RISHENA
瑞神安医疗

# Implantable Rechargeable Spinal Cord Stimulation System (SCS)

# Spinal Cord Stimulation, SCS

**Spinal Cord Stimulation (SCS) is a therapeutic neuromodulation auxiliary treatment for chronic intractable pains. Electrodes are placed in the epidural space, and implanted stimulator sends stimuli to the spinal cord through the electrodes, blocking the pain signal from passing to the brain, and relieving the feeling of pain.**



**SCS modulates neural pain signal sent to the brain, relieving the pain.**

Pain signal is sent to the brain through the spinal cord,
Implanted spinal cord stimulator generates electric pulses,
Electric pulses stimulate neurons in the spinal cord through electrodes,
Pain signals to different parts in brain are blocked by modulated pulses.
By pain relieve, psychological and emotional sufferings are also relieved.

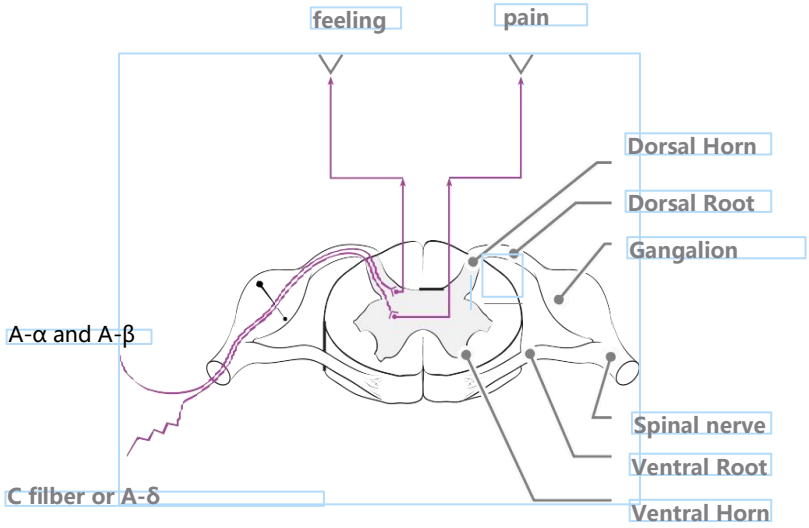
# Theoretical bases of SCS therapy

## Melzack & Wall introduced “gate control” theory in 1965

Afferent (feeling) nerves send information from all parts of the body to the spinal cord.

- A-α and A-β: contains myelin sheath, with fastest conduction rate, responding to feelings of touch, pressure and movement
- A-δ (delta): without myelin sheath, conducts slower, carrying acute pains
- C fiber: without myelin sheath, still slower, for chronical and persisting pains.

- Neurons in spinal dorsal horn receive pain signals, which are sent towards the brain along rising up fibers, produce perception of pains.
- By selectively and innocuously stimulate A-β fibers, pain signal gates can be shut, replaced with paresthesia (stinging or massaging) sensations.



# Pain types SCS may suppress

## In terms of diseases

1. Herpes zoster associated neuralgia（PHN）
2. Pain after brachial plexus injury
3. Perineal pain and cauda equina pain
4. Intractable pain after spinal surgery FBSS
5. Lower extremity vascular occlusive pain, diabetic foot
6. Pain after spinal cord injury
7. Central and thalamic pain
8. Stump and phantom pain
9. Head and face pain
10. Intercostal neuralgia, incision pain
11. Complex regional pain syndrome（CRPS）
12. Rare pain disorders

## In terms of locations

1. Head and face
2. Brachial plexus and upper limbs
3. torso
4. both lower extremities
5. perineum
6. Multiple pains

# Rishena SCS Product Portfolio

# Implantable Rechargeable Spinal Cord Stimulator

| Product | Implantable rechargeable spinal cord stimulator | |
|---|---|---|
| **Model & Spec.** | SCS301A | SCS301B |
| **H*W*D（mm)** | 54*51*9.5 | |
| **Weight（g)** | 40 | 38 |
| **Battery capacity (mAh)** | 220 | 250 |
| **No. of channels** | 16-Ch. Each channel arbitrarily definable to be +、-、off | |
| **Stim. Para.** | **Pulse width（μs）:** 20-1000<br>**Pulse amplitude（mA）:** 0-25.5<br>**Pulse frequency（Hz）:** 2-10000 | |



