SUMMARY OF SAFETY AND CLINCIAL PERFORMANCE (SSCP)

DEPTH ELECTRODES AND PLACEMENT ACCESSORIES

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PART 1 – INTENDED FOR HEALTH CARE PROFESSIONALS

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the devices.

The SSCP is not intended to replace the Instructions for Use (IFUs) as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for healthcare professionals.

1 GLOSSARY OF TERMS

Table 1: Glossary of Terms

Term/Abbreviation	Description
AD	Spencer Probe Depth Electrode, AD Style
BF	Behnke Fried Depth Electrode
CMR/ED	Carcinogenic, Mutagenic, Toxic to Reproduction, and Endocrine Disrupting Materials.
FO	Foramen Ovale Depth Electrode
FSCA	Field Safety Corrective Action
FSN	Field Safety Notice
LD	Spencer Probe Depth Electrode, LD Style
MD	Monopolar Depth Electrode
MDD	Medical Device Directive 93/42/EEC
MDR	Medical Device Regulation EU 2017/745
MM	Macro-Micro Depth Electrode
RD	Spencer Probe Depth Electrode, RD Style
sEEG	Stereoelectroencephalography
SD	Spencer Probe Depth Electrode, SD Style
UDI	Unique Device Identifier
WB	Wire Bundle Depth Electrode

2 DEVICE IDENTIFICATION AND GENERAL INFORMATION

2.1 DEVICE TRADE NAMES

This SSCP applies to the following devices:

2.1.1 DEPTH ELECTRODES

- AD-TECH® Spencer Depth Electrodes AD Style, S Type Contact
- AD-TECH® Spencer Depth Electrodes LD Style, S Type Contact
- AD-TECH® Spencer Depth Electrodes LD Style, A Type Contact
- AD-TECH® Spencer Depth Electrodes RD Style, S Type Contact
- AD-TECH® Spencer Depth Electrodes SD Style, S Type Contact

- AD-TECH® Spencer Depth Electrodes SD Style, A Type Contact
- AD-TECH® Monopolar Depth Electrode (MD)
- AD-TECH® Foramen Ovale Depth Electrodes (FO)
- AD-TECH® Behnke Fried Depth Electrodes (BF)
- AD-TECH® Wire Bundle Depth Electrodes (WB)
- AD-TECH® Macro-Micro Depth Electrode (MM)

2.1.2 PLACEMENT ACCESSORIES

- AD-TECH® LSB Series Anchor Bolts
- AD-TECH® Disposable Cranial Drill Kit – Non-sterile*
- AD-TECH® Disposable Cranial Drill Kit – Sterile*
- AD-TECH® Disposable Cranial Drill Bit – Non-sterile*
- AD-TECH® Slotted Cannula – Non-sterile
- AD-TECH® Slotted Cannula – Sterile
- AD-TECH® Obturators – Non-sterile
- AD-TECH® Obturators – Sterile

** Note: As AD-TECH® Disposable Cranial Drill Kit (sterile/non-sterile) and the Disposable Cranial Drill Bit – Non-sterile devices are used as placement accessories for an additional Class III AD-TECH device, these accessories will not be committed only to the MDR Depth Electrodes and Placement Accessories submission. This will be its own MDR submission and reviewed separately.*

2.2 MANUFACTURER

Table 2: Manufacture's Information

	AD-TECH® Medical Instrument Corporation 400 West Oakview Parkway Oak Creek, Wisconsin 53154 USA Tel: 262.634.1555 Fax: 262.634.5668 Toll Free (USA): 800.776.1555 Web: www.adtechmedical.com Email: sales@adtechmedical.com
	SRN: US-MF-000004795

2.3 BASIC UDI-DI

Table 3: UDI-DI Code Information

Device/Accessory	Basic UDI-DI
Depth Electrodes (All Models)	08418231RA2aJE

Device/Accessory	Basic UDI-DI
Anchor Bolts	08418231RA15bCA
Disposable Cranial Drill Kits	08418231RA15aC8
Slotted Cannulas	08418231RA15cCC
Obturators	08418231RA15dCE

2.4 MEDICAL DEVICE NOMENCLATURE DESCRIPTION/TEXT

Table 4: EMDN Code Information

Device/Accessory	EMDN Code
Depth Electrodes (All Models)	N0101020102, EEG DEPTH ELECTRODES
Anchor Bolts	Z12100601, STEREOTACTIC NEUROSURGERY SYSTEMS
Disposable Cranial Drill Kits	P091303 – ORTHOPEDIC PROSTHETICS DRILL BITS, SINGLE-USE
Slotted Cannulas	L030199, NEUROSURGERY OBTURATORS, REUSABLE
Obturators	L1110, NEUROSURGERY OBTURATORS, REUSABLE

2.5 CLASSIFICATION OF THE DEVICES/ACCESSORIES

Table 5: Device Classification

Device/Accessory	Classification as per MDR[1] Annex VIII
Depth Electrodes (All Models)	CLASS III
Anchor Bolts	CLASS III
Disposable Cranial Drill Kits	CLASS III
Slotted Cannulas	CLASS III
Obturators	CLASS III

[1] Medical Device Regulation EU 2017/745.

2.6 YEAR OF FIRST CE CERTIFICATION

The Depth Electrodes and Placement Accessories received their initial CE mark under the Medical Device Directive (MDD) 93/42/EEC in 1998.

2.7 AUTHORIZED REPRESENTATIVE

Table 6: Authorized Representative Information

EC REP	E C REP LIMITED 5 Fitzwilliam Square East Dublin 2, D02 R744, Ireland Tel: +353 1 2 544 944
	SRN: IE-AR-000003995

2.8 NOTIFIED BODY

Table 7: Notified Body Information

CE	BSI Group The Netherlands BV Say Building, John M. Keynesplein 9, 1066 EP Amsterdam The Netherlands
	NB: 2797

3 INTENDED USE OF THE DEVICE

3.1 INTENDED PURPOSE – DEPTH ELECTRODES

The Depth Electrodes are for temporary (<30 days) use with recording, monitoring, and stimulation equipment for the recording, monitoring, and stimulation of electrical signals at the subsurface level of the brain. The recording of electrical activity supports the definition of the location of epileptogenic foci and brain mapping.

3.2 INTENDED PURPOSE – PLACEMENT ACCESSORIES

3.2.1 ANCHOR BOLTS

The Anchor Bolts are optional accessories for temporary use (<30 days) with compatible Depth Electrodes. The Anchor Bolts may be applied when desired to minimize concerns about potential cerebrospinal fluid (CSF) leakage and infection of the subdural space while stabilizing the Depth Electrode. The Anchor Bolts are secured in the skull to provide an access point for Depth Electrodes.

3.2.2 DISPOSABLE CRANIAL DRILL KITS

The Cranial Drill Bits and Accessories are intended to be used for drilling holes in the skull for neurological procedures such as brain biopsy, brain contacting electrode, and electrode accessory placement.

See note in Section 2.1.2 for Disposable Cranial Drill Kit Submission.

3.2.3 SLOTTED CANNULAS

The Slotted Cannulas are optional accessories for use with Depth Electrodes. The Slotted Cannula may be applied when placing Depth Electrodes through a craniotomy or burr hole without using an Anchor Bolt. The Slotted Cannula is applied to create a path within the brain to facilitate the placement of the Depth Electrode.

3.2.4 OBTURATORS

The Obturators are optional accessories for use with Depth Electrodes. The Obturator may be applied before the placement of the Depth Electrodes. The Obturator is applied to create a path within the brain to facilitate the placement of the Depth Electrode.

3.3 INDICATIONS FOR USE – DEPTH ELECTRODES

The Depth Electrodes are indicated for patients undergoing diagnostic electrical brain mapping as part of neurological investigations and treatment planning.

3.4 INDICATIONS FOR USE – PLACEMENT ACCESSORIES

3.4.1 ANCHOR BOLTS

AD-TECH® Anchor Bolts are optional accessories for use with Depth Electrodes. The Anchor Bolts may be applied when it is desired to minimize concerns about potential cerebrospinal fluid (CSF) leakage and infection of the subdural space while stabilizing the electrode. Anchor Bolts are secured in the skull to provide an access point for Depth Electrodes.

3.4.2 DISPOSABLE CRANIAL DRILL KITS

The Cranial Drill Bits and Accessories are indicated for patients undergoing neurological procedures that require cranial access through a burr hole.

See note in Section 2.1.2 for Disposable Cranial Drill Kit Submission.

3.4.3 SLOTTED CANNULAS

Within the context of the Slotted Cannula being an accessory to the Depth Electrodes:

The Depth Electrodes are indicated for patients undergoing diagnostic electrical brain mapping as part of neurological investigations and treatment planning.

