Tunneling Tool Manual

For use with: # 5030

Rx ONLY

Symbols and Definitions

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

Symbol	Title	Description	Standard Reference
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	ISO 15223-1; ISO 7000-0434A
	Consult instructions for use or electronic instructions for use	Indicates the need for the user to consult the instructions for use	ISO 15223-1; ISO 7000-1641
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1; ISO 7000-3082
	Date of manufacture	Indicates the date when the medical device was manufactured	ISO 15223-1; ISO 7000-2497
	Do not reuse	Indicates a medical device that is intended for one single use only	ISO 15223-1; ISO 7000-1051
	Do not resterilize	Indicates a medical device that is not to be resterilized	ISO 15223-1; ISO 7000-2608
	Do not use if package is damaged	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information	ISO 15223-1; ISO 7000-2606
	Temperature limitation	Indicates the temperature limits to which the medical device can be safely exposed	ISO 15223-1; ISO 7000-0533
	Relative humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed	ISO 15223-1; ISO 7000-2620
	Medical device	Indicates the item is a medical device	ISO 15223-1
	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified	ISO 15223-1; ISO 7000-2493
	Lot	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1; ISO 7000-2492
	Model number	Indicates the model number or type number of a product	ISO 15223-1; IEC 60417-6050
	Unique device identifier	Indicates a carrier that contains unique device identifier information	ISO 15223-1
	Use by date	Indicates the date after which the medical device is not to be used	ISO 15223-1; ISO 7000-2497
	Sterilized using ethylene-oxide gas with a single sterile barrier system	Indicates a single sterile barrier system that has been sterilized using ethylene oxide	ISO 15223-1; ISO 7000-2501; ISO 7000-3707
	Sterilized using ethylene-oxide gas with a single sterile barrier system and protective packaging outside	Indicates a single sterile barrier system that has been sterilized using ethylene oxide with protective packaging outside	ISO 15223-1; ISO 7000-3709

	Packaging unit/ quantity	Indicates the number of pieces in the package	IEC 60417; ISO 7000-2794
	Peel/open here	Identifies the location where the package can be opened and to indicate the method of opening it.	IEC 60417; ISO 7000-3079
Rx ONLY	Federal (USA) law restricts this device to sale by or on the order of a physician	Indicates that Federal (USA) law restricts this device to sale by or on the order of a physician	CFR Title 21

Description and Intended Purpose/Indications for Use

The Model 5030 Inspire Tunneling Tool is intended to facilitate subcutaneous tunneling of the lead by the implanting clinician. It enables passage of Inspire leads with IS-1 connectors between the Inspire generator and the targeted nerve.

Clinical Benefit

The Tunneling Tool is used to facilitate the successful implant of the Inspire Upper Airway System.

Device Specifications

The tunneling tool includes the handle, the shaft, and the core which comes assembled (Figure 1).

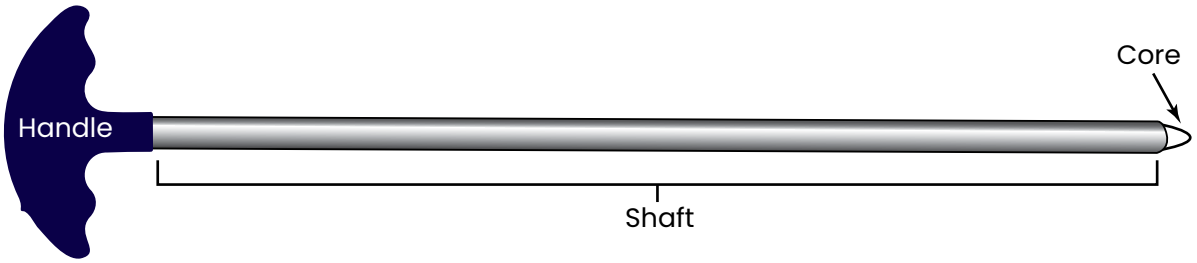

Figure 1. *Tunneling Tool*

Table 1. *Tissue Contacting Materials and Specifications (all measurements are approximate).*

Component	**Dimensions**	**Material**
Handle	Length: 8.2 cm Height: 4.8 cm Width: 1.3 cm	Polypropylene
Shaft	Length: 36.5 cm Diameter: 4.75 mm	Stainless steel (Contains nickel. Nickel is used in mixtures of metals, such as stainless steel, and is a known allergen)
Core Tip	Diameter: 4.95 mm (0.195 in)	Polypropylene
Core Middle	Diameter: 1.7 mm (0.067 in)	Polypropylene
Core Tab	Diameter: 4.95 mm (0.195 in)	Polypropylene

Contraindications

There are no known contraindications to the use of the tunneling tool.