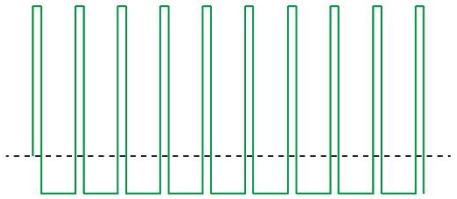

**SCS301A**



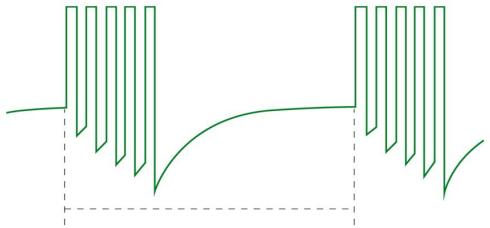

**SCS301B**

# Multiple Stimulation Modes for Customized Therapies

## Normal mode, HF mode



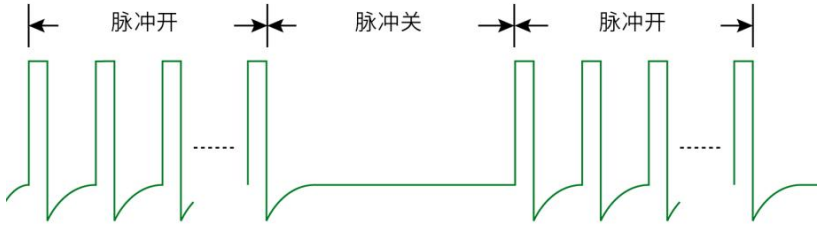
## 10KHz UHF mode



## Burst mode

## Cycle mode

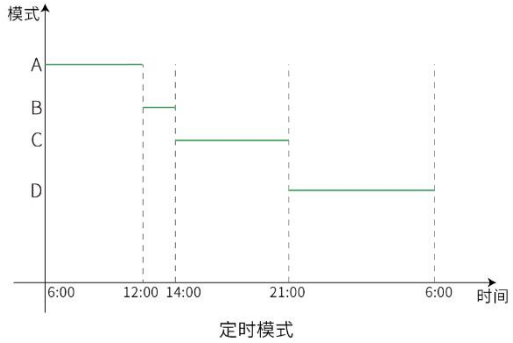
Settable ON/OFF time




## Timed mode

Specific programs for differen time periods

Each program can have different stimuli frequencies




## Postural mode

Auto-sense patient postures

Auto-select stimulation programs for each posture


stand


Reclining

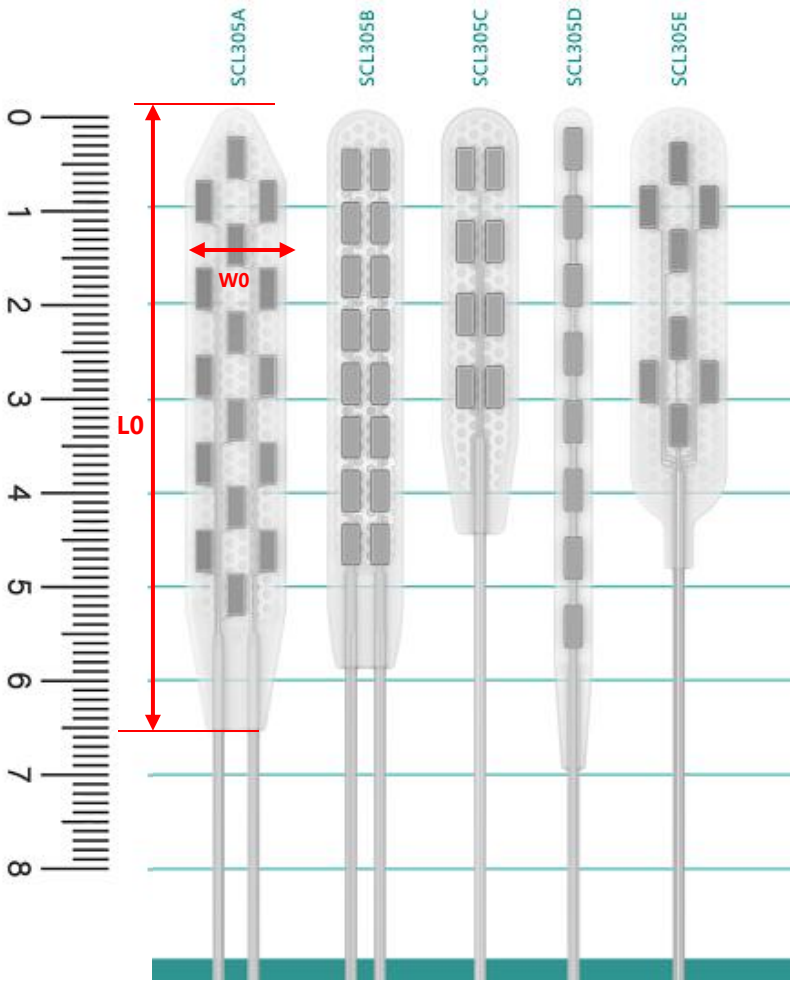

supine


prone


left lying

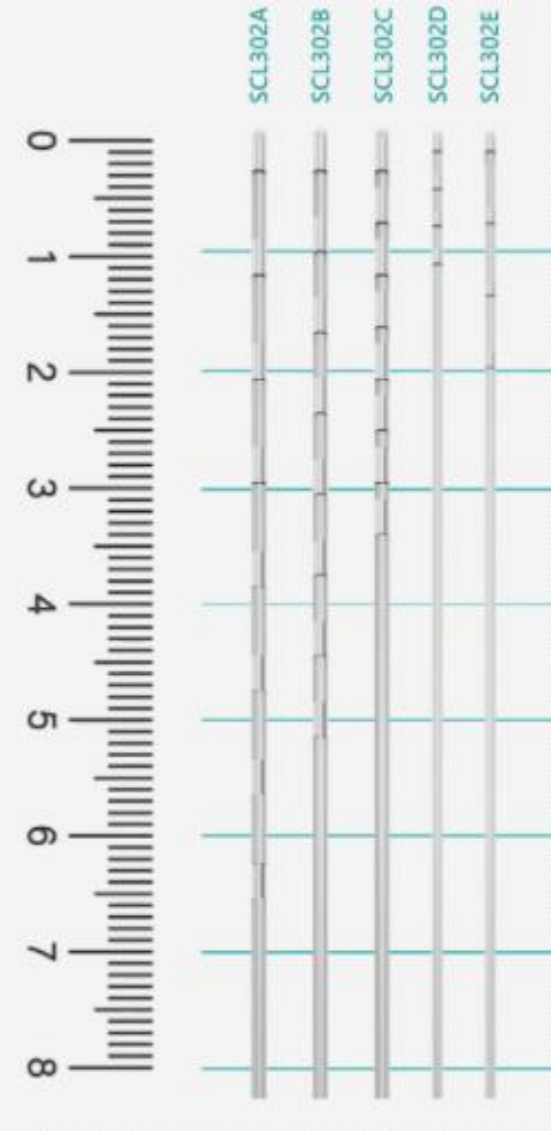

right lying

