Agilis HisPro™

Steerable Catheter With Electrodes
Model DS3H010-38

Instructions for Use

Abbott

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

⚠ WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

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Pat. http://www.abbott.com/patents

EN: English

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Description

The Agilis HisPro™ Steerable Catheter With Electrodes is a deflectable, slittable catheter with two distal tip electrodes. It serves as a delivery conduit for devices such as cardiac leads. The distal portion can be formed into a "U" shape, when fully deflected, to facilitate positioning of the tip at a desired location in the heart. The tip electrodes provide the ability to sense intracardiac electrograms (EGM) and pace when connected to the WorkMate Claris™ Recording System or the Merlin™ Pacing System Analyzer (PSA). The 10.5Fr catheter has a 7Fr inner diameter to allow delivery of a 6Fr cardiovascular transvenous device, including a 6Fr pacing lead. The catheter shaft is slittable allowing for removal following lead placement.

Note: Safety and effectiveness of the Agilis HisPro catheter to deliver leads to the His Bundle has not been evaluated by the FDA.

Table 1. Agilis HisPro™ model

Model	Effective Length	Outer Diameter	Inner Diameter
DS3H010-38	38cm	10.5Fr	7Fr

The catheter is compatible with the following Abbott Medical recording and pacing systems:

Table 2. Device Compatibility

System Device	Connect via
WorkMate Claris™ Recording System	Supreme Electrophysiology Cable (401980, 401981, 401982, or 401983)
Merlin™ Pacing System Analyzer (PSA)	Supreme Electrophysiology Cable (401980, 401981, 401982, or 401983), Adapter Pins

Refer to the Merlin™ PSA Help Manual for a complete list of cables required to connect the PSA to the Adapter Pins.

Indications for Use

The Agilis HisPro™ Slittable Catheter With Electrodes is indicated to provide a pathway for delivery and support of transvenous devices within the chambers and vasculature of the heart and can be used for electrogram recording and stimulation.

Contraindications

Crossing a mechanical tricuspid valve with this device is contraindicated.

Package Contents

The following accessories are included with the Agilis HisPro™ Steerable Catheter With Electrodes.

Table 3. Package Contents

Accessory	Intended Use
.035-inch guidewire	Enables intravascular introduction of the dilator and Agilis HisPro Steerable Catheter With Electrodes.
Dilator	Dilates the vasculature and facilitates access to vasculature.
Adaptor pins (2)	Connects to the Merlin™ PSA via electrophysiology cable.
Valve bypass tool (2)	Aids entry of devices through the hemostasis valve.
Slitter tool	Slits the catheter for removal after delivery of the pacing lead.
Stopcock	Facilitates aspiration and flushing.

Note: Slitter tool model DS3A001 may be ordered separately. For more information, contact your local Abbott Medical representative.

Note: The guidewire material is PTFE coated type 304 stainless steel.

Complications

As with any catherization procedure, potential complications include thromboembolism, local and systemic infection, bleeding or hematoma at the puncture site, vascular dissection or perforation, cardiac perforation, and cardiac tamponade.

Warnings

- This device is intended for one time use only. Do not reprocess or reuse. Thorough cleaning of biological and foreign material is not possible. Reuse can cause device failure, patient injury, and/or the communication of infectious disease(s) from one patient to another.
- This device should be used by or under the supervision of physicians thoroughly trained in the techniques of pacing lead implantation.
- Thrombus Generation: Thrombogenicity testing was performed using a four-hour heparinized ovine model. If the patient cannot be anticoagulated during the procedure, thrombus formation may occur during use of the product.
- Cardiac catheterization procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as increased risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Careful consideration must be given for the use of this catheter in pregnant women.
- Careful catheter manipulation must be performed in order to avoid device component damage, thromboembolism, cerebrovascular accident, cardiac damage, perforation, pericardial effusion, or tamponade. If resistance is encountered, DO NOT FORCE THE CATHETER. Withdraw the catheter, correct the difficulty, and reinsert.
- Risks associated with electrical stimulation may include, but are not limited to, the induction of arrhythmias, such as atrial fibrillation (AF), ventricular tachycardia (VT) requiring cardioversion, and ventricular fibrillation (VF).
- FROM THE STOPCOCK ONLY, ASPIRATE ALL AIR PRIOR TO FLUID INFUSION.