For a list of contraindications for Inspire Therapy, see the Inspire Patient Manual or System Implant Manual based on the model chosen.

Warnings and Precautions

Single Use Only — This tool is for single use only. Do not reuse, reprocess, or resterilize this product. Reuse may compromise the structural integrity of the tool or create a risk of contamination of the tool that could result in patient injury or illness.

This tool has not been tested for use with non-Inspire products. The use of components not provided by Inspire Medical Systems may result in damaged components, improper operation, or increased risks to the patient.

Ensure that the product and its accessories are operated and used only by persons with the requisite training, knowledge, or experience. Inadequate training or failure to follow instructions may result in harm to the patients.

Component packaging — The contents of the package have been sterilized according to the process indicated on the package label. Inspect the sterile package before opening it.

- Prior to use, inspect the product for loose, bent, broken, cracked or fractured components. If the tool is damaged, do not use the product and contact an Inspire representative.
- If the package is damaged or opened, do not use the product and contact an Inspire representative.
- Do not store or transport the package or its contents at temperatures above 70 °C (158 °F) with 93% humidity, or below -35 °C (-31 °F) with 25% humidity. Exposure to conditions outside this range may damage the components.
- Do not use the product after its expiration date.

Potential Adverse Effects

The following are foreseeable potential adverse events associated with the use of the tunneling tool:

- Allergic reaction
- Bleeding
- Bruising
- Infection
- Pain
- Swelling
- Tissue Inflammation
- Hematoma

Failure to use as indicated could pose injury to the user such as lacerations or pinches.

The Inspire System Implant Manual provides a complete list of adverse events for Inspire Therapy.

Tunneling the Lead

Use the tunneling tool to pass the lead connector from the point of lead implantation to the subcutaneous pocket, avoiding sharp angle bends of the lead body.

1. Perform blunt dissection under direct visualization from one or both incisions along the desired tunneling path.
2. Open the sterile packaging and remove the tip protector. The shaft may be bent to aid tunneling. Generally, it is better to grasp the shaft with both hands and make multiple gentle bends rather than a single sharp bend. Subcutaneously advance the tunneling tool between the lead incision and the generator incision until the tip is exposed.

