Instructions for Use

Brain Interchange System

CAUTION – Investigational Device
Limited by Federal (or United States) law to
investigational use.

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1. Content

2. Introduction

This instruction is written for clinicians and staff associated with the EFS and consist of essential information on the system “Brain Interchange System”, including warnings and notes for the implantation procedure.

Throughout this guidance important information, cautions and warnings are marked with the following symbols:

	Note:	Essential information or advice.
 CAUTION	Caution:	Potential hazard which could cause equipment damage.
 WARNING	Warning:	Potential hazard which could cause harm to person.


WARNING

Warning: Read the whole guidance attentively before performing the surgery or using the device.


CAUTION

Caution: The implantation should be done by an experienced neurosurgeon.

Note: This is a general guidance. Circumstances or factors of individual cases are not covered. The appropriate surgical approach is at the discretion of the surgeon performing the procedure.

3. Information

3.1. General Information

The system consists of the following components:

Table 1: General Information

Information	Art. No.	Description
Packaging Content	1011.5013.00	1 x Set with sterile Implantable Unit and sterile Implant Dummy
	1011.5012.02	1 x Headpiece
	1011.1051.01	1 x Communication Unit
	4041.1003.00	1 x USB Cable
	4041.1004.00	1 x Connector for Trigger Input
	4041.1001.00	1 x Personal Computer (incl. Power Supply and Power Cord)
	-	1 x USB Flash Drive incl. IFU and marketing material

The system may be used within the following environmental conditions:

Table 2: Environmental Conditions

Condition	Value
Pressure	70kPa (3000m above sea level) to 150kPa (5m below sea level)
Relative Humidity	10% to 95%, non-condensing
Temperature (transport)	15 °C to 50 °C (59 °F to 122 °F)
Temperature (storage)	15 °C to 35 °C (59 °F to 95 °F)
Temperature (use)	15 °C to 29 °C (59 °F to 84 °F)

Warning: Avoid strong pressure and temperature fluctuations during transport, storage and use. If the device has been exposed to high temperature or pressure fluctuations (for example during a flight), the functionality of the device must be checked before the next use.

Warning: Transport by air is allowed only if the equipment is carried in the hand luggage in the passenger cabin.

3.2. Technical Description

Table 3: Technical Description

Feature	Value
System and Interfaces	
Inductive Energy transmitting transfer frequency	Factory setting: 129,73 kHz (Possible range 120 – 140 kHz)
Distance range between implant and headpiece	2 to 6 mm
Type of radio transmission	Modulated carrier
Type of modulation	GFSK
Wireless Protocol	Proprietary 5-Mbps
Frequency Band	2400 MHz to 2483.5 MHz
Tx output power	5 dBm
Power consumptions External Unit powering the implant	~2.2W (5V, ~440 mA) @ 8 mm distance
Electromagnetic Environment	HEALTHCARE ENVIRONMENT according to IEC 60601-1-2:2014, EN 55011 / CISPR 11 group 1 Class B
Safety for medical electrical equipment	General requirements for basic safety and essential performance according to IEC 60601-1:2005 + Cor. :2006 + Cor. :2007 + A1:2012

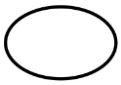
Implant	
Dimension Implant	67 x 38 x 7 mm³
Electrode Material	Silicone Elastomer, Platinum Iridium
Ground Electrode Contact Size	Ring: 1.8 mm diameter x 6 mm length
Ground Electrode Material	Silicone Elastomer, Platinum Iridium
Recording channels	32
Sampling rate / channel	1 kHz
Sampling dynamic range	16 bit
High pass filter cut-off	~2 Hz
Low pass filter cut-off	325 Hz
Amplifier pass band gain	User selectable: • 57.5 dB (750x) • 51.5 dB (375x) • 45.5 dB (188x) • 39.5 dB (95x)
Band pass roll-off	20 dB/decade
Amplifier input capacitance	Ca. 15 pF
Amplifier input voltage	Max 4 mVpp to 30 mVpp, dependent on amplifier gain
Input referred amplifier voltage offset	<250µVmax (varies across channels)
Number of stimulation sources	1 (can be directed to any electrode contact)
Stimulation pulse output	Current controlled
Stimulation pulse shape	Cathodic first, asymmetric rectangular, biphasic
Charge balancing counter pulse	4x pulse width, -1/4 current amplitude of stim. pulse
Max. stimulation pulse amplitude	6.12 mA
Stimulation amplitude increment	≤ 3 mA range: 12 µA, >3 mA range: 24 µA
Max. stimulation pulse width	2550 µs
Stimulation pulse width increment	10 µs
Max. pulse repetition frequency	200 Hz
Communication Unit	
Dimension Communication Unit	90 x 98 x 48 mm³
Weight	~160 g (maximum)
Operating Voltage	+5 V (USB)
Power uptake	Up to 2.2 W / 5 Vdc
Mounting	Wearable device
Trigger Input Interface	Threshold ≥ 1.25 V for ≥ 2 ms; No higher voltages than 30 V allowed; Cable length <3 m
Cable Length USB	2 m
IP Rating	42
Applied Part	BF
Enclosure Material	HB
Class of Equipment	II
Headpiece	
Dimension Headpiece	69 x 37 x 12 mm³
Cable Length Headpiece	59 cm
Weight	~35 g
IP Rating	44
Applied Part	BF
Power Supply	
Primary	65 W (up to 20 Vdc/3.25 A)
Rated Voltage	100 V-240 V (automatic)

Rated frequency	50 Hz-60 Hz (automatic)
Standards	EU Power Supply complies with IEC 60950-1:2005, AMD1:2009, AMD 2:2013 US- Power Cord is “Hospital Grade” and complies with UL Specification 60601-1

4. List of Symbols

Table 4: List of Symbols

	Article number
	Serial number
	Manufacturing date
	Use-by date
	Sterilized using ethylene oxide
	Do not re-sterilize
	Single use only / Do not reuse
	Non-Sterile
	Type BF applied part
	Keep dry
	Keep away from sunlight
	Temperature limit
	Do not use if package is damaged
	Quantity
	Separate collection for electrical and electronic equipment

	Read instructions for use
	MR unsafe
	Double sterile barrier system
	Single sterile barrier system
	Manufacturer
	Patient name or patient ID
	Date of implantation
	Name and address of the implanting health care institution/ provider
IPN_1N_2	N_1 = 4 Protected against solid foreign objects of 1.0 mm Ø and greater N_2 = 2 Protection against vertically falling water drops when enclosure tilted up to 15° 4 Protection against splashing water

5. Abbreviations and Glossary

5.1. Abbreviations

Table 5: List of Abbreviations

Abbreviation	Description
API	Application programming interface
BIC	Brain Interchange System
CISPR	Comité international spécial des perturbations radioélectriques
GND	Ground
EMI	Electromagnetic interference
EO	Ethylene Oxide
ESD	Electrostatic discharge
EU	European Union
LED	Light emitting diode (optical indicator)
REF	Reference
RF	Radio frequency
TTL	Transistor-transistor logic, 5.0 V supply
LVTTL	Low-voltage transistor-transistor logic, 3.3 V supply
nc	Not connected
MR	Magnetic resonance
MRI	Magnetic resonance imaging
pos	Position
TX	Transceiver (indicator for data transmission / reception)
US	United States (of America)
USB	Universal serial bus

5.2. Glossary

Terminology used in this document refers to the glossary further specified in Table 6.