# Implantable Spinal Cord Lead （Paddle)



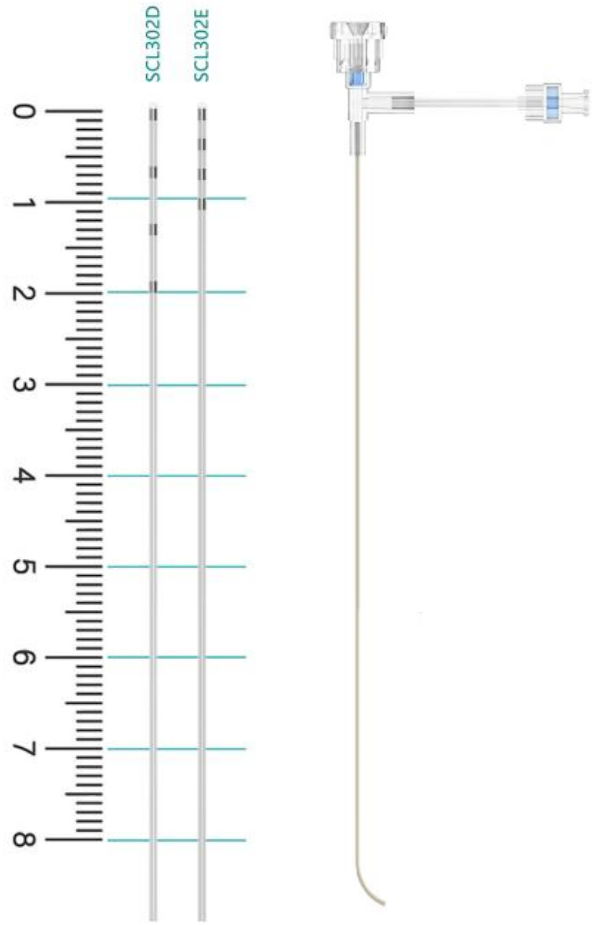

| Model & Spec. | **SCL305A-L** | **SCL305B-L** | **SCL305C-L** | **SCL305D-L** | **SCL305E-L** |
|---|---|---|---|---|---|
| Number of contacts | 16 | 16 | 8 | 8 | 8 |
| Arrangement | 5-6-5 | 2×8 | 2×4 | 1×8 | 2-4-2 |
| Contact shape L1×W1 (mm)±10% | 4.5×2 | | | | |
| Lead diameter D(mm)±10% | 1.3 | | | | |
| Pad length L0 (mm) ±10% | 64 | 57.5 | 44 | 68 | 47 |
| Pad width W0 (mm) ±10% | 10 | 7.8 | 7.8 | 4 | 10 |
| Lead length L (cm)±10% | 35，50，75，90 | | | | |

# Implantable Spinal Cord Lead （percutaneous）




| Type | Model & Spec. | Diameter (mm) ±10% | No. of Contacts | Length of Pt-Ir ring (mm)±10% | Pt-Ir ring spacing (mm)±10% | Lead length L(cm)±10% |