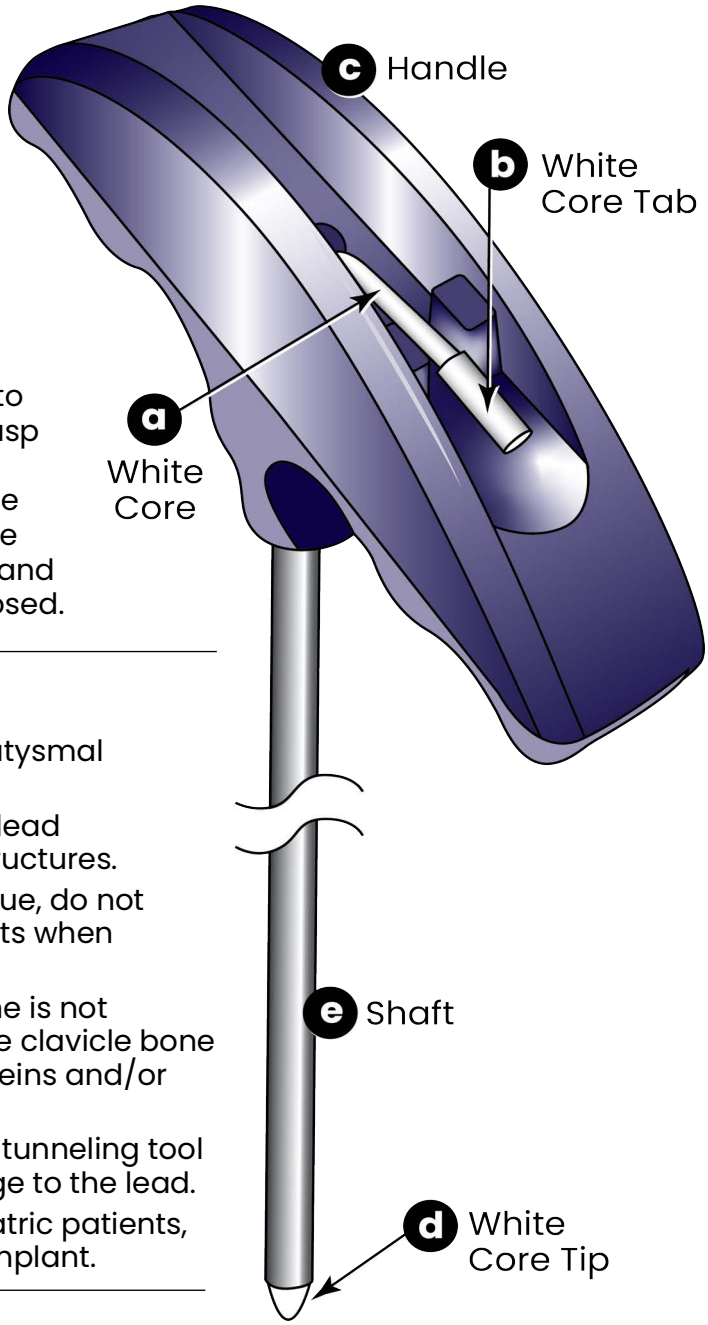

Figure 2. *Tunneling Tool Componentsf*

CAUTIONS:

- It is recommended to maintain a sub-platysmal plane while tunneling.
- Deep tunneling is not desirable. Pass the lead superficially to avoid damage to deep structures.
- To avoid damage to the lead or body tissue, do not use excessive force or surgical instruments when using the tunneling tool.
- Tunneling the lead under the clavicle bone is not recommended. A lead tunneled under the clavicle bone creates an increased risk of damage to veins and/or arteries.
- Use care when inserting the lead into the tunneling tool shaft. Rough handling may cause damage to the lead.
- To accommodate future growth for pediatric patients, breast tissue should be avoided during implant.

3. Unhook the white core Figure 2 (a) from the setting in the handle by grasping the white core tab Figure 2 (b) end and pulling up.
4. Hold the handle Figure 2 (c) and pull the white core tip Figure 2 (d) from the bottom of the shaft out of the tunneler near the generator incision site.
5. Set aside the core.

6. While holding the shaft Figure 2 (e) in place, pull the handle from the shaft and set aside.
7. Insert the stimulation lead Figure 3 (a) into the tunneling tool by grasping the strain relief segment of the stimulation lead and insert the tip into the tunneling tool, making sure that both sets of seal rings Figure 3 (b) are inside of the tunneler Figure 3 (c).

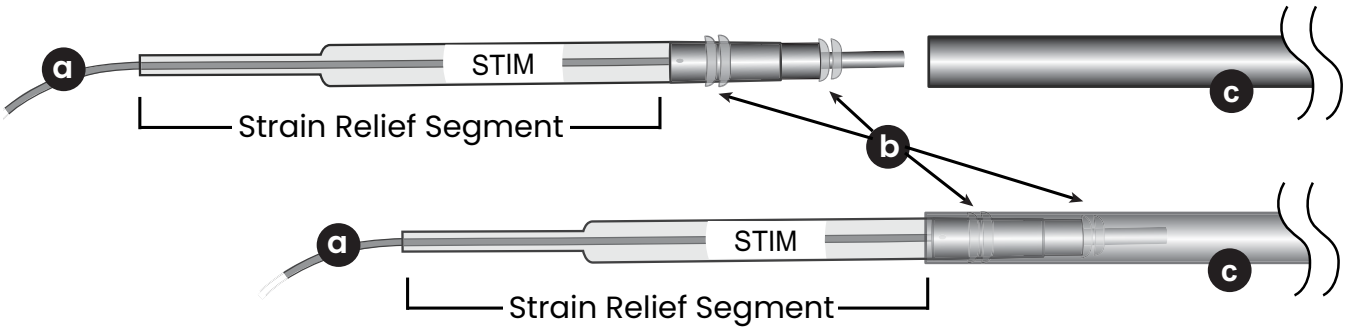

Figure 3. *Setting the Stimulation Need*

8. Gently pull the tunneling tool out through the exit site of the generator pocket, which will pull the lead through with it.
9. Grasp the strain relief segment to hold the lead in place and remove the tunneler.

CAUTION:
Leave a small amount of excess lead length at both ends of the subcutaneous tunnel so normal body motions do not stretch the lead body.

Disposal

Dispose of the single-use tool according to local environmental requirements.

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