Lead and Extension Kits

for Deep Brain Stimulation Systems

Clinician's Manual

St. Jude Medical

Contents

Prescription and Safety Information

Read this section to gather important prescription and safety information.

Intended Use

St. Jude Medical™ deep brain stimulation leads are intended to deliver stimulation to target areas in the brain. Deep brain stimulation extensions are intended to connect the leads to implantable pulse generators (IPGs).

Additional Prescription Information

Refer to the clinician's manual for the appropriate neurostimulation system to get additional prescription information, including indications for use and contraindications. For specific instructions, warnings, precautions, and adverse effects about other system components, see the clinician's manual for those components.

Warnings

The following warnings apply to these components.

Magnetic resonance imaging (MRI). Do not perform MRI on a patient with any implanted neurostimulator or lead (or any portion of a lead) from this system. Even if the neurostimulator has been removed, the patient should not have an MRI if any part of a lead or the cranial prosthesis is still

implanted. The neurostimulation system is MR Unsafe. Testing has not been performed to define conditions of use to ensure safety of the neurostimulation system in an MR environment.

Poor surgical risks. Neurostimulation should not be used on patients who are poor surgical risks or patients with multiple illnesses or active general infections.

Device components. The use of components not approved for use by St. Jude Medical may result in damage to the system and increased risk of injury.

Other active implanted devices. Physicians need to be aware that the neurostimulation system may interfere with the normal operation of another active implanted device. Conversely, the other active implanted device may interfere with the operation of the neurostimulation system.

Coagulopathies. Physicians should use extreme care with lead implantation in patients with a heightened risk of intracranial hemorrhage. Physicians should also consider underlying factors, such as previous neurological injury or prescribed medications (anticoagulants), that may predispose a patient to the risk of bleeding.

Charge density. A risk of tissue damage exists with stimulation parameter settings of high amplitudes and wide pulse widths. Higher amplitude and pulse width settings required to achieve therapy may indicate a system problem or suboptimal lead placement. Parameter values exceeding the charge density limit of 30 $\mu C/cm^2$ should only be programmed with due consideration of the warnings concerning charge densities. Charge density can be reduced by lowering the stimulation amplitude or pulse width.

Precautions

The following precautions apply to these components.

General Precautions

Surgeon training. Implanting physicians should be experienced in stereotactic and functional neurosurgery.

Clinician training. Clinicians should be familiar with deep brain stimulation therapy and be experienced in the diagnosis and treatment of the indication for which the deep brain stimulation components are being used.

Patient selection. Select patients appropriately for deep brain stimulation.

Infection. Follow proper infection control procedures. Infections may require that the device be explanted.

Electromagnetic interference (EMI). Some equipment in home, work, medical, and public environments can generate EMI that is strong enough to interfere with the operation of a neurostimulation system. Patients should avoid getting too close to these types of EMI sources, which include the following examples: commercial electrical equipment (such as arc welders and induction furnaces), communication equipment (such as microwave transmitters and high-power amateur transmitters), high-voltage power lines, and some medical procedures (such as therapeutic radiation and electromagnetic lithotripsy).

Sterilization and Storage

Single-use, sterile device. The implanted components of this neurostimulation system are intended for a single use only. Sterile components in this kit have been sterilized using ethylene oxide (EtO) gas before shipment and are supplied in sterile packaging to permit direct introduction into the sterile field. Do not resterilize or reimplant an explanted system for any reason.

Storage environment. Store components and their packaging where they will not come in contact with liquids of any kind.

Handling and Implementation

Expiration date. An expiration date (or "use-before" date) is printed on the packaging. Do not use the system if the use-before date has expired.

Care and handling of components. Use extreme care when handling system components. Excessive heat, excessive traction, excessive bending, excessive twisting, or the use of sharp instruments may damage and cause failure of the components.

Package or component damage. Do not implant a device if the sterile package or components show signs of damage, if the sterile seal is ruptured, or if contamination is suspected for any reason. Return any suspect components to St. Jude Medical for evaluation.

Body fluids or saline. If the metal contacts on the proximal end of the led or extension are exposed to body fluids or saline before connection, corrosion can occur. If exposure occurs, clean the metal contacts with sterile, deionized water or sterile water (not saline) and dry them completely before connection and implantation.

Electrosurgery devices. Electrosurgery devices should not be used in close proximity to an implanted IPG, lead, or extension. Contact between an active electrode and an implanted IPG, lead, or extension can cause severe injury to the patient. For additional electrosurgery information and guidance, refer to the IPG manual.

Skin erosion. To avoid the risk of skin erosion, implant components at the appropriate depth and inform patients to avoid touching their skin where components are implanted.

System testing. To ensure correct operation, the system should always be tested after implantation and before the patient leaves the surgery suite.

Device modification. To prevent injury or damage to the system, do not modify a lead or extension in any way. If needed, return the device to St. Jude Medical.

Component disposal. Return all explanted components to St. Jude Medical for safe disposal.

Hospital and Medical Environments

External defibrillators. The safety of discharging an external defibrillator on patients with an implanted deep brain stimulation system has not been established.

