS increased by an average of 30.8% (median = 16.7%) from the subject's acoustic hearing aid (p-value < 0.0001, Paired t-test).
- Sixty-three of 94 subjects (67%) reported having feedback with their acoustic hearing aid. At 20 weeks, only 8 (9%) subjects reported feedback using the SOUNDTEC® DDHS (p-value < 0.0001, McNemar's Test).
  Out of 94 subjects responding, 93 subjects (99%) preferred the DDHS as having the least amount of feedback.
- Subject Perceived Quality of Speech was rated on a 7-point scale. The mean percentage increase relative to the subject's optimally fit hearing aid equaled 27.8% (median = 19.2%) for the SOUNDTEC® DDHS (p-value< 0.0001, Paired t-test).
- Out of 94 subjects responding, 84 of those subjects (89%) responded that they preferred the DDHS over their acoustic hearing aids in the area of sound quality.
- Fifty of 92 subjects (54%) reported occlusion with their acoustic hearing aids. 21 of 92 subjects (23%) reported occlusion with the DDHS using the SOUNDTEC® DDHS (p-value < 0.0001, McNemar's Test). (Two of 94 subjects did not respond to the question concerning occlusion).
- Twenty-one of 41 (51%) subjects reporting tinnitus pre-implant reported that their hearing aid decreased their perception of tinnitus.

  Twenty of 30 (67%) subjects reporting tinnitus post-implant reported that the Direct System℠ decreased their perception of tinnitus.

STORAGE, HANDLING AND STERILIZATION

Store the Direct System℠ at a temperature not exceeding 50° C (122° F). An expiration date is printed on the device packaging. Expired product should be returned to SOUNDTEC®, Inc. The Sound Processor and Earmold Coil Assembly are not subject to aging.

Handle the Direct System℠ package with care. Damage to the outer storage package may rupture the inner sterile tray.

The Direct System℠ implant is supplied sterile. Before opening, inspect the sterile package for integrity and to ensure the seal is not broken. If the package or seal is damaged return the device to SOUNDTEC®, Inc.

This device is intended for single subject use only. Do not reuse or sterilize.

INFORMATION FOR USE AND RECOMMENDED TRAINING

Surgeons should be experienced in middle ear surgery including stapedectomy. It is recommended that surgeons receive specific training regarding the deep ear impression procedure and implantation technique of the Direct System℠. It is strongly recommended that a surgeon work closely with an audiologist when selecting candidates to be implanted and during the post-operative management of subjects. Surgeons should refer to the Direct System's Surgeon's Manual for specific instruction for use.

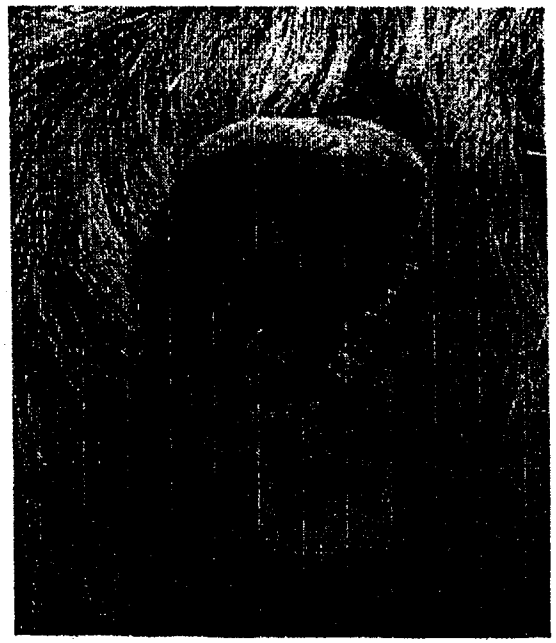
If you have any questions, contact our Customer Service Department at:
1-800-793-9587

SOUNDTEC®, Inc.
2601 NW Expressway, Suite 400 W
Oklahoma City, OK 73112

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

the direct system℠

USER GUIDE



SOUNDTEC inc.

2601 NW Expressway
Suite 400 W
Oklahoma City, Oklahoma 73112

(405) 842-5045 or 1-800-793-9587

www.soundtecinc.com

P/N 403-0005-001 Rev. A 04/01

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CAUTION:

FEDERAL (U.S.) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Read all directions in this guide before using the *SOUNDTEC*® Direct System℠. Contact your hearing care professional if you have any questions or concerns about your Direct System℠.

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Contacts for information and assistance:

Doctor: _____ **Tel. No.:** _____

Center: _____ **Tel. No.:** _____

Other: _____ **Tel. No.:** _____

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FOR CLINICAL STUDY INFORMATION, PLEASE REFER TO THE PATIENT INFORMATION GUIDE.

USER GUIDE
Table of Contents

HOW DOES THE DIRECT SYSTEM℠ WORK?

The SOUNDTEC® Direct System℠ works with a magnetic implant attached to the ossicular bones in your middle ear. The two bones used in the process are called the incus and the stapes. After the implant surgery is performed, you will receive the Earmold Coil Assembly (ECA) and the Sound Processor. These components complete your SOUNDTEC® Direct System℠.

The Sound Processor receives sound, amplifies it, and sends electrical signals to the ECA. The electromagnetic coil at the tip of the ECA changes the sounds to electromagnetic signals, which cause the implant to vibrate. These vibrations travel through the cochlea, stimulating the hair cells and nerves that send impulses to the brain that are interpreted as sound.

IS THE DIRECT SYSTEM℠ RIGHT FOR ME?
INDICATIONS/CONTRAINDICATIONS

The SOUNDTEC® Direct System is indicated for use in adults, 18 years of age or older, who have a moderate to severe sensorineural hearing loss and desire an alternative to an acoustic hearing aid.

Prior to receiving the device, it is recommended that an individual have experience with appropriately fit hearing aids.

The SOUNDTEC® Direct System℠ is contraindicated for subjects who have:

- Conductive hearing loss
- Retrocochlear or central auditory disorder (brain stem disorder)
- Active middle ear infections
- Tympanic membrane (ear drum) perforations associated with recurrent middle ear infections
- Disabling tinnitus (ringing in the ear)

Your doctor or audiologist/hearing instrument specialist will perform several audiometric tests and a medical examination to determine whether you are a candidate for the Direct System℠.

TROUBLESHOOTING

Problem	Possible Cause	Remedy
No sound	• Sound processor not turned on	• Find On/Off switch on Sound Processor. Move to "T" or "M".
	• Battery low or dead	• Replace battery.
	• Volume turned down on Sound Processor	• Find volume control on Sound Processor. Turn to higher number.
	• Sound Processor not tightly connected to ECA	• Check to make sure the ECA and Sound Processor are tightly joined at the connector cable.
Weak or distorted sound	• Battery low	• Replace battery.
	• Device needs internal adjustments	• Do not try to adjust the internal controls of the device yourself. Contact your hearing health care professional.
Loud sounds uncomfortable	• Volume too high	• Locate the volume on the Sound Processor and turn to lower number.
	• Device needs internal adjustments	• Do not try to adjust the internal controls of the device yourself. Contact your hearing health care professional.
Intermittent performance/ Sound "breaking up"	• Battery low	• Replace battery
	• Moisture in the device	• Remove battery and place in dehumidifier for a minimum of 4 hours.
	• Device needs internal adjustments	• Do not try to adjust the internal controls of the device yourself. Contact your hearing health care professional.
Damage to the outside of the ECA or Sound Processor	• Device was dropped or mishandled • ECA or Sound Processor broken	• Contact your hearing health care professional for repair or replacement.