3.4.4 OBTURATORS

Within the context of the Obturators being an accessory to the Depth Electrodes:

The Depth Electrodes are indicated for patients undergoing diagnostic electrical brain mapping as part of neurological investigations and treatment planning.

3.5 TARGET PATIENT POPULATION

The Depth Electrodes and Placement Accessories are used in pediatric and adult populations, regardless of gender.

3.6 CONTRAINDICATIONS – DEPTH ELECTRODES

- The Depth Electrodes are not for use on any patient whom the physician/surgeon considers at risk of infection.
- The Depth Electrodes are not for continuous stimulation. Stimulation should only be applied to support brain mapping.

3.7 CONTRAINDICATIONS – PLACEMENT ACCESSORIES

3.7.1 ANCHOR BOLTS

- The Anchor Bolts are not for use on any patient whom the physician/surgeon considers at risk of infection.
- The Anchor Bolts are not for use with patients with low bone density or softening of the skull.

3.7.2 DISPOSABLE CRANIAL DRILL KITS

- The Cranial Drill Bits and Accessories are not for use on any patient whom the physician/surgeon considers at risk of infection.

3.7.3 SLOTTED CANNULAS

- The Slotted Cannulas are not for use on any patient whom the physician/surgeon considers at risk of infection.

3.7.4 OBTURATORS

- The Obturators are not for use on any patient whom the physician/surgeon considers at risk of infection.
- The Obturator must not be used for the application of thermal energy.

4 DEVICE DESCRIPTION

4.1 DEVICE DESCRIPTION – DEPTH ELECTRODES (AD, LD, RD, SD, MD, FO)

The Depth Electrodes are slender, cylindrical tubes inserted into the brain.

Depth Electrodes have conductive contacts at the distal end to monitor the brain's electrical signals or deliver electrical stimulation.

The contacts connect to internal wires that run throughout the device's body to the tail, where they attach to electrical contacts that allow connection to compatible cable systems.

When connected to compatible equipment, the electrodes serve as the patient-electrode interface for temporary stimulation and recording electrical signals at the subsurface of the brain.

The Depth Electrodes are available in different configurations, including the number of contacts, the contact length, and the contact spacing as specified by the physician.

4.2 DEVICE DESCRIPTION - DEPTH ELECTRODES (BF, WB)

The Behnke Fried and Wire Bundle Depth Electrodes provide macro and micro monitoring and stimulation.

The Behnke Fried Macro Depth Electrode is a cylindrical tube with conductive contacts at the distal end to monitor the brain's electrical signals or deliver electrical stimulation at the macro level. The contacts connect to internal wires that run throughout the device's body to the tail, where they attach to electrical contacts that allow connection to compatible cable systems. An inner lumen runs the electrode length to accommodate the Wire Bundle Depth Electrode. The Behnke Fried Macro Depth Electrode incorporates a stylet to keep it ridged during placement.

The Wire Bundle Depth Electrode consists of an outer tube with a wire bundle that passes through the inner lumen and protrudes from the distal end. The surgeon trims the wires to the required length to monitor the brain's electrical signals or deliver electrical stimulation at a micro level. The wire bundle terminates to proximal contacts allowing connection to a compatible cable system.

The Wire Bundle Depth Electrode fits inside the Behnke Fried Depth Electrode, creating a seal to prevent CSF leakage. The surgeon places the complete assembly in the desired location to provide macro and micro monitoring and stimulation.

The Behnke Fried Macro Depth Electrodes have eight macro contacts. The Wire Bundle Depth Electrode provides eight or nine micro-contacts.

4.3 DEVICE DESCRIPTION – DEPTH ELECTRODES (MM)

The Depth Electrodes are slender, cylindrical tubes inserted into the brain.

Depth Electrodes have conductive contacts at the distal end to monitor the brain's electrical signals or deliver electrical stimulation. The Macro-Micro Depth Electrodes combine macro and micro contacts in a single lumen.

The contacts connect to internal wires that run throughout the device's body to the tail, where they attach to electrical contacts that allow connection to compatible cable systems.

When connected to compatible equipment, the electrodes serve as the patient-electrode interface for temporary stimulation and recording electrical signals at the subsurface of the brain.

The Depth Electrodes are available in different configurations, including the number of contacts, the contact size, and the contact spacing as specified by the physician.

4.4 DEPTH ELECTRODES - CATALOGUE NUMBER DESCRIPTION

Table 8 describes the catalog numbering system for the Depth Electrodes, excluding the Macro-Micro model.

Table 9 describes the catalog numbering system for the Macro-Micro Depth Electrodes.

Table 8: Catalogue Numbering System – Depth Electrodes (Excluding MM)

Variable	Definition	Values
X_{1-2}	Electrode Design Intent	Spencer: **SD, RD, LD, or AD** Monopolar: **MD** Foramen Ovale: **FO** Behnke Fried (macro): **BF** Wire Bundle (micro): **WB**
X_{3-4}	Number of Contacts	**01 – 16**

Variable	Definition	Values
X_5	Tail Numbering	**0 – 9** or **A - Z**
Y_1	Contact Style	Standard: **S** Alternative: **A**, **B**, **C**, or **D**
Y_2	Contact Material	Platinum: **P**
Y_{3-4}	Contact Spacing	**00 – 99**
Y_5	Sterility Status	Sterile: **X**
Z_1	Stylet and Needle Codes	**0** or **A – Z**
Z_{2-3}	Non-Significant Options	**00 – 99**, **A0 – Z9**, or **AA – ZZ** Electrode Body Options Tail Options Marker Options
Devices are ordered according to the formula: X_{1-2} X_{3-4} X_5 – Y_1 Y_2 Y_{3-4} Y_5 – Z_1 Z_{2-3}		

Table 9: Catalogue Numbering System – Depth Electrodes (MM)

Variable	Definition	Values
X_{1-2}	Electrode Design Intent	Macro-Micro: **MM**
X_{3-5}	Configuration	**01A – 32Z**
Y_1	Contact Style	Standard: **S** Alternative: **A**, **B**, **C**, or **D**
Y_2	Contact Material	Platinum: **P**
Y_{3-4}	Contact Spacing	**00 – 99**
Y_5	Sterility Status	Sterile: **X**
Z_1	Stylet and Needle Codes	**0** or **A – Z**
Z_{2-3}	Non-Significant Options	**00 – 99**, **A0 – Z9**, or **AA – ZZ** Electrode Body Options Tail Options Marker Options
Devices are ordered according to the formula: X_{1-2} X_{3-5} – Y_1 Y_2 Y_{3-4} Y_5 – Z_1 Z_{2-3}		

4.5 DEVICE DESCRIPTION – PLACEMENT ACCESSORIES

4.5.1 ANCHOR BOLTS

The Anchor Bolts are optional accessories to support the placement of the following AD-TECH® Depth Electrodes:

- AD-TECH® Spencer Probe Depth Electrodes, Styles LD, RD, and SD
- AD-TECH® Behnke Fried Depth Electrode (BF)
- AD-TECH® Macro-Micro Depth Electrode (MM)

Anchor Bolts are secured in the skull to provide an access point and minimize concerns about potential cerebrospinal fluid (CSF) leakage and infection of the subdural space while stabilizing the Electrode.

The Anchor Bolt consists of a tube through which the Depth Electrode can pass. The proximal end is threaded, allowing the surgeon to screw it into the patient's skull via an appropriately sized burr hole. The distal end is threaded to accept the Anchor Bolt Cap.

The surgeon passes the Anchor Bolt Cap over the distal end of the Depth Electrode and screws it tight, compressing the internal Gasket against its outer wall. The compression between the Gasket and the Electrode body is the primary seal to prevent CSF leakage.

A Silicone Cap protects the Anchor Bolt Cap and provides additional strain relief for the Depth Electrode tail.

The Anchor Bolts are available in Titanium Grade 2 and Anodized Titanium Grade 2.

The color of the Anchor Bolt gasket denotes the compatible Depth Electrodes as follows:

- Spencer Probe Depth Electrode, SD Style = Green
- Spencer Probe Depth Electrode, RD Style = Blue
- Spencer Probe Depth Electrode, LD Style = Clear
- Behnke Fried (BF) and Macro-Micro Depth Electrodes (MM) = Clear

Table 10 describes the catalog numbers for the Anchor Bolts.