Psychotherapeutic procedures. The safety of psychotherapeutic procedures, such as electroshock therapy and transcranial magnetic stimulation, which use equipment that generates electromagnetic interference, has not been established.

Home and Occupational Environments

Damage to shallow implants. Inform patients that falling and other traumatic accidents can damage shallowly implanted components such as the leads and extensions.

Adverse Effects

Deep brain stimulation potentially has the following adverse effects associated with this device:

> NOTE: For information about stimulation-related complications, see the clinician's manual for the implantable pulse generator.

Possible surgical complications. Surgical complications include, but are not limited to, the following: intracranial hemorrhage (which can lead to paralysis or death); subcutaneous hemorrhage or seroma, erosion, or infection; pain at the implant site; seizure or convulsions; aphasia or paralysis; stroke; bleeding' complications from anesthesia, including death; complications from unusual physiological variation in patients, including foreign body rejection phenomena; and leakage of cerebrospinal fluid surrounding the brain.

Possible device-related complications. Device-related complications include, but are not limited to, the following: paresthesia; jolting or shocking sensations; postoperative pain, stress, or discomfort; lead fracture, migration, or dislodgement; undesirable changes in stimulation related to cellular changes in tissue around the electrodes, changes in the electrode position, loose electrical connections, or lead fracture; persistent pain at the incision sites or general pain; and allergic or rejection response to implanted materials.

Product Description

This section describes the St. Jude Medical™ deep brain stimulation leads and extensions. For detailed specifications of the leads and extensions, see the appropriate appendix in this manual.

> NOTE: For more information about the neurostimulation system, see the clinician's programming and reference manual for this system.

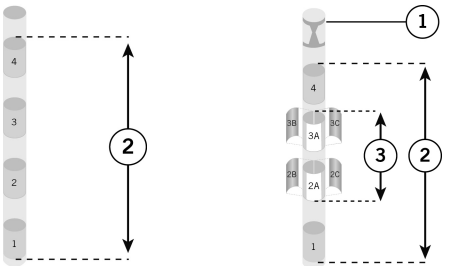
Leads

St. Jude Medical™ deep brain stimulation (DBS) leads are designed for introduction into the brain using standard stereotactic neurosurgical techniques. St. Jude Medical offers two families of leads: traditional leads and leads for the St. Jude Medical Infinity™ DBS System. (For more information about lead features and specifications, see the appropriate appendix in this manual.)

- Traditional leads feature electrodes on the distal end with a longer, active electrode on the lead tip. The proximal end of the lead contains contact bands that correspond with each of the distal electrodes and an inactive band that functions as an insertion handle.
- Leads for the St. Jude Medical Infinity DBS System feature electrodes on a stiff distal end with an inactive lead tip. The proximal end of the lead contains contact bands that correspond with each of the distal electrodes and an inactive band that functions as a contact for a setscrew when connecting to a compatible extension. Additionally, the leads have colored bands that help during implantation to differentiate between the right and left sides of the body. Two types of leads for the St. Jude Medical Infinity DBS System are available: 4 channel and 8 channel. The 4-channel leads

contain cylindrical electrodes that provide stimulation in all directions around the lead. The 8-channel leads contain segmented electrodes that can be activated independently to focus stimulation in one direction to help exclusively target desired neurological structures. The following figure shows an isometric view of each lead for the St. Jude Medical Infinity DBS System.

Figure 1. Isometric view of leads for the St. Jude Medical Infinity™ DBS System



4-channel lead

8-channel lead

1. Directional marker
2. Electrodes
3. Center 2 electrodes with 3 segments each

In addition to the lead, the lead kit contains the following items:

- **Lead protection boot.** Used to protect the contact bands on the proximal end of the lead and allow you to identify the lead subcutaneously while implanting the extension and the IPG
- **Lead stop.** Used to mark the depth of the lead during implantation
- **Lead stylet.** Inserted in the lumen of the lead body to help position the lead
- **Torque wrench.** Used to tighten the setscrew on the lead protection boot
- **Trial cable.** Used to connect an external trial stimulator to an implanted lead (included in traditional lead kits only)

Extensions

St. Jude Medical™ deep brain stimulation (DBS) extensions are designed to connect the lead to the IPG. One end of the extension is designed to receive the proximal end of the lead, and the opposite end of the extension is designed for insertion and connection with the IPG. St. Jude Medical offers two families of extensions: traditional extensions and extensions for the St. Jude Medical Infinity™ DBS System. (For more information about extension features and specifications, see the appropriate appendix in this manual.)

Traditional extensions are intended to connect to only traditional leads. Extensions for the St. Jude Medical Infinity DBS System are intended to connect to only leads for the St. Jude Medical Infinity DBS System: the 4-channel extensions connect to 4-channel leads, and the 8-channel extensions connect to 8-channel leads. Additionally, extensions for the St. Jude Medical Infinity

DBS System have colored bands that can help during implantation to differentiate between the right and left sides of the body.