Table 6: Glossary

Term	Description
Application Programming Interface (API)	Interface that permits to control the key performances of the system and to read and react on status information via a customized software.
Application Software	Software which allows the user to operate the Brain Interchange System. The software runs on a Personal Computer.
Brain Interchange System	The complete system which consists of an Implantable Unit, an External Unit and a Computing Unit with Software.
Channel	The BIC System provides 32 channels. Each channel can be dynamically assigned to one of the following functions: recording, recording reference, stimulation, or GND. These channels are connected to electrodes.
Communication Unit	The Communication Unit powers and controls the Headpiece, it communicates with the Implantable Unit via radio frequency transmission, it is powered via USB by the Personal Computer. The same USB interface is used to exchange information with the Personal Computer. The Communication Unit also provides the input connector for an External Trigger signal.
Component	Functional part of the System that can be physically separated from the System.
Dynamic Power Regulation	The power inductively provided to the Implantable Unit is dynamically regulated according to the Implantable Unit demand.

Electrode	Electrode Contact(s) embedded into a carrier substrate material. The term “electrode” does not specify if a cable is attached or not.
Electrode Cable	Cable that connects an Electrode to the Implantable Unit
Electrode Lead	See “Electrode Cable”, synonym.
Electrode Contact	Metallic contact that electrically couples the technical system to the biological tissue
Electrode Grid	Array of electrode contacts assembled to a multi-contact neural interface.
External Trigger	A voltage signal provided to the Communication Unit trigger input is classified as high (1) or low (0) signal and threaded into the data stream coming from the implant, relayed to the Personal Computer.
Grid Electrode	See “Electrode Grid”, synonym.
Headpiece	Inductive coil incl. coil driving circuitry that permits wireless powering of the Implantable Unit. The cable that connects the coil with the Communication Unit is a hard-wired part of the Component Headpiece.
Headpiece Cable	Cable that connects the Headpiece to the Communication Unit. This cable is firmly attached to the Headpiece,
Headpiece Connector	Connector system that permits the reversible electrical connection of Headpiece and Communication Unit.
Implantable Unit	Electronic circuitry that wirelessly provides the system key performances. The unit is protected against humidity and is fully implanted in the patient’s body. Electrodes are attached to the Unit.
Implant	See “Implantable Unit” (synonym)
Implantable Unit Body	Part of the Implantable Unit that carry the electronics, the magnet, and the coil.
Personal Computer	Software running on the Personal Computer controls the function of the Implant and manages the data stream coming from it.
Research Software	Software created by the user that operates the BIC System. This software requires the CorTec Application Programming Interface.
System	All components of the BIC System incl. the Personal Computer
USB Cable	The USB Cable connects the Communication Unit with the Personal Computer

6. General Description

The Brain Interchange System (also referred to as “BIC” or “the System”) was developed for research and therapy development.
The System consists of a long-term implant and associated external components to provide cortical stimulation together with sensing capabilities.

6.1. Intended Use

The Brain Interchange System is intended to provide cortical stimulation to induce neural plasticity and improve motor function in patients (≥ 22 years) who have suffered a stroke and have persistent (> 6 months) upper limb impairment.

6.2. Contraindications

The implant is contraindicated in patients requiring:

- MRI scanning
- TMS (transcranial magnetic stim)
- TDCS (transcranial direct current stimulation)
- TACS (transcranial alternating current stimulation)
- Ultrasound scanning or therapies
- Other active implantable medical devices of known medical treatments where an electrical current conducted or induced into the body from an external source.
- Medical procedure using effects caused by electrical fields (e.g. diathermy)
- Subjects with profession/hobby that includes activity imposing an unacceptable risk for trauma against the device or the site of implantation (e.g. rigorous physical activity).

Warning: The implant can be damaged if exposed to impacts. Inform the patient to exercise caution for any activity that may put the patient at higher risk of fall/head injury (e.g., navigating stairs, sloping surfaces, etc.). In case the site of implantation has been exposed to physical injury, the patient shall contact the study responsible.

Caution: Wear a helmet in activities which entail an increased risk of falling and suffering a head injury.

6.3. Adverse Events

Potential patients must be informed of the following possible adverse events and complications related to the implantation of an implantable neurostimulator include, but are not limited to, the following:

- risks associated with surgery and anesthesia
- intracranial hemorrhage
- subcutaneous hemorrhage or seroma
- breakdown of the skin flap
- subdural injury
- erosion and/or infection
- pain at the implant site
- seizure or convulsions
- aphasia or paralysis

- stroke
- leakage of cerebrospinal fluid surrounding the brain
- complications from unusual physiological variation in patients, including foreign body rejection / response phenomena
- operational failure of the implant might result in a reduction/loss of functionality and might require a replacement or removal of the device.
- Known risks associated with electrical stimulation of the brain include but are not limited to:
    - epileptic seizures
    - localized tissue necrosis
    - astrogliosis
    - microgliosis
    - pathological changes in meningeal tissue (including dura mater)

6.4. Electromagnetic Compatibility (EMC)

Electromagnetic interference (EMI) is a field of energy generated by equipment found in the home, work, medical, or public environments. Very strong EMI can interfere with the System. The device includes features that provide protection from EMI. Most electrical device and magnets encountered in a normal day will not affect the operation of the system. The Brain Interchange System is intended for use in HEALTHCARE ENVIRONMENT.

If the patient is outside the clinical environment, potentially hazardous environments should be avoided. These include, for example,

- Military areas (e.g., submarines, radar installations, weapons control systems)
- Heavy industrial areas (e.g., power plants, steel and paper mills, foundries, automotive and appliance manufacturing, smelting and mining operations, oil and gas refineries)
- Aircraft environments (e.g., planes, helicopters)
- Other critical environments (e.g. High-power amateur transmitters/antennas or citizen band (CB), electric arc welding or resistance welding equipment)

If the patient has entered a potentially hazardous environment, then this shall be reported back to the clinical staff.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment should be observed to verify, that they are operating normally.

Warning: Do not use of the system where the intensity of EM disturbances is high (e. g. near active HF surgical equipment or near RF shielded room of a system for magnetic resonance imaging).

Warning: Use of accessories, transducers and cables other than those specified or provided by the CorTec of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning:

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Brain Interchange System, including cables specified by the CorTec. Otherwise, degradation of the performance of this equipment could result.

Warning:

Even whenever the implant is powerless, the patient shall be informed to avoid strong external electromagnetic fields when leaving the hospital, because this could lead to a malfunction of the electronics of the implant.

Warning:

If the system is exposed to increased electromagnetic interference, data recording may be briefly disturbed or interrupted. This has no influence on the validity of the existing recorded data and its subsequent evaluation.