Precautions

- For specific details in the use of electrophysiology devices and the techniques employed in an electrophysiology study, refer to the medical literature and rely on training and practical experience.
- This device should only be used with equipment that complies with international electrical safety standards.
- Do not use if the catheter appears damaged, kinked, or if there is difficulty in deflecting the distal section to achieve the desired curve. Do not use if the catheter does not hold its curve and/or if the irrigation port or hemostasis valve is blocked.
- Do not alter this device.
- Bending, stretching, and/or kinking of the catheter may result in damage. Handle with care.
- Do not immerse the handle or cable connector in fluids; electrical performance could be affected.
- Do not expose to organic solvents.
- Precautions to prevent clotting should be taken whenever entering the vascular system. The patient's clotting system should be evaluated prior to catheterization. Use anticoagulant as training and experience may dictate.
- Flush the lumen of the catheter and dilator with saline prior to use.
- Aspirate slowly only from the stopcock.
- Inject or saline flush only from the stopcock.
- Not intended for use with high-pressure injection equipment.
- This catheter should only be maneuvered under fluoroscopic guidance. The long-term risk of protracted fluoroscopy (i.e., fluoroscopic radiation) has not been established. Careful consideration must be given for the use of the device.
- Care must be taken to avoid damage to the wall of the vessels through which these catheters pass.
- THE CATHETER IS OPTIMIZED FOR THE DELIVERY OF 6FR PACING LEADS (58CM+). DO NOT USE LEADS SHORTER THAN 58CM.
- To prevent entanglement with existing or abandoned leads, use care when using the catheter in proximity of the other leads.
- Exercise caution when using movable core guidewires. Avoid twisting or excessive force on guidewires, which may cause core wire to penetrate the coil spring of the guidewire and damage the catheter or vessel.
- Do not attempt to advance or withdraw the guidewire if unusual resistance is felt. Use fluoroscopy to determine cause.
- Do not inadvertently allow the guidewire to advance completely into the patient or device.
- The sealing force of the hemostasis valve may alter or impair the function of some guidewires.
- Damage to the hemostasis valve may occur if the guidewire or other inserted device is withdrawn rapidly.
- Use care to isolate any unused connector pins of the electrogram cable. This will reduce the chances of developing accidental current pathways to the heart.
- Make sure deflection knob is in the neutral position when advancing, retracting, or while slitting the catheter.
- THE CATHETER IS ONLY INTENDED TO BE SLIT USING THE SLITTER TOOL INCLUDED IN THIS PACKAGE. NO OTHER COMMERCIALLY AVAILABLE SLITTER SHOULD BE USED.

Sterilization

- The package contents have been sterilized with ethylene oxide before shipment. The package contents are for single use only and are not intended to be resterilized.
- If the sterile package has been compromised, do not use. Contact Abbott Medical.

Storage and Handling

Handle with care. Items should be stored at temperatures between -20ºC (-4ºF) and 50ºC (122ºF). Store in a well-ventilated area under conditions that protect items from extreme humidity. In addition, cartons containing these items should be protected from water and should not be crushed. Do not remove from outer box.

Packaging and Shelf-Life

The catheter packaging is designed to prevent crushing of the product, to minimize product exposure to the atmosphere, and to provide for aseptic product transfer. It is recommended that the product remain in the unopened package until time of use. Contents are sterile if the package is unopened and undamaged. Do not resterilize. The expiration date is marked on the outside of the package. Dispose of used product and packaging following standard solid biohazard waste procedures.

Instructions for Use

Preparing the Catheter

1. Review the label carefully for product identification. Do not use if the device is expired.

   Note: International formatting has been used for the expiration date (YEAR-MONTH-DAY)

2. Inspect the package prior to use. Do not use if the package is opened or damaged.
3. Remove the components of the sterile package within the sterile field.
4. Inspect the catheter and both distal tip electrodes for integrity and overall condition. Do not use if the catheter is damaged.
5. Verify that the catheter deflects properly by rotating the deflection knob clockwise (see figure below). Do not use if the catheter is damaged.
6. Turn the deflection knob counterclockwise to the neutral position.