The Sound Processor and Earmold/Coil Assembly should be removed before you go to bed. Open battery compartment door when the Sound Processor is not in use in order to preserve battery life and allow moisture to evaporate.

The deep fit of the ECA may cause some initial discomfort. You may need to wear your ECA for a limited amount of time and slowly increase wearing time as you become accustomed to it. Please follow the instructions given by your hearing health care professional. You will be provided with a wearing schedule similar to the sample on the following page to assist you in getting used to the device.

SAMPLE ECA WEARING SCHEDULE:

Days 1 & 2	A one-hour period two times during the day
Days 3 & 4	A two-hour period two times during the day
Days 5 & 6	A four-hour period once during the day
Days 7 & 8	A four-hour period two times during the day
Days 9 & 10	An eight-hour period once during the day
Days 11 & future	Amount of time as desired

If the ECA is not comfortable after 2 weeks of wearing it, contact your hearing health care professional.

NOTICE:
If your ear becomes sore, stop using the ECA for five days. Then, try the wearing schedule again. If your ear becomes sore again or if any draining or bleeding occurs, stop using the ECA and contact your hearing care professional.

WARNINGS AND PRECAUTIONS

The SOUNDTEC® Direct System℠ is proven safe and effective if used and cared for responsibly. The following warnings and precautions should be noted to avoid potential harm to yourself and damage to the device.

Warnings:

Inform your physician that you are implanted with the Direct System℠ before having the following medical or surgical procedures:

- ***Magnetic Resonance Imaging (MRI) examinations***
  Patients implanted with the SOUNDTEC® Direct System℠ should not undergo an MRI examination, enter a room where MRI exams are performed, or get close to other strong magnetic fields. The effects of these exams on the implant are unknown. If an MRI is necessary, the implant should be removed and re-implanted after the exam.

- ***Diathermy and Electroconvulsive Therapy***
  The effects of diathermy and electroconvulsive therapy on the Direct System℠ implant are unknown. You should inform your physician of your implant and consult about any possible risks before undergoing these procedures.

- ***Cobalt treatment, PET scans, transcranial diagnostic ultra sound, or linear acceleration techniques***
  The effect of cobalt treatment, PET scans, transcranial diagnostic ultrasound, and linear acceleration techniques on the implant are unknown. Before undergoing any of these procedures, Direct System℠ users should consult their physicians about the potential risks.

PRECAUTIONS

Do not allow others to tamper with or wear any part of the Direct System℠.
Each system is individually prescribed and use by others could result in bodily injury or damage to the device.

Do not swallow any part of the Direct System℠ or use in any manner other than that described in this manual.
Doing so can result in illness, injury, or damage to the device.

Do not wear the Earmold Coil Assembly (ECA) when engaging in contact sports of any kind.
This could result in damage to the ear canal and/or ear drum, as well as damage the device.

Do not get the SOUNDTEC® Direct System℠ wet.
Doing so could cause intermittent performance or damage the device beyond repair. If the device does get wet, remove the battery and store the device in the dehumidifier overnight, leaving the battery door open. If the device still malfunctions, notify your hearing care professional.

Do not allow any part of the device to be exposed to excessive heat, such as direct sunlight, blow dryer, or flame, or leave on the dashboard or inside of a car.
Contact with a hot device may cause minor skin irritation or burns. Heat may also damage the device beyond repair.

Do not use hair care products, such as hairspray or gel, while wearing your Direct System℠.
This may damage the device.

Do not attempt to open the Sound Processor except to remove the battery.
Exposing or tampering with the internal controls could seriously alter the device performance and output. Only hearing care professionals should make adjustments to the internal controls.

CLEANING THE Direct System℠

CLEANING THE ECA

Clean the tip of the ECA every evening with a disinfectant/cleaning solution. A disinfectant solution is provided in your set and is also available from your hearing health care professional's office. Other acceptable disinfectants include rubbing alcohol. Dampen a cloth or tissue with the disinfectant/cleaning solution and swab the ECA canal tip. Dry the tip with a dry cloth or tissue and be sure it is very dry before putting the ECA into your ear. Do not soak the Sound Processor or ECA in cleaning solution or any other liquids because that may harm your device.

CLEANING THE SOUND PROCESSOR

The Sound Processor does not require any special cleaning. Periodically wipe it with a clean *dry* cloth or tissue.

COMFORT AND WEARING SCHEDULE

Your SOUNDTEC® Direct System℠ allows you to use the telephone by placing the receiver over the microphone on the top of the Sound Processor. The receiver should be parallel with your head and centered over the top of the Sound Processor, where the microphone is located. You might need to adjust the volume on your Sound Processor to pick up the sound from the telephone receiver.

The Sound Processor and Earmold Coil Assembly should be removed before you bathe. Bathing with the device or accidentally getting it wet may result in device malfunction. If this occurs, do not dry it with a hair dryer. First remove the battery, then dry the device with a cloth. Place it in the dehumidifier overnight and then check performance. In case of malfunction, notify your hearing health care professional.

USE AND CARE OF BATTERIES

BATTERY INSERTION

The SOUNDTEC® Direct System℠ uses a size 675 battery. Any brand of 675 battery should work with your device *except* for the high power 675 battery.

To install a battery, open the battery compartment by using the lip on the battery door. Place the battery into the ring or ledge with the "+" side of the battery up.

If the battery is placed incorrectly, the battery compartment door will not shut easily and the Sound Processor could be damaged. The battery will usually last 2-4 weeks, depending on the settings and the number of hours the hearing device is worn each day.

BATTERY DISPOSAL

Batteries must be disposed in accordance with federal, state, and local regulations.

BATTERY SAFETY

The button cell batteries used to power the SOUNDTEC® Direct System℠ are small and could be easily swallowed. Keep them away from children, pets, or anyone who might not understand the dangers associated with swallowing batteries.

In case a battery is swallowed, immediately contact:
National Button Battery Hotline
1-202-625-3333
or your local physician

Notify your hearing care professional promptly if you experience any interference.
It is possible that there may be electromagnetic interference, resulting in humming or buzzing sounds, when close to appliances such as televisions, computers, or other electronic appliances. This is not uncommon, and your hearing care professional will help you with the problem.

Do not ingest batteries; batteries are harmful if swallowed.
The button cell batteries used to power the Direct System℠ are small and could be easily swallowed. Keep them away from children, pets, or anyone who might not understand the dangers associated with swallowing batteries.

In case a battery is swallowed, immediately contact:
National Button Battery Hotline
1-202-625-3333
or your local physician

If you experience any medical problems, such as pain or discomfort, which you believe are related to the use of the SOUNDTEC® Direct System℠, or if there are problems with the function of the SOUNDTEC® Direct System℠, immediately contact your hearing care professional.. See page 2 of this guide for the phone number.