Table 7: Electromagnetic Emission

Subpart	EMI Phenomenon	Compliance
Enclosure	Radiated interference field strength EN 55011 / CISPR 11	Group 1 Class B
AC Mains power Input/Output ports	Conducted interference voltage EN 55011 / CISPR 11	Group 1, Class B
	Harmonic current emission EN / IEC 61000-3-2	Class A
	Voltage fluctuations and flicker EN / IEC 61000-3-3	Compliant
DC power Input/Output ports	Conducted interference voltage EN 55011 / CISPR 11	N/A
Patient coupled port	Conducted interference voltage EN/IEC 60601-1-2 Annex H.1	Compliant

Table 8: Electromagnetic Immunity

EMI Phenomenon	Test Level IEC 60601-1-2:2014	Compliance Level
Electrostatic discharge EN / IEC 61000-4-2	+/- 8kV contact +/- 2/4/8/15 kV air	+/- 8kV contact +/- 2/4/8/15 kV air
Radiated RF electromagnetic field EN / IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz
Proximity fields from RF wireless communications equipment EN / IEC 61000-4-3	385 MHz: 27 V/m 450, 810, 870, 930, 1720, 1845, 1970, 2450 MHz: 28 V/m 710, 745, 780, 5240, 5500, 5785 MHz: 9 V/m Distance: 0.3 m For modulation, max. power see table 9 of IEC 60601-1-2:2014	385 MHz: 27 V/m 450, 810, 870, 930, 1720, 1845, 1970, 2450 MHz: 28 V/m 710, 745, 780, 5240, 5500, 5785 MHz: 9 V/m
Electrical fast transient a.c. mains EN / IEC 61000-4-4	± 2 kV 100 kHz Repetition frequency	± 2 kV 100 kHz Repetition frequency
Electrical fast transient SIP/SOP ports EN / IEC 61000-4-4	1 kV (I/O lines > 3 m)	N/A
Surge EN / IEC 61000-4-5	± 0.5 / ±1 kV (line-to-line) ± 0.5 / ±1 / ±2 kV (line-to-ground)	± 0.5 / ±1 kV (line-to-line) ± 0.5 / ±1 / ±2 kV (line-to-ground)

Conducted RF a.c. mains EN / IEC 61000-4-6	3 V, 150 kHz to 80 MHz 6V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 150 kHz to 80 MHz 6V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Conducted RF SIP/SOP ports EN / IEC 61000-4-6	3V, 150 kHz to 80 MHz 6V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	N/A
Power frequency magnetic fields EN / IEC 61000-4-8	30 A/m 50 Hz and 60 Hz	30 A/m 50 Hz and 60 Hz
Voltage dips, short interruptions, and voltage variations EN / IEC 61000-4-11	0% U_T for 0.5 cycle at 0° to 315° in 45° steps 0% U_T for 1 cycle 70% U_T for 25 cycles (50 Hz) 0% U_T; 250 cycles (50 Hz)	0% U_T for 0.5 cycle at 0° to 315° in 45° steps 0% U_T for 1 cycle 70% U_T for 25 cycles (50 Hz) 0% U_T; 250 cycles (50 Hz)

6.5. Electrostatic Discharge (ESD)

Strong electrostatic discharge can result in the malfunction of the External Unit. The system then switches to the safe state. Recommissioning can be successfully performed disconnecting und reconnecting the USB port (power off/on cycle).

6.6. Federal Communications Commission Statement

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference and
2. This device must accept any interference received, including interference that may cause undesired operation of the device.

FCC RF Radiation Exposure Statement:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure limits. This transmitter must not be colocated or operating with any other antenna or transmitter.

6.7. MRI Safety Information

All components of the Brain Interchange System are MR unsafe.

6.8. Cybersecurity

Warning: Connect the USB cable directly to the computing unit. Do not use an USB-hub.

Warning: In case of suspicious/abnormal system behavior, unplug the USB cable from the Computing Unit and contact support.

Warning: The BIC System shall not be connected to any IT Network or the internet during patient therapy sessions.

Warning: Store the device safely while not using it. Restrict physical access to the device.

Warning: Persons holding access means to the devices shall be registered. Access to the system shall be protocolled.
During use, at least one person with allowed access to the device shall be present at all times.

Warning: There shall be no 'guest' or password free accounts on the computing unit.

Warning: Boot loading and updating the system software is restricted to a trained service user only.

Warning: The Computing Unit shall be protected with a strong password.

Warning: Do a regular backup for therapy related data.

Caution: The hard drive of the Computing Unit shall be encrypted using a state-of-the-art encryption method, such as XTS-AES (Bitlocker).

Caution: The Computing Unit's operating systems shall apply updates promptly. Check for updates at least once a month.

Caution: The Computing Unit shall employ a state-of-the-art anti-virus and anti-malware software to prohibit or detect viruses and malware on the system. The software shall be regularly updated (at least once a month).

7. General Warnings

 Warning:	Inform patients, that they should always inform any healthcare personnel that they have an implanted system before any procedure is performed.
 Warning:	Do not modify this equipment without authorization of the CorTec.
 Warning:	To avoid the risk of electric shock, only use authorized equipment from CorTec.
 Warning:	Non-pyrogenic: not so labeled, but bacterial endotoxin testing demonstrates that the subject device meets ≤ 2.15 EU/device endotoxin limit requirement.
 Warning:	Do not use other accessories, components, and cables than those supplied by the CorTec.
 Warning:	In the event that the patient is exposed to a defibrillator, damage may occur within the implantable system.
 Warning	Before mobile activities, remove external components from patient.
 Warning	Check integrity of housings, cables and connectors before using the device.
 Warning	Do not use the Implantable Unit beyond product lifetime of 12 months.
 Warning	Use the device only in an environment with a temperature of 15 °C to 29 °C (59 °F to 84 °F) to avoid malfunctions.
 Caution:	Increased amplitude and pulse width settings required to achieve therapy may indicate a system problem or suboptimal lead placement.
 Caution:	Product shall be handled by clinicians and professional staff associated with the EFS only.
 Caution:	Do not drop any component.
 Note:	The System is limited to a charge density of 30µC/cm² which cannot be exceeded to avoid possible tissue damage. Charge density can be further reduced by lowering the stimulation amplitude or pulse width.

8. System Description

The system key performances are neural recording, electrical stimulation, and measurement of electrode impedance. These performances are provided by a wireless system, which includes an inductive link for power supply and an RF link for data communication.

8.1. System Overview

The system (Figure 1) consists of an Implantable Unit (1), an External Unit (2, 3) and a Computing Unit (5).

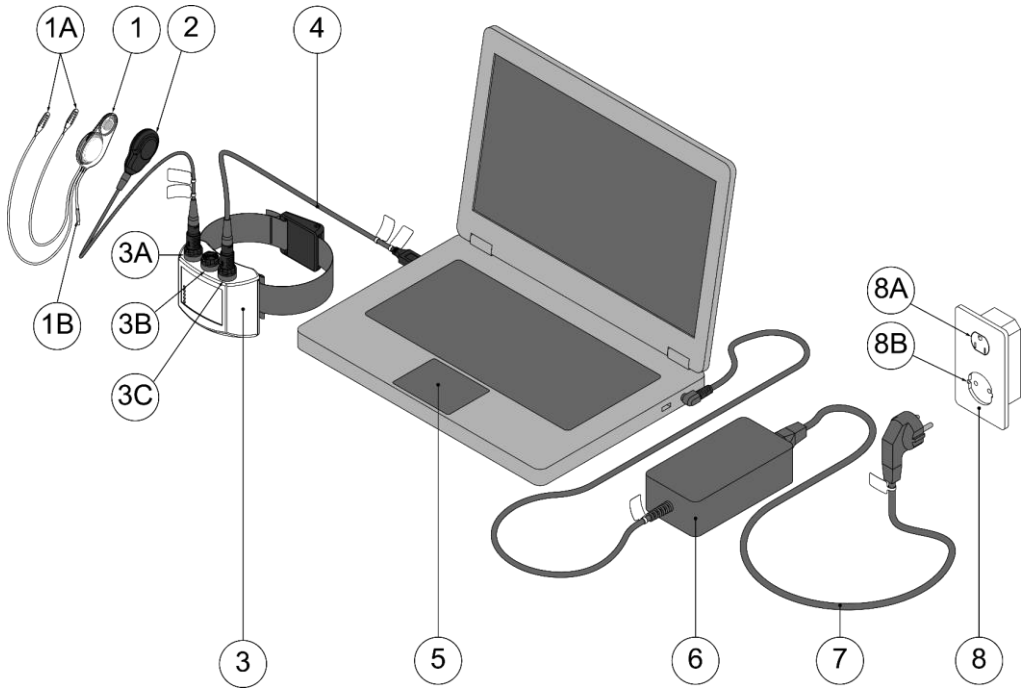


Figure 1: BIC System

1: Implantable Unit
   1A - Grid Electrodes
   1B - Ground Electrode (Optional)
2: Headpiece
3: Communication Unit
   3A - Head Piece Cable Connector
   3B - Trigger Input Connector
   3C - USB Cable Connector
4: USB Cable
5: Personal Computer
6: Power Supply
7: Power Cord (US / EU Power Cord)
8: Power Socket
   8A - US Power Socket
   8B - EU Power Socket

8.2. Component Description

The BIC System consists of several components that are described hereinafter.