Table 10: Catalog Numbers for the Anchor Bolts

Catalog Number	Description	Material	Distal Opening Diameter	Length
LSBK1-AX-05 (Green)	Use with SD Depth Electrodes	Titanium	1.5 mm	21 mm
LSBK1-AX-06 (Clear)	Use with BF, LD, or MM Depth Electrodes	Titanium	1.5 mm	21 mm
LSBK2-BX-04 (Blue)	Use with RD Depth Electrodes	Anodized Titanium	0.99 mm	13 mm
LSBK1-BX-05 (Green)	Use with SD Depth Electrodes	Titanium	1.5 mm	13 mm
LSBK1-BX-06 (Clear)	Use with BF, LD, or MM Depth Electrodes	Titanium	1.5 mm	13 mm
LSBK1-CX-04 (Blue)	Use with RD Depth Electrodes	Titanium	1.5 mm	26 mm
LSBK1-CX-05 (Green)	Use with SD Depth Electrodes	Titanium	1.5 mm	26 mm
LSBK1-CX-06 (Clear)	Use with BF, LD, or MM Depth Electrodes	Titanium	1.5 mm	26 mm
LSBK2-AX-04 (Blue)	Use with RD Depth Electrodes	Anodized Titanium	0.99 mm	21 mm

4.5.2 DISPOSABLE CRANIAL DRILL KITS

The Disposable Cranial Drill Kits consist of two Cranial Drill Bits, Drill Stops, and Drill Wrenches.

AD-TECH® also supplies single Disposable Cranial Drill Bits.

Cranial Drill Bits and Accessories are used to drill holes in the skull for neurological procedures, such as brain biopsy, brain contacting electrode, and electrode accessory placement.

The Cranial Drill Bit can be used with manual or powered surgical drills with a compatible chuck, such as a keyed or keyless Jacobs chuck.

The Drill Stop is secured to the Drill Bit using the Drill Stop Wrench to set the drilling depth.

The Drill Stop will not stop the drill. The Drill Stop is designed only to provide the user with a marker for drilling depth. The Drill Stop must be adjusted to the proper position before drilling.

The Disposable Cranial Drill Kits are available either sterile or non-sterile.

The Disposable Cranial Drill Kits and Disposable Cranial Drill Bits are single-use.

Table 11 describes the catalog numbers for the Disposable Cranial Drill Bit Kits.

See note in Section 2.1.2 for Disposable Cranial Drill Kit Submission.

Table 11: Catalog Numbers for the Disposable Cranial Drill Bit Kits

Catalog Number	Description	Drill			Drill Stop Quantity	Drill Wrench Quantity	Sterile Yes/No
		Quantity	Length (YY)	Diameter (a.a)			
DDK2-2.4-30N	Disposable Drill Kit – Non-sterile	2	30cm	2.4mm	2	2	No
DRL-2.4-22N	Disposable Drill Bit – Non-sterile	1	22cm	2.4mm	0	0	No
DDK2-2.4-16X	Disposable Drill Kit – Sterile	2	16cm	2.4mm	2	2	Yes
DDK2-2.4-30X	Disposable Drill Kit – Sterile	2	30cm	2.4mm	2	2	Yes
DDK2-2.8-30X	Disposable Drill Kit – Sterile	2	30cm	2.8mm	2	2	Yes
DDK2-3.2-30X	Disposable Drill Kit – Sterile	2	30cm	3.2mm	2	2	Yes

4.5.3 SLOTTED CANNULAS

The Slotted Cannulas are optional accessories to support the placement of the following Depth Electrodes:

- AD-TECH® Spencer Probe Depth Electrodes, Styles RD and SD
- AD-TECH® Behnke Fried Depth Electrode (BF)
- AD-TECH® Macro-Micro Depth Electrode (MM)

The Slotted Cannula may be applied when placing Depth Electrodes through a craniotomy or burr hole without using an Anchor Bolt. The Slotted Cannula is applied to create a path within the brain to facilitate the placement of the Depth Electrodes.

The Slotted Cannula is a two-part device consisting of a thin split tube called the Outer Sheath and an Inner Obturator.

The Slotted Cannula, including the Inner Obturator, is advanced along the planned placement trajectory until reaching the target location.

The surgeon removes the Inner Obturator and inserts the Depth Electrode through the Outer Sheath.

After placement of the Depth Electrode, the surgeon removes the Outer Sheath.

The Slotted Cannulas are available either sterile or non-sterile.

The Slotted Cannulas are reusable up to twenty-five times.

Table 12 describes the catalog numbers for the Slotted Cannulas.

Table 12: Catalog Numbers for the Slotted Cannulas

Catalog Number	Description	Quantity	Length	Diameter	Supplied Sterile
2SC-190N	Two-piece Slotted Cannula	1	190 mm	2.4 mm	No
2SC-190X	Two-piece Slotted Cannula	1	190 mm	2.4 mm	Yes
2SC-240N	Two-piece Slotted Cannula	1	240 mm	2.4 mm	No
2SC-240X	Two-piece Slotted Cannula	1	240 mm	2.4 mm	Yes
2SCK1-190X	Two-piece Slotted Cannula	2	190 mm	2.4 mm	Yes
2SCK1-240X	Two-piece Slotted Cannula	2	240 mm	2.4 mm	Yes

4.5.4 OBTURATORS

The Obturators are optional accessories to support the placement of the following Depth Electrodes:

- AD-TECH® Spencer Probe Depth Electrodes, Styles LD, RD, and SD
- AD-TECH® Behnke Fried Depth Electrode (BF)
- AD-TECH® Macro-Micro Depth Electrode (MM)

An Obturator is a solid stainless steel rod with a rounded tip and a Delrin® hub.

The Obturator is used in conjunction with an Anchor Bolt. The Obturator is advanced through the Anchor Bolt along the planned placement trajectory to create a pathway in the brain.

The Obturator is withdrawn, and the Depth Electrode is advanced in the same manner along the path made by the Obturator until the Depth Electrode reaches the target location.

Obturator selection is dependent on the type of Depth Electrode.

The Obturators are available either sterile or non-sterile.

The Obturators are reusable up to twenty-five times.

Table 13 describes the catalog numbers for the Obturators.

Table 13: Catalog Numbers for the Obturators

Catalog Number	Compatible Electrodes	Length (L)	Diameter	Supplied Sterile
OB-20-190X	LD, RD, SD, BF, MM	190 mm	0.86 mm	Yes
OB-20-190N	LD, RD, SD, BF, MM	190 mm	0.86 mm	No
OB-17-240X	LD, SD, BF, MM	240 mm	1.17 mm	Yes
OB-17-240N	LD, SD, BF, MM	240 mm	1.17 mm	No
OB-20-190X	LD, RD, SD, BF, MM	190 mm	0.86 mm	Yes
OB-20-190N	LD, RD, SD, BF, MM	190 mm	0.86 mm	No

4.6 METHOD OF STERILIZATION – DEPTH ELECTRODES

AD-TECH® sterilizes the Depth Electrodes using ethylene oxide.

4.7 METHOD OF STERILIZATION – PLACEMENT ACCESSORIES

4.7.1 ANCHOR BOLTS

AD-TECH® sterilizes the Anchor Bolts using ethylene oxide.

4.7.2 CRANIAL DRILL BITS AND ACCESSORIES – STERILE

AD-TECH® sterilizes the Cranial Drill Bits and Accessories using ethylene oxide.

4.7.3 CRANIAL DRILL BITS AND ACCESSORIES – NON-STERILE

Clean and sterilize non-sterile Cranial Drill Bits and Accessories before use as directed in the instructions for use.

4.7.4 SLOTTED CANNULAS – STERILE

AD-TECH® sterilizes the Slotted Cannulas using ethylene oxide.

4.7.5 SLOTTED CANNULAS – NON-STERILE

Clean and sterilize non-sterile Slotted Cannulas before use as directed in the instructions for use.

4.7.6 OBTURATORS – STERILE

AD-TECH® sterilizes the Obturators using ethylene oxide.

4.7.7 OBTURATORS – NON-STERILE

Clean and sterilize non-sterile Obturators before use as directed in the instructions for use.

4.8 MATERIALS – DEPTH ELECTRODES

The following materials used in the construction of the Depth Electrodes make contact with the patient:

- Polyurethane
- Platinum
- Cyanoacrylate
- Polyimide
- Iridium
- Silicone
- Stainless Steel
- Marking ink

4.8.1 MATERIALS – PLACEMENT ACCESSORIES

The following materials used in the construction of the Placement Accessories make contact with the patient:

4.8.2 ANCHOR BOLTS

- Titanium
- Silicone

4.8.3 DISPOSABLE CRANIAL DRILL KITS

- Stainless steel

4.8.4 SLOTTED CANNULAS

- Stainless steel

4.8.5 OBTURATORS

- Stainless steel

4.9 MEDICINAL SUBSTANCES

The Depth Electrodes and Placement Accessories do not incorporate medicinal substances.

4.10 TISSUES OF HUMAN OR ANIMAL ORIGIN

The Depth Electrodes and Placement Accessories are not manufactured using tissues or cells of human or animal origin.

4.11 SUBSTANCES ABSORBED OR LOCALLY DISPERSED

The Depth Electrodes and Placement Accessories are not composed of substances or combinations of substances absorbed by or locally dispersed in the human body.