HOW DOES THE DIRECT SYSTEM[SM] DIFFER FROM MY ACOUSTIC HEARING AID?

SOUNDTEC® designed the Direct System[SM] as an altemative to conventional acoustic hearing aids. Data was collected from 95 people participating in a clinical trial to illustrate the safety and effectiveness of the Direct System[SM] . Though individual results may vary, you may experience many benefits using the Direct System[SM] . They include:

- HEARING OF SOUND:

  Compared to your well-fit regular hearing aid, you may perceive a higher fidelity sound. You may also hear more sounds in the "speech" range, which are mid to high frequency sounds. In other words, you may follow a conversation more easily and it may sound more natural to you.

- ACOUSTICAL FEEDBACK:

  You may experience whistling or squealing when you increase the volume on your current hearing aid. However, many patients who used the Direct System[SM] reported no feedback and ;almost all patients preferred the Direct System[SM] as having the least amount of feedback.

- OCCLUSION EFFECT:

  When you speak with your hearing aid on, you may experience the feeling that you're talking into a barrel or tunnel. This is called the "occlusion effect." The Direct System[SM] has been found to produce reduced occlusion compared to a hearing aid.

- SOUND QUALITY:

  Sounds may be clearer, and more natural, including the sound of your own voice. Most patients preferred the Direct System[SM] in the area of sound quality compared to their hearing aid.

TO REACTIVATE THE DESSICANT

A conventional oven or microwave may be used to reactivate the desiccant.

CONVENTIONAL OVEN DIRECTIONS

1. Set the temperature between 245 to 260 degrees and then
2. Place the desiccant in the oven for approximately one hour.
3. Take the desiccant from the oven and check the color of the humidity indicator. If the indicator is blue and stays blue for then go to step 4. If it turns back to pink, repeat steps 1-3 for up to 12 hours.
4. Place the dessicant back in the dehumidifier kit after it cools down.

MICROWAVE DIRECTIONS

1. Place the desiccant in a microwave at low setting for 10-15 minutes.
2. Check the humidity indicator. In a few minutes, the indicator will turn blue if the desiccant is reactivated. If the indicator stays blue then go to step 4. If it turns back to pink, repeat steps 1-2.
3. Put the dessicant back in dehumidifier kit after it cools down.

HOW SHOULD I STORE MY DEVICE?

When not in use should remove the battery from your Sound Processor and store it in the dehumidifier with the batter door open. Keep the battery and Earmold Coil Assembly in a safe, dry place.

HOW DO I USE THE DEHUMIDIFIER?

Moisture can cause problems with the function of your Sound Processor and ECA. In order to reduce moisture and improve performance of the device, the ECA and Sound Processor should be placed in the de-humidifying kit for a minimum of 4 hours once a week, or immediately after exposure to high humidity (85%) or perspiration. If the system is consistently exposed to high humidity or perspiration, use the dehumidifier 2-3 times a week. The battery should be removed from your Sound Processor before putting it in the de-humidifier.

TO USE THE DEHUMIDIFIER

Open the de-humidifier kit. Make sure that the desiccant, which looks like small rocks or pebbles and will come in a container or jar, is in the kit and the humidity indicator is blue. Remember to remove the battery first, then insert your ECA and Sound Processor. Tightly close the de-humidifier kit. You may leave your Sound Processor and ECA in the kit overnight or as long as desired, but they should be kept in for a minimum of 4 hours.

HOW DOES IT WORK?

The desiccant in the de-humidifier kit will absorb the moisture from your Sound Processor and ECA and allow the devices to work more effectively.

After you have used the de-humidifier many times it becomes saturated and loses its ability to draw moisture from your Sound Processor and ECA . The desiccant should be reactivated at least once a year or when the humidity indicator turns from blue to pink.

02

- **SURGICAL IMPLANT:**

  The procedure used to implant the internal portion of the Direct System[SM] is minimally invasive, and is similar to other surgeries performed through the ear canal (stapedectomy, tympanoplasty).

WHAT ARE THE PARTS OF THE DIRECT SYSTEM℠ ?

The SOUNDTEC® Direct System℠ consists of three components:

Implant
Earmold/Coil Assembly (ECA)
Sound Processor

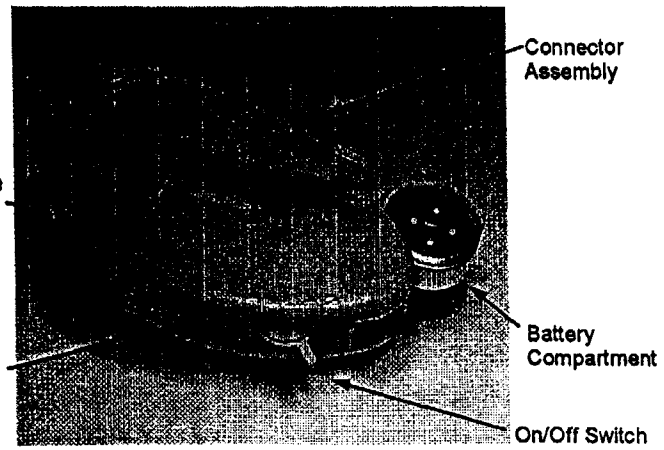
The implant is surgically implanted by your physician. The (ECA) is placed in your ear whenever you want to use the SOUNDTEC® Direct System℠ . The Sound Processor is attached to the ECA by the Connector Assembly and placed behind your ear. See the following illustrations and information for details.

SOUND PROCESSOR

The Sound Processor is made of ABS plastic. The processor fits behind your ear, and has controls that include the following:

On/Off Switch
Volume Control
Battery Compartment

The Sound Processor receives and amplifies sound vibrations and transforms them to electrical signals. The signals are received by the ECA.



HOW TO USE THE SOUND PROCESSOR

- **ON/OFF SWITCH**

The On/Off switch has three positions, which are printed on the case of the Sound Processor.

O = Off
T = On
M = On

Push the switch lever to the "O" position to turn the Sound Processor **OFF**.

Push the switch lever to either the "T" or "M" position to turn the Sound Processor **ON**. There is no functional difference in the T and M settings. Both turn on the Sound Processor.

- **VOLUME CONTROL**

The Volume Control can be rolled upward to increase the volume and rolled downward to lower the volume. The Volume Control is marked with the numbers 1 – 4 indicating softest to loudest settings.

1 = softest setting
4 = loudest setting

- **CONNECTOR CABLE**

The Connector Cable connects the Sound Processor to the ECA. Your local SOUNDTEC provider will connect them for you.

- **BATTERY COMPARTMENT**

The door to the Battery Compartment swings out of the Sound Processor case to allow access to the battery for easy insertion and removal. When you are not using the Sound Processor, be sure to open the Battery Compartment. This saves battery energy, and allows moisture that might have accumulated in the battery case to evaporate.

The Sound Processor also contains internal controls for adjusting the frequency response and output of the device. These should only be adjusted by your hearing care professional.