8.2.1. Implantable Unit

The Implantable Unit (Figure 2) of the system is surgically implanted subcutaneously. The Implantable Unit consists of an Implantable Unit Body (7) placed in the cranial bone recess, a ground electrode which is placed subcutaneously and two grid electrodes which are placed subdural on the brain tissue.

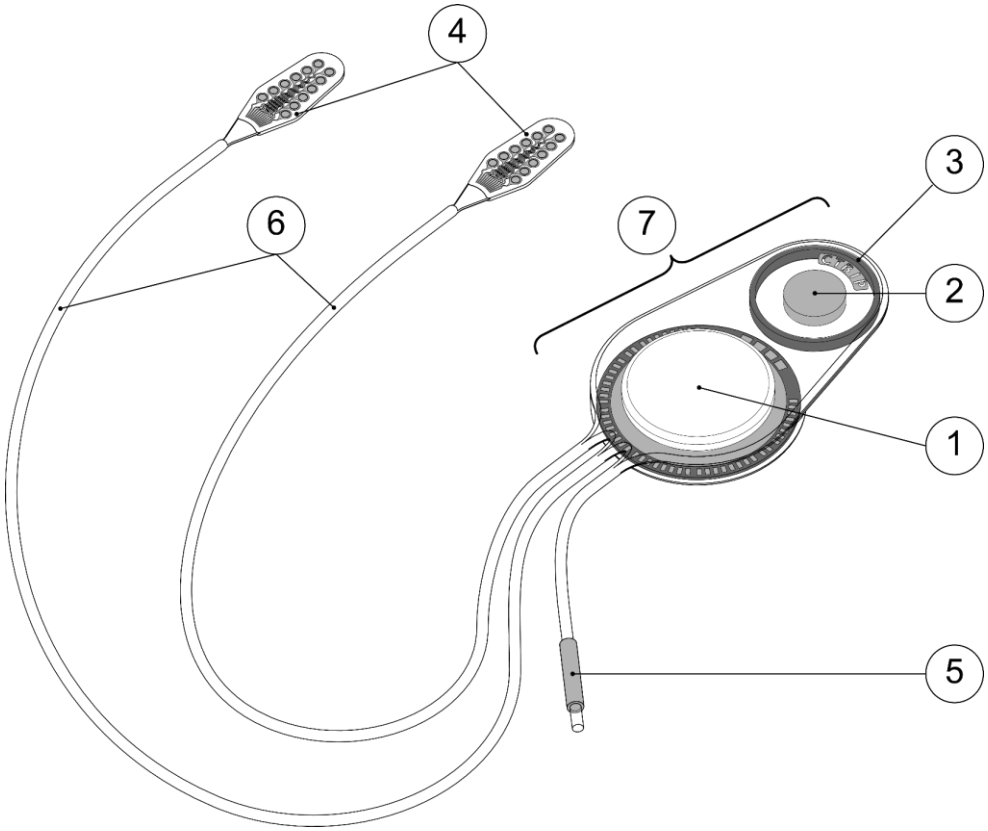


Figure 2: BIC Implantable Unit

1: Hermetic Capsule
2: Magnet
3: Coil
4: Grid Electrodes
5: Ground Electrode
6: Electrode Cable
7: Implantable Unit Body

Warning: Implantable Unit can be damaged by therapeutic ionizing radiation. Damage might not immediately be detectable.

Warning: Do not use therapeutic ultrasound in proximity of the implant.

Warning: Do not implant if encapsulation/insulation has defects.

WARNING

Warning: Single-use item. Do not use more than once.

WARNING

Warning: Never try to re-sterilize component.

WARNING

Warning: Do not use if component become non-sterile (e.g., if dropped or mishandled in theatre).

Note: Supplied sterile. Sterilized with ethylene oxide.

8.2.2. External Unit

The External Unit (Figure 3) consists of the Communication Unit (1) which is connected to the Personal Computer with a USB cable (4). The Headpiece (2) is connected to the Communication Unit and powers wirelessly the Implantable Unit. The Connector for Trigger Input (3) can also be connected to the Communication Unit.

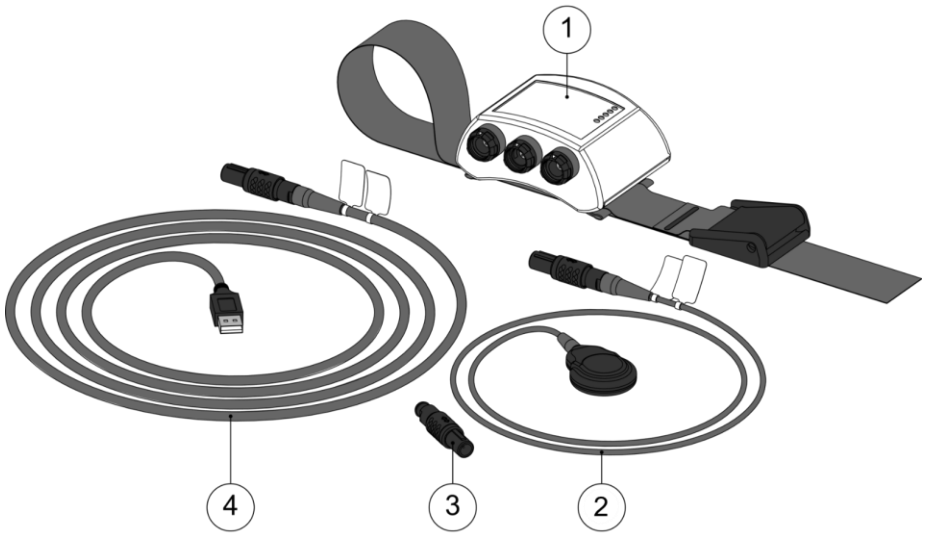


Figure 3: External Unit

WARNING

Warning: Do not expose the external components to water/ liquids while in use (powered)

WARNING

Warning: Do not use the External Unit if it has defects.

CAUTION

Caution: Handle external components with care and do not drop them.

8.2.2.1. Headpiece

The Headpiece (Figure 4) provides an alternating magnetic field, wirelessly suppling power to the Implantable Unit. Therefore, it is placed on the head of the patient during use. The magnetic field is generated through a coil (primary coil) in the Headpiece and picked up by the implanted coil (secondary coil). To facilitate good alignment, permanent magnets are placed

in the center of the coils that attract each other and keeps the Headpiece in place. The Headpiece has a cable which connects it to the Communication Unit.

