



Synergy[®] Cranial Optical Pocket Guide



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Intended Use

Your Medtronic computer-assisted surgery system and its associated applications are intended as an aid for precisely locating anatomical structures in either open or percutaneous procedures. Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, can be identified relative to a CT- or MR-based model, fluoroscopic images, or digitized landmarks of the anatomy.

Contraindications

Medical conditions which contraindicate the use of a Medtronic computer-assisted surgery system and its associated applications include any medical conditions which may contraindicate the medical procedure itself.

Warnings



Marning: The system and its associated applications should be used only by qualified medical professionals who are trained on and familiar with the proper operation of Medtronic computerassisted surgery systems.



Marning: The system and its associated applications should be used only as an adjunct for surgical guidance. They do not replace the surgeon's knowledge, expertise, or judgement.



/ Warning: If system navigation seems inaccurate and steps to restore accuracy are unsuccessful, abort use of the system.



Warning: Discard before use any pre-sterilized component whose sterile packaging appears to be compromised.



Marning: Prior to use, examine all components for damage and deterioration. Do not use any compromised component. Abandon use of any component damaged during the procedure.



Warning: Do not re-process, re-sterilize, or re-use any singleuse device. Attempts to re-process or re-sterilize a single-use device may be ineffective and may compromise its structural integrity. Any re-use creates a risk of contamination which could result in patient injury, illness, or death.



Warning: Verify that all necessary instrumentation has been properly sterilized before surgery. Refer to the Equipment Cleaning and Sterilization sheet (9730713) for cleaning and sterilization instructions. For non-sterilizable components, refer to the Non-Sterilizable Equipment Cleaning sheet (9733205).

- Warning: Accessory equipment connected to the analog and digital interfaces of the Medtronic computer-assisted surgery system must be certified according to the respective IEC standards (e.g., IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the system standard IEC 60601-1-1. Any person who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible for ensuring that the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, contact technical support or your local representative.
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Warning: Some system components may contain batteries. Batteries can explode if mishandled. Do not recharge or disassemble batteries. Do not dispose of batteries in fire. Observe local regulations concerning battery disposal.



Warning: The system is not suitable for use in the presence of a flammable, anesthetic mixture with air or oxygen or nitrous oxide. Position the system at least 25cm from any source of flammable gas.



Warning: There is currently no effective sterilization method for components that are tainted with the infectious agent that causes Creutzfeld-Jakob Disease (CJD). Therefore, you must discard immediately after surgery any components that come into contact with biologic material from patients who carry or are suspected to carry this infectious agent. As a precaution, drape all non-disposable components that could otherwise come into contact with such material.



Warning: Clean the camera lenses before each use.

Precautions



Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.



Caution: The system and its associated applications contain no user-repairable parts. For repair or replacement of any part of the system, contact a technical support representative.



Caution: The system has been successfully tested against the requirements of IEC 60601-1-2. However, RF interference could hamper its operation or the operation of other nearby electrical devices. If you suspect either of these conditions, move the conflicting equipment farther apart, separate the equipment with an RF barrier, or discontinue use of the system.



Caution: Do not exceed the recommended electrical ratings for the system. Exceeding the ratings could damage the system.



Caution: Before moving the system cart, shut down all components, and remove any loose items from the top of the cart.

△ **Caution:** The system mouse is not designed for sterilization and may be damaged if sterilization is attempted.

Procedure

Logging In

- 1. At the login screen, click the **Cranial** icon and then click **[Launch]**.
- 2. The Select Surgeon screen appears.

Hedtronic



Selecting a Surgeon

1. Select Standard Profile or select a primary surgeon.

You may add or customize surgeon profiles by clicking **[Add or Remove Surgeon]**. Surgeon profiles allow you to save surgeon-specific preferences such as instruments, navigation options, and view settings.

2. Click 🕑 to advance to the next task.

	1	23	4	
	Select Surgeon Profile Select the surgeon's name from to Click the right arrow to advance	Select Sergeon the list below. to the next task.	Select Procedure	
Medtronic	Standard Proble			
SYNERGY™ EXPERIENCE STEALTHSTATION [®] System	Add or Remove Surgeon			
				? Poly Admin Est

1	The procedure flow bar indicates the current task as well as the previous and next tasks.
2	Previous task
3	Current task
4	Next task

Selecting a Procedure

1. Select the surgical procedure to be performed.

You may add or customize procedures by clicking [Add or Remove Procedure]. Customizing a procedure allows you to save preferences such as tracking method, registration method, and whether to include the **Plan** task.

2. Click 🕑 to advance to the next task.

Select Procedure Select the procedure from the list below. Click on the right arrow to advance to the	next task.	• Select Surgeon Select F	Bood n Selos Papent 🔶	Standard Prof PROCIDIE: Not Yes Selected MURE: Not Yet Selected
Tumor Resection (Tor/Milmage, Optic/Tocking	2	Turner Resection CF or Milinaging, AulWTacking		
Shunt Placement (T in MR Imaging Optical Franking	Z	Shunt Placement (T or Milmaging AniM Tacking		
Biopsy Cl or MI Imaging, Optical Facebing	Z			
Add or Remove Procedure				
				? <u>~</u>

Selecting a Patient

The software displays a list of exams that were previously imported. If your patient's exam is not in the list, use one of three standard methods to import a new exam: CD/DVD-ROM, USB, or DICOM. (Sony brand magneto-optical disc is also an option for importing exams on some systems.) If your patient's exam appears in the list, proceed to page 18.

Importing Exams

To import an exam, insert a CD-ROM or a USB drive or push an exam across the DICOM network.

- When you insert a CD-ROM or a USB drive, the system displays the list of exams available to import. Click the patient's name in the list and then click [Select].
- When you push an exam across the DICOM network, the exam automatically appears in the list of imported exams.



1	Patient names
2	Imported exams
3	Exams available to import

If you experience problems while importing an exam, refer to "Exam Import Problems" on page 105 for troubleshooting tips.

Selecting Exams

When your patient's name appears in the list of imported exams:

- 1. Click the patient's name. The software displays all of the exams associated with the patient, preview images from the most recent exam, and exam details for the surgeon's review. To browse additional slices, click _____ on the right side of the screen.
- If you plan to navigate on an exam other than the most recent one in the list, click that exam in the Exams list and preview the images.
- 3. Confirm that all aspects of the exam are correct including patient data. Make sure that the anatomy of interest is captured in the exam.



