



CONTENT

- 4 DIXI MEDICAL
- 5 SEEG (Stereoelectroencephalography)
- 6 MICRODEEP®
SEEG ELECTRODES
- 8 IMPLANTATION TOOLS
- 12 CONNECTION CABLES CBL
- 13 REMOVAL TOOLS
- 14 INTRAOPERATIVE CORTEX STRIP /GRID ELECTRODES
- 18 DIXI MEDICAL SUPPORT

DIXI medical

Back in the 1970s, a group of physicians and scientists from Rennes University Hospital visited a fair focusing on the watchmaking and microtechniques industries in Besançon in the hope of finding new partners to develop tools for neurosurgery.

Prof. Scarabin and his team worked on SEEG (Stereo-Electro-Encephalography), a new surgical technique to treat drug-resistant epilepsy developed in the 1960s at St-Anne hospital in Paris with Prof. Talairach. The collaboration between the neuroscientists and the precision industry experts blossomed over the years.

DIXI, a family-owned company founded in 1904 in Le Locle, Switzerland, specialized in precision industry, microtechnology and neurology, took over in 1988. In the 1990s, the industrial production of the SEEG electrodes and implantation tools started. The French company slowly expands internationally DIXI medical products are FDA approved since November 2018.

For more than 40 years, DIXI medical never ceased to innovate and improve its intracerebral electrodes and implantation accessories, working hand in hand with neurosurgeons, neurologists and scientists from all around the world. The factory and its 100 highly skilled and knowledgeable employees are based since the beginning in Besançon, France.

SEEG (Stereoelectroencephalography)

SEEG is a minimally invasive diagnostic procedure for drug-resistant focal epilepsy. The objective is to identify the epileptic foci. To do so, electrodes are implanted in predefined brain parts to record electrical activities and epileptic seizures. The patient stays a few days (maximum 30) in the hospital under EEG monitoring and video recording surveillance. The data collected is analyzed to refine the diagnosis and plan the following treatment options.

SEEG vs. Subdural Strips and Grids

While subdural strip and grids electrodes provide a large coverage over the bare surface of the cerebral cortex, they do not reach deeper brain structures (e.g., hippocampus or insula). By comparison, SEEG electrodes can enable monitoring of superficial and deep cortical structures and facilitate electrical stimulation mapping of these regions. Thus, they allow testing hypotheses about the localization of the seizure onset zone in three dimensions and studying the seizure network in detail¹.

Several reports document the benefits and risks of SEEG electrodes relative to the subdural ones. These reports demonstrate that SEEG electrodes allow targeting deeply situated foci with a non-inferior safety profile to subdural electrodes and comparable seizure outcome²⁻⁵.

¹ Gholipour, T., Koubeissi, M. Z. & Shields, D. C. Stereotactic electroencephalography. *Clin. Neurol. Neurosurg.* 189, 105640 (2020).

² Joswig, H. et al. Stereoelectroencephalography Versus Subdural Strip Electrode Implantations: Feasibility, Complications, and Outcomes in 500 Intracranial Monitoring Cases for Drug-Resistant Epilepsy. *Neurosurgery* 87, E23-E30 (2020).

³ Remick, M., Ibrahim, G. M., Mansouri, A. & Abel, T. J. Patient phenotypes and clinical outcomes in invasive monitoring for epilepsy: An individual patient data meta-analysis. *Epilepsy Behav.* 102, 106652 (2020).

⁴ Toth, M. et al. Surgical outcomes related to invasive EEG monitoring with subdural grids or depth electrodes in adults: A systematic review and meta-analysis. *Seizure* 70, 12-19 (2019).

⁵ Yang, M. et al. A Retrospective Analysis of Stereoelectroencephalography and Subdural Electroencephalography for Preoperative Evaluation of Intractable Epilepsy. *Stereotact. Funct. Neurosurg.* 95, 13-20 (2017).