In addition to the extension, the extension kit contains the following items:

- **Torque wrench.** Used to tighten the setscrew on the extension
- **Tunneling tool.** Used to create a subcutaneous tunnel to route the lead and extension to the IPG site

Directions for Use

Read this section carefully for suggested directions for use related to the leads and extensions. For directions for use for other system components not covered in this document, see the clinician's manual for the appropriate device.

> CAUTION: Before implanting, inspect components for damage. Do not implant any damaged components. Return them to St. Jude Medical for evaluation.

Implanting the Lead

To implant a lead, follow these steps:

1. Conduct imaging planning to determine the appropriate length of the lead to reach the target site and connect to the extension.

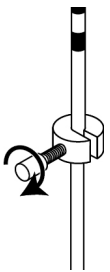
2. After placement of the stereotactic frame, use standard imaging techniques to determine coordinates for the lead's target site.
3. Prepare the patient per normal stereotactic surgical techniques.
4. Make a skin incision, with consideration given to burr hole placement.
5. Create the burr hole at the desired cranial location and open the dura.
6. Adjust the stereotactic frame so that an insertion cannula (or probe) will enter the brain at the desired entry point and follow the desired trajectory.

   NOTE: The cannula inner diameter must be at least 1.6 mm (0.062 in) for traditional leads and 1.4 mm (0.055 in) for leads of the St. Jude Medical Infinity™ DBS System.
7. With a stylet inserted in the cannula, advance the cannula (or probe) into position in the brain, and then remove the stylet (or probe).
8. If desired, determine the position for the lead stop on the lead, and then place the lead stop on the lead (see the following figure).

   NOTE: Confirm the lead stylet is fully inserted in the lead before tightening the lead stop.

NOTE: When determining the position for the lead stop, measure from the distal end of the lead only. Measuring from the proximal end can introduce errors that may impact lead placement. See the appendix for detailed specifications of the lead length.

Figure 2. Attach the lead stop



9. Insert the lead into the insertion cannula and slowly advance it to the target.
10. If desired, use imaging to confirm the lead position.

Intraoperative Testing

Perform intraoperative testing to confirm proper lead electrode placement and to confirm that the leads are functional. Traditional lead kits contain a trial cable for performing intraoperative testing. For leads of the St. Jude Medical Infinity™ DBS System, refer to the clinician's manual for the appropriate intraoperative testing components.

Intraoperative Testing for Traditional Leads

For traditional leads, the testing system consists of an external trial stimulator and options of trial cables. The traditional lead kits contain the Model 6001 trial cable for monopolar and bipolar stimulation. For any other trial cables not included in the lead kit or testing components not covered in this document, see the clinician's manual for the appropriate device.

CAUTION: Carefully review the clinician's manual for the trial stimulator before using it for intraoperative testing.

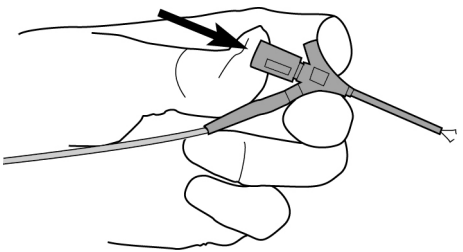
Connecting the Model 6001 Trial Cable for Bipolar Testing

To prepare the Model 6001 trial cable for testing using bipolar stimulation, follow these steps:

1. Determine which contact band on the proximal end of the electrode corresponds to the desired cathode electrode. See the lead specifications in the appendix for information about which contact band corresponds with each electrode.

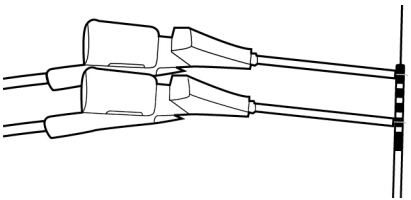
2. Push the button on the contact clamp of the trial cable to expose the metal hooks on the end of the clamp.

Figure 3. Push the button on the contact clamp to expose the metal hooks



3. Attach the clamp to the lead so that the metal hooks touch the contact band that corresponds to the desired cathode electrode.
4. Repeat steps 2 and 3 to attach a second contact clamp to the contact band that corresponds to the desired anode electrode.

Figure 4. Attach the clamps to the desired cathode and anode contact bands



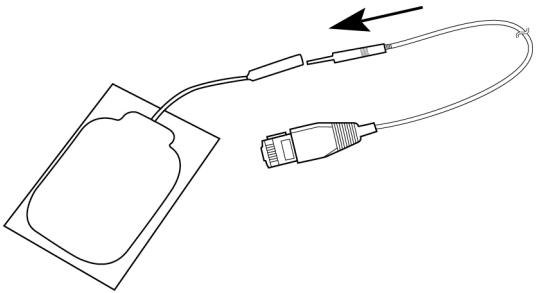
Connecting the Model 6001 Trial Cable for Monopolar Testing

To prepare the Model 6001 trial cable for testing using monopolar stimulation, follow these steps:

CAUTION: The anode patch and anode patch cable are nonsterile.