REMOVAL OF THE HEARING DEVICE

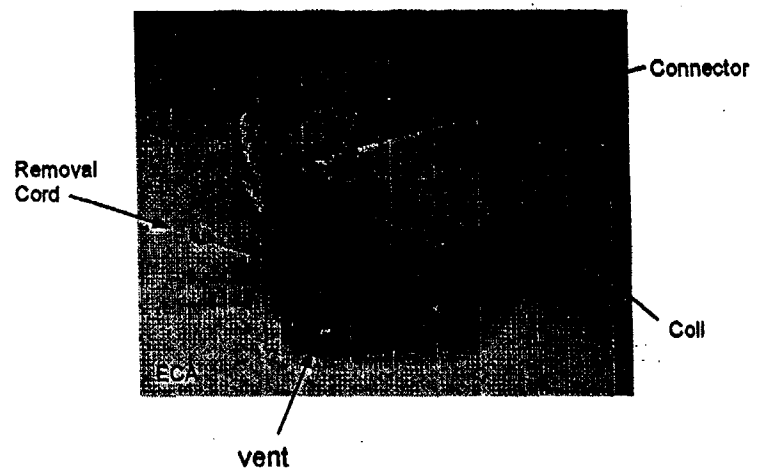
Grasp the removal cord and carefully pull the ECA from your ear. There is a small ball at the end of the removal cord to help you (see picture 5).

Picture 5

EARMOLD COIL ASSEMBLY (ECA)

The ECA is a custom earmold shell composed of acrylic polymer with an electromagnetic tip at its coil. It is custom designed from an impression of your ear canal. The ECA and the Sound Processor are joined by a small connector. A small removal cord assists you in easily removing this assembly from your ear.

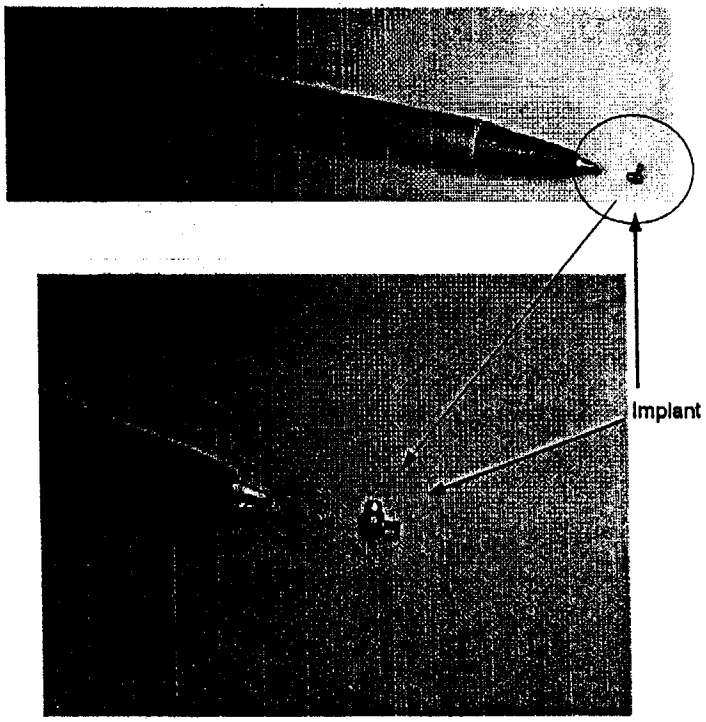
The ECA receives electrical signals from the Sound Processor and converts them to electromagnetic energy, which is received by the magnetic implant.



IMPLANT

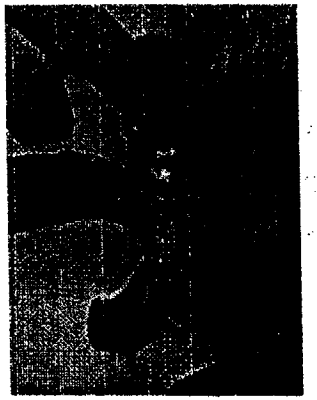
The implant consists of a small rare earth magnet sealed in a titanium metal canister. A wire-form ring composed of titanium alloy wire holds the magnet to the incudo-stapedial joint in the middle ear.

The implant receives electromagnetic energy from the ECA, causing the middle ear ossicles to vibrate. These vibrations cause perceived amplification of sound and improved hearing.



3. Insert the ECA starting with this angle and gently twist the ECA backwards and forwards slightly to work the ECA as far into the ear canal as you can comfortably place it (see picture 2,3).

Picture 2



Picture 3 →

4. Place the Sound Processor over the top of the ear so it rests on top of and behind the ear, as shown in picture 4.

Picture 4 →

5. Adjust the final seating of the ECA with your index finger and thumb gripping the removal cord while gently moving it to get the best hearing and most physical comfort.

USE AND CARE OF THE DIRECT SYSTEM[SM]

Now you are ready to begin using your new SOUNDTEC® Direct System[SM] . The following information will help you get the best results and the maximum amount of wear from your Direct System[SM] .

INSERTION AND REMOVAL OF THE ECA AND SOUND PROCESSOR

INSERTING THE HEARING DEVICE

Your ECA is custom made for your ear. Do not force the ECA into your ear. The ECA is a custom device and can only fit your ear.

1. Lubricate the tip of the ECA with polysporin ointment, mineral oil, or another lubricant prescribed by your ear doctor.

2. Hold the ECA with your index finger on the top portion of the ECA and your thumb on the bottom ridge with the tip aimed towards your ear. Refer to picture 1 and turn the top portion of the ECA forward a quarter turn (towards your face).

Picture 1

HOW LONG WILL MY DIRECT SYSTEM[SM] LAST?

LIFE EXPECTANCY

When exposed to an average frequency of sound at 1000 Hz and used an average of eight hours a day, the life expectancy of the Direct System is 4 years.

WHAT HAPPENS AFTER SURGERY?

You will be discharged the day of surgery and should schedule a one-week follow-up appointment. If your ear has healed completely from the surgery, you will be fitted for the Sound Processor and ECA during a ten-week follow appointment.

ARE THERE POST-OPERATIVE COMPLICATIONS?

A few hours after surgery you may notice a loss of hearing. This is a normal and temporary reaction to the surgery. It should begin to improve shortly after and you will notice continued improvement for many weeks following your surgery.

It is common to experience some ear pain and swelling after surgery. This is temporary, and will subside with time. It is also possible that a hematoma (blood blister) or tympanic membrane perforation will occur, both of which may resolve themselves or can be resolved with medicine or surgery.

In order to minimize these complications, many types of movement and activities will be restricted temporarily. You will also need to take special care of your ear while it is healing. The post-operative care and precautionary rules should be followed to avoid excessive pain and damage to your ear, hearing, and the implant.

POST-OPERATIVE PRECAUTIONS

- Do not exercise or move your head quickly for the first two weeks after surgery.
- Do not engage in vigorous exercise or contact sports, such as basketball, football, soccer, hockey, etc., for three months.
- Do not wear the earmold in the ear canal when engaging in contact sports *at any time*.
- Do not blow your nose for three weeks. Any accumulation in the nose may be drawn back and expectorated through the mouth.
- Keep your nose and mouth open while sneezing.
- Flying is permissible after one week, but only on commercial airlines for the first month.
- Do not blow on musical instruments for three weeks.
- No swimming for two months. Avoid diving until advised.
- Later, when you are using your SOUNDTEC® device, report to your doctor any swelling or pain you experience in the external ear canal.