MICRODEEP®

SEEG ELECTRODES

For SEEG exploration and functional mapping
of epileptic foci

Class III, CE mark issued by GMED 0459

Single-use sterile material

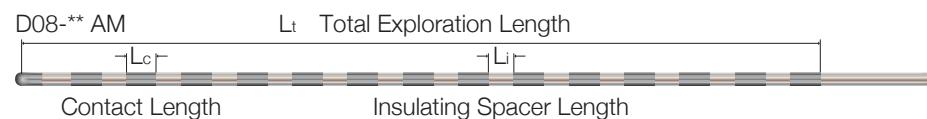


MICRODEEP® is a multi-contact flexi-rigid intracerebral electrode, with a diameter of 0.8 mm and a hemispherical tip.

The active part is hand polished for an optimized smooth surface.

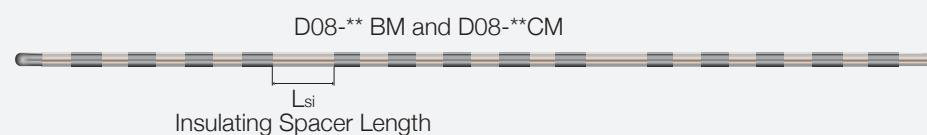
- Diameter 0.8 mm
- Platinum / Iridium
- From 5 to 18 contacts
- Active exploration length ranges from 16 mm to 80.5 mm
- Proprietary cap designed to prevent the electrode from moving to ensure a good seal and to serve as a depth maker
- Total length: 100 cm
- Connection cables CBL (page 12)

Reference	Nr of contacts	Dimensions (mm)		
		Lt	Lc	Li
D08-05AM	5	16	2	1.5
D08-08AM	8	26.5	2	1.5
D08-10AM	10	33.5	2	1.5
D08-12AM	12	40.5	2	1.5
D08-15AM	15	51	2	1.5
D08-18AM	18	61.5	2	1.5



To optimize the recording of deep surfaces and avoid losing contacts in white matter, three long electrodes are designed with specific spacing in between groups of contacts.

Reference	Nr of contacts	Dimensions (mm)			
		Lt	Lc	Li	Lsi
D08-15BM	15 (3x5)	62	2	1.5	7
D08-15CM	15 (3x5)	70	2	1.5	11
D08-18CM	18 (3x6)	80.5	2	1.5	11



IMPLANTATION TOOLS

DIXI medical optimizes the SEEG flow in the OR by offering implantation tools to be used in sequential order to provide the best and most accurate implantation.

All implantation tools have an outer diameter of 2.45 mm and fit through a guide tube of min 2.5 mm¹.

BONE STARTER **ACS-745**

Class I, CE mark

Delivered Non-sterile



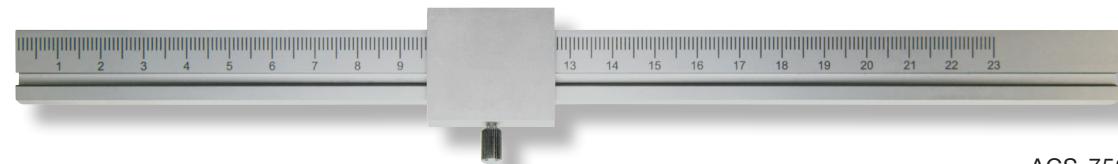
ACS-745

- To pierce the skin and mark the skull before drilling

SLIDING RULER **ACS-750**

Class Im, CE mark issued by GMED 0459

Delivered Non-sterile



ACS-750

- To measure the length of DIXI medical implantation accessories

COAGULATION ELECTRODE & STOP **KIP-ACS-605**

Class III, CE mark issued by GMED 0459

Single-use sterile material



KIP-ACS-605

- To coagulate the skin

IMPLANTATION TOOLS

DRILL BIT & STOP **KIP-ACS-515**

Class III, CE mark issued by GMED 0459

Single-use sterile material

- Drill bit to perforate the skull with suitable diameter for the use of guiding screw
- Cutting diameter 2.1 mm
- Drill bit total length: 200 mm
- Cutting bit length: 20 mm
- Single stop to control the depth of the drill bit
- A dedicated screwdriver for securing the stop exists – ACS-714