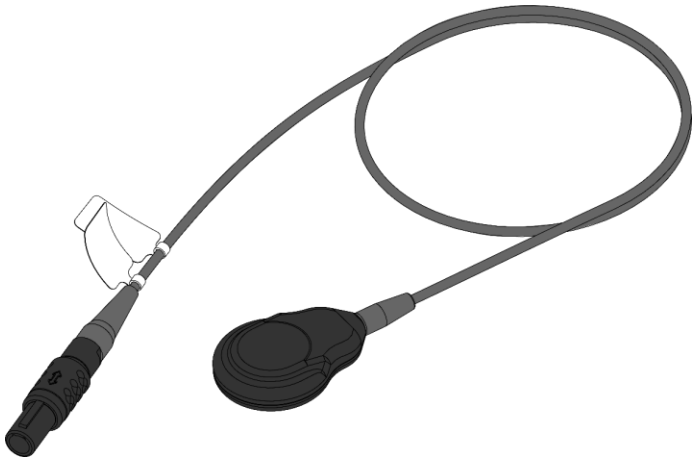


Figure 4: Headpiece

Warning: During use, do not cover device in textiles/clothes/blankets. Do not wear hats/caps/scarfs/headband. Do not fixate the headpiece with a bandage.

Warning: Do not expose headpiece to direct sunlight.

8.2.2.2. Communication Unit

The Communication Unit (Figure 5) is supposed to be placed on the patients arm and fixated with a strap during use. It has several functions:

- Wire-bound (USB) communication with the Personal Computer
- Wireless communication with the Implantable Unit
- Driving the Headpiece
- Recording an external trigger signal and threading this into the data stream coming from the Implantable Unit which is relayed to the Personal Computer
- Status indication via LEDs.

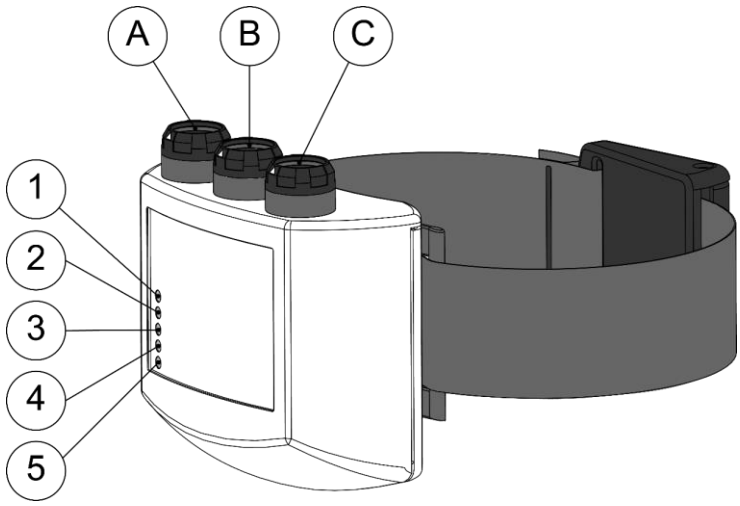


Figure 5: Communication Unit

Interfaces

A Headpiece Connector
B Trigger Input Connector
C USB Connector

Optical Indicator	Color	Mode	Meaning
1. READY	Green	Continuous	Com. Unit is ready
2. TRIGGER	Green	Continuous (if trigger is high)	Trigger signal is detected
3. ERROR	Red	Continuous	An error has occurred
4. TX	Green	Blinking	Wireless communication is active
5. I-POWER	Green	Continuous	Wireless powering is active

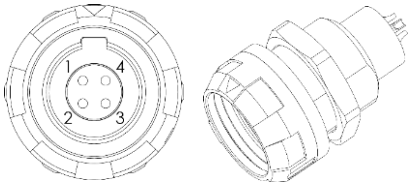
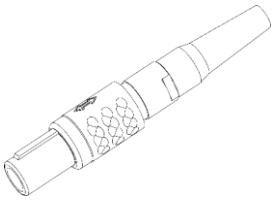
8.2.2.3. USB Cable

The USB Cable (see Figure 3, no. 4) connects the Communication Unit to the Personal Computer.

8.2.2.4. Connector for Trigger Input

The Communication Unit can receive a trigger input signal that permits the user to record the occurrence of events. This is of use for labelling of neural data and particularly helpful for data post-processing.
The System is shipped with a connector that mates with the trigger input of the Communication Unit (see Figure 3, no.3). The user of the system can customize its own trigger cable using this connector.

Table 9: Trigger Input Connector Interface Description

Figure	Pin description	Cable Connector
 (Front view of female connector of Communication Unit))	1 GND 2 Trigger Signal 3 Not connected 4 Not connected	 male cable connector

Warning: Trigger Input shall be used with low voltage (battery -based) equipment only or with power supplies which have been qualified according to IEC 60601-1 or IEC 62353!

8.2.3. Computing Unit

The Personal Computer and its accessories (power supply, cables) are called Computing Unit (Figure 6). The Personal Computer runs the CorTec proprietary software with the interface for the physician using the system. The manual for the Personal Computer is supplied with the device.

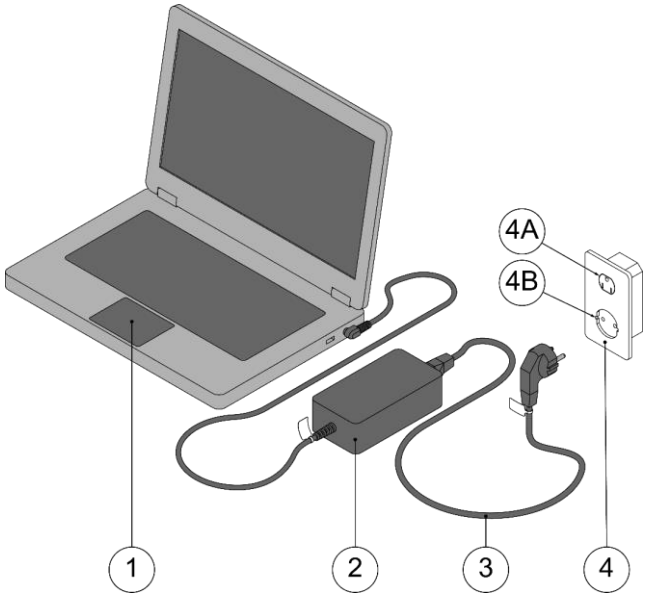


Figure 6: Computing Unit

1: Personal Computer
2: Power Supply
3: Power Cord (US / EU power cord)
4: Power Socket
4A - US Power Socket
4B - EU Power Socket

8.2.3.1. Personal Computer

The Personal Computer controls the system either via the Application Software or via Research Software written by the user, using the API provided by CorTec. The Personal Computer also receives status data from the system as well as – in recording mode – the stream of neural data and the trigger status.
As a measure of protection against data theft, CorTec demands activating "BitLocker" software to encrypt neural data stored on hard drive (see chapter 6.8).

8.2.3.2. Power Supply and Cord

The Power Supply allows the connection to a supply main. The laptop itself carries a battery which allows the use of the system for a limited time.

8.3. Operating Modes

The system has different modes of operation, listed below. In case the system detects a faulty condition, the Implantable Unit is shut down, exiting the current mode of operation for the safety of the patient.

Idle

In the Idle mode, the Implantable Unit is powered by and communicates with the Communication Unit. The system has identified safe operation conditions and is awaiting further commands. Dynamic Power Regulation (wireless power transfer from Headpiece to Implantable Unit) is active.

Recording

The Implantable Unit records neural data from all channels and transfers the digitized data wirelessly via Communication Unit together with the trigger input status to the Personal Computer.

Stimulation

Electrical stimulation is performed.

Warning: Clinicians have to (re-) determine patient-specific limits in order to avoid unwanted stimulation effects (e.g. epileptic seizures).