|---|---|---|---|---|---|---|
| typical | **SCL302A**-50/75/90 | 1.3 | 8 | 3 | 6 | 50,75,90 |
| | **SCL302B**-50/75/90 | | | | 4 | 50,75,90 |
| | **SCL302C**-50/75/90 | | | | 1.5 | 50,75,90 |
| DRG electrode | **SCL302D**-50/75/90 | 1 | 4 | 1.25 | 2 | 50,75,90 |
| | **SCL302E**-50/75/90 | | | | 5 | 50,75,90 |

# Full Range of Electrode Types for Varying Clinical Scenarios




DRG electrode



curved stylet

**DRG electrode, 1.0mm diameter,**

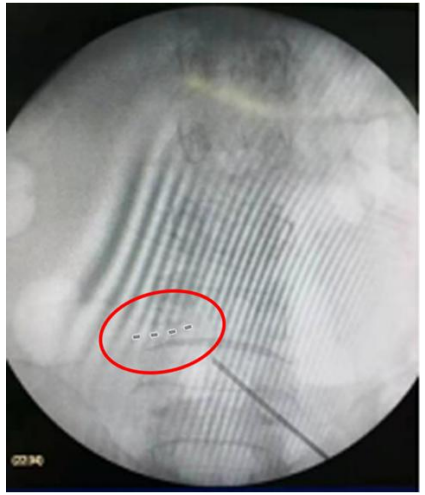
**Guided by curved stylet, can precisely reach nerve roots, ganglions, peripheral nerves through foramen ovale (Skull), foramen intervertebral, and foramen sacral,**

