

FIGURE 1

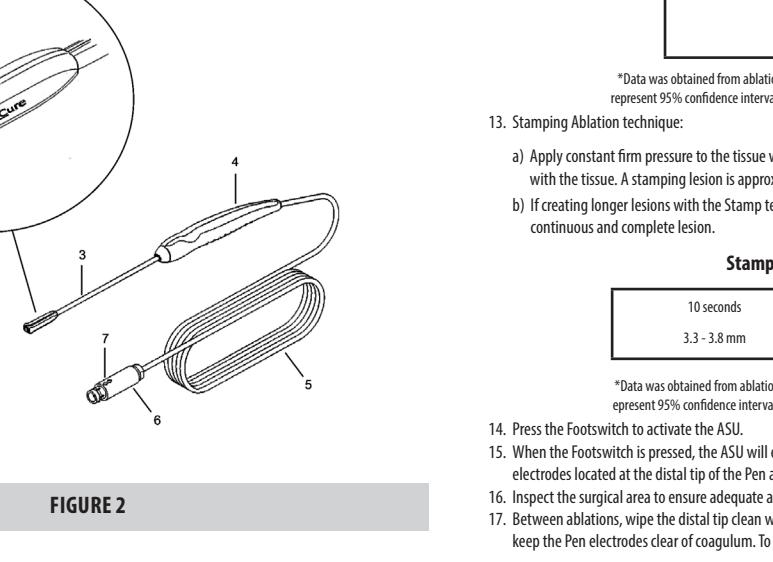


FIGURE 2

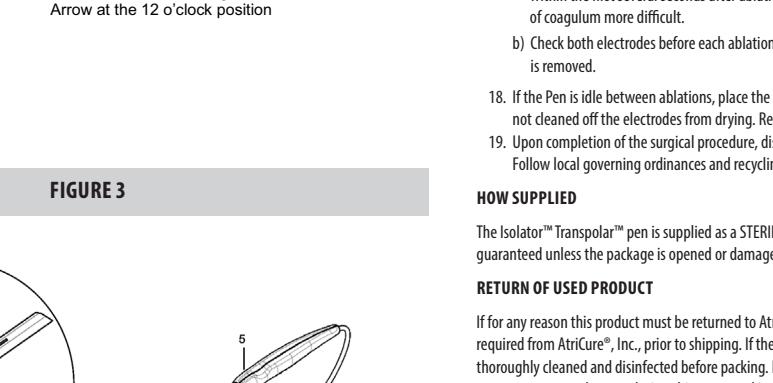
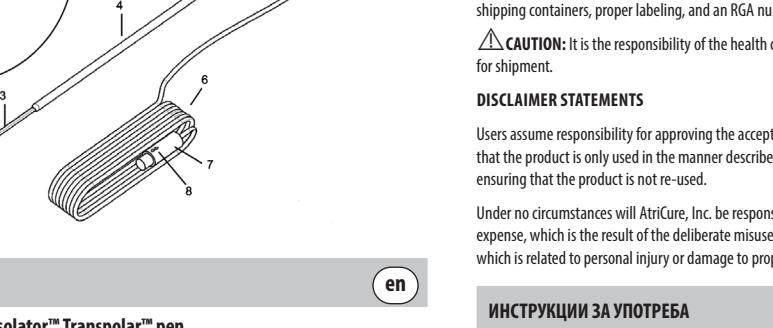


FIGURE 3



INSTRUCTIONS FOR USE

Isolator™ Transpolar™ pen

DESCRIPTION The "Isolator™ Transpolar™ pen" System is composed of the AtriCure® Isolator and Isolator™ pen (the "Isolator™ Transpolar™ pen"). The Isolator™ pen is a single-patient use electrocautery device designed for use with the AtriCure® Isolator. The Isolator™ pen is a transpolar electrocautery device that uses a combination of high-frequency energy (HF) and low-energy (LE) energy during both electrosurgical and RF modes. When the Pen is connected to an auxiliary mode, sense, or stimulation device, the Pen is designed to provide temporary pacing or monitoring.