Note: Corrupted wireless communication might lead to stimulation commands to not be started. In this case the user is informed by a warning message.

Recording and Stimulation in Parallel

The Implantable Unit records neural data from all channels and transfers the digitized data to the Communication Unit and Personal Computer. Additionally, electrical stimulation is performed (amplifiers are disconnected from corresponding electrodes/channels). At the very instance of stimulation, actual neural recording from the stimulation electrode contacts is not possible. However, the signals from the stimulation electrode contacts might still show artifacts.

Impedance Measurement

Through low-intensity electrical stimulation pulses, the system calculates the electrode impedance by relating voltage responses to the stimulation pulses. As this impedance obtained as impulse response, it predominantly correlates to tissue impedance.

8.4. Accessories

8.4.1. Sterile Silicone Implant Dummy

The sterile Implant Dummy (Figure 7) is made of silicone and packed within the same cardboard box as the Implantable Unit but in a separate sterile package. One sterile silicone implant dummy is packaged with each implant. The dummy is designed for single use and is not re-sterilizable.

The implant dummy is used during surgery in the sterile field to test the fit of the bone recess and the positioning of the implant.

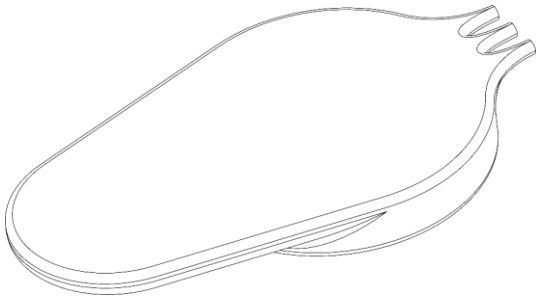


Figure 7: Sterile Implant Dummy

WARNING	Warning:	Do not use if the sterile pack has been damaged or previously opened.
WARNING	Warning:	Do not use if component become non-sterile (e.g., if dropped or mishandled in theatre).
WARNING	Warning:	For temporary use only. Not for implantation.
WARNING	Warning:	Single-use item. Do not use more than once.
WARNING	Warning:	Never try to re-sterilize component.
WARNING	Warning:	Use with BIC implants only.
	Note:	After surgery it is advisable to dispose of the instruments, even if not used.
	Note:	Dispose of instruments according to your institution's policy for disposal of biohazardous waste.
	Note:	Supplied sterile. Sterilized with ethylene oxide.

8.5. Interfaces

8.5.1. Radio Frequency Communication

Data communication is implemented using a proprietary protocol in the 2.4 GHz band.

Note: The alignment of Communications Unit with the Implantable Unit can play an important role in communication quality and can minimize or increase data loss or even lead to a loss of connection.

8.5.2. Inductive Link for Power Transfer

The energy transfer takes place inductively in the range from 120 kHz to 140 kHz.

Note: The energy transfer can be disrupted or completely interrupted by metallic objects in the immediate vicinity, especially in between the Headpiece and the Implant Unit.

9. Surgical Procedures

9.1. Implantation Preparation

Ensure that all the components of the BIC system are available for the surgery and for testing the functionality of the system during the surgery. The following components of the BIC system are necessary:

- Implantable Unit
- Implant Dummy
- Headpiece
- Communication Unit
- USB cable
- Computing Unit (incl. power supply and power cord)

Warning: Do not use the Implantable Unit if the sterile pack has been damaged or previously opened. In such case, the content must be returned to CorTec.

Warning: Pay careful attention to the “use by date” of the Implantable Unit and the Implant Dummy. Do not use if exceeded.

Warning: Do not re-sterilize the Implantable Unit or the Implant Dummy.

Warning: Single-use item. Do not use the Implantable Unit or the Implant Dummy more than once.

Note: To enable the functional testing during surgery, a sterile sheath is required to cover the Headpiece, the Communication Unit and the USB cable. The sterile sheath is not delivered by CorTec.

Note: For the fixation of the electrodes the use of suture sleeves is recommended. Suture sleeves are not delivered by CorTec.

9.2. Implantation Procedure

The procedure described here is only one possible approach for implanting the BIC Implantable Unit. The appropriate surgical approach is always at the discretion of the surgeon performing the procedure.

The suggested procedure aims for one incision leading from the forehead area over the top of the head to the area behind one ear. This incision covers the position for the bone recess for the Implantable Unit Body as well as the craniotomy to place the electrodes. This approach does not require tunning the electrodes.

Warning: The appropriate surgical approach is at the discretion of the surgeon performing the procedure.

Warning: Pay special attention to not damage the Implantable Unit when using sharp objects or tools such as sharp tweezers or cautery when implanting the device. Use of blunt, non-toothed forceps is recommended for handling unit.

Warning: Cautery / HF electrosurgical equipment should be avoided during and after device implantation. If cautery is required, only bipolar cautery should be employed.

Note: It may be advisable to engage a second health care professional to assist the primary implanter with stabilization of the Implantable Unit during the procedure.

The suggested procedure consists of the following steps:

1. Functional testing of the Implantable Unit before surgery
2. Introduce sterile components to sterile field
3. Pre-incision planning
4. Incision and milling of bone recess
5. Placing of the Implantable Unit Body
6. Placing of the grid electrodes
7. Functional testing of the Implantable Unit during surgery
8. Craniotomy closure and wound closure

Where a surgical instrument is mentioned in the procedure, see chapter 8.4.

9.2.1. Functional Testing Before Surgery

For purposes of this clinical study the testing will be performed by CorTec field clinical staff or by CorTec trained individuals.

9.2.2. Introduce Sterile Components to Sterile Field

Note: For warnings and more information see chapter 8.4.

To open the package:

Non-Sterile Field

1. Remove the two packages out of the blue cardboard box.

2. Confirm that:
   - the EO sterilization indicator dots on the inner package of Implantable Unit and Silicone Dummy are yellow (=content sterilized) and not white (=content not sterilized).
   - the package is not damaged.

Warning: Do not use components if the sterile pack has been damaged or previously opened. In such case, the content must be returned to CorTec.

WARNING

Warning: If the EO indicator indicates not sterilized content do not use the component. In such case, the unit must be returned to CorTec.

3. Open the outer packages and pass the inner packages to the assistant in the sterile field.

Sterile Field

1. Keep the sealed inner package with the Implantable Unit to one side, within the sterile field, until later in the surgery.
2. Open the inner package of the Implant Dummy.
3. Lift the Implant Dummy from the blister.

WARNING

Warning: Care not to contaminate the Implant Dummy while removing it from its sterile packaging.

9.2.3. Pre-Incision Planning

1. Use the Implant Dummy to plan the position of the Implantable Unit and the craniotomy. It is suggested to place the Implantable Unit Body comparable to the position of a cochlea implant (see Figure 8).

Figure 8: Photo in a cadaver study showing the Implantable Unit Body position

CAUTION

Caution: The Implantable Unit should be placed with the coil directing downwards, cables pointing towards the top of the skull.

2. Mark the positions of the Implantable Unit and the craniotomy and the necessary incision/s on the skull.

CAUTION

Caution: Avoid later scarring over the Implantable Unit to ensure good attraction of the magnets of the Implantable Unit and the Headpiece.

9.2.4. Incision and Milling of Bone Recess

1. Make the incision/s to enable the placing of the Implantable Unit Body.

Note: One incision is suggested to avoid tunneling of the grid electrodes.

2. Use the Implant Dummy to check the position and orientation of the Implantable Unit Body.

3. Mark the contour of the necessary bone recess to accommodate the thicker part of the Implantable Unit Body.

4. Mill the bone recess.

WARNING

Warning: Do not perform a full thickness craniotomy as this would lead to a subsidence of the Implantable Unit Body.