**Clinically verified its full coverage from the head to the sacral foramen.**

**DRG electrode implanted through foramen ovale**



**Transforaminal implantation of DRG electrode**



**Transsacral implantation of DRG electrode**

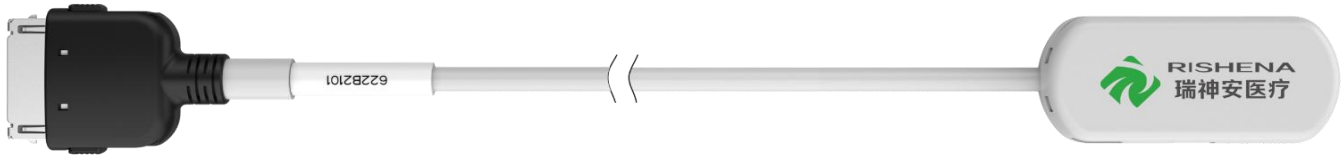


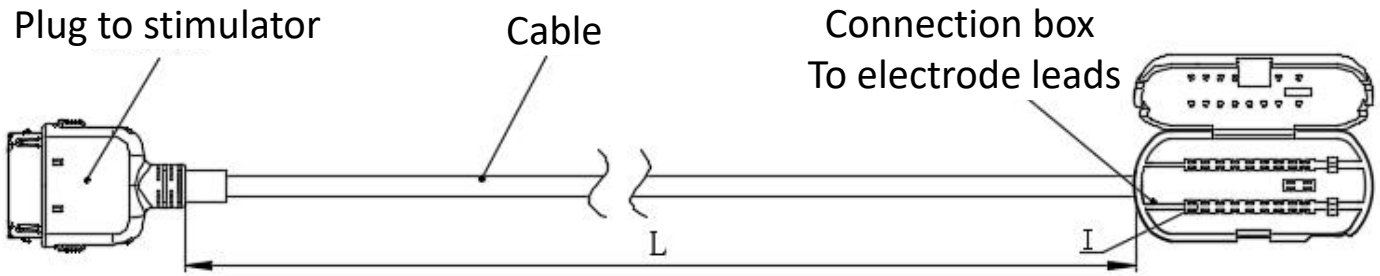
# External Spinal Cord Stimulator

- ☑ **Functionally External = Implantable**
- ☑ **Stimulation parameters can be transferred to implantable from external with one command**



# External Stimulator Extension Cable




| Parameter | SCL322A | SCL322B | SCL322C |
|---|---|---|---|
| Cable length L（cm） | 150±15 | 15±5 | 150±15 |
| Elastic contact groove width w（mm） | 1.15±0.2 | 1.15±0.2 | 0.8±0.2 |
| Designed for | 1.3mm lead, 8-contact | 1.3mm lead, 8-contact | 1.0mm lead, 4-contact |

# Combined Patient Programmer and Recharger

| Product | Combined Patient Programmer and Recharger |
|---|---|
| Model | SCR303B |
| Consists of | Patient programmer/charger（SCR303B），<br>Charging coil unit（SCR313A，with waistband） |
| Usage | Programing and wireless charging of implantable rechargeable spinal cord stimulator, or programing of external stimulator. For patients aged 18 years and up. |
| Features | • Temperature is monitored in real time, the temperature rise is kept within 2℃ for safety.<br>• Real time monitoring of alignment between charging coil unit and the implanted stimulator, helps optimal placement of the unit for high charging efficiency;<br>• Auto alarm beep for alignment degradation.<br>• Charging current can exceed 40mA, reducing charging time. |