POST-OPERATIVE CARE

- Change cotton in ear daily for one week. Use only sterile cotton. Wash your hands for 2 to 3 minutes with soap and water before touching your ear. If necessary, the external ear may be cleansed with cotton dampened with rubbing alcohol.
- Do not wash your hair or get water in the ear for one week after surgery and keep water out of the ear canal for three weeks. A cotton plug placed in the canal and covered with Vaseline will prevent water entering the ear while washing the face or taking a shower.
- Do not use Q-tips to clean your ear.
- It is very normal for hearing to regress a few hours after surgery. It will be very distorted and poor for some time. Do not be discouraged over this. Often the hearing will be poor initially but will continue to improve for many weeks after surgery.
- Call your physician if you develop a cold or have an elevation in temperature above normal. Please call if you should have excessive pain or dizziness during the first few weeks following surgery. Call if there is excessive pain or drainage. (A small amount of bloody drainage on the cotton the first few days after surgery is not unusual.

WILL THE IMPLANT WORK WITHOUT THE ECA AND SOUND PROCESSOR?

The SOUNDTEC® Direct works as a system—the implant will not improve your hearing without the Sound Processor and ECA. If or some unforeseeable reason you choose not to have the Sound Processor and ECA fitted, or if these external portions of the system cannot be fitted, the Direct System℠ will not be able to amplify sounds for you. The degree of benefit will vary between individuals. SOUNDTEC® anticipates that users will receive the benefit of amplified sound perception as proven in clinical trial data. However, individual results will vary.

CAN I WEAR MY HEARING AID IN MY IMPLANTED EAR?

The implant does not interfere with your hearing aid. You may resume use of your hearing aid in the implanted ear if desired.

CAN THE IMPLANT BE REMOVED?

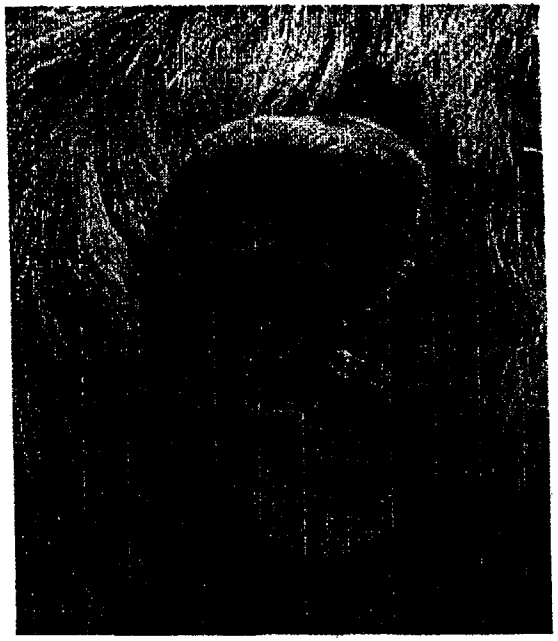
The implant can be removed through a similar surgical procedure with similar risks. It may also be re-implanted once the structures of the middle ear have been allowed to heal and can withstand surgery.

WILL I NEED FUTURE SURGERY IN ORDER TO UPGRADE MY DEVICE?

Future upgrades of the external parts of your device will not require a change to your implant. However, as future technology becomes available, it will be possible to upgrade the implant through a similar surgery.

the direct system℠

PATIENT INFORMATION



SOUNDTEC inc.

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P/N 403-0005-001 Rev. A 04/01

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CAUTION:

FEDERAL (U.S.) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Read all directions in this guide before using the *SOUNDTEC*® Direct System℠. Contact your hearing care professional if you have any questions or concerns about your Direct System℠.

Contacts for information and assistance:

Doctor: _____ **Tel. No.:** _____

Center: _____ **Tel. No.:** _____

Other: _____ **Tel. No.:** _____

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PATIENT INFORMATION
Table of Contents

HOW DO WE HEAR?

The hearing process begins when sound waves enter the ear and travel from the outer ear to the middle ear through the ear canal. At the end of the ear canal, the sound waves reach the eardrum. When this happens, the sound waves cause the eardrum to vibrate.

When the eardrum vibrates, the bones in the middle ear also vibrate. These bones are known as the malleus, incus, and stapes (also known as the hammer, anvil, and stirrup). Together, they make up what is called the ossicular chain. The ossicular chain connects the middle ear to the inner ear.

The inner ear contains the cochlea, which is filled with fluid, membranes, and tiny hair cells. The vibrations of the ossicular chain cause movement in the fluid of the cochlea. This movement stimulates the hair cells, which are connected to nerve fibers. As the hair cells are stimulated, the nerve fibers send electrical pulses to the brain, and the brain recognizes and interprets these pulses as sound.

WHAT CAUSES HEARING LOSS?

There are three types of hearing loss: conductive, sensorineural, and mixed. Mixed hearing loss is a combination of conductive and sensorineural hearing impairment.

Conductive hearing loss is usually caused by a disease or disorder that affects how sound waves travel through the outer or middle ear. Because of this, the sound waves have difficulty reaching the eardrum, and the hearing process is interrupted. This is usually treated with medication or surgery.

Most adults with hearing problems have sensorineural hearing loss. This type affects the inner ear and/or the neural pathways. Sound waves can reach the middle ear without difficulty, but there is some type of damage to the inner ear, usually the hair cells or nerve fibers. If the hair cells or nerve fibers are not working correctly, the inner ear loses its ability to transmit the necessary signals to the brain for sound recognition. Sensorineural hearing loss is usually treated with a hearing aid.

5. Speech testing in noise results with the Speech Perception in Noise (SPIN) test showed no difference between the Direct System[SM] and acoustic hearing aids.

6. The Abbreviated Profile of Hearing Aid Benefit (APHAB) scores showed an improvement of approximately 20% across three different sub-scales with the DDHS when compared to acoustic hearing aids.

7. When subjects compared the DDHS with their acoustic hearing aid in the Hough Ear Institute Profile* (HEIP) test, the results showed that:
   a. Out of 94 subjects responding, 84 of those subjects (89%) preferred the DDHS in terms of overall satisfaction.
   b. Sixty-three of 94 subjects (67%) reported feedback with their acoustic hearing aids. Eight of 94 subjects (8.5%) reported feedback with the DDHS. Out of 94 subjects responding, 93 of them (99%) preferred the DDHS as having the least amount of feedback.
   c. Fifty of 92 subjects (54%) reported occlusion with their acoustic hearing aids. 21 of 92 subjects (23%) reported occlusion with the DDHS.
   d. Out of 94 subjects responding, 84 of those subjects (89%) responded that they preferred the DDHS over their acoustic hearing aids in the areas of sound quality.
   e. Twenty-one of 41 (51%) subjects reporting tinnitus pre-implant reported that their hearing aid decreased their perception of tinnitus.

      Twenty of 30 (67%) subjects reporting tinnitus post-implant reported that the Direct System[SM] decreased their perception of tinnitus.