Marning: Verify that the exam orientation matches the patient's anatomy.

If you need to adjust level or width, or reorient the images, click [Modify Images].

- 4. If you plan to merge multiple exams from the same patient, click each exam in the Exams list to preview the images and check the orientation.
- 5. After confirming that everything is correct in the patient's exam(s), click 🕞 to advance to the next task.



1	Tools for modifying images
2	Patient data

For additional information about the buttons on this screen, see "Buttons" on page 112.

If you want to merge multiple exams from the same patient, see "Using StealthMerge[™] Image Registration" on page 76.

Setting Up Equipment

Confirm that the equipment and instruments used for the procedure are present in the OR. Connect the equipment to the Medtronic Navigation Computer-Assisted Surgery System. Connection status links display automatically. Solid green lines indicate verified connections and dashed orange lines indicate unverified connections.

If the camera connection does not verify, see "Camera Problems" on page 108.

When all connections are verified, click 🕑 to advance to the next task.



Verifying Instruments

The Verify Instruments screen displays the instruments selected for the procedure, indicates whether those instruments are within the camera's tracking view, and indicates whether they are verified.



Marning: Physically inspect instruments for any defects. Never attempt to use a bent or damaged instrument.



Caution: Always verify an instrument before use.

If you need to verify a SureTrak[®] II instrument, refer to "Performing SureTrak[®] II Calibration" on page 100.

You can verify instruments either now or later at the Register or Navigate task. To verify an instrument:

1. Snap sterile spheres onto the instrument and the patient reference.

Note: You do not need to attach the patient reference to the Vertek[®] Articulating Arm or to the patient at this point in the procedure.

- 2. Make sure that the screen shows the correct patient reference.
- Insert the tip of the instrument into the bottom of the divot in the 3. patient reference. Keep the instrument as perpendicular to the divot as possible.



- 4. Click **[Camera]** and confirm that both the instrument and the patient reference are visible in the **Tracking View**.
- 5. Hold the instrument steady for 2 seconds or press the footswitch.

When an instrument is verified, the system makes a positive sound (chime), the instrument's picture turns green, and **Verified** appears under the picture. When an instrument verification fails, the system makes a negative sound (bonk). Refer to "Instrument Problems" on page 109 for instrument verification troubleshooting tips.

- 6. Repeat this process for each instrument to be verified.
- Click to advance to the next task.



1	Patient reference
2	Instrument

Defining a Surgical Plan

The software automatically creates a three dimensional model from the patient's exam. Verify that the model accurately represents the patient. If you want to modify the 3D model see "Building or Editing a 3D Model" on page 78.

To define a surgical plan:

- 1. Click **[Browse]** and scroll through slices to find the slice that contains the surgical target.
- 2. Click a target point in one of the 2D images. Refine its location by clicking in any of the other images.
- 3. Click [Set Target].
- Click an entry point on one of the 2D images or on the surface of the 3D model. Refine its location by clicking in any of the other images.
- 5. Click [Set Entry].
- 6. Move the plan slider to simulate movement along the plan.

Click **[Go To Entry]** or **[Go To Target]** to move the crosshairs to either of the two stored points.

You can click the target and entry points in the 2D images and drag them to refine their positions.

If you move a point by mistake, click **[Undo]** to undo your last change.



1 Plan slider

To create another plan, click **[New]** in the task panel and then repeat the steps above.

To display multiple plans, click **[Show Multiple Plans]** and then click the check box beside each plan that you want to show.

Setting Up the Patient Reference

- 1. Secure the patient in the Mayfield® Skull Clamp.
- 2. Attach the Vertek[®] Articulating Arm to the Mayfield[®] Skull Clamp.

Note: If you plan to use the Vertek[®] Passive Biopsy Kit, connect the dual starburst to the Mayfield[®] Skull Clamp before attaching the articulating arm.

- 3. Attach the patient reference (961-337) to the articulating arm.
- 4. Move the patient reference as close as possible to the surgical field such that its location will not impede navigation.

Note: During patient registration the system displays a message if a touched landmark is more than 30 cm from the center of the reference frame.

- 5. Lock the patient reference in place.
 - Warning: The position of the anatomy is defined by the position of the patient reference. If the patient reference moves with respect to the anatomy after you register the patient, navigation will be inaccurate. Make sure that the Vertek[®] Articulating Arm is locked securely in position. If the arm slips after registration, re-secure it and register the patient again before navigating.



1	Patient reference
3	Vertek [®] Articulating Arm
3	Mayfield [®] Skull Clamp

Aiming the Camera

- 1. Clear the line-of-sight between the camera lenses and the sterile spheres on the patient reference.
- Position the camera head approximately 1.75m (6ft) from the patient reference. Aim the camera head at the patient reference.
- Press the laser trigger button on the camera handle and aim the camera head so that the laser beam passes through the center of the desired field of view.



- ∧ Warning: The laser positioning system transmits laser radiation. Use caution when operating the device, and never allow the laser beam to enter someone's eye. Laser radiation, even at low levels, can damage the eyes.
- 4. Click 👧 to display the **Tracking View**.
- 5. Fine-tune the left/right and up/down aim of the camera head so that the sterile spheres on the patient reference and navigated instruments will fall safely within the camera's view during navigation.
- Move the camera closer to or further from the patient reference until the distance indicator is near the middle of the bar. Reposition the patient reference, if necessary, to obtain optimal recognition.





Registering

To navigate you must match the patient's exam to the patient's anatomy by using either Tracer[™] registration, Touch-n-Go registration, or PointMerge® registration. If you plan to use Touch-n-Go registration, refer to page 84. For PointMerge registration, refer to page 88.



Marning: Do not bump or reposition the patient reference after registration because such movement will result in inaccurate navigation. If the patient reference moves in relation to the patient anatomy at any time after registration, you must reregister.

Performing Tracer[™] Registration

If you merged exams, you can change the exam used for registration by clicking the Exam drop-down list.

If you need to change the location of the first landmark, click a new location on the 3D model.

- 1. Touch the registration pointer to landmark 1 on the patient (the tip of the nose or the most anterior point included in the exam) and hold the pointer steady until you hear a verification sound (or press the footswitch).
- Touch landmark 2 on the patient (the center of the forehead) and hold the pointer steady until you hear a verification sound.
- 3. Touch landmark 3 on the patient (three centimeters to the patient's left of landmark 2) and hold the pointer steady until you hear a verification sound.