4.12 CMR/ED SUBSTANCES

The Depth Electrodes and Placement Accessories are not made from materials that contain or consist of carcinogenic, mutagenic, or toxic to reproduction or endocrine-disrupting substances.

4.13 MATERIALS THAT RESULT IN SENSITIZATION OR ALLERGIC REACTIONS

AD-TECH® has tested the Depth Electrodes and Placement Accessories and found that the devices do not cause sensitization. Furthermore, Ad-Tech's post-market surveillance (PMS) has not identified any cases of sensitization or allergic reaction related to the Depth Electrodes and Placement Accessories.

4.14 PREVIOUS GENERATIONS OR VARIANTS

No previous generations or variants of the Depth Electrodes and Placement Accessories exist.

4.15 ACCESSORIES NOT INCLUDED BUT NECESSARY FOR USE

4.15.1 LIGHTWEIGHT CABRIO CABLE

The Lightweight CABRIO Cable is designed to provide an easy method for making a secure connection between an AD-TECH® electrode and standard clinic EEG monitoring and/or stimulation equipment.

4.15.2 TECH-ATTACH CONNECTION CABLES

The TECH-ATTACH Cables are one component of the TECH-ATTACH Connection System. The system is designed to provide an easy method for making a secure connection between an AD-TECH® electrode and standard clinic EEG monitoring.

4.15.3 TECH-ATTACH DISPOSABLE CONNECTOR BLOCKS

The TECH-ATTACH Disposable Connector Block is one component of the TECH-ATTACH Connection System. The system is designed to provide an easy method for making a secure connection between an AD-TECH® electrode and standard clinic EEG monitoring and/or stimulation equipment.

4.15.4 STAY FLANGE

The Stay Flange is an AD-TECH® SD Style Spencer Depth Electrode accessory. The Stay Flange is sutured to the scalp, providing additional security for the SD Depth Electrode.

4.15.5 RULER

The Ruler is an optional accessory to the AD-TECH® Depth Electrode. The surgeon uses the Ruler for Drill Stop and Depth Electrode measurements.

4.15.6 ANCHOR BOLT PLACEMENT AND REMOVAL WRENCHES

The wrenches are used for the placement and removal of Anchor Bolts.

4.15.7 DISPOSABLE DRILL STOP AND DRILL STOP WRENCH

The Drill Stop and Drill Stop Wrench are accessories to the AD-TECH® Cranial Drill Bits. The Drill Stop is attached to a Cranial Drill Bit by the Drill Stop Wrench as a depth guide to the Drill Bit.

4.15.8 DRILL SLEEVE GUIDE

The Drill Sleeve Guide is an accessory to the AD-TECH® Cranial Drill Bits. It is a long, stainless steel tube with a through-hole inner diameter sized to interface with Ad-Tech's 2.4mm Cranial Drill Bit, which maintains a specified trajectory along the skull when used with stereotactic equipment.

4.15.9 LEKSELL GUIDE BLOCKS

The Guide Blocks are accessories to the AD-TECH® Cranial Drill Bits. The Guide Blocks support the placement of the AD-TECH® Drill Sleeve Guide on a stereotactic frame.

4.15.10 SLOTTED CANNULA SLEEVE GUIDE

The Slotted Cannula Sleeve Guide (SCSG) is an accessory to the AD-TECH® Slotted Cannula. The SCSG fits compatible stereotactic head frames to provide trajectory alignment and set the penetration depth for the Slotted Cannula.

4.15.11 BRAINLAB NAVIGATION GUIDE

The AD-TECH® BrainLab Navigation Guide (BLNG) is a depth placement device used as an accessory item for placing or using Ad-Tech's electrodes, electrode systems, or Biopsy Needles.

4.15.12 STEALTHSTATION NAVIGATION GUIDE

The AD-TECH® StealthStation Navigation Guide (SNG) is a depth placement device used as an accessory item for placing or using Ad-Tech's electrodes, electrode systems, or Biopsy Needles

4.16 OTHER DEVICES AND PRODUCTS

The Depth Electrodes are designed to connect to third-party EEG monitors/stimulators.

The physician must select the appropriate equipment for connection to the Depth Electrodes based on the indication and diagnostic procedure.

The Depth Electrodes connect to EEG monitoring equipment capable of processing signals greater than 32 Hz with a minimum input voltage of 50 µV.

The Depth Electrodes connect to EEG stimulation equipment with a constant-current generator of less than or equal to 34 mA and a constant-voltage stimulator of less than or equal to 10 V.

5 RISKS AND WARNINGS

The IFUs provide complete instructions for safely using the Depth Electrodes and Placement Accessories. Following the IFUs will reduce the likelihood of user error. The IFUs are available via the link http://ad-tech.imgmgmt.com/instructions-use-documents.

5.1 RESIDUAL RISKS

The IFUs provide comprehensive lists of warnings, precautions, and contraindications which guide the intended user to minimize patient harm due to residual risks.

5.2 UNDESIRABLE SIDE EFFECTS

All undesirable side effects related to using the AD-TECH® Depth Electrodes are expected when considering the invasive nature of the procedure. The undesirable side effects are presented in Table 14.

AD-TECH® has identified the possible undesirable side effects from the clinical literature on AD-TECH® Depth Electrodes and the literature on state-of-the-art brain mapping using Depth Electrodes.

Specifically, where clinical data is available on Ad-Tech's devices, the probability of occurrence has been reported in Table 14.

Clinical literature searches identified n=32 studies covering n=640 patients subject to electrical brain mapping using the AD-TECH® Depth Electrodes. Undesirable side effects were reported in n=3 studies.

Where no clinical data on AD-TECH® devices are available, the occurrence rates from the state-of-the-art literature analysis are reported.

NOTE: Undesirable side effects may be described using alternative terms such as adverse events, incidents, or complications in the literature. The term undesirable side effect has been used in this document for consistency.

Table 14: Probability of Occurrence of Undesirable Side Effects

Undesirable Side Effect	Probability of Occurrence of Harm	Source
Abscess	0.2%	Gross et al. (2019)[2]
Bleeding	0.4%	Mullin et al. (2016)[3]
CSF leakage/drainage/pseudomeningocele	0.8%	Gross et al. (2019)[2]
Death	0.6%	Mullin et al. (2016)[3]
Epidural hemorrhage	0.6%	Mullin et al. (2016)[3]
Intracerebral hemorrhage	0.2%	Gross et al. (2019)[2]
Medical complications, including deep vein thrombosis, pulmonary embolisms, allergic reactions, and psychiatric changes	1.6%	Mullin et al. (2016)[3]
Meningitis	0.5%	Gross et al. (2019)[2] Ladisch et al. (2021)[2]
Permanent neurologic deficit	0.3%	Gross et al. (2019)[2]
Subarachnoid hemorrhage	0.2%	D'Agostino et al. (2020)[2]
Subdural hemorrhage	0.5%	D'Agostino et al. 2020[2] Gross et al. 2019[2]
Superficial wound infection	0.3%	Gross et al. 2019[2]
Transient neurologic deficit	0.3%	Gross et al. 2019[2]
Worsening seizures	0.6%	Mullin et al. (2016)[3]

Note: The undesirable side effects may present during the monitoring period and up to 30 days post removal.

5.3 WARNINGS – DEPTH ELECTRODES

- This product should only be used by a physician/surgeon experienced in the use of Depth Electrodes and the associated Placement Accessories. Incorrect use of this device may result in severe patient harm.
- Placement of the Depth Electrodes without the correct preoperative planning may result in severe patient harm.
- Placement of the Depth Electrodes without the correct stereotactic guidance may result in severe patient harm.

[2] Data on Ad-Tech Depth Electrodes taken from published clinical literature. For patient numbers refer to Table 16.

[3] Data from state-of-the-art published clinical literature. Meta-analysis of n=30 studies covering n=2,624 patients.