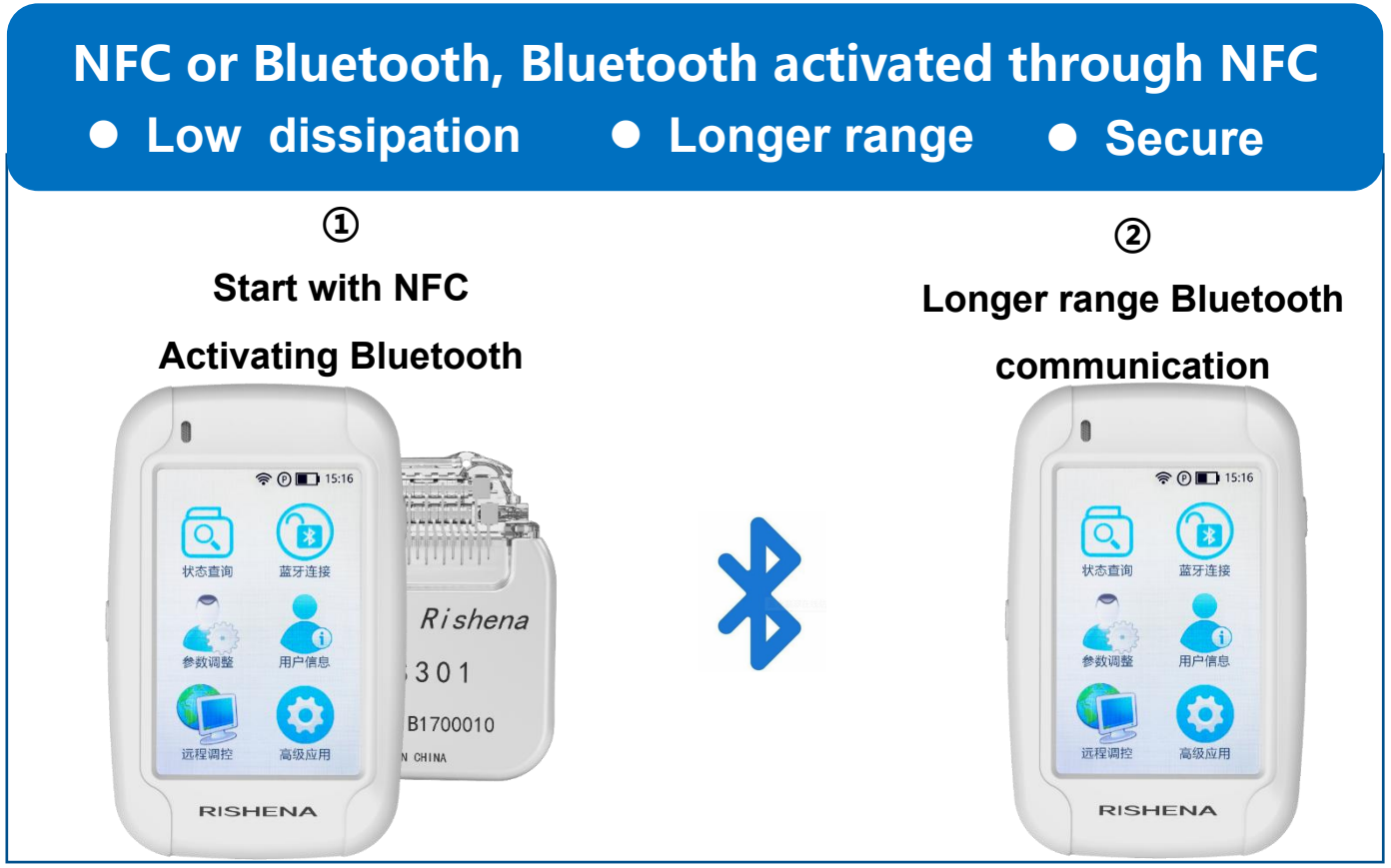
# Combined Clinician Programmer and Recharger




| | |
|---|---|
| **Product** | **Combined Clinician Programmer and Recharger** |
| **Model** | SCR303A |
| **Consists of** | Doctor programmer/charger（SCR303A）<br>Charging coil unit（SCR313A，with waistband） |
| **Usage** | Programing of external spinal cord stimulator, or programing and wireless charging of implantable rechargeable stimulator. (For doctors' use only.) |

# Dual Communication Modes, Power/Range Selectable

- **NFC mode**: no standby power dissipation, close range (<5 cm) , handling inconvenience;
- **Bluetooth mode**: longer distance (<2m), more power hungry.



# Remote Control for Patient Management

1

## Remote control Anytime, anywhere, without hospital visits.

- Both doctor & patient programmers connect to internet through Wi-Fi. Doctor is able to control the implanted stimulator with patient programmer as the relay agent.

2

## Patient management Continued follow-up after the operation.

- Query of stimulator parameters, status, battery performance etc. sent to the cloud for analysis, trace back, and assist to clinical diagnosis and treatment.