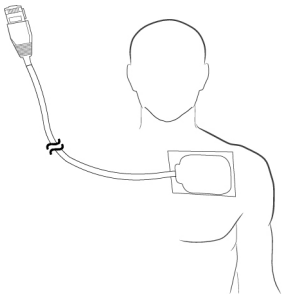
1. Connect the anode patch cable to the anode patch as shown in the following figure.

Figure 5. Connect the anode patch cable to the patch



2. Remove the backing from the anode patch, and place the patch directly on the patient's skin in the subclavicular upper quadrant of the torso.

Figure 6. Place the patch (nonsterile) on the skin in the upper quadrant of the torso

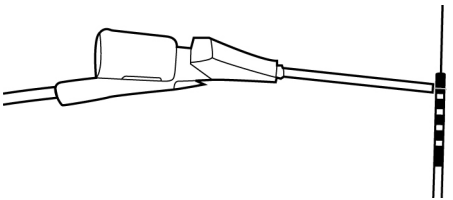


3. Determine which contact band on the proximal end of the electrode corresponds to the desired cathode electrode. See the lead specifications in the appendix for information about which contact band corresponds with each electrode.

4. Push the button on the contact clamp of the trial cable to expose the metal hooks on the end of the clamp.

5. Attach the clamp to the lead so that the metal hooks touch the contact band that corresponds to the desired cathode electrode.

Figure 7. Attach the clamp to the desired cathode contact band



Securing the Lead

When the lead is properly positioned, it should be secured to prepare the patient for the next procedure.

1. Turn off any intraoperative testing equipment and remove it from the lead.
2. Taking care not to inadvertently reposition the lead, remove the lead stop, stylet, insertion cannula, and guide tube assembly.

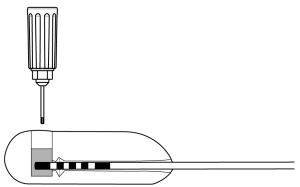
3. Use a cranial burr hole cover system or other method to secure the lead.
4. Verify lead placement with standard imaging techniques.
5. Use the lead protection boot (see the following section) to protect the lead connector and facilitate lead palpation at the subsequent surgical implantation of the IPG and extension.

To Use the Lead Protection Boot

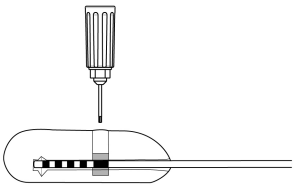
1. Ensure that all blood and tissue are cleaned from the proximal end of the lead. If necessary, clean the proximal end of the lead with sterile, deionized, or distilled water (not saline) and dry it completely.
2. Slide the proximal end of the lead fully into the protection boot (see the following figure).
   - For traditional leads, ensure that the most proximal contact band on the lead is fully within the setscrew block of the lead boot.
   - For leads of the St. Jude Medical Infinity™ DBS System, ensure that the most distal contact band (the inactive setscrew contact band) is fully within the setscrew block of the lead boot.
3. While the lead is fully inserted in the protection boot, use the torque wrench to tighten the protection boot setscrew (see the following figure). Turn the setscrew clockwise until the torque wrench clicks.

   NOTE: Do not excessively manipulate the lead protection boot when it is attached to the lead.

Figure 8. Tighten the setscrew of the lead boot (cross-section view)



Lead boot for traditional lead



Lead boot for lead of the
St. Jude Medical Infinity™ DBS System

4. Prepare a subgaleal pocket by blunt dissection at the top of the skull along the edge of the burr hole incision for placement of the excess lead wire.
5. Carefully coil any excess lead in the subgaleal pocket. Use loops no smaller than 2.5 cm (1 in) in diameter.

Connecting and Tunneling to the Extension

To tunnel the extension to the IPG pocket and connect the lead to the extension, follow these steps:

1. Select the IPG pocket site, ensuring that the extension is long enough to reach the desired pocket site and to allow for strain relief loops.
2. Create the IPG pocket parallel to the skin surface and no deeper than recommended by the neurostimulator labeling.
3. Select a site in the mastoid region to create a small pocket for the extension connector.

   CAUTION: To prevent lead or extension fracture, do not place the extension connector in the neck.

4. With the cannula sleeve in place on the tunneling tool, create a subcutaneous tunnel between the extension connector site and the IPG pocket. The tunneling tool is malleable and can be bent to conform to the contour of the patient's body.
5. Withdraw the tunneling tool from the cannula sleeve, leaving the cannula sleeve within the subcutaneous tunnel.
6. Carefully pass the proximal end of the extension through the cannula sleeve from the extension connector site to the IPG pocket.

7. Gain access to the proximal end of the lead. Then do the following:
   - If the lead protection boot is present, remove it by loosening the setscrew (counter-clockwise) with the torque wrench provided in the extension kit and carefully slide the lead protection boot from the lead.
   - Clean any blood or tissue from the proximal end of the lead using sterile, deionized or distilled water (not saline) and dry completely. Inspect the lead, and ensure that it is free from damage.

