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AtriCure GPT Series Glidepath Tape



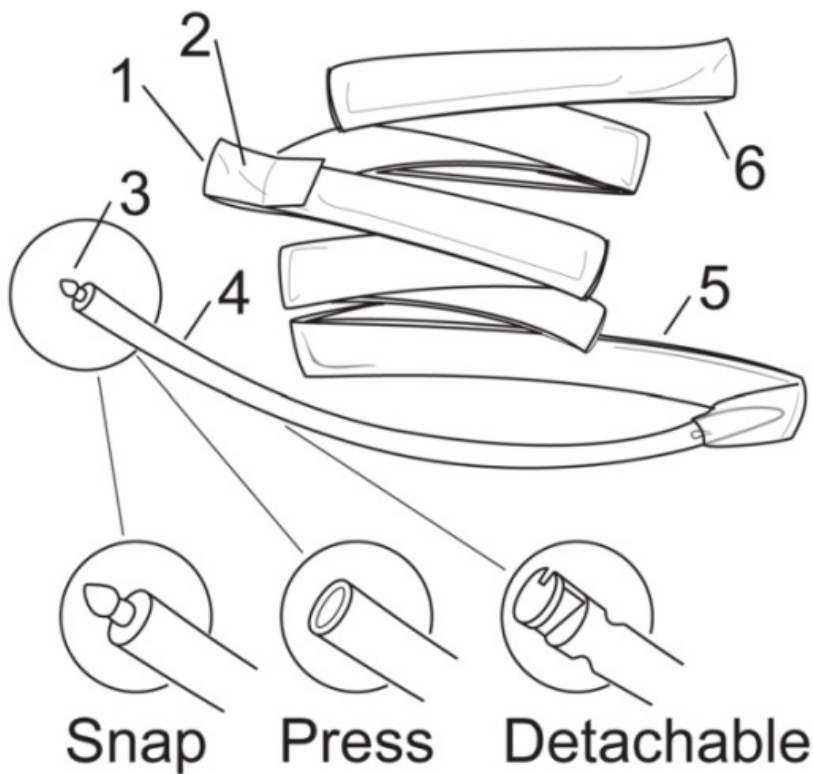
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PRODUCT OVERVIEW

NOMENCLATURE (SEE FIGURE 1)

1. Lateral Tab
2. Distal Pocket
3. Instrument Attachment Tip
4. Red Elastic Leader
5. Primary Transfer Tape (Clear)
6. Accessory Ribbon



DESCRIPTION

The AtriCure Glidepath™ Tape (Guide) is a single patient, surgical device designed to facilitate the guidance of surgical instruments through soft tissue during general surgical procedures.

There are three families of Guides for use with ATRICURE ISOLATOR Devices.

- The Snap Guide (See Figure 1) is designed to fit devices that have the integral permanent attachment tip.
- The Press Guide (See Figure 1) is designed to fit instruments without integral attachment tips.
- The Detachable Guide (See Figure 1) is designed to fit devices that have the integral detachable attachment tip.

INDICATION FOR USE

The AtriCure Glidepath™ Tape is a sterile, disposable device for use in general surgical procedures.

CONTRAINDICATIONS

- None Known

WARNINGS

To avoid the risk of patient infection, inspect the product packaging prior to opening to ensure that the sterility barrier is not breached. If the sterility barrier is breached, do not use the Guide.

PRECAUTIONS

1. Carefully read all instructions for the AtriCure Glidepath™ Tape (Guide) prior to using the device. Failure to properly follow instructions may lead to injury and/or may result in improper functioning of the device.
2. Do not re-sterilize or reuse the Instrument. Resterilization may cause loss of function or injury to the patient. Single Patient use only.
3. Ensure Guide is removed from the surgical field prior to the completion of the surgical procedure.
4. If the Guide incorporates the press fit connection feature, ensure that the Guide is removed from the clamp and sterile field prior to ablation.

INSTRUCTIONS FOR USE

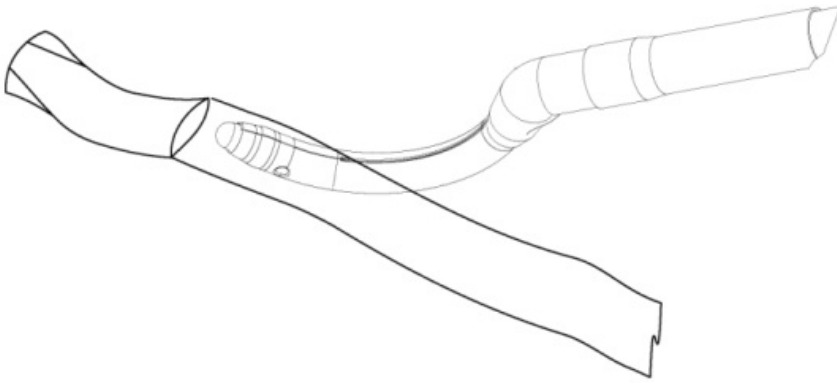
SET UP

1. Examine the packaging of the devices to ensure the sterility of the product has not been breached. Remove the sterilized instruments from their package per standard sterile technique.