# Complete SCS System

## Test and temporary stimulation




## Permanent implantation



# SCS Surgery Operation

1. **Patient selection**
   - Indication evaluation
   - Psychological evaluation
   - **Efficacy target**

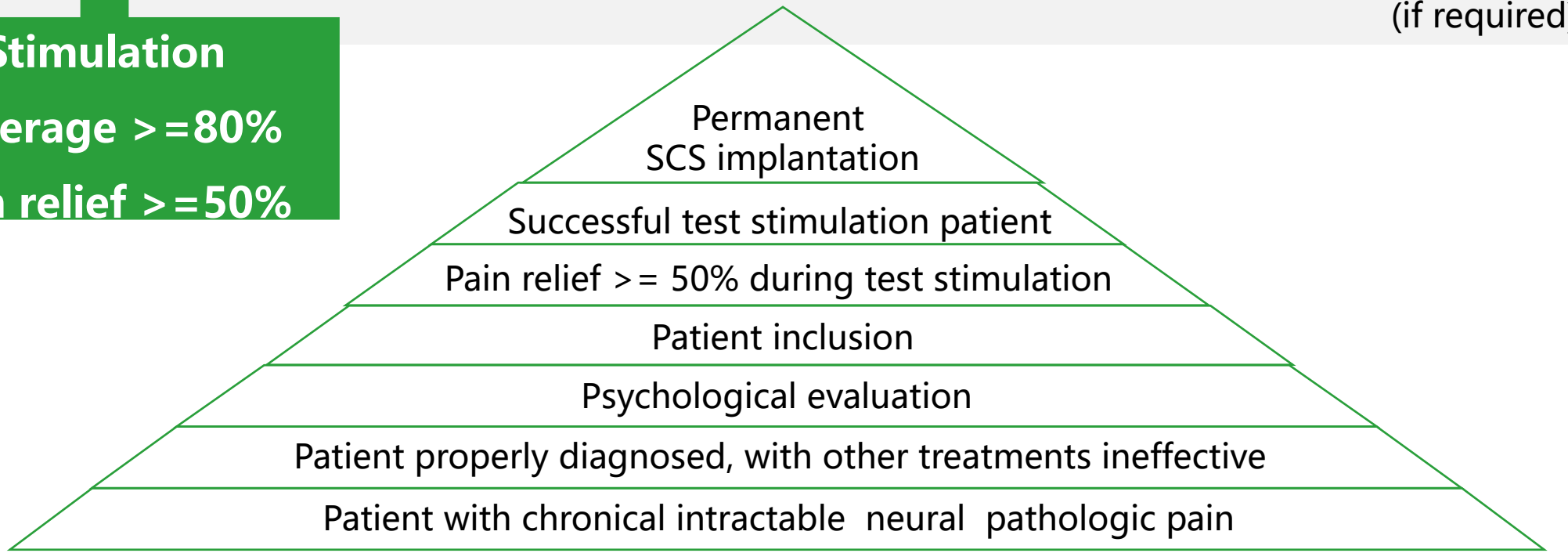
2. **Test Treatment**
   - Preoperative education
   - Test treatment
   - **Efficacy evaluation**

3. **Permanent implantation**
   - Implantation
     - Procedures & precautions
     - Postoperative education
   - Programming
     - Initial programing
     - Clinical follow-up

4. **Long term patient management**
   - Follow-up, programing
   - Problem solving
   - Adjust electrode (if required)