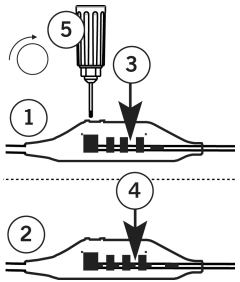
   NOTE: Traditional leads are compatible only with traditional extensions. Leads for the St. Jude Medical Infinity™ DBS System are compatible only with extensions for the St. Jude Medical Infinity™ DBS System: the 4-channel leads connect to 4-channel extensions, and the 8-channel leads connect to 8-channel extensions.

8. Carefully slide the proximal end of the lead into the extension connector. Ensure that the lead contacts align with the connector contacts.

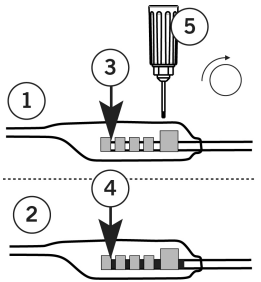
   NOTE: The colored band on the lead is not an insertion handle. Do not use the colored band as a guide to confirm full insertion of the lead into the extension or the extension into the IPG.

9. Tighten the setscrew clockwise until the torque wrench clicks.

Figure 9. Correct and incorrect lead insertion into the extension connector



Traditional extensions (Models 6345, 6346)



Traditional extensions (Models 6315, 6316, 6319) and extensions for the St. Jude Medical Infinity™ DBS System

1. Correct insertion
2. Incorrect insertion
3. Window between each connector contact is clear
4. Window between each connector contact is partially blocked by electrode
5. Tighten the setscrew by turning the torque wrench clockwise

10. Withdraw the cannula sleeve from the subcutaneous tunnel, taking care to avoid traction on the extension. Do not leave excess extension anywhere except in large loops placed behind the IPG in its pocket.

Determining the Direction of Segmented Electrodes on 8-Channel Lead for the St. Jude Medical Infinity™ DBS System

The 8-channel lead for the St. Jude Medical Infinity™ DBS System contains four electrodes, with the two center electrodes segmented into three segments each. The lead contains a directional marker that helps determine the direction of the segmented electrodes. After the lead is implanted at the desired target, use fluoroscopy to view the directional marker. You can conduct fluoroscopy for intraoperative or postoperative assessment.

1. Scan the patient along the Anterior-Posterior (AP) for your primary scan, and note the shape of the directional marker.
2. Rotate the direction of the fluoroscope 90 degrees clockwise from the AP looking head to foot to scan along the lateral view, and note the shape of the directional marker.
3. Use the X-ray images in the following table to determine the direction of the reference electrode based on the two scans.

Table 1. Directional marker on X-ray views

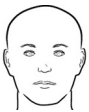
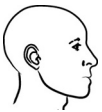
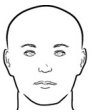
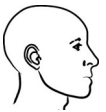
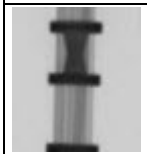
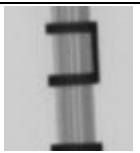
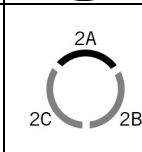
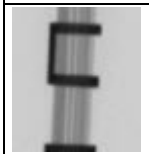
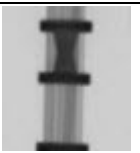
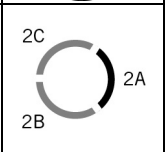
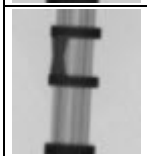
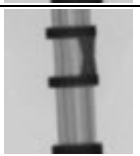
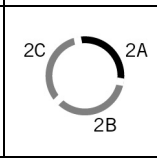
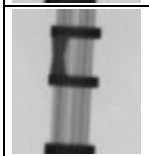
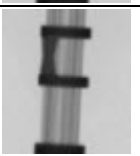
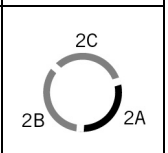
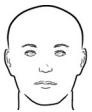
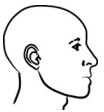
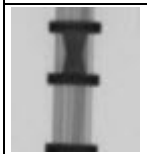
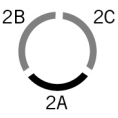
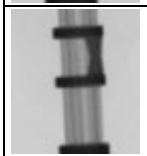
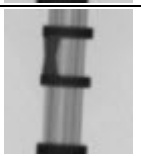
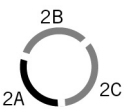
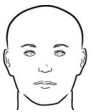
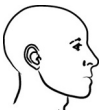
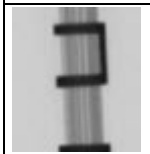
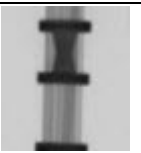
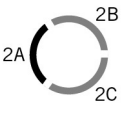
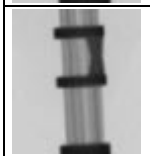
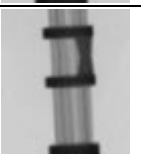
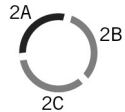
AP View	Lateral View	Electrode Orientation	AP View	Lateral View	Electrode Orientation
					
					
					

Table 1. Directional marker on X-ray views

AP View	Lateral View	Electrode Orientation
		
		
		

AP View	Lateral View	Electrode Orientation
		
		
		

Disposing of Explanted Components

Explanted St. Jude Medical™ components should be returned to St. Jude Medical for proper disposal. To return an explanted component, place it in a container or bag marked with a biohazard label and coordinate the return with your St. Jude Medical representative or Technical Support.