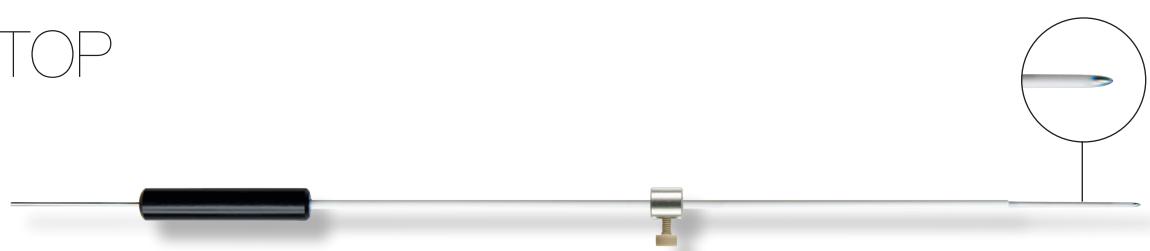


COAGULATION ELECTRODE & STOP **KIP-ACS-600**

Class III, CE mark issued by GMED 0459

Single-use sterile material

- To pierce and coagulate the dura mater



IMPLANTATION TOOLS

GUIDING SCREWS ACS-0XXSMS-10

Class III, CE mark issued by GMED 0459

Single-use sterile material

- Made to be fixed into the bone through the skin.
- Fits through the guide tube secured to the screwdriver to optimize the placement's accuracy
- Self-tapping tip allowing a direct fixing into a hole ø 2.1 mm
- Specific threading to secure the electrode's cap to the guiding screw
- Flat area for removal using the wrench
- Individually packed, delivered per box of 10
- The guiding screws are available in 5 different lengths:
 - 15 mm - ACS-015SMS-10
 - 20 mm - ACS-020SMS-10
 - 25 mm - ACS-025SMS-10
 - 30 mm - ACS-030SMS-10
 - 35 mm - ACS-035SMS-10



ACS-015SMS-10



ACS-020SMS-10



ACS-025SMS-10



ACS-030SMS-10



ACS-035SMS-10

IMPLANTATION TOOLS

SCREWDRIVER ACS-710

Class I, CE mark

Delivered Non-sterile



ACS-710

- Long screwdriver used for placement of guiding screw ø 2.5 mm
- Screwdriver for simple stop to adjust the tightening

DEPTH REPORT DEVICE ACS-751

Class Im, CE mark issued by GMED 0459

Delivered Non-sterile



ACS-751

- To measure the length of DIXI medical stylet and MICRODEEP® electrode
- Unique design for DIXI medical products