- The Depth Electrode is for surgical use only. Placement must be in a sterile surgical environment. Failure to observe surgical asepsis and sterile techniques may result in infection and severe patient harm.
- The Depth Electrodes shall be surgically removed.
- The Depth Electrode is for short-term use (<30 days) only. Failure to observe the use conditions may result in severe patient harm.
- Do not use the Depth Electrodes if the packaging is damaged or unintentionally opened before use. Using a device from damaged packing may result in contamination and severe patient harm.
- The Depth Electrodes are for single use only. Do not reuse the device. Reuse of the device may result in contamination and severe patient harm.
- Do not re-sterilize the Depth Electrodes. Re-sterilization may result in device failure.
- The Depth Electrode should be introduced easily and NOT FORCED. Forcing the Depth Electrode into position may result in severe patient harm.
- Do not withdraw the wire carrier (tail) into the incision. Drawing the carrier tail into the incision may contaminate the wound and result in severe patient harm.
- Failure to comply with the recommended stimulation parameter may result in severe patient harm. Disconnect all Depth Electrodes from all monitoring equipment during cardiac defibrillation. Failure to disconnect the Depth Electrodes during cardiac defibrillation may result in severe patient harm
- Do not use RF surgical equipment on patients undergoing EEG monitoring or stimulation with the Depth Electrodes. Using RF surgical equipment during EEG monitoring may result in severe patient harm.
- The AD and LD Style Spencer Probe Depth Electrodes are MRI unsafe. Using the AD or LD Style Depth Electrodes in an MRI environment may lead to severe patient harm.
- The Monopolar Depth Electrodes are MRI unsafe. Using the Monopolar Depth Electrodes in an MRI environment may lead to severe patient harm.
- The Behnke Fried and Wire Bundle Depth Electrodes MRI unsafe. Using the Behnke Fried and Wire Bundle Depth Electrodes in an MRI environment may severely harm the user and patient.
- The Foramen Ovale Depth Electrodes are MRI unsafe. Using the Foramen Ovale Depth Electrodes in an MRI environment may lead to severe patient harm.
- The Macro-Micro Depth Electrodes are MRI unsafe. Using the Macro-Micro Depth Electrodes in an MRI environment may lead to severe patient harm.
- The SD and RD Style Spencer Probe Depth Electrodes are safe in an MRI environment under defined scanning conditions. Failure to adhere to the recommended scanning conditions may result in severe patient harm.

5.4 WARNINGS – PLACEMENT ACCESSORIES

5.4.1 ANCHOR BOLTS

- This product should only be used by a physician/surgeon experienced in the use of Depth Electrodes and the associated Placement Accessories. Incorrect use of this device may result in severe patient harm.
- Placement of the Depth Electrodes without the correct preoperative planning may result in severe patient harm.

- Placement of the Depth Electrodes without the correct stereotactic guidance may result in severe patient harm.
- The Anchor Bolt is for surgical use only. Placement must be in a sterile surgical environment. Failure to observe surgical asepsis and sterile techniques may result in infection and severe patient harm.
- The Anchor Bolt shall be surgically removed.
- The Anchor Bolt is for short-term use (<30 days) only. Failure to observe the use conditions may result in severe patient harm.
- Do not use the Anchor Bolt if the packaging is damaged or unintentionally opened before use. Using a device from damaged packing may result in contamination and severe patient harm.
- The Anchor Bolt is for single use only. Do not reuse the device. Reuse of the device may result in contamination and severe patient harm.
- Do not re-sterilize the Anchor Bolts. Re-sterilization may result in device failure
- The Anchor Bolts are safe in an MRI environment under strict scanning conditions. Failure to adhere to the recommended scanning conditions may result in severe patient harm.

5.4.2 DISPOSABLE CRANIAL DRILL KITS

- This product should only be used by a physician/surgeon experienced in the use of the Cranial Drill Bits and the associated Accessories. Incorrect use of this device may result in severe patient harm.
- Use of the Cranial Drill Bits and Accessories without the correct preoperative planning may result in severe patient harm.
- The Cranial Drill Bits and Accessories without the correct stereotactic guidance may result in severe patient harm.
- The Cranial Drill Bits and Accessories are for surgical use only. The Cranial Drill Bits and Accessories must be used in a sterile surgical environment. Failure to observe surgical asepsis and sterile techniques may result in infection and severe patient harm.
- Do not use the Cranial Drill Bits and Accessories if the packaging is damaged or unintentionally opened before use. Using a device from damaged packaging may result in contamination and severe patient harm.
- The Cranial Drill Bits and Accessories are for single use only. Do not reuse the devices. Reuse of the devices may result in contamination and severe patient harm.
- Clean and sterilize non-sterile Cranial Drill Bits and Accessories before use as directed. Incorrect cleaning and sterilization of the devices may result in contamination and severe patient harm.
- Do not re-sterilize the sterile Cranial Drill Bits and Accessories. Re-sterilization may result in device failure.
- The Cranial Drill Bits and Accessories are MRI-unsafe. Using the Cranial Drill Bits and Accessories in an MRI environment may severely harm the user and patient.

5.4.3 SLOTTED CANNULAS

- This product should only be used by a physician/surgeon experienced in the use of Depth Electrodes and the associated Placement Accessories. Incorrect use of this device may result in severe patient harm.

- Placement of the Depth Electrodes without the correct preoperative planning may result in severe patient harm.
- Placement of the Depth Electrodes without the correct stereotactic guidance may result in severe patient harm.
- The Slotted Cannula is for surgical use only. Placement and extraction must be in a sterile surgical environment. Failure to observe surgical asepsis and sterile techniques may result in infection and severe patient harm.
- Do not use the Slotted Cannula if the packaging is damaged or unintentionally opened before use. Using a device from damaged packing may result in contamination and severe patient harm.
- Clean and sterilize the Slotted Cannula as directed. Incorrect cleaning and sterilization of the device may result in contamination and severe patient harm.
- The Depth Electrode should be introduced easily and NOT FORCED. Forcing the Depth Electrode into position may result in severe patient harm.
- The Slotted Cannulas are MRI unsafe. Using the Slotted Cannulas in an MRI environment may severely harm the user and patient.

5.4.4 OBTURATORS

- This product should only be used by a physician/surgeon experienced in the use of Depth Electrodes and the associated Placement Accessories. Incorrect use of this device may result in severe patient harm.
- Placement of the Depth Electrodes without the correct preoperative planning may result in severe patient harm.
- Placement of the Depth Electrodes without the correct stereotactic guidance may result in severe patient harm.
- The Obturator is for surgical use only. Placement and extraction must be in a sterile surgical environment. Failure to observe surgical asepsis and sterile techniques may result in infection and severe patient harm.
- Do not use the Obturator if the packaging is damaged or unintentionally opened before use. Using a device from damaged packing may result in contamination and severe patient harm.
- Clean and sterilize the Obturator as directed. Incorrect cleaning and sterilization of the device may result in contamination and severe patient harm.
- The Depth Electrode should be introduced easily and NOT FORCED. Forcing the Depth Electrode into position may result in severe patient harm.
- The Obturators are MRI unsafe. Using the Obturators in an MRI environment may severely harm the user and patient

5.5 PRECAUTIONS – DEPTH ELECTRODES

- Handle the Depth Electrode with care to prevent damage. Pulling, stretching, or twisting the Depth Electrode may result in signal loss.
- Ensure that the Depth Electrode contacts are kept free from moisture and contamination.
- Do not remove the stylet before placement of the Depth Electrode. Removing and replacing the stylet before placement may damage the device. The stylet ensures that the Depth Electrode remains rigid during the delivery procedure.

- Observe the recommended storage conditions. Failure to observe storage conditions may result in device failure.
- Upon completion of placement and tunneling, connect the electrode contacts outside the body to the electrode cable. At no time should the electrode contacts outside the body be exposed or unprotected. Connection to an electrode cable protects the electrode contacts outside the body. If the patient becomes mobile, the electrode contacts must remain connected to the electrode cable.
- Ensure that the Depth Electrode implant sites are kept clean and dry. Monitor for any signs of infection.
- Dispose of the Depth Electrodes following the healthcare facility's biohazardous and pathological waste procedures.
- Dispose of any accessories that pose the risk of needle sticks, cuts, or puncture injuries in a sharps disposal container.
- Federal Law (USA) restricts this device to sale by or on the order of a physician.

5.6 PRECAUTIONS – PLACEMENT ACCESSORIES

5.6.1 ANCHOR BOLTS

- Handle the Anchor Bolts with care to prevent damage. Do not apply excessive torque to the Anchor Bolt during placement. When using the recommended burr hole diameter, the Anchor Bolt will screw easily into the skull. Excess torque may result in a bent or broken anchor bolt.
- Do not use the Anchor Bolts if the third-party interface (e.g., stereotactic/head frame) is damaged or flawed.
- Discontinue Anchor Bolt placement if you experience any instrument (e.g., the Placement/Removal Wrench, Cranial Drill, etc.) bending during the placement procedure.
- Protect the Anchor Bolt from the blunt impact that may occur if the patient has a seizure. Significant force may fracture the Anchor Bolt.
- Observe the recommended storage conditions. Failure to observe storage conditions may result in device failure.
- Dispose of the Anchor Bolts following the healthcare facility's biohazardous and pathological waste procedures.
- Dispose of any devices/accessories that pose the risk of needle sticks, cuts, or puncture injuries in a sharps disposal container.
- Federal Law (USA) restricts this device to sale by or on the order of a physician.