**Stimulation coverage >=80%**

**Pain relief >=50%**

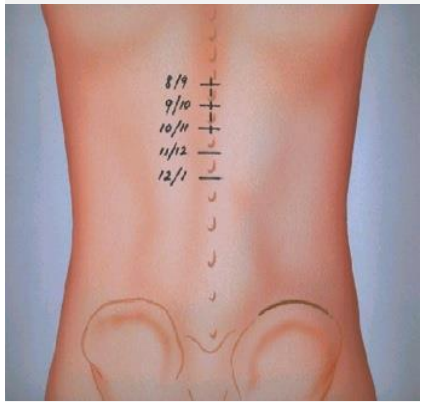


# SCS Surgical Procedure

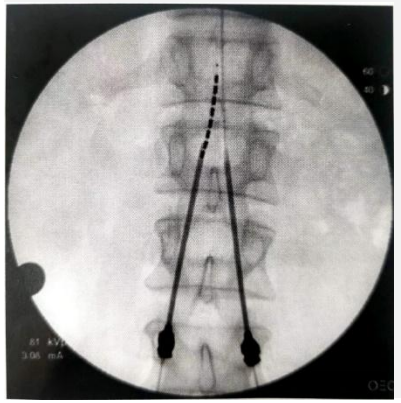
①patient preparation



②locate & mark




③electrode implantation





④intraoperative test





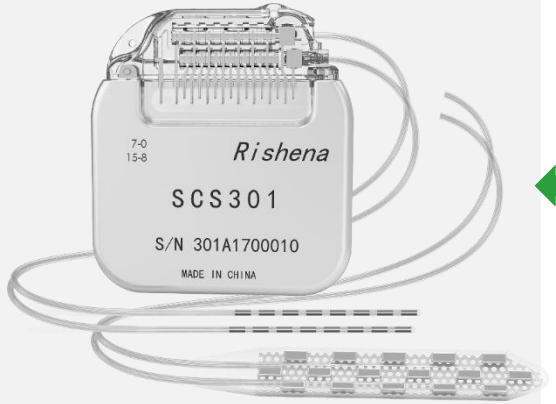

⑤anchoring electrode



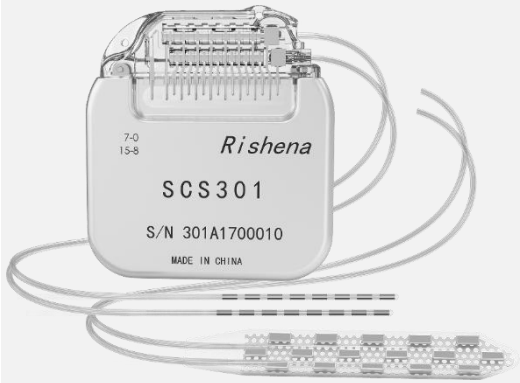
⑥temporary stimulation




⑦permanent implantation



# MRI Safety Verified in Registered Clinical Trials




## MRI compatible materials

- stimulator：titanium alloy
- electrode：platinum - iridium alloy, nickel - cobalt alloy
- Extension lead：nickel - cobalt alloy



## MRI safety verified

- 61 patients in registered clinical trials underwent postoperative MRI examinations, no occurrence of overheat harm to patients, no stimulator failures.
- **Note：Stimulator should be turned off before MRI exam.**

# Advantages of Rishena SCS in Clinical Applications



**1**

**Full range of electrode types, Multiple fixer types, syringe style tie-down**

- Electrodes: Needle, sheet, DRG
- Fixers: Mace, Bi-finned, Ti-locker
- Syringe style tie-down for easy handling, reliable anchoring

**2**

**Multiple stimulation modes, External=implantable functionally**

- 10K UHF、Burst、cycled、timed、postural modes
- Test stimulator supports all modes
- All settings in test stimulator transferable to permanent stimulator with one touch

**MRI safety verified in registered clinical trials**

**3**

**Innovative combined programmer/charger**

- Programmer/charger in one
- Large screen, easy UI for patient self-control
- Overheat protection for charging
- Intelligent charging alignment assist, charging efficiency display.

**4**

**Remote control, patient management**

- Doctor & patient programmers link over internet through Wi-Fi, remote regulation anywhere, anytime
- Programed parameters, battery performances, sent to cloud in real time, for analysis, trace back, and assist clinical diagnosis/treatments.

# Rishena SCS vs Competitors

| | Item | Rishena | Medtronic | Abbott | Nevro |
|---|---|---|---|---|---|
| component | DRG electrode | ✔ | × | ✔ | × |
| Stimulation mode | High Frequency (Hz) | 10K | 1200 | 1200 | 10K |
| | Burst Stimulation | ✔ | × | ✔ | × |
| | Postural Auto Adjust | ✔ | ✔ | × | × |
| Communication mode | Bluetooth | ✔ | × | ✔ | × |
| | Dual-mode | ✔ | × | × | × |
| | Remote control | ✔ | × | × | × |
| Programing & charging | Programmer/charger 2 in 1 | ✔ | × | × | × |
| | Wireless charging | ✔ | ✔ | ✔ | ✔ |
| | Intelligent charging | ✔ | × | × | × |

# Thank You!