STYLET ACS-770S-10

Class III, CE mark issued by GMED 0459

Single-use sterile material



ACS-770S-10

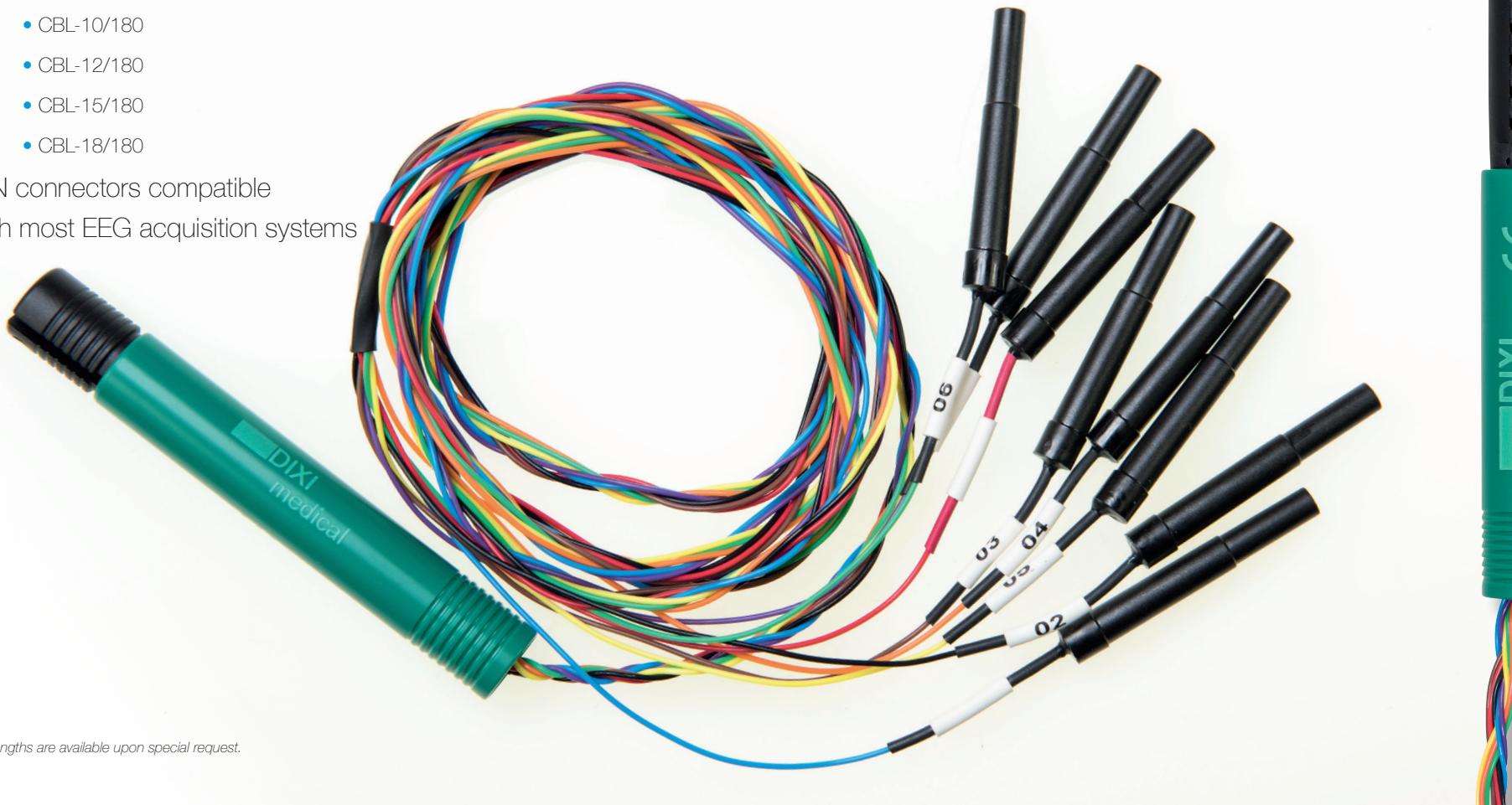
- Used to preform the path of the electrode
- Adjustable stop integrated
- Individually packed, delivered per box of 10

CONNECTION CABLES CBL

CBL-XX/180

Class I, CE mark

- Suitable for connecting MICRODEEP® electrodes 5 to 18 contacts
- Suitable for sterilization
- Overall length of 180 cm¹ for greater flexibility at the EMU and creation of damper:
 - CBL-05/180
 - CBL-08/180
 - CBL-10/180
 - CBL-12/180
 - CBL-15/180
 - CBL-18/180
- DIN connectors compatible with most EEG acquisition systems



REMOVAL TOOLS

WRENCH FOR GUIDING SCREW REMOVAL ACS-715

Class I, CE mark

Delivered Non-sterile

- To unlock and loosen the guiding screws
- Insert the wrench on the two flat areas of the guiding screws