5.6.2 DISPOSABLE CRANIAL DRILL KITS

- Handle the Cranial Drill Bits and Accessories with care to prevent damage.
- Do not use the Cranial Drill Bits and Accessories if the third-party interface (e.g., stereotactic/head frame) is damaged or flawed.
- Do not over-tighten the Drill Stop set screw when applying the drill bit. Overtightening may deform the drill bit.
- The Drill Stop will not stop the drill. The Drill Stop is designed only to provide the user with a marker for drilling depth.
- Exercise caution when perforating the dura to avoid damage to underlying structures.

- Ensure the Drill Bit is kept straight in the Drill Sleeve Guide to avoid seizing between the Drill Bit and Drill Sleeve Guide.
- Discontinue using the Cranial Drill Bits and Accessories if you experience bending during use.
- Observe the recommended storage conditions. Failure to observe storage conditions may result in device failure.
- Dispose of the Cranial Drill Bits and Accessories following the healthcare facility's biohazardous and pathological waste procedures.
- Dispose of any accessories that pose the risk of needle sticks, cuts, or puncture injuries in a sharps disposal container.
- Federal Law (USA) restricts this device to sale by or on the order of a physician.

5.6.3 SLOTTED CANNULAS

- Handle the Slotted Cannulas with care to prevent damage.
- Dispose of devices that show signs of wear or damage, irrespective of the number of reuse cycles.
- Do not use the Slotted Cannulas if the third-party interface (e.g., stereotactic/head frame) is damaged or flawed.
- Discontinue using the Slotted Cannula if you experience bending during the placement procedure.
- Observe the recommended storage conditions. Failure to observe storage conditions may result in device failure.
- Dispose of the Slotted Cannulas following the healthcare facility's biohazardous and pathological waste procedures.
- Dispose of any devices/accessories that pose the risk of needle sticks, cuts, or puncture injuries in a sharps disposal container.
- Federal Law (USA) restricts this device to sale by or on the order of a physician.

5.6.4 OBTURATORS

- Handle the Obturators with care to prevent damage.
- Dispose of devices that show signs of wear or damage, irrespective of the number of reuse cycles.
- Do not use the Obturators if the third-party interface (e.g., stereotactic/head frame) is damaged or flawed.
- Discontinue using the Obturator if you experience bending during the placement procedure.
- Observe the recommended storage conditions. Failure to observe storage conditions may result in device failure.
- Dispose of the Obturators following the healthcare facility's biohazardous and pathological waste procedures.
- Dispose of any devices/accessories that pose the risk of needle sticks, cuts, or puncture injuries in a sharps disposal container.
- Federal Law (USA) restricts this device to sale by or on the order of a physician.

5.7 OTHER RELEVANT ASPECTS OF SAFETY

A summary of all Field Safety Notices (FSNs), Field Safety Corrective Actions (FSCAs), and recalls issued within the PMS data collection period from JANUARY 2017 to OCTOBER 2022 are summarized in Table 15.

Table 15: Field Safety Corrective Action

Device/Accessory	FSCA Reference Number	Summary of the Circumstances and Actions Taken by Ad-Tech	FSCA Finalized
Disposable Cranial Drill Kits	2018/001/005/601/008 (03-01-2018-00001)	Drill bit diameters are not per device labeling. Not used on patients. Recall issued by Ad-Tech (n=2 LOTs).	14-MAR-2018
Spencer Probe Depth Electrode SD Style	2020/005/013/601/002 (17-04-2019-00001)	Depth Electrode contact numbers were not per device labeling. No patient impact. Recall issued by Ad-Tech (n=2 LOTs).	24-FEB-2021
Anchor Bolts	2020/005/013/601/003(18-06-2019-00001)	Ad-Tech offered non-sterile Anchor Bolts that economic operators sterilized before clinical use. Ad-Tech established a Demonstration Product and Marketing Sampling Procedure to ensure traceability of samples subsequent to distribution.	09-DEC-2020
Anchor Bolt DFU Update	2020/007/016/487/004 (02-07-2019-00001)	The Anchor Bolt IFU did not include use for up to 30 days, as well as steps to take in the event of a device failure. The Anchor Bolt IFU was updated to include that the devices can be used for less than 30 days. Steps were added to the IFU in the event of a device failure.	06-OCT-2020
Depth Electrodes – All Anchor Bolts	2020/005/013/601/004 (11-06-2019-00001)	Ad-Tech marketed MR safety claims without completed safety validation. Ad-Tech updated the information accordingly. Labeling has been updated to reflect MR Unsafe.	20-FEB-2023

6 SUMMARY OF CLINICAL EVALUATION AND POST-MARKET FOLLOW-UP

6.1 SUMMARY OF CLINICAL DATA RELATED TO THE EQUIVALENT DEVICE

AD-TECH® has not used clinical data from equivalent devices to support the Depth Electrodes and Placement Accessories regulatory compliance.

6.2 NOTIFIED BODY ENDORSEMENT OF EQUIVALENCE

AD-TECH® has not used clinical data from equivalent devices to support the Depth Electrodes and Placement Accessories regulatory compliance.

6.3 SUMMARY OF CLINICAL DATA FROM CLINICAL INVESTIGATIONS

AD-TECH® has not conducted pre- or post-CE mark clinical investigations on the Depth Electrodes and Placement Accessories. The Depth Electrodes and Placement Accessories are legacy devices marketed in the EU since 1998.

6.4 SUMMARY OF CLINICAL DATA FROM OTHER SOURCES

Clinical literature searches identified n=32 studies covering n=640 patients subject to electrical brain mapping using the AD-TECH® Depth Electrodes, summarized in

Table 16. While there is little direct clinical data on using the AD-TECH® Placement Accessories, their clinical benefits are achieved by facilitating the Depth Electrodes to fulfill their clinical benefit.

Table 16: Summary of Clinical Data

Source	Study Details	Safety Outcomes	Performance Outcomes	Clinical Benefit Outcomes
Antezana et al. (2021)	Brain mapping of patients with tumor (vestibular schwannoma) Patients: n=2 Age: 23 and 53 years	No undesirable side effects reported	Successful signal acquisition of 8th cranial nerve in 2/2 (100%) of patients	Brain mapping led to successful (100% and 80%) tumor resection in two patients.
Bottan et al. (2020)	Brain mapping of epileptic patients Patients: n=41 Age: mean 35 years	No undesirable side effects reported	Successful signal acquisition in 41/41 (100%) of patients	Ideal targeting trajectories identified for insular brain mapping.
D'Agostino et al. (2020)	Brain mapping in epileptic patients Patients: n=13 Age: mean 36 years (range: 21-57)	Subdural hemorrhage: n=2/13 Subarachnoid hemorrhage: 1/13	Successful signal acquisition and seizure focus localization in 13/13 (100%) of patients	Brain mapping led to successful resection (6/13; 47%) seizure-free patients.
Ervin et al. (2021)	Brain mapping of epileptic patients Patients: n=35 Age: mean 13 years (range 4-21)	No undesirable side effects reported	No performance results reported	The accuracy of depth electrode placement was validated by Fascile software. Results will aid placement optimization.
Gibert et al. (2022)	Hippocampal brain mapping of epileptic patients Patients: n=8 Age: mean 34 years (range 22-48)	No undesirable side effects reported	Successful brain mapping in 8/8 (100%) of patients	Brain mapping informed clinicians of hippocampal function in epileptic patients.
Gross et al. (2019)	Brain mapping of epileptic patients Patients: n=62 Age: Not reported	Meningitis: n=2/62 Abscess: n=1/62 Long-term neurological deficit[4]: n=2/62 Parenchymal hemorrhage[5]: 1/62	Seizure focus located in 88.9% of 62 patients / 63 procedures (1 patient underwent a second procedure)	Brain mapping identified epileptic zones.
Hays et al. (2021a)	Brain mapping of epileptic patients Patients: n=18 Age: mean 36 years (range 19-62)	No undesirable side effects reported	Successful brain mapping in 18/18 (100%) of patients	Brain mapping led to successful resection (Engel Class I and Class II) in 2/4 (50%).
Hays et al. (2021b)	Brain mapping of epileptic patients Patients: n=13 Age: median 42 years (range 20-54)	No undesirable side effects reported	Successful brain mapping 13/13 (100%) of patients	Stimulation parameters were established for optimized cortical brain mapping.
Kaufmann et al. (2021)	Brain mapping of epileptic patients	No undesirable side effects reported	Successful brain mapping and focus of	Brain mapping identified loci clinically relevant ictal

[4] Categorized as 'permanent neurological deficit' in Table 14.

[5] Categorized as 'intracerebral hemorrhage' in Table 14.