Technical Support

For technical questions and support for your St. Jude Medical™ neuromodulation product, use the following information:

- +1 972 309 8000
- +1 800 727 7846 (toll-free within North America)

For additional assistance, call your local St. Jude Medical representative.

Appendix A: Product Specifications

NOTE: Not all models are available in all countries. Contact your local representative for more information.

Storage Specifications

Store the components according to the following conditions.

Table 2. Storage conditions for components

Temperature	-10°C–55°C (14°F–131°F)
Humidity	10%–90% (noncondensing)
Pressure	70–150 kPa (10.2–21.8 psi)

Product Materials

Table 3. Product materials for deep brain stimulation leads and extensions

Component	Patient Contact Material
Leads	Platinum iridium, polycarbonate urethane
Extensions	Platinum iridium, polycarbonate urethane, silicone elastomer
Extensions, flexible	Platinum iridium, silicone polycarbonate polyurethane, silicone elastomer

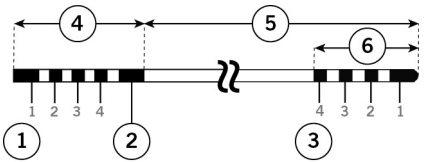
Traditional Lead Specifications

Table 4. Specifications for traditional leads

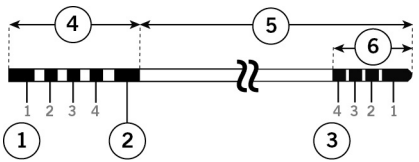
Model number by lead length		1.5-mm electrode spacing	0.5-mm electrode spacing
	25 cm	6142	6146
	30 cm	6143	6147
	35 cm	6144	6148
	40 cm	6145	6149
Lead diameter		1.4 mm	1.4 mm
Number of electrodes		4	4
Electrode length		1.5 mm	1.5 mm
Terminal electrode length		3.0 mm	3.0 mm
Length between electrodes		1.5 mm	0.5 mm
Length of electrode array		12 mm	9 mm
Length of contact band-insertion handle array		1.47 cm	1.47 cm

Table 4. Specifications for traditional leads

Lead with 1.5-mm electrode spacing



Lead with 0.5-mm electrode spacing



1. Contact bands (1 - 4)
2. Insertion handle
3. Electrodes (1 - 4)
4. Length of contact band-insertion handle array
5. Lead length
6. Length of electrode array

Each kit listed in the previous table contains the following items:

- 1 lead with stylet
- 1 torque wrench (Model 1101)
- 1 DBS lead stop (Model 1140)
- 1 DBS stylet
- 1 4-channel lead protection boot (Model 1149)
- 1 set of two trial cables, one anode cable, and one anode patch (Model 6001)

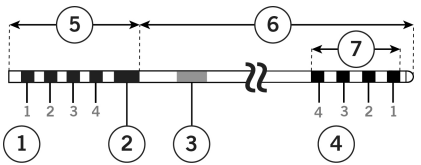
Lead Specifications for the St. Jude Medical Infinity™ DBS System (4-Channel)

Table 5. Specifications for 4-channel leads of the St. Jude Medical Infinity™ DBS System

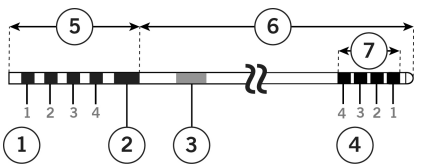
Model number by lead length		1.5-mm electrode spacing		0.5-mm electrode spacing	
	30 cm	6167	6159	6166	6158
	40 cm	6169	6161	6168	6160
Color of insertion handle		Black	White	Black	White
Lead diameter		1.27 mm		1.27 mm	
Number of electrodes		4		4	
Electrode length		1.5 mm		1.5 mm	
Length between electrodes		1.5 mm		0.5 mm	
Length of electrode array		10.5 mm		7.5 mm	
Length of contact band-setscrew band array		14.7 mm		14.7 mm	

Table 5. Specifications for 4-channel leads of the St. Jude Medical Infinity™ DBS System

Lead with 1.5-mm electrode spacing



Lead with 0.5-mm electrode spacing



1. Contact bands (1 - 4)
2. Setscrew contact band
3. Colored insertion handle
4. Electrodes (1 - 4)
5. Contact band-setscrew band array
6. Lead length
7. Electrode array

Each kit listed in the previous table contains the following items:

- 1 lead with stylet
- 1 4-channel lead protection boot
- 1 torque wrench (Model 1101)
- 1 DBS lead stop (Model 1140)