***HEIP is a validated but not standardized questionnaire addressing the patients' perception of the presence of tinnitus, feedback, and occlusion as well as sound quality judgments and device preference.**

Clinical Study Summary

One hundred-three (103) subjects underwent the implant procedure with the SOUNDTEC® Direct System℠. The following clinical study summary is based on ninety-five (95) subjects who had completed 20-week assessments. The assessment compared preoperative results with an optimally fit acoustic hearing aid in the ear to be implanted to post operative results with the SOUNDTEC® Direct System℠. "Optimally fit" as defined by the clinical study included insertion gain matching using National Acoustic Laboratories-Revised (NAL-R) prescriptive target ranges (±5 dB for 500, 1000, and 2000 Hz and ± 12 dB for 3000 and 4000 Hz) and evidence of improvement in aided benefit.

Subjects were tested to find hearing thresholds, sound field thresholds, speech testing in quiet and noise, aided benefit, and subject perceptions.

All items showing improvements were determined to be statistically significant. For more detailed information about the SOUNDTEC Direct Drive Hearing System (DDHS) / Direct System℠ please refer to the Clinical Study Results.

1. For most subjects, the change in residual hearing was not significant. Average decrease in air conduction thresholds at 20 weeks was 4.2 dB across the frequency range of 250 to 8000 Hz. Average bone conduction thresholds decreased by 1.1 dB. Few subjects (10/95 or 10.5%) had greater than 10 dB of change by air conduction. Few subjects (4/95 or 4%) had greater than 10 dB of change by bone conduction.

2. There was an average increase in functional gain of 7.9 dB with the DDHS compared to their acoustic hearing aid. For the high frequencies of 2000, 3000, and 4000 Hz, there was an average increase in functional gain of 9.6 dB.

3. The Articulation Index score results showed an improvement of 11.9% with the DDHS. The Direct System℠ shows an improved audibility over acoustic hearing aids.

4. Speech recognition in quiet showed a 5.3% improvement with the DDHS when compared with the subjects' acoustic hearing aids.

HOW DOES THE DIRECT SYSTEM℠ WORK?

The SOUNDTEC® Direct System℠ works with a magnetic implant attached to the ossicular bones in your middle ear. The two bones used in the process are called the incus and the stapes. After the implant surgery is performed, you will receive the Earmold Coil Assembly (ECA) and the Sound Processor. These components complete your SOUNDTEC® Direct System℠.

The Sound Processor receives sound, amplifies it, and sends electrical signals to the ECA. The electromagnetic coil at the tip of the ECA changes the sounds to electromagnetic signals, which cause the implant to vibrate. These vibrations travel through the cochlea, stimulating the hair cells and nerves that send impulses to the brain that are interpreted as sound.

IS THE DIRECT SYSTEM℠ RIGHT FOR ME?
INDICATIONS/CONTRAINDICATIONS

The SOUNDTEC® Direct System℠ is indicated for use in adults, 18 years of age or older, who have a moderate to severe sensorineural hearing loss and desire an alternative to an acoustic hearing aid.

Prior to receiving the device, it is recommended that an individual have experience with appropriately fit hearing aids.

The SOUNDTEC® Direct System℠ is contraindicated for subjects who have:

- Conductive hearing loss
- Retrocochlear or central auditory disorder (brain stem disorder)
- Active middle ear infections
- Tympanic membrane (ear drum) perforations associated with recurrent middle ear infections
- Disabling tinnitus (ringing in the ear)

Your doctor or audiologist/hearing instrument specialist will perform several audiometric tests and a medical examination to determine whether you are a candidate for the Direct System℠.

WARNINGS AND PRECAUTIONS

The SOUNDTEC® Direct System℠ is proven safe and effective if used and cared for responsibly. The following warnings and precautions should be noted to avoid potential harm to yourself and damage to the device.

Warnings:

Inform your physician that you are implanted with the Direct System℠ ***before having the following medical or surgical procedures:***

- ***Magnetic Resonance Imaging (MRI) examinations***
  Patients implanted with the SOUNDTEC® Direct System℠ should not undergo an MRI examination, enter a room where MRI exams are performed, or get close to other strong magnetic fields. The effects of these exams on the implant are unknown. If an MRI is necessary, the implant should be removed and re-implanted after the exam.

- ***Diathermy and Electroconvulsive Therapy***
  The effects of diathermy and electroconvulsive therapy on the Direct System℠ implant are unknown. You should inform your physician of your implant and consult about any possible risks before undergoing these procedures.

- ***Cobalt treatment, PET scans, transcranial diagnostic ultra sound, or linear acceleration techniques***
  The effect of cobalt treatment, PET scans, transcranial diagnostic ultrasound, and linear acceleration techniques on the implant are unknown. Before undergoing any of these procedures, Direct System℠ users should consult their physicians about the potential risks.

WILL THE IMPLANT WORK WITHOUT THE ECA AND SOUND PROCESSOR?

The SOUNDTEC® Direct works as a system—the implant will not improve your hearing without the Sound Processor and ECA. If or some unforeseeable reason you choose not to have the Sound Processor and ECA fitted, or if these external portions of the system cannot be fitted, the Direct System℠ will not be able to amplify sounds for you. The degree of benefit will vary between individuals. SOUNDTEC® anticipates that users will receive the benefit of amplified sound perception as proven in clinical trial data. However, individual results will vary.

CAN I WEAR MY HEARING AID IN MY IMPLANTED EAR?

The implant does not interfere with your hearing aid. You may resume use of your hearing aid in the implanted ear if desired.

CAN THE IMPLANT BE REMOVED?

The implant can be removed through a similar surgical procedure with similar risks. It may also be re-implanted once the structures of the middle ear have been allowed to heal and can withstand surgery.

WILL I NEED FUTURE SURGERY IN ORDER TO UPGRADE MY DEVICE?

Future upgrades of the external parts of your device will not require a change to your implant. However, as future technology becomes available, it will be possible to upgrade the implant through a similar surgery.

POST-OPERATIVE PRECAUTIONS

- Do not exercise or move your head quickly for the first two weeks after surgery.
- Do not engage in vigorous exercise or contact sports, such as basketball, football, soccer, hockey, etc., for three months.
- Do not wear the earmold in the ear canal when engaging in contact sports *at any time*.
- Do not blow your nose for three weeks. Any accumulation in the nose may be drawn back and expectorated through the mouth.
- Keep your nose and mouth open while sneezing.
- Flying is permissible after one week, but only on commercial airlines for the first month.
- Do not blow on musical instruments for three weeks.
- No swimming for two months. Avoid diving until advised.
- Later, when you are using your SOUNDTEC® device, report to your doctor any swelling or pain you experience in the external ear canal.

POST-OPERATIVE CARE

- Change cotton in ear daily for one week. Use only sterile cotton. Wash your hands for 2 to 3 minutes with soap and water before touching your ear. If necessary, the external ear may be cleansed with cotton dampened with rubbing alcohol.
- Do not wash your hair or get water in the ear for one week after surgery and keep water out of the ear canal for three weeks. A cotton plug placed in the canal and covered with Vaseline will prevent water entering the ear while washing the face or taking a shower.
- Do not use Q-tips to clean your ear.
- It is very normal for hearing to regress a few hours after surgery. It will be very distorted and poor for some time. Do not be discouraged over this. Often the hearing will be poor initially but will continue to improve for many weeks after surgery.
- Call your physician if you develop a cold or have an elevation in temperature above normal. Please call if you should have excessive pain or dizziness during the first few weeks following surgery. Call if there is excessive pain or drainage. (A small amount of bloody drainage on the cotton the first few days after surgery is not unusual.