Exam drop-down list

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4. Place the tip of the instrument on the patient's nose and press and hold the footswitch. Move the tip of the registration pointer lightly around the firm and bony areas of the patient's nose, brow, mastoids, and scalp. Include as many uniquely-shaped areas as possible, but only trace anatomy that is included in the patient exam. Continue until the progress bar indicates 100%.

Gently maintain contact with skin at all times while tracing. If you need to lift the registration pointer to move around an obstruction, release the footswitch before you lift the pointer. Then reposition the pointer before you press the footswitch.

When **Tracing Progress** reaches 100%, the software matches the points to the 3D model.

If Tracer[™] registration is successful, the software autoadvances to the accuracy verification screen.

Note: If registration fails, a message displays and the software returns to the first step in Tracer[™] registration.

You can cancel Tracer[™] registration at any time by clicking **[Restart Tracer Registration]**. The software returns to the first step in Tracer registration.



Verifying Tracer[™] Registration Accuracy

Check the accuracy of the registration process before continuing. The points shown on the screen are color coded by status. Green points are included in the registration and red points are excluded.

- 1. Use the registration probe to touch an identifiable point on the patient's anatomy.
- 2. Compare the location of this point to the centers of the crosshairs in the images.
- 3. Repeat the process for at least two more points.
- If you are satisfied with the registration accuracy, click to advance to the Navigate task.


If the accuracy is not acceptable, repeat Tracer[™] registration by clicking [**Restart Tracer**]. To switch to Touch-n-Go or PointMerge[®] registration, click [**Register with Touch-n-Go**] or [**Register with PointMerge**]. See "Performing Touch-n-Go Registration" on page 84 or "Performing PointMerge[®] Registration" on page 88.

Setting Up for Sterile Navigation

1. Remove the non-sterile patient reference and drape the patient.

Note the orientation of the Medtronic logo on the surface of the reference. When you re-attach the reference after sterilization, make sure the logo resides in the same orientation.

2. Match the mounting screw and the alignment post on the underside of the sterile patient reference with the corresponding screw hole and alignment notch on the swivel mount of the Vertek[®] Articulating Arm. Puncture the plastic drape with the mounting screw and secure the reference to the swivel mount by tightening the mounting screw.



1	Alignment post
2	Alignment notch

Navigating

During navigation, the software updates the 2D images in real time to reflect changes in the position of the surgical instrument's tip on the anatomy. When navigation is active, the crosshairs display green. When navigation halts, the crosshairs display red.



Marning: Frequently confirm navigation accuracy and system responsiveness during live navigation. Use the probe to touch several bony anatomical landmarks and confirm that the locations identified on the images match the locations touched on the patient. If accuracy degrades, re-register the patient.

If you have not already verified the instrument that you plan to use for navigation, do so now by holding its tip in the divot. Refer to page 100 for instructions on calibrating a SureTrak[®] II instrument.

The following are optional features in the **Navigate** task:

- If you want to create accuracy checkpoints, see page 98. If you neglect to establish accuracy checkpoints and the patient reference moves in relation to the patient anatomy at any time after surgery begins, you will have to re-register the patient or abandon use of the system.
- To display microscope output in the image area, click an image selection button and select Video.
- If you want to use tip projection, see page 103. ٠



Using Look Ahead View

The look ahead view gives you a preview of the anatomy you will encounter as you advance the pointer along the current trajectory. To display the look ahead view:

- 1. Click the image selection button in the upper left corner of a view to display the list of available views.
- 2. Select Look Ahead from the list.

The look ahead view displays four probe's eye views, which mimic what you would see if you sighted along the shaft of the instrument. The upper left view shows the plane that is located at the instrument tip, perpendicular to the instrument. The other three views are 5mm, 10mm, and 15mm beyond the instrument tip.



Shunt Placement: Guiding the Catheter



Marning: The point identified by the crosshairs in the 2D views represents the tip of the instrument.

Note: Using the guidance view is the preferred method for aligning the instrument along the desired trajectory. However, the guidance view is functional only if you have created a surgical plan. (See "Defining a Surgical Plan" on page 26.)

- 1. Replace one of the 2D views with the guidance view. To do this, click the image selection button and select Guidance from the list.
- 2. Replace the other 2D views with Trajectory 1, Trajectory 2, and Probes Eye.
- Insert the sterile stylet through the sterile catheter.
- 4. Place the tip of the stylet at the entry point you stored earlier.
- The guidance view shows the target as a small orange circle. The large green circle represents the aiming area around the probe tip. Use the guidance view to align the center of the aiming circle with the target.
- 6. As you advance the instrument along the surgical plan, keep the dot centered inside the small circle.



1	Image selection button
8	Guidance view
3	Target
4	Aiming circle around probe tip
5	Trajectory views

Biopsy

Attaching and Aiming the Guidance System

The two guidance systems that may be used for a passive biopsy procedure are the Trajectory Guide Kit and the Vertek[®] Passive Biopsy Kit. If you plan to use the Vertek[®] Passive Biopsy Kit, proceed to page 53.

Option 1: Attaching the Trajectory Guide Kit

- 1. Mark the entry point on the scalp where you will affix the base.
- 2. Select the appropriate type of base.

Consider both the location of the entry point and the required angle of the needle when deciding whether to use the standard base or the angled base. With a 14mm burr hole, the needle's range of motion in the standard base is about 10° from vertical in any direction. The needle's range of motion in the angled base is 5° to 25° (depending on direction).

- 3. Create a scalp incision large enough to accept the base you selected.
- 4. Strip the periosteum away from the surface of the skull.
- 5. Create a burr hole of adequate diameter.

Note: For an internal base, the burr hole must be 14mm in diameter to accommodate the portion of the base that projects below the base plate.



1	External base
8	Internal base
3	Angled external base
4	Tactile markers

 Anchor the selected base to the skull using the three titanium screws (1.6mm x 8mm) included with the standard base. Be careful to tighten each screw a little at the time, so all three screws are evenly tight.



Caution: When the base is on a curved area, over tightening the screws may cause the base to crack.

Note: Orient the angled base so that the tactile markers are parallel to the intended path of the biopsy needle.