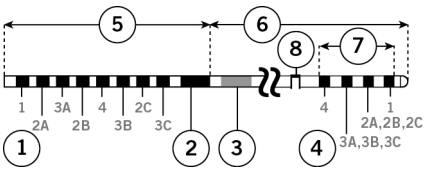
Lead Specifications for the St. Jude Medical Infinity™ DBS System (8-Channel)

Table 6. Specifications for 8-channel leads of the St. Jude Medical Infinity™ DBS System

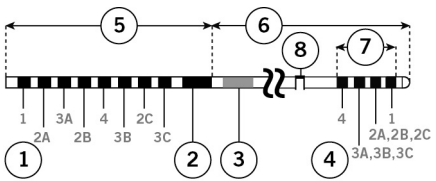
Model number by lead length		1.5-mm electrode spacing		0.5-mm electrode spacing	
	30 cm	6171	6179	6170	6178
	40 cm	6173	6181	6172	6180
Color of insertion handle		Black	White	Black	White
Lead diameter		1.27 mm		1.27 mm	
Number of electrodes		8		8	
Electrode length		1.5 mm		1.5 mm	
Length between electrodes		1.5 mm		0.5 mm	
Length of electrode array		10.5 mm		7.5 mm	
Length of contact band-setscrew band array		24.8 mm		24.8 mm	

Table 6. Specifications for 8-channel leads of the St. Jude Medical Infinity™ DBS System

Lead with 1.5-mm electrode spacing



Lead with 0.5-mm electrode spacing



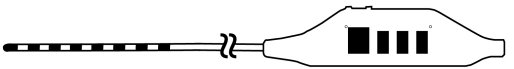
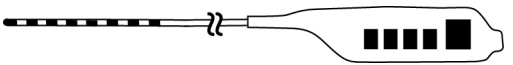
1. Contact bands (1 - 8)
2. Setscrew contact band
3. Colored insertion handle
4. Electrodes (1 - 8)
5. Contact band-setscrew band array
6. Lead length
7. Electrode array
8. Directional marker

Each kit listed in the previous table contains the following items:

- 1 lead with stylet
- 1 8-channel lead protection boot
- 1 torque wrench (Model 1101)
- 1 DBS lead stop (Model 1140)

Traditional Extension Specifications

Table 7. Specifications for traditional extensions

Model number by extension length	50 cm	60 cm	90 cm
	6345	6346	—
	6315	6316	6319[a]
Connector strength (lead to extension)		5 N	

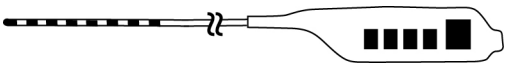
[a] Denotes extension with a low-iron header

Each kit listed in the previous table contains the following items:

- 1 extension
- 1 torque wrench (Model 1101)
- 1 tunneling tool, 0.156-in diameter (Model 1191)

Extension Specifications for the St. Jude Medical Infinity™ DBS System (4-Channel)

Table 8. Specifications for 4-channel extensions of the St. Jude Medical Infinity™ DBS System

Model number by extension length			
	50 cm	6339	6343
	60 cm	6340	6344
	50 cm	6355[a]	6361[a]
	60 cm	6356[a]	6362[a]
	90 cm[b]	6359[a]	6363[a]
Color of identification band		Black	White
Connector strength (lead to extension)		5 N	

[a] Denotes flexible extension

[b] Denotes extension with a low-iron header

Each kit listed in the previous table contains the following items:

- 1 extension
- 1 torque wrench (Model 1101)
- 1 tunneling tool, 0.156-in diameter (Model 1191)

Extension Specifications for the St. Jude Medical Infinity™ DBS System (8-Channel)

Table 9. Specifications for 8-channel extensions of the St. Jude Medical Infinity™ DBS System

Model number by extension length			
	50 cm	6371[a]	6377[a]
	60 cm	6372[a]	6378[a]
	90 cm[b]	6373[a]	6379[a]
Color of identification band		Black	White
Connector strength (lead to extension)		5 N	

[a] Denotes flexible extension

[b] Denotes extension with a low-iron header

Each kit listed in the previous table contains the following items:

- 1 extension
- 1 torque wrench (Model 1101)
- 1 tunneling tool, 0.156-in diameter (Model 1191)

Appendix B: Regulatory Statements

This section contains regulatory statements about your product.

Declaration of Conformity

Hereby, St. Jude Medical declares that this medical device is in compliance with the essential requirements and other relevant provisions of AIMD directive 90/385/EEC. For a copy of the declaration of conformity, please contact Technical Support.