POSITIONING OF GLIDEPATH TAPE GUIDE

2. The Guide may be used with commercially available general dissection or surgical clamping tools (auxiliary tools) to create and maintain a dissection plane that facilitates placement of the ISOLATOR clamp around structures per standard surgical technique.
3. Secure the proximal end of the Guide to the sterile drape near the surgical site.
4. Insert the distal end of the auxiliary tool completely into the distal pocket of the clear ribbon portion of the Guide.

(See Figure 2)

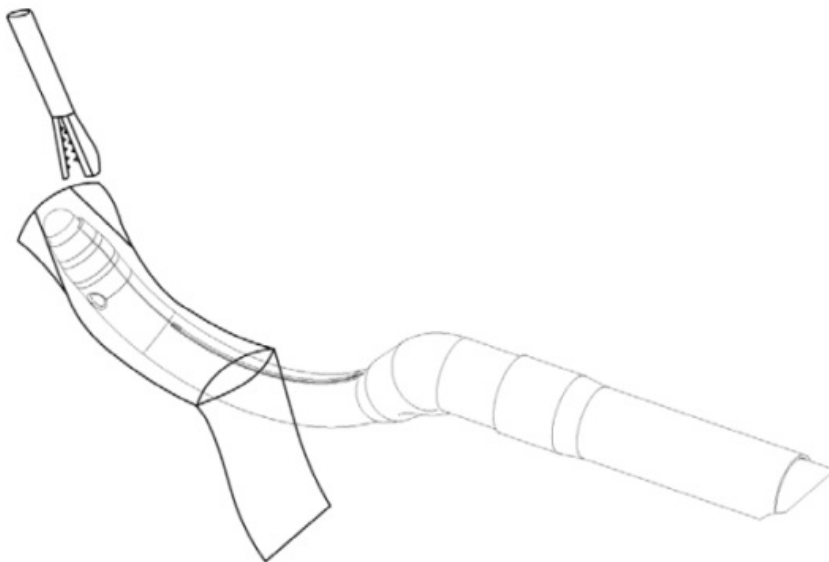


5. The distal portion of the Guide will remain attached to the auxiliary tool during positioning.

Note: Lubrication may be applied to the Guide at the user's discretion.

6. Once the desired placement of the Guide is achieved, use a grasping device to grasp one of the Lateral Tabs (**Figure 3**) on the Guide and remove it from the auxiliary tool. Externally secure the distal end of the Guide near the surgical site.

(See Figure 3)



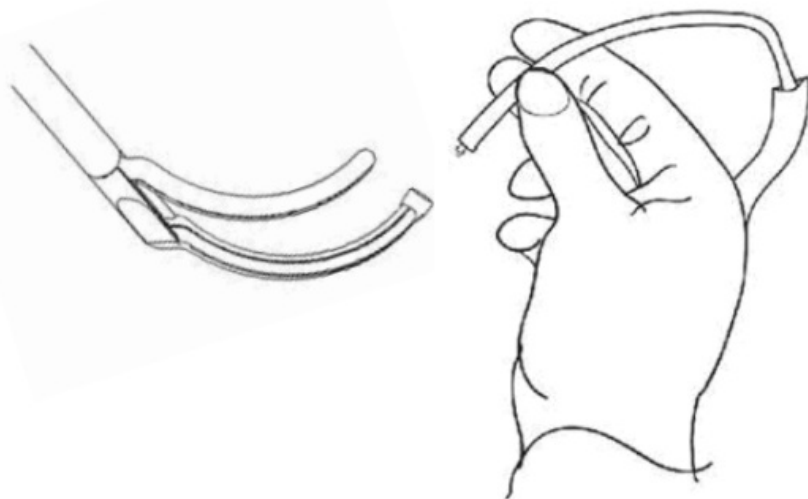
Note: If an articulating dissection tool is used, un-articulating the device may facilitate removal of the Guide.

7. If desired, the Guide can be used for soft tissue retraction or to introduce additional Instruments through the previously created dissection plane.
8. If the Guide incorporates a snap feature, refer to steps 11-12 for instrument exchange.
9. If the Guide incorporates a press feature, refer to steps 13-17 for instrument exchange.
10. If the Guide incorporates a detachable feature, refer to steps 18-21 for instrument exchange.

INSTRUMENT EXCHANGE

(SNAP GUIDE)

11. Prior to attaching the Guide to the ISOLATOR clamp, unclamp the proximal end of the leader from the sterile drape.
12. While holding the Guide, insert the instrument attachment pin into the ISOLATOR clamp attachment tip. Once Guide is attached, do not attempt to remove by forcibly pulling on Guide. **(See Figure 4)**



INSTRUMENT EXCHANGE (PRESS GUIDE)

13. If using an AtriCure Instrument Press Guide, attach the guide to the distal tip of the ISOLATOR per standard surgical technique.
14. Use the guide to facilitate the placement of the ISOLATOR in the previously created positioning plane.
15. Carefully remove the guide from the distal jaw after ISOLATOR placement.