- 7. Snap the spherical end of the guide stem into the base.
- 8. Thread the locking ring onto the base, and tighten the locking ring so that the guide stem remains in place when released.



1	Guide stem
2	Locking ring
3	Base

Aiming the Trajectory Guide

Note: Using the guidance view is the preferred method for aligning the instrument along the desired trajectory. However, the guidance view is functional only if you have defined a surgical plan. (See "Defining a Surgical Plan" on page 26.)

- 1. If you have not verified the Navigus[®] Probe, hold the tip of the probe in the bottom of the patient reference divot until you hear a verification sound.
- 2. Click [Control Panel] and then click [Biopsy] to display the biopsy buttons.

3. Hold the Navigus[®] Probe in the guide stem, loosen the locking ring, and use the trajectory views and guidance view to aim the guide assembly along the planned surgical trajectory.



Caution: Failure to loosen the locking ring before attempting to align the guide stem will place stress on the assembly.



The guidance view shows the target as small orange crosshairs. The large green circle represents the aiming area around the probe tip. Use the guidance view to align the center of the aiming circle with the target.



1	Guidance view
8	Target
3	Aiming circle around probe tip
4	Trajectory views

- 4. Tighten the locking ring to secure the assembly so the guide stem cannot move during the procedure.
- 5. With the Navigus[®] Probe in the guide stem, press the footswitch or click [Lock Trajectory] to lock the trajectory.
- 6. Remove the Navigus[®] Probe and insert the adapter into the quide stem.



Marning: Always use the 2.2mm adapter with the passive biopsy needle.



(1)	Traiectory locked
	Trajectory locked

Proceed to "Performing the Guided Biopsy" on page 60.

Option 2: Attaching the Vertek® Passive Biopsy Kit

- 1. Mark the entry point on the scalp where you will create a burr hole.
- 2. Connect the Vertek[®] Articulating Arm to the dual starburst. Puncture the surgical drape with the base attachment screw of the articulating arm to complete the attachment.
- 3. Attach the precision aiming device to the instrument swivel mount on the articulating arm.
- 4. While supporting all arm segments, loosen the locking knob on the articulating arm and position the arm such that the precision aiming device sits above the entry point for the biopsy. Tighten the locking knob securely.



1	Vertek [®] Articulating Arm
2	Precision aiming device
3	Dual starburst attachment

- 5. With the precision aiming device still attached, remove the articulating arm from the dual starburst and set it aside in the sterile field.
- 6. Create a scalp incision and strip the periosteum away from the surface of the skull.
- 7. Create a burr hole of adequate diameter.

8. Re-attach the articulating arm with the precision aiming device to the dual starburst and secure it in place with the base attachment screw.



1	Base attachment screw
3	Locking knob
3	Reducing tube

Aiming the Precision Aiming Device

- 1. If you have not verified the Vertek[®] Probe, hold the tip of the probe in the bottom of the patient reference divot until you hear a verification sound.
- 2. Hold the Vertek[®] Probe in the precision aiming device, loosen the two adjustment screws, and use the trajectory views and guidance view to aim the guide assembly along the planned surgical trajectory. Tighten the adjustment screws to secure the assembly so the precision aiming device cannot move during the procedure.



The guidance view shows the target as small orange crosshairs. The large green circle represents the aiming area around the probe tip. Use the guidance view to align the center of the aiming circle with the target.



1	Guidance view
8	Target
3	Aiming circle around probe tip
4	Trajectory views

- 3. With the Vertek[®] Probe in the precision aiming device, press the footswitch or click [Lock Trajectory] to lock the trajectory.
- 4. Remove the Vertek[®] Probe and insert the reducing tube into the precision aiming device.



Marning: Always use the 2.2mm reducing tube with the passive biopsy needle.



1 Trajectory locked

Performing the Guided Biopsy

Note: Instructions for the Vertek[®] Passive Biopsy Kit are in parentheses.

 While the trajectory is locked, the system reports the Tip Stop Point necessary to deliver the needle's tip to the target point. To deliver the center of the cutting window to the target point, add 7 mm to the Tip Stop Point because the needle's cutting window begins 3 mm from the tip and is 8 mm long. Use the stop adjustment tool to set the depth stop on the needle.

Warning:The system automatically calculates the Tip Stop Point. It is the sum of two quantities:

- The length of the adapter [50mm] (or the reducing tube [70mm])
- The length of the surgical plan

When the adapter is fully seated in the guide stem, the tip of the adapter is at the center of the guide stem's spherical end. When you locked the trajectory, the system redefined the entry point of the surgical plan at the center of the guide stem's spherical end. Therefore, if you are using the trajectory guide kit, the system adds the length of the adapter [50 mm] to the length of the surgical plan to obtain the Tip Stop Point. (Similarly, if you are using the Vertek[®] Passive Biopsy Kit, the system adds the length of the reducing tube [70mm] to the length of the surgical plan to obtain the Tip Stop Point.)



1 Tip Stop Point



1	Stop adjustment tool: Use this to position either the needle tip or cutting window at the Tip Stop Point.
2	Needle tip at 140mm
3	Center of cutting window at 140mm, tip at 147mm

Warning: When the notches at the top of the biopsy needle and inner cannula are aligned, the cutting window is open. Rotating the inner cannula 180° from the open position closes the cutting window. Visually confirm that the cutting window is closed before advancing or retracting the needle through the needle adapter. Moving the needle while the cutting window is open could cause unnecessary patient trauma.



1 Notches are aligned, so cutting window is open

Note: The system tracks the location of the needle tip. A graphical representation of the needle cutting window displays on the guidance view to assist in visualization of the cutting window position.

- Carefully advance the biopsy needle through the adapter (or reducing tube) until the depth stop contacts the top of the adapter (or reducing tube). The system reports the distance to target as the needle advances.
- Acquire the biopsy sample by opening the cutting window, drawing suction, and closing the cutting window. Make sure the biopsy window is closed and then carefully retract the inner cannula of the biopsy needle to retrieve the sample.

Note: Suction may be drawn using the aspirator tube and a syringe, or by attaching a syringe directly to the inner cannula hub.

4. If another sample is needed, slide the inner cannula of the biopsy needle into the outer needle sheath. Repeat the previous step.

Note: Do not remove the guide assembly from the patient until a satisfactory sample is acquired.