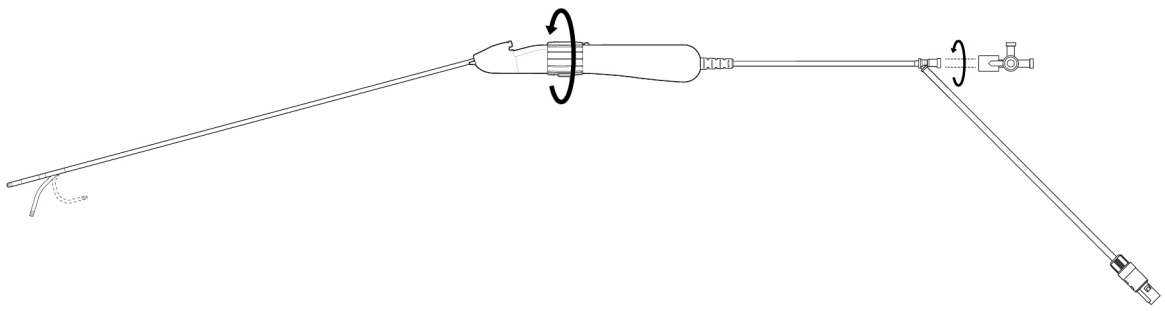
   Note: After the catheter has been deflected, the catheter shaft may not return to a fully straight position.

7. Connect the three-way stopcock to the luer fitting prior to flushing the catheter (Figure 1). Luer fitting is specifically for fluid, do not use luer port for guide wire delivery.

   CAUTION: Catheter should be flushed with the stopcock attached.

8. Flush the catheter with normal saline or heparinized saline via the stopcock. Close the stopcock.
9. Flush the dilator with normal saline or heparinized saline.
10. Insert the dilator into the hemostasis valve and advance the dilator until it extends beyond the distal tip of the catheter shaft.

Figure 1. Deflecting and Flushing the Catheter



Note: Connect the three-way stopcock to the luer fitting prior to flushing the catheter.

Positioning the Distal Tip

1. After gaining vascular access, load the dilator into the catheter using the hemostasis seal and advance the catheter and dilator over the guidewire to track the position of the guidewire, catheter, and dilator.

   CAUTION: Deflecting the catheter while the dilator is inserted may cause catheter damage.

   CAUTION: The dilator is designed to be loaded into the Agilis HisPro and advanced over the guidewire.

2. After reaching the right atrium, retract the dilator and guidewire from the catheter.

   CAUTION: Excessive manipulation of the catheter while retracting the dilator may lead to catheter damage.

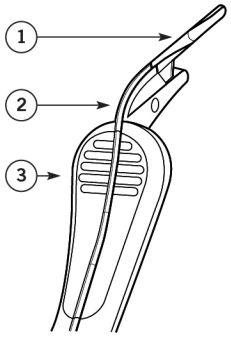
3. Aspirate for the presence of air and flush the catheter through the stopcock. Close the stopcock.
4. Use the valve bypass tool to open the hemostasis valve and advance the lead and stylet to the distal tip of the catheter. Use fluoroscopy to confirm the position of the lead within the catheter.
5. Aspirate for the presence of air and flush the catheter through the stopcock. Close the stopcock.

Finding the Target Location

1. Connect the WorkMate Claris™ Recording System or the Merlin™ PSA to the catheter via the Supreme Electrophysiology Cable and adapter pins.
2. Use the deflection knob to deflect the distal tip of the catheter to the target location.
3. Adjust the position of the catheter until the target location is captured via the distal tip electrodes and confirm with pacing and EGM signals.