PRECAUTIONS

Do not allow others to tamper with or wear any part of the Direct System℠.
Each system is individually prescribed and use by others could result in bodily injury or damage to the device.

Do not swallow any part of the Direct System℠ or use in any manner other than that described in this manual.
Doing so can result in illness, injury, or damage to the device.

Do not wear the Earmold Coil Assembly (ECA) when engaging in contact sports of any kind.
This could result in damage to the ear canal and/or ear drum, as well as damage the device.

Do not get the SOUNDTEC® Direct System℠ wet.
Doing so could cause intermittent performance or damage the device beyond repair. If the device does get wet, remove the battery and store the device in the dehumidifier overnight, leaving the battery door open. If the device still malfunctions, notify your hearing care professional.

Do not allow any part of the device to be exposed to excessive heat, such as direct sunlight, blow dryer, or flame, or leave on the dashboard or inside of a car.
Contact with a hot device may cause minor skin irritation or burns. Heat may also damage the device beyond repair.

Do not use hair care products, such as hairspray or gel, while wearing your Direct System℠.
This may damage the device.

Do not attempt to open the Sound Processor except to remove the battery.
Exposing or tampering with the internal controls could seriously alter the device performance and output. Only hearing care professionals should make adjustments to the internal controls.

Notify your hearing care professional promptly if you experience any interference.
It is possible that there may be electromagnetic interference, resulting in humming or buzzing sounds, when close to appliances such as televisions, computers, or other electronic appliances. This is not uncommon, and your hearing care professional will help you with the problem.

Do not ingest batteries; batteries are harmful if swallowed.
The button cell batteries used to power the Direct System[SM] are small and could be easily swallowed. Keep them away from children, pets, or anyone who might not understand the dangers associated with swallowing batteries.

In case a battery is swallowed, immediately contact:
National Button Battery Hotline
1-202-625-3333
or your local physician

If you experience any medical problems, such as pain or discomfort, which you believe are related to the use of the SOUNDTEC® Direct System[SM], or if there are problems with the function of the SOUNDTEC® Direct System[SM], immediately contact your hearing care professional. See page 2 of this guide for the phone number.

WHAT ARE THE RISKS OF THE IMPLANT PROCEDURE?

The SOUNDTEC® Direct System[SM] has been proven safe and effective in all pre-clinical testing. However, with any surgical procedure there are associated risks. Potential complications of surgery seen in clinical studies include normal risks such as postoperative bleeding, postoperative infection, nausea and vomiting, and the risks associated with anesthesia. There is a small risk of tympanic perforation (tear in the ear drum) which may be corrected surgically. There is also a remote risk of facial paralysis or weakness, which may be permanent or temporary. There may also be a temporary or permanent disturbance of balance or taste, vertigo (dizziness), tinnitus (ringing in the ear), and/or a decrease of hearing (conductive or sensorineural).

WHAT HAPPENS AFTER SURGERY?

You will be discharged the day of surgery and should schedule a one-week follow-up appointment. If your ear has healed completely from the surgery, you will be fitted for the Sound Processor and ECA during a ten-week follow appointment.

ARE THERE POST-OPERATIVE COMPLICATIONS?

A few hours after surgery you may notice a loss of hearing. This is a normal and temporary reaction to the surgery. It should begin to improve shortly after and you will notice continued improvement for many weeks following your surgery.

It is common to experience some ear pain and swelling after surgery. This is temporary, and will subside with time. It is also possible that a hematoma (blood blister) or tympanic membrane perforation will occur, both of which may resolve themselves or can be resolved with medicine or surgery.

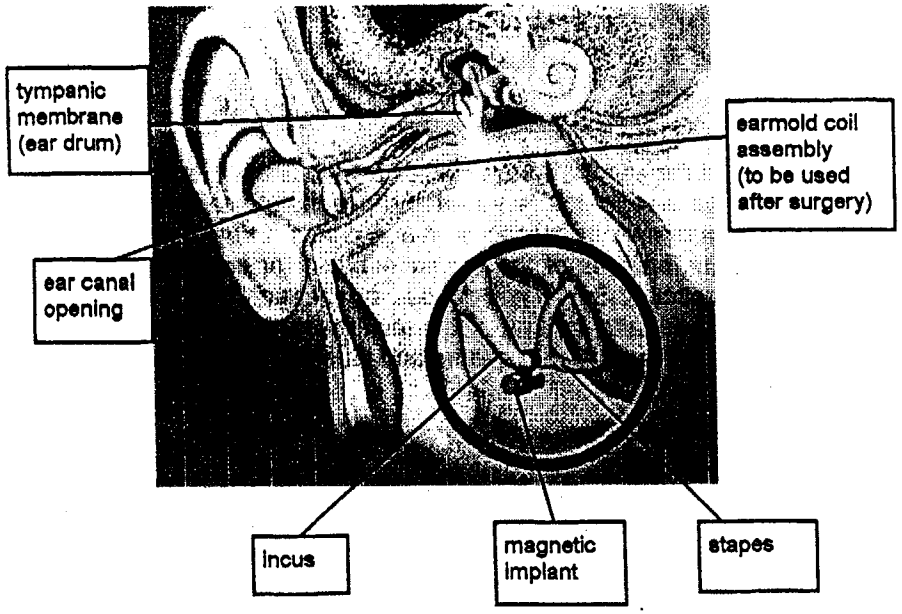
In order to minimize these complications, many types of movement and activities will be restricted temporarily. You will also need to take special care of your ear while it is healing. The post-operative care and precautionary rules should be followed to avoid excessive pain and damage to your ear, hearing, and the implant.

HOW IS IT DONE?

A local anesthetic is used to numb the middle ear and ear drum area. The actual surgical procedure lasts between 20-40 minutes. Patients are usually discharged the same day.

The least invasive method of reaching the middle ear is through the ear canal. In order to gain access to the bones in the middle ear on which the implant must be placed, a small incision will be made in the tympanic membrane (ear drum). After reaching the middle ear area, the surgeon will separate the joint between the incus and the stapes. The wireform ring of the implant will be placed around the end of this joint, holding the magnet in place (Figure 1).

FIGURE 1



HOW DOES THE DIRECT SYSTEM[SM] DIFFER FROM MY ACOUSTIC HEARING AID?

SOUNDTEC® designed the Direct System[SM] as an alternative to conventional acoustic hearing aids. Data was collected from 95 people participating in a clinical trial to illustrate the safety and effectiveness of the Direct System[SM] . Though individual results may vary, you may experience many benefits using the Direct System[SM] . They include:

- **HEARING OF SOUND:**
  Compared to your well-fit regular hearing aid, you may perceive a higher fidelity sound. You may also hear more sounds in the "speech" range, which are mid to high frequency sounds. In other words, you may follow a conversation more easily and it may sound more natural to you.