\bigcirc	Needle moving toward target
2	Cutting window
3	Target
4	Distance to target

Archiving (Optional)

- 1. Click [Admin] and then click the Patients tab.
- 2. Insert a blank CD or a USB drive.
- 3. Click the patient's name and click [Archive Selected Patients].
- 4. Select the kind of archive, select the archive media, and click **[OK]**.

Deleting Patients

To delete an unused patient, follow the steps below.

To delete the current patient, return to the **Select Patient** task and then follow these steps.

- 1. Click [Admin] and then click the Patients tab.
- 2. Select a patient.
 - To delete specific exams, click the exams and click [Delete Selected Exams].
 - To delete all of the patient's exams click [Delete Selected Patients].



Exiting

- 1. Click the exit button at the bottom of the task panel.
- 2. Click [Exit] to confirm that you want to exit.



Appendixes

A: Standard Equipment

Unless special cleaning or sterilization instructions are noted, follow the standard cleaning and sterilization protocols in the *Equipment Cleaning and Sterilization* sheet (9730713).

Equipment for Tumor Resection, Shunt Placement, and Biopsy



Sterile Spheres (9730950, 5 pack 9730951)

This item is pre-sterilized and single-use. For more information, refer to the Package Insert which accompanied this item (9730951-99).

Cranial Reference (961-337)

The Cranial Reference permits dynamic referencing of the patient's head during surgery.

Passive Planar Registration Probe (960-556)

Use the Passive Planar Registration Probe to identify the location of points on the patient.

Touch-n-Go Pointer (9731965)

Use the Touch-n-Go Pointer to identify the locations of the fiducial markers on the patient during Touch-n-Go registration.



Vertek[®] II Articulating Arm (9734252)

The Vertek[®] II Articulating Arm attaches to the Short Bedrail Adapter and supports the Cranial Reference or the precision aiming device. Adjust the position of the articulating arm at the pivot points. All pivot points lock in place with rotation of the locking knob.

For more information, refer to the instructions which accompanied this item (9733940).

For Tumor Resection Only



Scope Probe (9730269)

The Scope Probe has a compact bayonet pointer for use when space is limited (for example, when a microscope is used in the surgical field).

For Shunt Placement Only



Passive Catheter Introducer (PCI)

The PCI is used in the placement of ventricular catheters and shunts. The PCI is composed of two parts:

- PCI Handle (9730092)
- PCI Tip (9731116)

The PCI Tip is pre-sterilized and single-use. For more information, refer to the Package Insert which accompanied this item (9730842).

For Biopsy Only Biopsy Needle Kit (9733068)

This kit is pre-sterilized and single-use. For more information, refer to the Package Insert which accompanied this item (9733068-01).



Passive Biopsy Needle

The Passive Biopsy Needle is a side-cutting needle for acquiring cranial tissue biopsies. The Passive Biopsy Needle includes dash marks at 10mm intervals. The first dash mark begins 10mm from the center of the cutting window.

Biopsy Needle Stop

The Biopsy Needle Stop is used to limit the depth of advancement.




The Stop Adjustment Tool includes a metric ruler to aid in setting the Biopsy Needle Stop at the correct position.

Aspirator Tube

The Aspirator Tube may be used in conjunction with a syringe to produce suction.

Guidance Systems

You can use either the Trajectory Guide Equipment or the Vertek[®] Passive Biopsy Kit with the Biopsy Needle Kit.

Trajectory Guide Equipment



Navigus[®] Probe (9733157)

The Navigus[®] Probe is used to aim the guide assembly along the planned surgical trajectory.

Trajectory Guide Kit (External 9733065, Internal 9733066)

This kit is pre-sterilized and single-use. For more information, refer to the Package Insert which accompanied this item (9733065-01).



Bases

Both Internal and External bases may be used for biopsy procedures.







Guide Stem

The Guide Stem snaps into the base and is aimed along the planned surgical trajectory.

Adapters

The Internal and External Trajectory Guide Kits contain three adapters with internal diameters of 1.9mm, 2.2mm, and 2.6mm. An adapter is placed in the guide stem to precisely guide the biopsy needle along the central axis of the guide stem.

Locking Ring

The Locking Ring secures the guide stem in position and prevents it from moving during the procedure.

Screwdriver

The Screwdriver is used to insert the three titanium screws in the base.

Vertek[®] Passive Biopsy Kit (9733936)



Vertek[®] Probe (9733158)

The Vertek[®] Probe is used to aim the guide assembly along the planned surgical trajectory.









Dual Starburst (960-535)

The Dual Starburst provides attachment points for two Vertek[®] Articulating Arms.

Precision Aiming Device (960-539)

The precision aiming device secures the reducing tube in place for biopsy needle guidance. Two independent pivot points enable precise alignment of the needle with the planned surgical path.

Vertek[®] II Articulating Arm (9734252) The Vertek[®] II Articulating Arm attaches to the Short Bedrail Adapter and supports the precision aiming device. Adjust the position of the articulating arm at the pivot points. All pivot points lock in place with rotation of the locking knob.

For more information, refer to the instructions which accompanied this item (9733940).

Reducing Tubes (3) (9733213 1.9 mm; 9733214 2.2 mm; 9733215 2.6 mm)

Place a reducing tube in the precision aiming device to precisely guide the biopsy needle along the central axis of the precision aiming device.

B: Using StealthMerge[™] Image Registration

To merge multiple exams from the same patient:

- 1. While you are in the **Select Patient**, **Plan**, or **Navigate** task, click **[StealthMerge]**.
- 2. On the left, click all of the exams that you want to merge.
- 3. On the right, click a reference exam.
- 4. Click [Start Merge].
- 5. When each merge completes, **[Verify Merge]** is highlighted. To examine merge accuracy, click **Blend** or **Split-window** and then use the slide controls under the images.
 - a. If you determine that the accuracy of the merge is sufficient for the procedure, click [Verify Merge].
 - b. If the merge is not aligned correctly, click and drag the merge exam into approximate alignment with the reference exam and click **[Start AutoMerge]**.
 - c. If the exam does not contain anatomical images (such as a PET or fMRI), click the **Pre-Merged Exams** tab and select the appropriate anatomical reference exam.

After you click **[Verify Merge]**, the next merged exam displays for your verification.

6. When you have verified all merges, click [Done].

When you merge exams, the merged set is always used in the **Plan**, **Register**, and **Navigate** tasks. See "StealthMergeTM Tips" on page 111 if you want to change the merged display in these tasks.