Anchoring the Lead

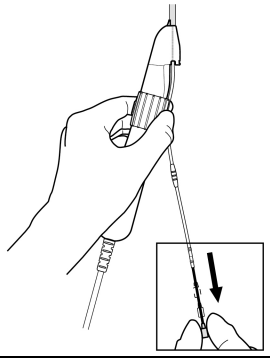
1. After finding the target location, advance and anchor the lead helix into the target location.
2. Attach electrical connectors to the lead.
3. Confirm placement of the lead via EGM and pacing analysis. Use fluoroscopy to visually confirm location of the lead.
4. If repositioning is necessary, retract the lead helix and repeat earlier steps, as applicable, to reposition.
5. Once the lead is anchored and placement is confirmed, detach the electrical connections from the lead and catheter.

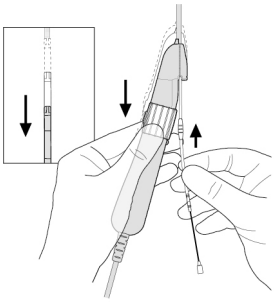


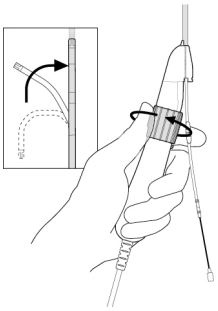
1. Lead Stabilization Channel (metal): protects the lead and engages the shaft of the delivery sheath
2. Lead Retention Channel (plastic): passively maintains the lead position
3. Thumbpad: Actively maintains the lead position

Removing the Catheter

Table 4. Slitting the Catheter

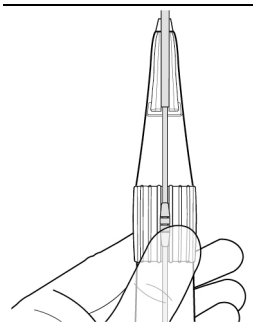
	1. Flush the catheter through the stopcock.
	2. Partially retract the stylet to prevent lead dislodgement.
	3. Move the suture sleeve away from the valve.



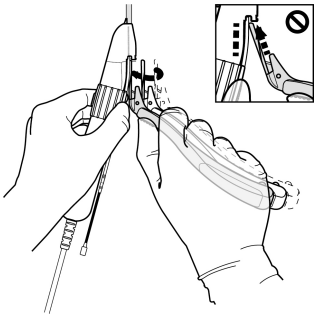


4. To prevent lead dislodgement, hold forward force on the lead to maintain its position while slowly retracting the catheter as you return the deflection knob to the neutral position.

   Note: Return to neutral position by rotating the deflection knob counterclockwise completely.

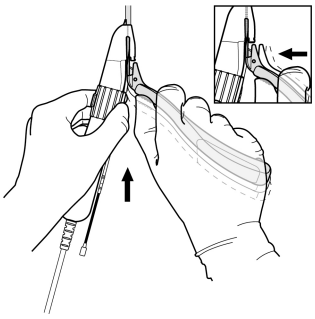


5. Position the lead within the channel on the deflection knob. Secure the lead with thumb to maintain lead position within the catheter while the Slitter tool is applied.



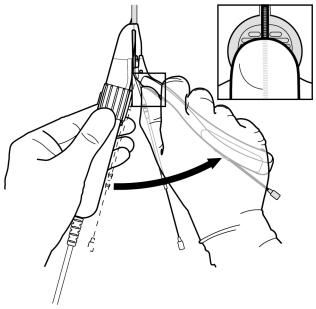
6. Align the Slitter tool metal lead stabilization channel with the lead; cup and secure the lead in the metal channel.

   CAUTION: Inaccurate alignment or exertion of too much force during engagement may damage lead or Slitter tool.



7. With thumb against the deflection knob, slowly advance the Slitter tool toward the hemostasis valve. After entering the valve, gently press the plastic lead retention channel against the catheter to seat the lead in the channel.