- **ACOUSTICAL FEEDBACK:**
  You may experience whistling or squealing when you increase the volume on your current hearing aid. However, many patients who used the Direct System[SM] reported no feedback and ;almost all patients preferred the Direct System[SM] as having the least amount of feedback.

- **OCCLUSION EFFECT:**
  When you speak with your hearing aid on, you may experience the feeling that you're talking into a barrel or tunnel. This is called the "occlusion effect." The Direct System[SM] has been found to produce reduced occlusion compared to a hearing aid.

- **SOUND QUALITY:**
  Sounds may be clearer, and more natural, including the sound of your own voice. Most patients preferred the Direct System[SM] in the area of sound quality compared to their hearing aid.

- SURGICAL IMPLANT:

  The procedure used to implant the internal portion of the Direct System[SM] is minimally invasive, and is similar to other surgeries performed through the ear canal (stapedectomy, tympanoplasty).

ARE THERE RISKS WITH THE DEEP EAR IMPRESSION?

This procedure, developed as a result of a similar procedure widely used in the hearing aid industry and was tested in a 103 patient trial. Possible adverse events which were observed in clinical studies include a possible hematoma (blood blister) of the ear canal. The hematoma resolves naturally in a short healing period. There is also a slight risk of puncturing or perforating the ear drum, which generally requires remedial surgery to correct. There is a very slight risk of damaging middle ear structures, and a very slight risk of hearing loss (conductive or sensorineural).

During an examination, your physician may use a device called the search coil to ensure that your implant is in proper alignment. This device may cause minor tympanic membrane or ear canal irritation that resolves itself without treatment.

THE IMPLANT SURGERY:

WHY IS IT NEEDED?

The implant is placed on the joint of the incus and the stapes in the middle ear, which is known as the incudostapedial joint. The implant must be placed on these bones in order to cause increased vibrations of the ossicular chain for amplification of sound to occur. Surgery is necessary to reach this portion of the middle ear and safely position the implant in the most effective place to stimulate the middle and inner ear.

HOW LONG WILL MY DIRECT SYSTEM LAST?

LIFE EXPECTANCY

When exposed to an average frequency of sound at 1000 Hz and used an average of eight hours a day, the life expectancy of the SOUNDTEC® Direct System℠ is 4 years.

WHAT HAPPENS AFTER I CHOOSE THE DIRECT SYSTEM?

THE DEEP EAR IMPRESSION

WHY DO I NEED IT?

In order to make sure that your Direct System℠ is as comfortable as possible, the Earmold Coil Assembly is custom designed to fit your individual ear canal shape. Your audiologist will make an impression of your ear canal, and your ECA will be designed from that mold.

HOW IS IT DONE?

The physician may use a topical anesthetic on the ear canal walls to make the procedure as comfortable. A light oil will be used to coat the ear canal, making the impression easier to remove. Your ear canal will then be filled with the impression material. It will take a few minutes for the impression material to set, and then the impression will be removed from your ear.

After the impression is completed, it will be sent to SOUNDTEC®, Inc. so that your custom Earmold Coil Assembly can be made specifically for your ear.

WHAT ARE THE PARTS OF THE DIRECT SYSTEM℠?

The SOUNDTEC® Direct System℠ consists of three components:

Implant
Earmold/Coil Assembly (ECA)
Sound Processor

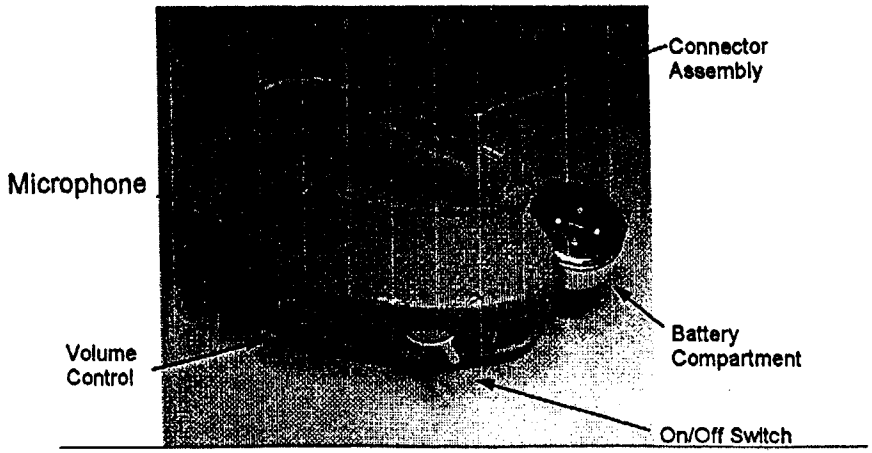
The implant is surgically implanted by your physician. The (ECA) is placed in your ear whenever you want to use the SOUNDTEC® Direct System℠. The Sound Processor is attached to the ECA by the Connector Assembly and placed behind your ear. See the following illustrations and information for details.

SOUND PROCESSOR

The Sound Processor is made of ABS plastic. The processor fits behind your ear, and has controls that include the following:

On/Off Switch
Volume Control
Battery Compartment

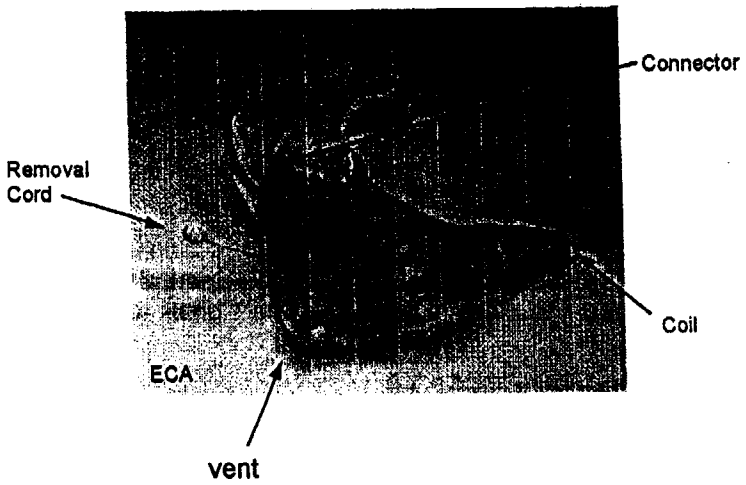
The Sound Processor receives and amplifies sound vibrations and transforms them to electrical signals. The signals are received by the ECA.



EARMOLD COIL ASSEMBLY (ECA)

The ECA is a custom earmold shell composed of acrylic polymer with an electromagnetic coil at the tip. It is custom designed from an impression of your ear canal. The ECA and the Sound Processor are joined by a small connector. A small removal cord assists you in easily removing this assembly from your ear.

The ECA receives electrical signals from the Sound Processor and converts them to electromagnetic energy, which is received by the magnetic implant.



IMPLANT

The implant consists of a small rare earth magnet sealed in a titanium metal canister. A wire-form ring composed of titanium alloy wire holds the magnet to the incudo-stapedial joint in the middle ear.

The implant receives electromagnetic energy from the ECA, causing the middle ear ossicles to vibrate. These vibrations cause perceived amplification of sound and improved hearing.