C: Building or Editing a 3D Model

To prevent an unintended registration change or deletion, the **Registration** model can only be viewed in the **Register** task. The model that appears by default in the **Plan** and **Navigate** tasks is based on the exam you selected in **Select Patient**, but it is not the **Registration** model. If you want to view a different model in the **Plan** or **Navigate** tasks, you must build a new model.

To build a new 3D model or edit an existing model:

- 1. Click [Build 3D Model].
- Click the Select Model drop-down list to select an existing model, or click [New].

If you clicked **[New]**, select a model type, select the exam, name the model, check **Use for Registration** if you are building a skin model that you plan to use for registration, and click **[OK]**.

3. Reposition the dashed clipping lines in each 2D view so that they closely surround the anatomy that you are modeling.



1	Clipping lines
2	Select model drop-down list

4. Adjust the threshold to highlight only the anatomy that you want to model.

The model updates automatically.

- To return the threshold settings to their default values, click [Reset Model].
- To retain only a portion of the model, click the object you want to retain and then click **[Retain Selection]**.
- To delete a portion of the model, click the object you want to delete and then click [Delete Selection].
- 5. Build all of the skin, bone, and tumor models that you want to view in the **Plan** and **Navigate** tasks, and then click **[Done]**.

To display your new models in the Plan and Navigate tasks:

- a. Click [Edit 3D].
- b. Click the exam that has a layer number in the upper-right corner, and click **[Remove]** to remove the default model from the **Composite View**.
- c. Click the View Models tab, click the model that you want to display in Plan and Navigate, click [Add] to add it to the Composite View, and click [Done].

See "Adjusting 2D Images or 3D Models" on page 82 for additional information about the **Composite View**.



D: Adjusting 2D Images or 3D Models

If you only need to adjust the level and width of images, click **[Adjust]**. To make more advanced adjustments, such as rendering style and colormap of 2D images or 3D models, click **[Edit 2D]** or **[Edit 3D]**.

1. In the **View Exams** tab or the **View Models** tab, click an exam or a model.

If no models display in the **View Models** tab, click **[Cancel]** and then click **[Build 3D Model]** to build a model.

- 2. Adjust the exam modality, rendering style, colormap, level, or width. The changes appear in the **Selected View** window.
- 3. Click [Add] to add the Selected View to the Composite View.

The **Composite View** is a preview of all the adjustments that you have added.

When you add a model to the **Composite View**, a layer number appears in the upper-right corner of the model. The layer number indicates placement in the **Composite View** (for example, layer 2 appears on top of layer 1).

- 4. Adjust the blend level of the exam or model.
- 5. Click [Done].

The composite image displays in the **Plan** and **Navigate** tasks.



1 Layer numbers

E: Performing Touch-n-Go Registration

- 1. Click [Touch-n-Go].
- Confirm that Touch-n-Go Pointer is the instrument name displayed in the lower right corner of the image area. If necessary, verify the Touch-n-Go pointer.
- 3. If you merged exams, you can change the exam used for registration by clicking the exam button.
- 4. Hold the tip of the Touch-n-Go Pointer in the center of one of the fiducials for two seconds or until the **Touched** counter increments by one. The order in which you record the fiducials is not important. Repeat this process for the remaining fiducial points, or until you are satisfied with the predicted maximum error displayed.

To proceed to navigation you must have touched at least four fiducial points and the predicted maximum error must be less than 5.0 mm.

You may re-record any fiducial point in the same way you first recorded it. When you re-record a fiducial point, the **Touched** counter does not increment.

5. When finished, click 🕑 to advance to the **Navigate** task to verify registration accuracy.



1 Touched fiducial counter

Verifying Touch-n-Go Registration Accuracy

- 1. In the **Navigate** task, use the registration probe to touch an identifiable point on the patient's anatomy.
- 2. Compare the location of this point to the centers of the crosshairs in the images.
- 3. Repeat the process for at least two more points.
- 4. If you are satisfied with the registration accuracy, proceed with navigation (page 40).

If the accuracy is not acceptable, click the left arrow and then click **[Restart Touch-n-Go]**, **[Register with Tracer]**, or **[Register with PointMerge]** to repeat the registration process.



① Make sure that the point you touch on the patient matches the point displayed in all views.

F: Performing PointMerge® Registration

Storing Landmarks

Select and store up to eight landmarks on the images.

- 1. Click [Register with PointMerge].
- 2. If you merged exams, you can change the exam used for registration by clicking the exam button.
- 3. Click an identifiable anatomical landmark or a fiducial on the skin model, refine the position of the selected point in the 2D images, and then click **[Store]** beside **1**.
- 4. Click another identifiable point on the skin model and then click **[Store]** beside **2**.
- Continue clicking the landmarks and [Store] buttons until you have selected seven or eight well-distributed landmarks. A minimum of four landmarks is required.



Touching Landmarks

Touch the landmarks on the patient.

- 1. Place the tip of the registration probe on the patient at the first landmark. Hold the probe steady until you hear the confirmation sound. The circle around number **1** turns green.
- 2. The system automatically advances to the next landmark on the list, and the skin model auto-rotates to display the next landmark.
- 3. Repeat this process for the remaining landmarks.

Note: If a landmark changes to red, it is inaccurate and excluded from the registration. If a landmark changes to yellow, it is marginally accurate, and you may want to refine it. After you have touched the first four landmarks, you can refine a previously touched landmark by holding the probe tip on it for two seconds. Note that the least accurate landmark used in the registration will always be marked **Marginal**. This is normal.



1 Touched landmarks

The system displays a numerical predicted error value. If the predicted error value exceeds 5.0 mm, the system will not allow you to proceed to the **Navigate** task. In that case, re-register the patient.

Note: Clicking **[Clear All]** one time clears all of the touched points and selects the first landmark in the list. Clicking **[Clear All]** two times clears all of the stored landmarks.



1	Predicted error value
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Sphere of Accuracy

As soon as you match the fourth landmark, the software displays a sphere of predicted accuracy on the 3D model as well as green and yellow circles on the three orthogonal views. The green circles are cross sections of the sphere of accuracy. As you match more landmarks, the system may refine the sphere of accuracy. Within the green circles, localization error is estimated to be 1 mm or less. Within the yellow circles, localization error is estimated to be 2 mm or less. Make sure that the surgical area of interest lies inside the circles.