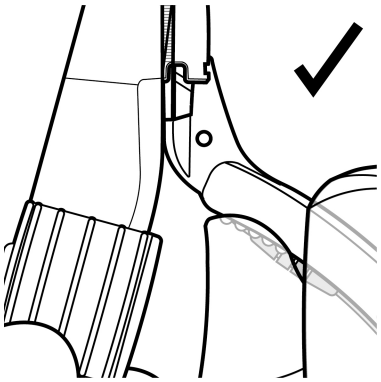
   CAUTION: Inaccurate alignment or exertion of too much force during engagement may damage lead or Slitter tool.



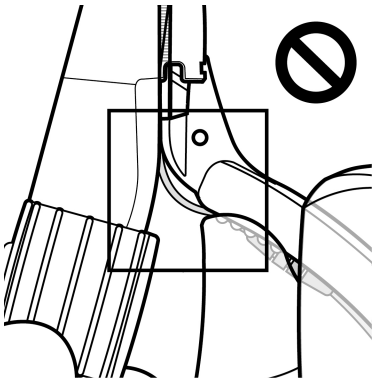
8. Guide the rest of the lead into the Slitter tool thumbpad groove and secure it with thumb.

   CAUTION: Lead must be fully seated within the Slitter tool plastic lead retention channel and thumbpad groove.

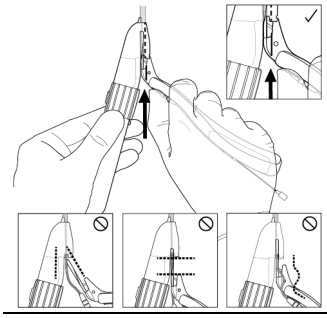
   CAUTION: Thumb position should not extend above thumbpad.



- The lead fully seated in the plastic lead retention channel

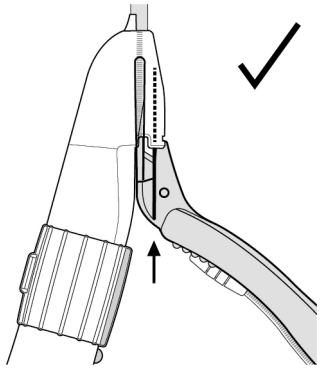


- Lead not seated fully in the plastic lead retention channel

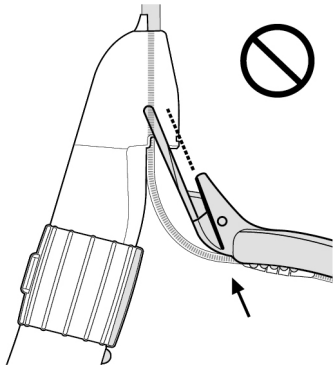


9. Ensure the Slitter tool reference line is parallel with the catheter shaft (see figure below).

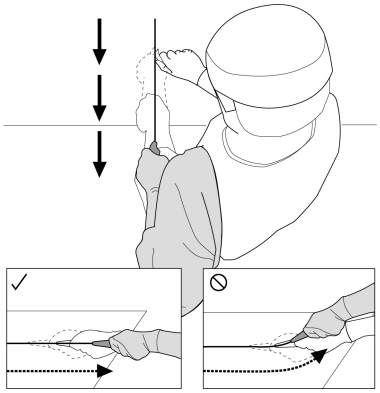
Figure 2. Slitter Tool-Catheter Shaft Alignment



- For a successful slit, the metal channel on the Slitter tool must be parallel to the catheter shaft.



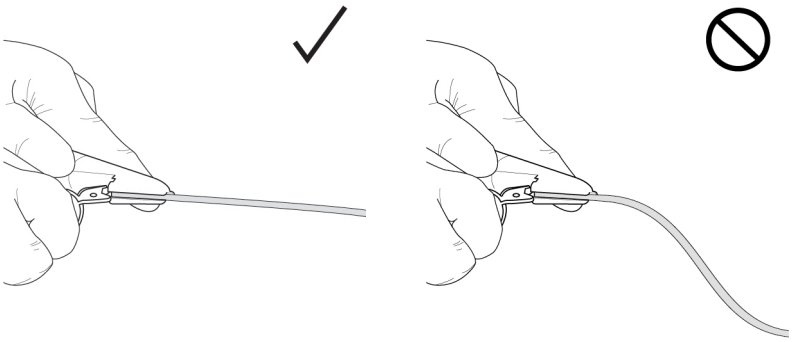
- Aligning the blade of the Slitter tool perpendicular to the catheter shaft will result in a difficult slit.