Source	Study Details	Safety Outcomes	Performance Outcomes	Clinical Benefit Outcomes
	Patients: n=16 Age: mean 32 years (s.d. 11)		ictal blinking response location in 16/16 (100%) of patients	responses in epilepsy patients.
Ladisch et al. (2021)	Brain mapping of epileptic patients Patients: n=17 Age: median 32 years (range 21-54)	Meningitis: 1/17	Adequate signals were detected in 219/220 Depth Electrodes (99.5%), and epileptic zones were identified in 15/ 17 (88.2%) patients.	Brain mapping led to clinical improvement after resection (7/8; 87.5%) Engel Ia (1/8; 12.5%) Engel Ib, Weiser class 3.
Lee et al. (2022)	Brain mapping of epileptic patients Patients: n=12 Age: mean 35 years (range 22-47)	No undesirable side effects reported	Successful brain mapping during a working memory task (100%).	Brain mapping informed clinicians of working memory function in epileptic patients.
Lehongre et al. (2022)	Brain mapping of epileptic patients Patients: n=56 Age: Not reported	No undesirable side effects reported	Successful brain mapping (100%). Seizures were identified in 91% of patients.	Stimulation parameters were established for optimized for pre-surgical brain mapping.
Li et al. (2020)	Brain mapping of epileptic patients with prior resection Patients: n=24 Age: range 6-24 years	No undesirable side effects reported	Seizure-free patients: 102/113 contacts in resection zone (sensitivity 89.4%) false positive 0.6% (specificity 99.4%). Non-seizure-free patients: 38/142 contacts in resection zone (26.8% sensitivity) false positive 7.5% (specificity 92.5%).	Brain mapping validated outcomes of prior resection and will aid in optimized procedures to improve patient outcomes.
MacLean et al. (2021)	Brain mapping of a Tourette syndrome patient Patients: n=1 Age: 15 years	No undesirable side effects reported	Successful brain mapping	Brain mapping led to successful stimulation probe placement. Depth electrode placement resulted in a serendipitous temporary cessation of motor and verbal tics.
Mankin et al. (2021)	Brain mapping of epileptic patients during a working memory task Patients: n=22 Age: No reported	No undesirable side effects reported	Successful brain mapping 22/22 (100%) of patients	Brain mapping informed clinicians of working memory function in epileptic patients.
Mascia et al. (2021)	Brain mapping of epileptic patients Patients: n=14 Age: mean 40 years	No undesirable side effects reported	Successful brain mapping of 14/14 (100%) patients	Brain mapping led to successful resection and clinical improvement (Engel class I) in 6/7 (86%) of patients.
Rampp et al. (2021)	Brain mapping of patients with Focal Cortical Dysplasia type II Patients: n=7 Age: median 18 years (range 3-43)	No undesirable side effects reported	Successful brain mapping 7/7 (100%) of patients	Brain mapping led to successful resection and clinical improvement in all patients (Engel Class Ia 5/7 (71%), Ib 1/7 (14%), and IIIa 1/7 (14%).
Ricci et al. (2021)	Brain mapping of epileptic patients Patients: n=35 Age: mean 12 years (s.d. 6)	No undesirable side effects reported	Successful brain mapping 35/35 (100%) of patients	Brain mapping led to successful resection and clinical improvement (seizure free) in 21/35 (60%) of patients.
Thomaschewski et al. (2020)	Brain mapping of epileptic patients undergoing a working memory task Patients: n=10	No undesirable side effects reported	Successful recording of ictal and inter-ictal high-frequency oscillations during working memory	Brain mapping informed clinicians of working memory function in epileptic patients.

Source	Study Details	Safety Outcomes	Performance Outcomes	Clinical Benefit Outcomes
	Age: mean 40 years (s.d. 11)			
Urgun et al. (2021)	Brain mapping of epileptic patients Patients: n=7 Age: mean 30 years (range 22-52)	No undesirable side effects reported	Successful brain mapping	Results indicate robot-assisted brain mapping with hybrid depth electrodes as accurate as standard depth electrodes. This data may inform future procedures.
Yazdani et al. (2021)	Brain mapping of epileptic patients undergoing subsequent MRI Patients: n=99 Age: median 33 years (4-67)	No undesirable side effects reported	Successful placement of electrodes verified in 97/99 (98%) of placements confirmed by low specific absorption rate MRI	Results provide evidence of the safe use of particular depth electrodes in an MRI environment. This data can inform subsequent treatment.
Blenkmann et al. (2017)	Brain mapping of epileptic patients Patients: n=20 Age: mean 29 years	No undesirable side effects reported	Successful brain mapping 20/20 (100%) of patients	Results provide evidence of the safe use of particular depth electrodes in an MRI environment. This data can inform subsequent treatment.
Granados et al. (2018)	Brain mapping of epileptic patients Patients: n=23 Age: Not reported	No undesirable side effects reported	Successful brain mapping with a sensitivity of 98.81% and a PPV of 95.01% Patient-level data not reported	Optimized method to localize depth electrodes and anchor bolts, informing subsequent treatment.
Inman et al. (2020)	Amygdala brain mapping of epileptic patients Patients: n=9 Age: mean 36 years (s.d. 10)	No undesirable side effects reported	Successful brain mapping/signal acquisition in 9/9 (100%) of patients	Brain mapping led to successful resection and clinical improvement in 4/6 (67%) of patients. One patient was unexpectedly seizure free after brain mapping alone.
Juárez-Martinez et al. (2018)	Brain mapping of epileptic patients Patients: n=9 Age: range 16-49 years	No undesirable side effects reported	Successful brain mapping in 9/9 (100%) of patients	Brain mapping with non-invasive magnetoencephalography (MEG) was compared to depth electrodes to determine epileptic zones. Brain mapping led to successful resection (Engel I or II) in 8/9 (88.8%) patients and an Engel IV outcome in one patient.
Kremen et al. (2017)	Pre-surgical brain mapping of epileptic patients Patients: n=7 Age: mean 34 years (s.d. 12)	No undesirable side effects reported	Classification accuracy of 97.8 ± 0.3% (normal tissue) and 89.4 ± 0.8% (epileptic tissue)	Brain mapping classification accuracy of 97.8 ± 0.3% was reported in normal tissue and 89.4 ± 0.8% in epileptic tissue. This data may inform clinicians regarding subsequent therapies.
Liberati et al. (2018)	Brain mapping of epileptic patients Patients: n=9 Age: range 19-43	No undesirable side effects reported	Successful signal acquisition in 6/6 (100%) of patients	Brain mapping provided data of signaling in nociceptive (evoking a pain response) and non-nociceptive stimuli in the insula of epileptic patients. This data may inform clinicians regarding subsequent therapies.
Liu et al. (2016)	Brain mapping of suspected bi-temporal epileptic patients Patients: n=13 (n=10 of which had Depth Electrodes) Age: mean 31 years	No undesirable side effects reported	Successful brain mapping (100%) in depth electrode patients	Brain mapping led to successful resection and clinical improvement (Engel Class I or II) outcomes in 11/13 (84.6%). One patient experienced an Engel Class III outcome.

Source	Study Details	Safety Outcomes	Performance Outcomes	Clinical Benefit Outcomes
Naftulin et al. (2018)	Brain mapping of epileptic patients Patients: n=17 Age: mean 41 years (s.d. 11)	No undesirable side effects reported	Successful brain mapping in 17/17 (100%) of patients	Brain mapping led to successful resection and clinical improvement (Engel Class Ia/Ib) in 6/10 (60%) of patients.
Nourski et al. (2017)	Brain mapping to identify epileptic foci in neurosurgical patients Patients: n=10 Age: median 35 years (range 27-51)	No undesirable side effects reported	The seizure focus was localized in 9/10 (90%) of patients, and 6/10 (60%) underwent surgical resection	Brain mapping was used to interpret differential patterns of auditory cortical activity during induction of anesthesia with propofol. This data may inform clinicians regarding subsequent therapies.
Schurr et al. (2018)	Brain mapping of epileptic patients Patients: n=3 Age: 17, 18 and 40 years	No undesirable side effects reported	Successful brain mapping	Brain mapping was used to determine hippocampal functionality during a cognitive task. This data provides additional information regarding eloquent structures and may inform clinicians regarding subsequent therapies.
Weil et al. (2016)	Brain mapping of epileptic patients Patients: n=11 Age: mean 8 years (range 0.5-16)	No undesirable side effects reported	Successful brain mapping (100%)	Brain mapping informed subsequent insular resection in all patients.

6.5 OVERALL SUMMARY OF CLINICAL PERFORMANCE AND SAFETY

6.5.1 EXPECTED CLINICAL BENEFITS

The clinical benefits of Ad-Tech Depth Electrodes and Placement Accessories are based on a review of the state-of-the-art and the data available for the devices themselves. Table 17 summarizes the clinical benefits.

Brain mapping has been used as a pre-surgical planning tool in treating other neurological conditions such as Parkinson's disease or essential tremor, medically intractable severe depression, Tourette's, and obsessive-compulsive disorders. However, the available clinical data on these indications is limited; therefore, the benefit-risk determination (Section 6.5.2) is focused on epilepsy.