Cross-sections of the sphere of predicted navigation accuracy: Within the green circles, localization error is estimated to be 1 mm or less.

Verifying PointMerge[®] Registration Accuracy

Click 🕐 to advance to the **Navigate** task to verify registration accuracy.

- 1. In the **Navigate** task, use the registration probe to touch an identifiable point on the patient's anatomy.
- 2. Compare the location of this point to the centers of the crosshairs in the images.
- 3. Repeat the process for at least two more points.
- 4. If you are satisfied with the registration accuracy, proceed with navigation (page 40).



① Make sure that the point you touch on the patient matches the point displayed in all views.

G: Creating Accuracy Checkpoints (Optional)



Warning: If you neglect to establish accuracy checkpoints and the patient reference moves in relation to the patient anatomy at any time after surgery begins, you will have to re-register the patient or abandon use of the system.

- 1. Create four fixed, identifiable points on the anatomy in the sterile field.
- 2. Click [Control Panel] and then click [Create Checkpoints].
- Place the sterile registration instrument on the first point and hold it steady for 2 seconds or press the footswitch. Listen for the confirmation sound.
- Store three more accuracy checkpoints in the same manner. When you have touched four checkpoints, the [Realign Registration] button becomes active.
- 5. At any time during the procedure, return the registration instrument to any of the accuracy checkpoints and observe the reported **Distance to Checkpoint** displayed in the lower-left corner of the screen. A distance in excess of 2mm indicates a potential shift in the position of the anatomy in relation to the patient reference. In these situations, carefully re-evaluate navigational accuracy by touching several anatomical points. If inaccuracy persists, click **[Realign Registration]** and then reregister the patient using the accuracy checkpoints as landmarks.



H: Performing SureTrak[®] II Calibration



N Warning: If you attach a SureTrak[®] II array to an instrument with interchangeable tips, you must recalibrate the instrument if you change the tip.



∧ Warning: Do not use the same geometry SureTrak[®] II array on two different instruments.



∧ Warning: Do not use a SureTrak[®] II array on flexible instruments

To calibrate an instrument with a SureTrak[®] II array:

 Confirm that the SureTrak[®] II assembly is rigidly secured to the instrument and lies within the maximum recommended distance from the tip.



Marning: Any movement of the assembly relative to the instrument after the instrument is calibrated will result in an inaccurate display of the instrument location.

- Choose a calibrating probe (for example, the Passive Planar Registration Probe). If necessary, verify the probe.
- 3. To specify the divot, place the tip of the calibrating probe in the bottom of the reference frame divot and press the footswitch.
- 4. Hold the tip of the SureTrak[®] II instrument in the bottom of the reference frame divot and press the footswitch. Try to hold the SureTrak[®] II instrument perpendicular to the divot.



- Place the tip of the SureTrak[®] II instrument on the surface of the reference frame, next to the divot. Hold the assembly at the same angle used in the previous step and press the footswitch to record the position.
- Hold the tip of the calibrating probe to the hind of the SureTrak[®] II instrument and press the footswitch.

Note: You can restart the calibration at any time by clicking **[Restart Calibration]**.

When a SureTrak[®] II instrument is fully calibrated, you can recalibrate it by clicking **[Camera]** and then **[SureTrak]** in the tracking view. Recalibration is required when you change the tip on a instrument with interchangeable tips.



I: Using Tip Projection

The tip projection feature allows you to localize at a point along the current instrument trajectory but beyond the instrument tip, as if the selected instrument were longer than it is.

To enable the projection feature:

- 1. Click [Select Projection] in the task panel.
- 2. Click [Show Projection] and then use the plus and minus buttons to adjust the length of the projection.
- 3. Select either Navigate Instrument Tip or Navigate Projection.

A vellow extension from the end of the instrument model visually indicates the projection. When Navigate Projection is enabled, the crosshairs are located at the end of the projection and displayed distances (like distance to target) are measured from the end of the projection. This holds true even when a microscope interface is the selected instrument.



Marning: Remember that the end of the projection is not the same as the tip of the instrument. The projection indicates the location to which you could travel by advancing along the current trajectory. Turn off the projection when you want to localize at the tip of the probe or focal point of the microscope.

To turn off tip projection, click [Select Projection] and then click [Hide Projection].



J: Troubleshooting

Exam Import Problems

Find the symptom in the table below and follow the troubleshooting steps:

Symptom	Troubleshooting Steps
You imported an exam across the DICOM network and slices are	Remove the exam: Click [Admin] and then click the Patients tab. Select the exam you want to remove and click [Delete Selected Exam(s)] .
missing.	Ask radiology to push the exam again. A status indicator appears in the upper left corner of the screen to show the number of exams and slices received.
You need to move an	Click [Admin] and then click the Patients tab.
exam from one patient name to another.	Select the patient, select the exam to move, and click [Move Selected Exams] .
	Click the drop-down menu under Select Patient Name . Select the patient's name, or select New Patient and enter a new name and medical record number.
	Click [OK] and then click [Done].
You need to change the exam modality.	Click [Exam Details] , click the MODALITY drop-down list, and select the correct modality.

Symptom	Troubleshooting Steps
Error: Exam name does not contain valid data for navigation. Check scanner settings and/or re-import the exam.	If you receive the same message when you re- import the exam, call for technical support.
Error:	Re-scan the patient without using gantry tilt.
<i>Exam name</i> contains gantry tilt and cannot be used for navigation.	If you have questions about re-scanning the patient, call for technical support.
Error:	Ask radiology to reformat the scan to comply
Exam name does not contain the minimum number of images needed for navigation.	with the Imaging Protocol (9732379).
Error:	Ask radiology to reformat the scan to comply
Exam name does not contain contiguous slices and cannot be used for navigation.	with the Imaging Protocol (9732379).
Warning:	If the orientation is incorrect, click [Modify
Exam name is a non- axial scan. Please verify that the orientation is labeled correctly.	Images], click [Reorient], and correct the orientation.
Warning message that includes "This may affect navigation accuracy."	Ask radiology to reformat the scan to comply with the Imaging Protocol (9732379).

Symptom	Troubleshooting Steps
You are importing exams	Click [Search for More].
from a CD or USB drive	
that contains archived	
Synergy [®] Cranial exams	
and the patient's name is	
not in the list.	