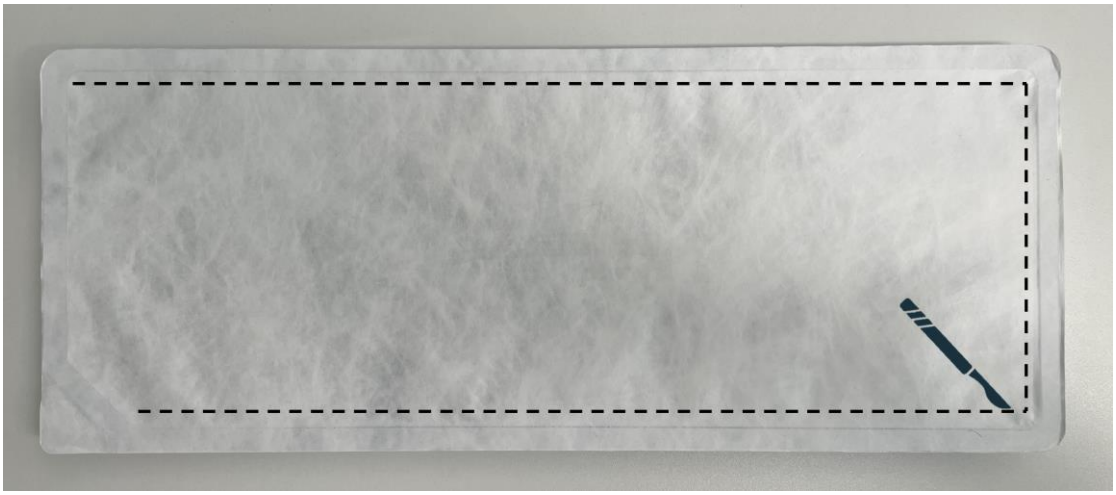
5. Use the Implant Dummy to test the depth and shape of the recess.

CAUTION

Caution: Chamfer the edge of the bone recess to not lead electrode cables over sharp bone edges.

9.2.5. Placing of the Implantable Unit Body

1. To avoid electrostatic charge buildup open the inner package of the Implantable Unit by cutting the lid on the sides with a scalpel without damaging the device.



CAUTION

Caution: Do not cut or damage the Implantable Unit, wires or electrodes.

2. Before touching the Implantable Unit, flood the inner package with saline to submerge the electrodes in saline. This lowers the risk adhesion of the electrodes to the packaging and electrostatic discharges.

WARNING

Warning: Care not to contaminate the Implantable Unit while removing it from its sterile packaging.

Caution: To avoid damage to the electrodes, avoid touching the electrode contacts. Handle Implantable Unit with care.

3. Place the Implantable Unit Body in the bone recess.

Caution: Skin thickness above the coil of the implantable unit must be between 2 and 6mm.

4. Secure the Implantable Unit Body in the bone recess (e.g. by securing it with suture material to the bone).

Caution: Do not puncture/damage the silicone of the Implantable Unit.

Caution: Avoid later scarring over the coil of the Implantable Unit to ensure good attraction of the magnets of the Implantable Unit and the Headpiece.

Caution: Do not use titanium or like to fixate the Implantable Unit Body. Keep a distance of at least 1 cm between metal elements and the implant.

5. Place the Ground Electrode subcutaneously.

9.2.6. Placing of the Grid Electrodes

1. Perform a craniotomy to enable the placement of the electrodes.

Warning: The electrode leads shall be led through the skull with a flat angle to avoid kinking of the leads and to avoid pressure on the brain tissue. Therefore, recesses in the edges of the craniotomy are recommended.

2. Place the Electrode Grids in the target area.

Caution: Before the placing to prevent movement of the electrode grid(s), ensure the electrode lead(s) is/are not twisted or coiled.

Caution: Pay special attention that the correct side of the electrode grid is facing the tissue. The electrode is placed correctly if the label “R” on the grid is readable after placing the electrode.

Caution: Place electrode carefully without crimping, twisting, or the like.

Caution: Only hold the electrode with forceps in the areas where there is only silicone.

3. Secure the position of the Electrode Grid(s).

Warning: The implanted lead(s) may migrate (move) from their desired implant location. Lead migration can result in changes in measurement and stimulation effectiveness and may require additional surgical procedures to modify the lead location. Use commonly used material (e.g. suture sleeves) to avoid electrode migration.

Caution: Use commonly used material (e.g. suture sleeves) to avoid damage or kinks on the electrode lead.

Warning: Use dura sealing to reduce the risk of CSF leakage.

4. Inspect the integrity of the dura. Any dural defects should be repaired in a watertight fashion by primary suture repair or suturing of dural graft. Dural sealant should be applied over any repair to add additional protection against a potential CSF (cerebrospinal fluid) leak.

9.2.7. Functional Testing During Surgery

For purposes of this clinical study the testing will be performed by CorTec field clinical staff or by CorTec trained individuals. Impedance tests will be done right after implantation. Electrode contacts showing an impedance of 1.5 kOhm (10x the expected value of about 150 Ohm for 2.4mm diameter contacts in cerebrospinal fluid) or higher must not be used for electrical stimulation.

Warning: Use sterile sleeves to protect patient from unsterile parts of the system during functional testing.

9.2.8. Closure

1. Close the craniotomy.
2. Close the wound.

Caution: If necessary, place excess cable length in a meandering fashion, not in loops. The cables shall not cross. Keep distance to the Implantable Unit Body if possible.

9.3. Postsurgical Treatment

Routine post-operative care shall be observed.

Warning: To avoid the risk of skin erosion, inform patients to avoid touching their skin where components are implanted.

Warning: Inform patients that falling, hitting hard objects with the head, and other traumatic accidents can damage shallowly implanted components such as the electrode leads.

CAUTION

Caution: Inform patients not to engage in rigorous physical activity.

9.3.1. Implant Card

The healthcare institution / provider shall fill out the implant card and give it to the patient or their care giver.

Instructions for completion:

1. Name of the patient or patient ID
2. Date of implantation
3. Name and address of the healthcare institution

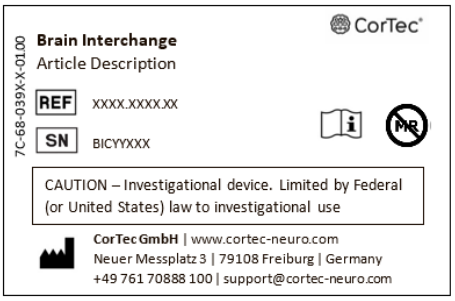


Figure 9: Frontside of Implant Card

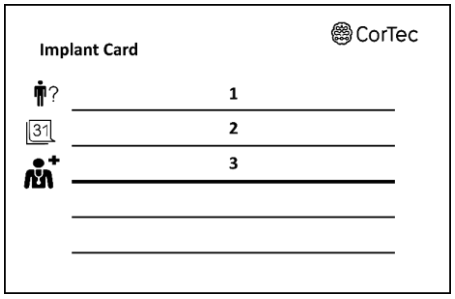


Figure 10: Backside of Implant Card

Note: Inform the patient or their care giver to always carry the patient identification card with them.

9.3.2. Identifying the Implantable Unit

After implantation it is possible to identify the Implantable Unit using the BIC software. Furthermore, the implant has an X-ray tag. It allows the identification of the implant type and model without any surgical intervention.

9.4. Explantation

1. Before explanting the Implantable Unit, inspect it for any defects. Note these (e.g. with photos).
2. Explant the device.