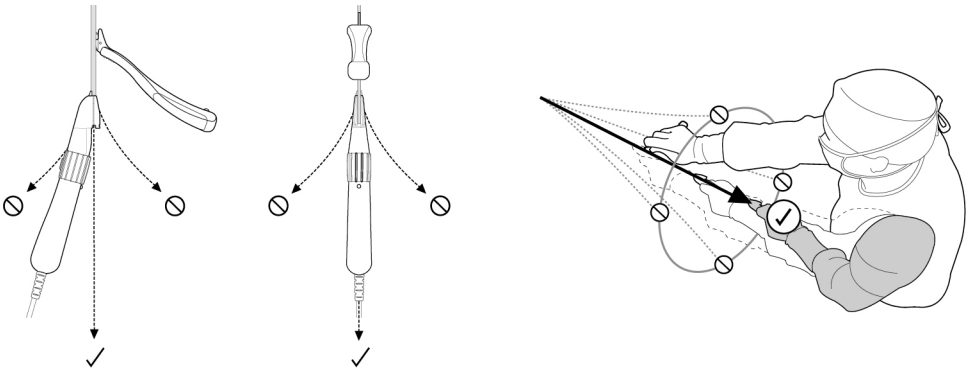
10. Prepare to slit the catheter.
    a. Ensure the exposed portion of Catheter shaft is straight, without significant curvature.
    b. Ensure both arms are extended.
    c. Rotate body position away from the table to allow room to pull hand straight back.
    d. Hold the Slitter tool in a stable fixed position.

CAUTION: Do not *advance* or *rotate* Slitter tool.

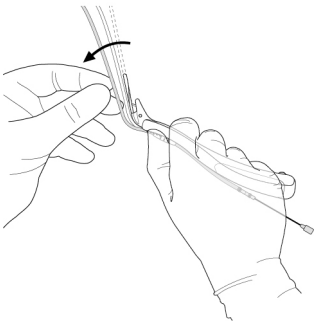
Slit the catheter: steadily pull the catheter through the Slitter tool in one continuous motion, straight back, avoiding rotation.



- For a successful slit, the proximal portion of the Catheter shaft should have minimal curvature.



- The Catheter should be slit by pulling straight back, avoiding rotation.



11. Carefully remove the lead from the Slitter tool.

12. Confirm placement of the lead via EGM and pacing analysis. Use fluoroscopy to visually confirm location of the lead.

13. Inspecting the integrity of the catheter: After slitting, ensure catheter components are still connected to the catheter.
    Inspecting the integrity of the lead: After catheter removal, inspect the lead for any visible scratches and gouges on the lead body where it may have had contact with the Slitter tool.

Technical Support

Abbott Medical maintains 24-hour phone lines for technical questions and support:

- 1 818 362 6822
- 1 800 722 3774 (toll-free within North America)
- + 46 8 474 4147 (Sweden)
- + 61 2 9936 1200 (Australia)
- medical.abbott/manuals

For additional assistance, call your local Abbott Medical representative.

Symbols

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at https://medical.abbott/manuals.

Symbol	Description
	Outer dimension
	Inner dimension
CE 0123	Affixed in accordance with European Council Directive 90/385/EEC. Hereby, St. Jude Medical declares that this device is in compliance with the essential requirements and other relevant provisions of these Directives.
	Length
	Open pouch from corner.
	Date of manufacture
	Use-by date
	Single sterile barrier system
	Contents
	Steerable catheter
	Accessories
UDI	Unique Device Identifier
	Follow instructions for use on this website
	Affixed to this device in accordance with European Council Directives 2012/19/EU and 2006/66/EC. These directives call for separate collection and disposal of electrical and electronic equipment and batteries. Sorting such waste and removing it from other forms of waste lessens the contribution of potentially toxic substances into municipal disposal systems and into the larger ecosystem.
℞ ONLY	Prescription only

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