Table 17: Clinical Benefits of the AD-TECH® Depth Electrodes and Placement Accessories

Device/Accessory	Clinical Benefit per the IFU[6]	Clinical Benefit Outcome Measure	Success Rate of Ad-Tech Depth Electrodes Achieving the Clinical Benefit (Determined from Table 16Error! Reference source not found.)
Depth Electrodes – All	Brain mapping allows the physician to gather detailed information about the electrical characteristics of the brain to identify areas related to	Engel classification following resection or ablation surgery	Engel classification I or II: 81% Engel classification III: 3%

[6] The IFUs are available via the link http://ad-tech.imgmgmt.com/instructions-use-documents.

Device/Accessory	Clinical Benefit per the IFU[6]	Clinical Benefit Outcome Measure	Success Rate of Ad-Tech Depth Electrodes Achieving the Clinical Benefit (Determined from Table 16Error! Reference source not found.)
	physiological symptoms enabling them to develop appropriate patient-specific treatment plans.	Percentage of seizure-free patients	57%
Anchor Bolts	When used, the Anchor Bolts minimize concerns about potential cerebrospinal fluid (CSF) leakage and infection of the subdural space while stabilizing the Depth Electrode.	N/A – Support the Depth Electrodes to fulfill their clinical benefit	N/A – Support the Depth Electrodes to achieve their clinical benefit
Disposable Cranial Drill Kits	The Cranial Drill Bits and Accessories allow surgical access to the brain as part of neurological assessment and treatment procedures.	N/A – Support the Depth Electrodes to fulfill their clinical benefit	N/A – Support the Depth Electrodes to achieve their clinical benefit
Slotted Cannulas	The Slotted Cannula creates a path through the brain to receive the Depth Electrode, reducing tissue trauma and supporting accurate placement.	N/A – Support the Depth Electrodes to fulfill their clinical benefit	N/A – Support the Depth Electrodes to achieve their clinical benefit
Obturators	The Obturator creates a path through the brain to receive the Depth Electrode, reducing tissue trauma and supporting accurate placement.	N/A – Support the Depth Electrodes to fulfill their clinical benefit	N/A – Support the Depth Electrodes to achieve their clinical benefit

6.5.2 BENEFIT-RISK ASSESSMENT

All undesirable side effects applicable to the AD-TECH® Depth Electrodes and Placement Accessories are expected. No unexpected side effects have been identified from the available clinical literature in the state-of-the-art or the use of Ad-Tech Depth Electrodes. Furthermore, the Post Market Surveillance data does not suggest any unexpected, undesirable side effects.

The device related failures are uncommon and have been considered within Ad-Tech's risk management process. The IFUs provide sufficient guidance and instructions to mitigate residual risks associated with user errors that may lead to device failure.

The clinical benefit of using Ad-Tech Depth Electrodes and Placement Accessories is significant. Data show that at least 84% of patients will experience the clinical benefit, and over 57% of patients that undergo resection surgery will be seizure-free.

Furthermore, compared with other diagnostic modalities, the accuracy of stereoelectroencephalography (sEEG) using Ad-Tech's Depth Electrodes and Placement Accessories has been demonstrated.

Ad-Tech has demonstrated that the clinical benefits of using Ad-Tech Depth Electrodes and Placement Accessories outweigh the risks.

6.6 ON-GOING AND PLANNED POST-MARKET CLINICAL FOLLOW-UP

All undesirable side effects applicable to AD-TECH® Depth Electrodes and Placement Accessories are expected. No unexpected side effects have been identified from the available clinical literature in the state-of-the-art or the use of AD-TECH® Depth Electrodes (the data does not suggest any unexpected, undesirable side effects).

AD-TECH® has initiated a post-market surveillance plan to collect safety and performance data for the Depth Electrodes and Placement Accessories. The methods of data collection include literature searches and customer-focused surveys.

This SSCP will be updated annually with relevant data gathered from post-market surveillance.

7 POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

There are no valid alternatives to sEEG per se. Each method of imaging provides valuable data to inform treatment decisions. These methods are usually used in concert, following an algorithm stepwise fashion, beginning with the least invasive and ending with the most invasive procedures. Therefore, when sEEG is used, it is typically only after less invasive methods have failed to provide the necessary clinical data. The clinician should evaluate the risks and benefits of each procedure regardless of which diagnostic or imaging method is used. Several imaging modalities and diagnostic tests are considered within the standard of care of neuroimaging and neurodiagnostic functions, as outlined in Table 18.

Table 18: Comparison of sEEG and Other Diagnostic Modalities

Brain Mapping Method	**State-of-the-art Literature Sources**	**Sensitivity (95% CI)**	**Specificity (95% CI)**	**Accuracy**
Magnetic Resonance Imaging (MRI)	Zeng et al. (2021)	74% (65%-82%)	35% (30%-90%)	88%
Magnetoencephalography (MET)	Brændholt and Jensen (2020)	77% (60%-90%)	75% (53%-90%)	Not reported
F-18-fluorodeoxyglucose – Positron Emission Tomography (FDG-PET)	Niu et al. (2021)	66% (58%-73%)	71% (63%-78%)	Not reported
Single-Photon Emission Computed Tomography (SPECT)	Not reported	Not reported	Not reported	Not reported
Stereoelectroencephalography (sEEG)	Centracchio et al. (2021) Granados et al. (2018)	94% 99%	99% Not reported	99% Not reported

8 SUGGESTED PROFILE AND TRAINING OF USERS

The Depth Electrodes and Placement Accessories are to be used by physicians/surgeons experienced in Depth Electrodes and the associated Placement Accessories.

Clinical and technical support is available directly from AD-TECH® using the contact information provided in Section 12.

9 HARMONIZED STANDARDS AND COMMON SPECIFICATIONS

9.1 STANDARDS APPLIED

Table 19 lists the standards applied to the AD-TECH® Depth Electrodes and Placement Accessories.

Table 19: Applicable Standards

Version	Description
EN ISO 13485: 2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
BS EN ISO 14971:2019+A11:2021	Medical devices. Application of risk management to medical devices
BS EN 60601-1:2006+A2:2021	Medical electrical equipment. Part 1: General requirements for safety and essential performance.
IEC 62366-1 Ed. 1.1 b:2020	Medical devices. Part 1: Application of usability engineering to medical devices
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN 556-1:2001/AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' - Part 1: Requirements for terminally sterilized medical devices
BS EN ISO 11135:2014+A1:2019	Sterilization of healthcare products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices
BS EN ISO 11607 1:2020+A11:2022	Packaging for terminally sterilized medical devices-Requirements for materials, sterile barrier systems and packaging systems
BS EN ISO 11607-2:2020+A11:2022	Packaging for terminally sterilized medical devices, Part 2: Part 2: Validation requirements for forming, sealing and assembly processes
ASTM F88/F88M-21	Standard Test Method For Seal Strength Of Flexible Barrier Materials
ASTM F1980-21	Standard Guide For Accelerated Aging Of Sterile Barrier Systems And Medical Devices
ASTM D4169-22	Standard Practice For Performance Testing Of Shipping Containers And Systems
BS EN ISO 17665-1:2006	Sterilization of health care products. Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-2:2022	Biological evaluation of medical devices – Part 2: Animal welfare requirements
ISO 10993-3:2014	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-4:2017	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity

Version	Description
ISO 10993-6:2016	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation
ISO 10993-10:2021	Biological evaluation of medical devices – Part 10: Tests for skin sensitization
ISO 10993-11:2017	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
ISO 10993-12:2021	Biological Evaluation of Medical devices – Part 17: Methods for the establishment of allowable limits for leachable substances
ISO/TS 21726:2019	Biological Evaluation of Medical devices - Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents
ISO 10993-18:2020	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process
ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
ASTM F2052-21	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
ASTM F2213-17	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
ASTM F2119-07	Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants (Withdrawn 2022)
ASTM F2182-19e2	Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging
ASTM F2503-20	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

9.2 COMMON SPECIFICATIONS

There are no Common Specifications applicable to the Depth Electrodes and Placement Accessories.

10 REVISION HISTORY

Table 20: Revision History

SSCP Revision Number	Date Issued	Change Description	Revision validated by the Notified Body
A	07-Nov-2024	Initial release. NB comments: - Note added to state that Disposable Cranial Drill Kit is not part of submission.	☒ Yes, Validation Language: ENGLISH ☐ No (only applicable for Class IIa or some IIb implantable devices for which the SSCP is not yet sampled for validation by the NB)

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12 ADMINISTRATIVE

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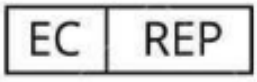	E C REP LIMITED 5 Fitzwilliam Square East Dublin 2, D02 R744, Ireland Tel: +353 1 2 544 944
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