Note: Try not to damage the device during explantation. If necessary, cut the electrode leads to avoid further device damage.

Note: If possible, the implant shall be explanted in one piece, i.e., without cutting off the electrodes.

3. Apply basic cleaning to all explanted parts and place them – even if they are damaged - in sterile pouches. Seal the pouches and label them at least with
    a. date and place of explantation
    b. name of explanting surgeon
    c. name of study director

    If required/helpful for exact identification of the system, add additional information.

4. Return all explanted parts in sealed pouches to CorTec together with your notes and any other information available.

Warning: The long-term safety associated with leads left in place without use and lead removal is unknown.

Warning: Make sure to remove all components and potentially parts of components from the patient during explantation procedure.

Note: Use suitable transport packaging to avoid damaging the device during transportation.

Note: The explanted parts shall be transported as carry-on luggage as it shall not experience temperatures below 15 °C (59 °F).

10. Operating the System

To operate the system all components must be connected as shown in Figure 1 (page 17). The user can control the system via software running on the Personal Computer. Either the System is controlled using the CorTec Application Software (chapter 10.2) or by Research Software written using the CorTec API (Python or C). After use, disconnect the components and store them in their dedicated packaging.

Warning: Do not use the system if the patient's head temperature is above 38°C (100,4 °F) or ambient (air) temperature is higher than 29˚C (84 °F).

Warning: Do not use the Computing Unit in the patient environment (1.5m around the patient).

Warning: Do not touch the patient and the Computing Unit at the same time.

Warning: Avoid pinch points when attaching the External Unit.

Warning: Use with Computing Unit provided with the device only.

Warning: Ensure that the External Unit does not contact uncovered skin. Utilize a piece of biocompatible material between the device and patient. Also perform regular skin checks.

Warning: Do not fasten the arm strap of Communication Unit too much to avoid blood flow disturbances.

Warning: Advice to the patient or caregiver to be aware of the signs of skin irritation.

Warning: In the case of significant skin irritation, blistering, or signs of skin breakdown, use of the device should be suspended until the wound site can be assessed by the clinical caregivers.

Warning: Closely observe skin beneath/around the headpiece and inquiry of patient about comfort while the implant is being powered.

Warning: Do not use the system for more than 6 hours continuously to avoid thermal tissue damage.

Warning: Remove the headpiece from the patients head within 15 minutes if the system gets stuck to prevent tissue heating.

Caution: Make sure to proper align the implant's and headpiece's magnets and keep an eye on misplacement or swollen skin (thickness increased).

Caution: Handle components with care.

Caution: Only authorized personal may access the Computing Unit which is running the Application Software.

Caution: Do not put blocking objects between Headpiece and implant.

Caution: Do not put blocking objects between Headpiece and Communication Unit.

Note: The External Unit automatically shuts down when disconnected.

Note: If the Headpiece heats up due to a malfunction, the communication unit provides a safety shutdown and limits the power supply to the Headpiece.

Note: Check with the patient for thermal comfort while the system is on.

Due to the massive data transfer during recording, recording packets sent by the Implantable Unit are not re-sent in case of corruption. Missing or corrupted recordings are identified on the Computing Unit.

Note: The clinical user shall monitor the quality of the recording data during recording, i.e. the rate of received to missing recording data packets.

If recording quality is too low, the following measures may be applied:

- Remove blocking objects between the External Unit and the Implantable Unit
- Remove or shut off other wireless transceivers in the vicinity that operate in the 2.4 GHz range.
- Change the orientation of the External Unit.
- Reduce the distance between the External Unit and the Implantable Unit.
- Re-connect the system.

10.1. System Testing during Clinical Study

The user is advised to carry out electrode impedance testing on a regular basis (min. once a day before initiating therapy sessions). In case of an abrupt change in impedance relative to the previous measurement (factor of 5 or higher), the user shall consider the corresponding electrode contact may be malfunctioning (e.g. potential electrode wire breakage), therefore recording signals picked up by this electrode contact must be considered with caution relative to clinical decision making. During neurostimulation, a broken electrode contact (in case of reduced electrode contact area) might lead to critical charge injection densities which can lead to electrode corrosion and/or biological tissue irritation.

Warning: Electrical stimulation must not be applied to a malfunctioning electrode contact.

10.2. Application Software

CorTec's Application Software permit fast and easy use of the systems basic functionality.
See **Annex 1** for introduction into the Application Software.

Caution: Do not modify the Application Software. Software modifications and installation procedures shall be performed by CorTec personnel only.

10.3. Research Software / Application Programming Interface (API)

The user can create application specific Research Software. CorTec's API provides all the functionality required to use and control the System. The documentation of the API is installed with the API itself (USB memory stick).

10.4. Error Messages

If error messages appear repetitively, contact CorTec service, referring to the error message number. See also chapter 10.5.
Error messages must be interpreted by CorTec.

10.5. Trouble Shooting

Try to solve a problem by checking Table 10 before contacting CorTec customer support by email and phone:

support@cortec-neuro.com
0049-761-70-888-111

Table 10: List of Potential Solutions to Problems

ID	Problem	Potential Solution
1	System does not power up	1. Make sure USB port of Personal Computer is working correctly. Connect / disconnect USB plug; try different USB port, if available.

		2. Make sure Headpiece is well aligned* with Implantable Unit. 3. Ensure good radio frequency communication (see problem: packet losses)
2	System shuts down	1. Disconnect USB port 2. Reconnect USB port
3	High loss of wirelessly transmitted packets	1. Improve week radio frequency (2.4 GHz) connection 2. Switch-off WLAN and Bluetooth devices nearby 3. Reduce distance between Implantable Unit and Communication Unit 4. Change orientation of Communication Unit relative to Implantable Unit
4	Communication Unit Error LED on	1. Disconnect Communication Unit from the Computing Unit 2. Verify that Headpiece is properly aligned* with Implantable Unit. 3. Reconnect the Communication Unit to the Computing Unit
5	Application Software log output “networkstack.CFtdiDmaCommLayerWorker: Not all bytes were written”	1. Disconnect all other USB devices from the Computing Unit 2. Reconnect the Communication Unit to the Computing Unit

*Errors might result from too large or too small distances between Headpiece and Implantable Unit.

10.6. Maintenance and Cleaning

Clean the Headpiece and Communication Unit after each use on the patient. Ensure sufficient ventilation when doing so.

Cleaning:

1. Moisten a soft cloth with an aqueous alcohol solution (70 % ethanol, 30 % water) or other cleaning solution suitable for plastic, better cleaning wipes or tissues, for sensitive medical devices.
2. Wipe the external devices

Note: Do not use any abrasive agents to clean the external parts.

WARNING

Warning: Do not use organic solvents, e.g. gasoline, alcohols or ethers to avoid material fatigue, discoloration or breakage, discoloration or breakage.

WARNING

Warning: To prevent injury or damage to the system, do not modify the system in any way. If needed, return devices to CorTec.

10.7. Disposal

Note: Return all components to CorTec for safe disposal.

Note: Put all components in sterile pouches before returning them to CorTec.

Note: The explanted parts shall be transported as carry on luggage as it shall not experience temperatures below 15 °C (59 °F).

Annex 1: Application Software Short Manual

See file: Annex 1_BIC_Application_Software_Short_Manual

Annex 2: Bip2x Short Manual

See file: Annex 2_BIP_bip2x_Short_Manual

This device has not been authorized as required by the rules of the Federal Communications Commission. This device is not, and may not be, offered for sale or lease, or sold or leased, until authorization is obtained.

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Germany