ACS-715

SCREWDRIVER FOR GUIDING SCREW REMOVAL ACS-711

Classe I, CE mark

Delivered Non-sterile

- Short screwdriver to remove the guiding screws



ACS-711

INTRAOPERATIVE CORTEX STRIP/ GRID ELECTRODES

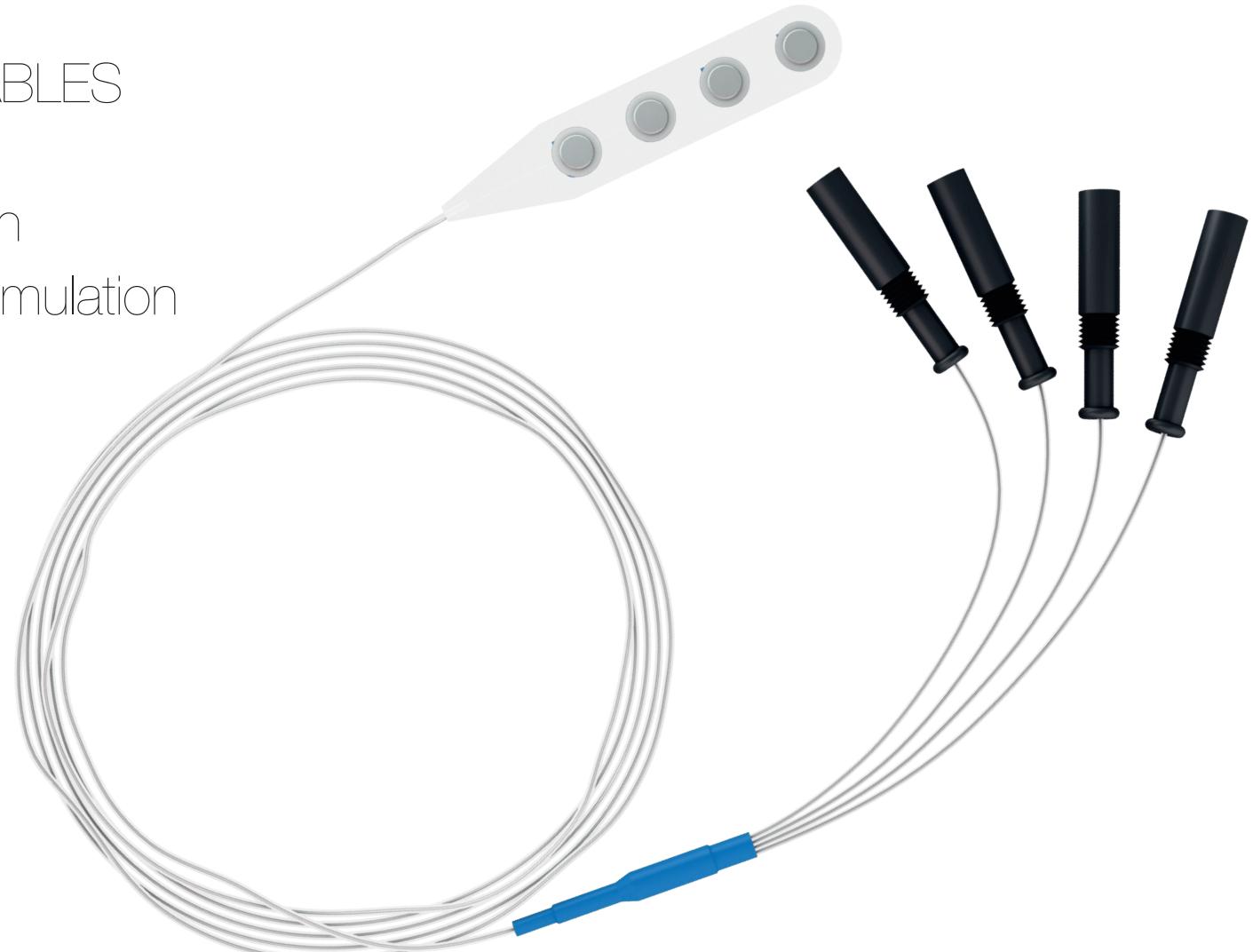
WITH CONNECTION CABLES

The intraoperative solution
for brain mapping and stimulation

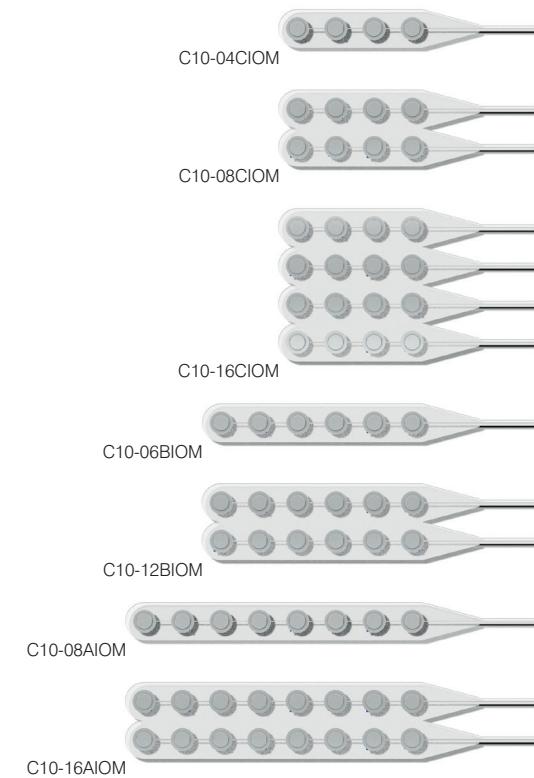
Classe III, CE mark

issued by notified body GMED 0459

Single-use sterile material



- Thin <0.8 mm and flexible to be as close as possible to brain tissue
- Contacts made of stainless steel
- Contacts useful diameter: 4 mm
- Distance between the contacts: 10 mm
- Width of strips: 10 mm
- Numbered contacts
- Dome shaped contacts
- Micro-perforations in between strips
- Built-in Touch-Proof connectors (DIN 42802) to ensure ease of use in the OR and compatibility with most acquisition and stimulation systems
- Contacts number engraved on the DIN
- Cable length : 2 m