Appendix C: Symbols and Definitions

The following symbols may be used in this document and on some of the products and packaging:

Table 10. Symbols and definitions

Symbol	Definition
	Caution, consult accompanying documents
	Consult instructions for use
	Follow instructions for use on this website
	Magnetic Resonance (MR) Unsafe, an item poses unacceptable risks to the patient, medical staff, or other persons within an MR environment
	Single use only
	Do not resterilize

Table 10. Symbols and definitions

Symbol	Definition
	Expiration date
	Date of manufacture
	Manufacturing facility
	Temperature limits for storage conditions
	Humidity limits
	Pressure limits
	Do not use if the product sterilization barrier or its packaging is compromised

Table 10. Symbols and definitions

Symbol	Definition
REF	Catalog number
	Manufacturer
	Contents quantity
	One lead
+	Accessories
SN	Serial number
LOT	Batch code
Rx ONLY	Prescription use only
STERILE EO	Ethylene oxide gas sterilization
EC REP	Authorized European representative

Table 10. Symbols and definitions

Symbol	Definition
CE 0086 0123	European conformity, affixed in accordance with the relevant provisions of AIMD directive 90/385/EEC. Hereby, St. Jude Medical declares that this device is in compliance with the essential requirements and other relevant provisions of this directive.

Additional Symbols for Product Labels

The following table shows additional symbols that may appear on the product labels for parts related to this kit.

Table 11. Additional symbols for product labels

Symbol	Definition
Torque Wrench	Torque wrench
DBS Lead Stop	DBS lead stop

Table 11. Additional symbols for product labels

Symbol	Definition
4-Ch Lead Protection Boot	4-channel lead protection boot
Tunneling Tool, 0.156" Diameter	Tunneling tool, 0.156 in (0.4 cm) diameter
Trial Cables Test Clip, Anode Patch	Trial cables, test clip, anode patch
4Ch DBS Lead, 25cm Contact 1.5 Space 1.5	4-channel DBS lead, 25 cm, contact 1.5, space 1.5
4Ch DBS Lead, 30cm Contact 1.5 Space 1.5	4-channel DBS lead, 30 cm, contact 1.5, space 1.5
4Ch DBS Lead, 35cm Contact 1.5 Space 1.5	4-channel DBS lead, 35 cm, contact 1.5, space 1.5
4Ch DBS Lead, 40cm Contact 1.5 Space 1.5	4-channel DBS lead, 40 cm, contact 1.5, space 1.5
4Ch DBS Lead, 25cm Contact 1.5 Space 0.5	4-channel DBS lead, 25 cm, contact 1.5, space 0.5
4Ch DBS Lead, 30cm Contact 1.5 Space 0.5	4-channel DBS lead, 30 cm, contact 1.5, space 0.5
4Ch DBS Lead, 35cm Contact 1.5 Space 0.5	4-channel DBS lead, 35 cm, contact 1.5, space 0.5
4Ch DBS Lead, 40cm Contact 1.5 Space 0.5	4-channel DBS lead, 40 cm, contact 1.5, space 0.5
4CH Lead, 30 cm, 1.5	4-channel lead, 30 cm, 1.5

Table 11. Additional symbols for product labels

Symbol	Definition
4CH Lead, 40 cm, 1.5	4-channel lead, 40 cm, 1.5
4CH Lead, 30 cm, 0.5	4-channel lead, 30 cm, 0.5
4CH Lead, 40 cm, 0.5	4-channel lead, 40 cm, 0.5
4-Ch DBS Extension Kit, 50cm	4-channel DBS extension kit, 50 cm
4-Ch DBS Extension Kit, 60cm	4-channel DBS extension kit, 60 cm
4-Ch DBS Extension Kit, 90cm	4-channel DBS extension kit, 90 cm
4CH Extn, 50 cm	4-channel extension, 50 cm
4CH Extn, 60 cm	4-channel extension, 60 cm
4CH Flex Extn, 50 cm	4-channel flexible extension, 50 cm
4CH Flex Extn, 60 cm	4-channel flexible extension, 60 cm
4CH Flex Extn, 90 cm	4-channel flexible extension, 90 cm
8CH Directional Lead, 30 cm, 1.5	8-channel directional lead, 30 cm, 1.5

Table 11. Additional symbols for product labels

Symbol	Definition
8CH Directional Lead, 40 cm, 1.5	8-channel directional lead, 40 cm, 1.5
8CH Directional Lead, 30 cm, 0.5	8-channel directional lead, 30 cm, 0.5
8CH Directional Lead, 40 cm, 0.5	8-channel directional lead, 40 cm, 0.5
8CH Flex Extn, 50 cm	8-channel flexible extension, 50 cm
8CH Flex Extn, 60 cm	8-channel flexible extension, 60 cm
8CH Flex Extn, 90 cm	8-channel flexible extension, 90 cm

Appendix D: CE Mark Date

The following table lists the year in which the CE mark was awarded from the applicable notified body by model number.

Table 12. Year in which the CE mark was awarded

Model	Year	Notified Body
1101	1999	0123
1140, 1149, 1191, 6001, 6142, 6143, 6144, 6145, 6146, 6147, 6148, 6149, 6345, 6346	2008	0123
6315, 6316, 6319	2010	0123
6158, 6159, 6160, 6161, 6166, 6167, 6168, 6169, 6170, 6171, 6172, 6173, 6178, 6179, 6180, 6181, 6339, 6340, 6343, 6344, 6355, 6356, 6359, 6361, 6362, 6363, 6371, 6372, 6373, 6377, 6378, 6379	2015	0086

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Coordination Center BVBA
The Corporate Village
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Manufacturing Site:
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