Define Surgical Plan Tips

Find the goal in the table below and follow the steps:

Goal	Steps
To drag a target or entry point in the 2D images	Click the plan name or click the plan in the 2D images to select it and then move the target or entry point.
To delete a plan	Click on the plan name in the task panel and click [Delete].
To change the exam modality	Click [Exam Details] , click the MODALITY drop-down list, and select the correct modality.
To display dots instead of crosshairs in 2D views	Click [Admin] and click the Options tab. In the Crosshair Visibility section, click Off . Click [Done] . Alternatively, press the <f4> key to toggle between crosshairs and dots.</f4>

3D Model Tips

Find the goal in the table below and follow the steps:

Goal	Steps
To delete a 3D model	Select the model and click [Delete] . You cannot delete the registration (Reg) model.
To set a different skin model as the registration model	Click the Select Model drop-down list, select a model, click [Use for Registration] , and click [OK] .

Camera Problems

Find the symptom in the table below and follow the troubleshooting steps:

Symptom	Troubleshooting Steps
The camera connection will not verify in the Set Up Equipment	Turn off power to the system. Check cables for crimps or damage. Check connector housing and pins for bent or broken components. Replace damaged cables.
task.	Make sure that the cable between the camera and the StealthStation [®] system is securely connected on both ends.
Instrument Problems

Find the symptom in the table below and follow the troubleshooting steps:

Symptom	Troubleshooting Steps
Instrument verification failed	 Make sure that the tip of the instrument is in the bottom of the verification divot. Keep the instrument perpendicular to the divot.
	• Check the distance to divot displayed on the screen. If the distance exceeds 2.0 mm, try another instrument. The distance does not display for SureTrak [®] II instruments.
	 Check the instrument geometry by clicking [Camera] and then [Camera Details]. If the geometry error exceeds 0.5 mm, try another instrument.

Symptom	Troubleshooting Steps
Instrument verification failed or your instrument has red status	 Rotate each sterile sphere on its mounting post, making sure the sphere is securely seated on the post.
	Check for damage to the reflecting surface of the sterile spheres. If a sphere is damaged, replace it.
	 Wipe away any dirt or fluid on the sterile spheres.
	 Make sure that the camera is aligned with the instrument and move the camera closer to the instrument.
	• Clear the line of sight between the camera and the instrument.
	 Clean the camera lenses with a camera cloth.
	• Cover surfaces that may reflect light into the camera. Temporarily turn off or redirect the OR lights.
	• Remove wrinkles in the drape covering the spheres on the patient reference.

StealthMerge[™] Tips

When you merge exams, the merged set is always used in the **Plan**, **Register**, and **Navigate** tasks.

Goal	Steps
To view only one of the merged exams	Click [Edit 2D] , click an exam that you do not want to view, and click [Remove] . Repeat this process until the Composite View contains only the exam you want to view.
To navigate on an exam that is not part of the merged set	In the Navigate task, click [StealthMerge] and add the exam to the merged set.
	If you do not want to add the exam to the merged set, move that exam under a different patient name. Then select that patient in the Select Patient task.
To unmerge exams	Delete the exams and re-import them.

K: Buttons

All Tasks

The following buttons display in all software tasks.



The left arrow returns to the previous task.



[Camera] opens the Tracking View window. (This button is disabled in the Select Surgeon and Select Patient tasks.)



The right arrow advances to the next task.



[Help] displays relevant help information.



[Admin] opens an Admin window in which you can choose system options.



[Exit] exits the software.



[Camera Details] displays connection status for the navigation system, patient reference, and instruments. Click [Camera] to display the [Camera Details] button.

Select Patient, Plan, or Navigate

The following buttons display in the **Select Patient**, **Plan**, or **Navigate** tasks.



[Modify Images] opens a new group of buttons which allow you to modify level, width, magnification, and image orientation as well as recenter and move images.



[Adjust] adjusts brightness and contrast. Click [Adjust], click in an image and drag the mouse up, down, left, or right. Up and down increase and decrease brightness. Right and left increase and decrease contrast.



[Zoom] magnifies an image. Click [Zoom], click on an image, and drag the mouse up to increase the image size. Drag down to decrease the image size.



[Move] changes the cursor to a hand. Click the hand on an image and drag to move images.



[Recenter] returns the crosshairs to the centers of the images.



[Edit 2D] allows you to adjust the level, width, rendering style, and colormap of exams and to blend merged exams for display in **Plan** and **Navigate**.



[Reorient] corrects the orientation of images from the scanner.



[Browse] scrolls through image slices. Click this button, click on an image, and drag the mouse up or down.



[Cycle Views] cycles through the presets in View Settings.

Û	

[Edit 3D] allows you to adjust the level, width, rendering style, and colormap of 3D models and to blend multiple models for display in Plan and Navigate.



[Snapshot] captures a snapshot of the screen and stores it with the exam.



[Select Projection] allows you to extend the instrument's tip on the 2D and 3D images.



[Rotate] allows you to rotate the 3D model. Click on the 3D model and drag in the direction that you want it to rotate.



[Measure] displays the distance in millimeters between any two selected points on an image.



The image selection button allows you to select the content in each view. Click this button and choose from the drop-down list (Axial, Coronal, Sagittal, 3D, Video, or Off).



[StealthMerge] allows you to merge multiple exams from the same patient. (This button is enabled when you purchase a StealthMerge™ license.) Manage Patient Data

[Manage Patient Data] allows you to move, archive, and delete exams.



[View Settings] allows you to configure your image display area.

The layout buttons change the screen layout to display 1, 2, 3, or 4 views.

The preset buttons allow you to save view settings in the surgeon profile. When you have selected a layout for the image display area and selected content for each view, click **[Set]** on one of the preset buttons.

Setup Equipment

The following button displays in the Setup Equipment task.

Move Equipment

[Move Equipment] allows you to change equipment placement on the screen. Click [Move Equipment]. When the Move Equipment window opens, click the piece of equipment that you want to move. Placement options (blue squares) appear. Click the appropriate placement and click [Done].

L: Symbols

The following symbols may appear on system equipment, system packaging, or in this document.





Quantity

STERILE EO Sterilized using ethylene oxide.



Non-sterile



Protective Earth (Ground)

Do not allow contact with patient. Temperature may exceed limits.

Notes