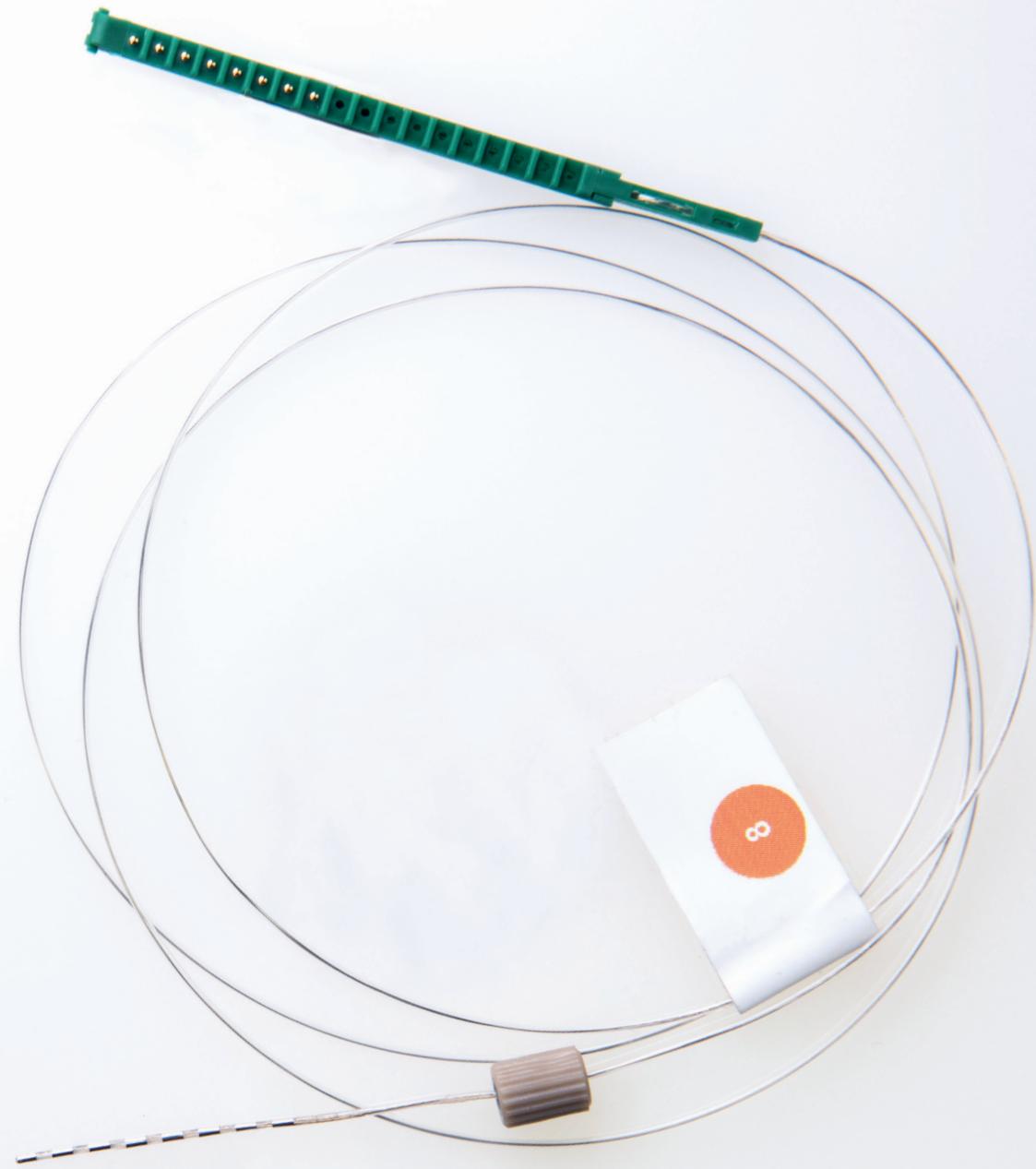


MICRODEEP®

5 contacts	D08-05AM
8 contacts	D08-08AM
10 contacts	D08-10AM
12 contacts	D08-12AM
15 contacts	D08-15AM
15 contacts	D08-15BM
15 contacts	D08-15CM
18 contacts	D08-18AM
18 contacts	D08-18CM

CONNECTION CABLES CBL

5 contacts	CBL-05/180
8 contacts	CBL-08/180
10 contacts	CBL-10/180
12 contacts	CBL-12/180
15 contacts	CBL-15/180
18 contacts	CBL-18/180



SINGLE USE IMPLANTATION TOOLS

Coagulation electrode & Stop (dura-mater)
Coagulation electrode & Stop (skin)
Drill bit & Stop (140 mm)
Drill bit & Stop (200 mm)
Guiding screws 15 mm
Guiding screws 20 mm
Guiding screws 25 mm
Guiding screws 30 mm
Guiding screws 35 mm
Stylet
Caps

KIP-ACS-600
KIP-ACS-605
KIP-ACS-510
KIP-ACS-515
ACS-015SMS-10
ACS-020SMS-10
ACS-025SMS-10
ACS-030SMS-10
ACS-035SMS-10
ACS-770S-10
ACS-050S-5

REUSABLE IMPLANTATION TOOLS

Bone starter ACS-745
Long screwdriver ACS-710
Screwdriver for stop ACS-714
Sliding ruler ACS-750
Depth report device ACS-751
Single stop ACS-760
Marking rod ACS-740

REUSABLE REMOVAL TOOLS

Short screwdriver ACS-711
Wrench ACS-715

DIXI medical support

DIXI medical supports hospitals worldwide to provide the best experience using our devices. We guide you from the first order through a dry-run to your first surgeries. The clinical support team is at your disposal to answer all your questions and concerns.

We take a lot of pride in manufacturing high-quality devices, and we want to provide you with the best service. Our Quality Affairs department handles your complaints and conducts thorough investigations to ensure it never happens again.

The Regulatory Affairs landscape is rapidly evolving, and it is why our capacities increased to properly answer the best way possible to the new demands from authorities.

Innovation also lies in DIXI medical's DNA. Our R&D team and the DIXI neurolab are constantly looking to improve and develop new technologies. Stay tuned!

We thank you for your confidence over the past 40 years and are pleased to count you as one of our contributors.



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Tel: 604 961 9283

Email: Info@neurosource.ca