NOTE: The Press Guide is to be removed prior to ablation. (Refer to Step 22)

NOTE: The accessory ribbon allows the surgeon to create a dissection plane in one direction (inferior or superior) and maneuver the tape and leader through the dissection plane so that an instrument (clamp) can be used from the opposite direction.

16. If it is required to reverse the direction of device placement, the accessory ribbon is attached to the distal pocket of the primary transfer tape.
17. After creation of the dissection plane, pull the distal end of the primary tape while providing counter traction on the proximal end of the accessory ribbon so that the leader is pulled through the dissection plane.

INSTRUMENT EXCHANGE (DETACHABLE GUIDE)

18. Prior to attaching the Guide to the ISOLATOR clamp, unclamp the proximal end of the

leader from the sterile drape.

19. While holding the Guide as shown, in the illustration below, align the rib with top surface of distal jaw and insert the Instrument Attachment Pin into the ISOLATOR attachment tip (Figure 4) and turn clockwise 180° until secured. Once Guide is secured, do not attempt to remove by forcibly pulling on Guide.
20. If it is required to reverse the direction of device placement, the accessory ribbon is attached to the distal pocket of the primary transfer tape.
21. After creation of the dissection plane, pull the distal end of the primary tape while providing counter traction on the proximal end of the accessory ribbon so that the leader is pulled through the dissection plane.

REMOVAL AND DISPOSAL

22. To remove the Press Guide Attachment Tip from the Instrument, place a grasping instrument at the distal end of the Instrument and carefully back the Attachment Tip off the Instrument Jaw using a rotating motion.
23. To remove Detachable Guide Attachment Tip from the Instrument, hold the Guide and turn counter-clockwise 180°.
24. Ensure Guide is removed from the surgical field prior to the completion of the surgical procedure. Discard the Guide after use. Follow local governing ordinances and recycling plans regarding disposal or recycling of device components.

HOW SUPPLIED

The Guide is supplied as a STERILE instrument and is for single patient use only.

Sterility is guaranteed unless the package is opened or damaged.

Do not resterilize.

Do not use the guide after the expiration date indicated.

RETURN OF USED PRODUCT

If for any reason these products must be returned to ATRICURE, a return goods authorization (RGA) number is required from ATRICURE prior to shipping.

If the products have been in contact with blood or body fluids, they must be thoroughly cleaned and disinfected before packing.

They should be shipped in either the original carton or an equivalent carton, to prevent damage during shipment; and they should be properly labeled with an RGA number and

an indication of the biohazardous nature of the contents of shipment.

Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number may be obtained from ATRICURE, Inc.










⚠ CAUTION: It is the responsibility of the health care institution to adequately prepare and identify the products for shipment.













DISCLAIMER STATEMENTS

Users assume responsibility for approving the acceptable condition of this product before it is used, and for ensuring that the product is only used in the manner described in these instructions for use, including, but not limited to, ensuring that the product is not re-used. Under no circumstances will AtriCure, Inc. be responsible for any incidental, special or consequential loss, damage, or expense, which is the result of the deliberate misuse or re-use of this product, including any loss, damage, or expense which is related to personal injury or damage to property.

This Instruction for Use describes the procedures for proper use of the products. Any deviation from these procedures, which may compromise the function of the products, is the responsibility of the user.

SYMBOLS GLOSSARY

| | | | |
|---|---|---|---|
|  | Authorized representative in the European Community |  | Use-By Date |
|  | Keep dry |  | Lot Number |
|  | Consult Instructions For Use |  | Product complies with the requirements of directive 93/42/EEC |
| | Manufacturer |  | Caution |
|  | Non-pyrogenic |  | Do Not Use if Package is Damaged |

| | | | |
|---|--|---|---|
|  | Sterilized using ethylene oxide |  | Do Not Resterilize |
|  | Do Not Re-Use |  | Not made with natural rubber latex |
|  | Single Sterile Barrier System with protective packaging inside |  | Single Sterile Barrier System with protective packaging outside |
|  | Country And Date of Manufacture |  | Does not contain Phthalates (DEHP, BBP, DBP) |
|  | Catalogue Number |  | Importer |
|  | Unique Device Identifier |  | Model Number |

CUSTOMER SUPPORT



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Documents / Resources

| | |
|---|--|
|  | AtriCure GPT Series Glidepath Tape [pdf] Instruction Manual GPT100, GPT200, GPT300, GPT Series Glidepath Tape, GPT Series, Gli depath Tape, Tape |
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References

- [User Manual](#)

◆ AtriCure, Glidepath Tape, GPT Series, GPT Series Glidepath Tape, GPT100, GPT200, GPT300,

■ AtriCure Tape

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