COMPATIBLE DEVICES

• OSCAR PAC 2030 and ORLAB

INDICATION FOR USE

The "Isolator™ Transpolar™ pen" System is a single-patient use electrocautery device intended to ablate cardiac tissue during cardiac surgery using radiofrequency (RF) energy when connected directly to the ASU or ASB in Ablation mode.

The "Isolator™ Transpolar™ pen" may be used for temporary cardiac pacing, sensing, and recording, but not during the evaluation of cardiac arrhythmias during surgery when connected to a temporary external cardiac pacemaker or recording device.

CONTRAINdications

• The device is not intended for contact bipolar coagulation (permanent female sterilization).

• Possible complications related to the creation of spot or linear lesions in cardiac and soft tissues are:

- Perforation, embolic complications

- Extension of resection cavity

- Perioperative heart rhythm disturbance (atrial and/or ventricular)

- Pericardial effusion or tamponade

- Damaged coronary artery or blood vessels

- Conduction disturbances (SA/AV node)

- Auto-arrhythmic myocardial event

WARNINGS & PRECAUTIONS

Read all instructions carefully for the AtriCure® ASI, Isolator Transpolar™ pen, ASU/Swift, and any compatible auxiliary device being used prior to the device. Failure to properly follow instructions may lead to electrical or thermal injury, which may result in death.

To reduce the risk of electrical burns, do not touch the device during surgery.

To prevent reperfusion arrhythmias, always remove the Pen from the patient during defibrillation.

The Pen device is intended for single use only. Reuse of the Pen device for another patient, or for another procedure, may cause loss of function or injury.

To avoid damage to the device, do not drop the Pen.

Ensures the safety of the device by using the correct connector and cable, prior to the first use.

Total duration of activation of the electrodes may not exceed 10 minutes by ablation activation or by ablation activation and/or overlay activation.

Do not connect the ASB/ASU auxiliary device to apply main line energy.

Supply unused equipment may encounter damage during storage if the device is not stored in a cool, dry place.

PRECAUTIONS

- Do not immerse the Pen in liquids, as this may affect the device performance.

- Do not touch the Pen to any metal, as this will interfere with the device's ability to detect the presence of metal.

- The use of the Pen device is contraindicated for use with the AtriCure® ASB.

- The Pen device is not intended for contact bipolar coagulation (permanent female sterilization).

- To prevent reperfusion arrhythmias, always remove the Pen from the patient during defibrillation.

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PRECAUTIONS

- Use single use technology, remove the Pen from its packaging.

- With the exception of Ablation mode, the Pen is a 20-second pulse width device. Connect the Pen to the ASB or ASU as per the Figure 3.

- Verify that the connections are secure, before use of the Pen.

- The Pen device is intended for use with the AtriCure® ASB. Use of the Pen with another manufacturer's compatible device may cause loss of function or injury.

- The Pen should be used with standard cardiac pacing and sensing devices.

- The Pen has an anti-reuse feature that is used to track the use of the Pen. If you attempt to plug in a device that has reached its time limit, the Pen will no longer function and the ASU will issue a warning message.

- Excessive bending of the male/female stents will cause the shaft to bend and may increase the potential for breakage. Only bend the shaft in the middle section.

- Use caution during device insertion and removal and bending the male/female portion of the shaft with the handle.

- Electrode(s) should be used with caution in the presence of internal or external pacemakers. Interference produced with the use of the electrocautery device could cause device failure, as pacemaker or internal cardioverter/defibrillator (ICD) devices are programmed to respond to electrical signals from the device.

- For pacemaker conductivity, consult the manufacturer of the pacemaker device.

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M B O L S G L A R Y : b g РЕЧНИК НА СИМВОЛЕТИ cs VYSVĚTVIVKY SYMBOLŮ : da SYMBOLOVERSIGT /
 GLOSSAR : el ΓΛΩΣΣΑΡΙΟ ΣΥΜΒΟΛΩΝ : es GLOSARIO DE SÍMBOLOS : et SÜMBOLITE SÖNASTIK : f SYMBOLIEN
 LÖSSAIRE DES SYMBOLES : hr POJMOWINY SIMBOLA : hu SZÍMBOLUMOK JEGYZÉK : orDALISTI YIFIR TÁKNA
 DEI SIMBOLI : it SIMBOLI A İŞKINAMASI ZODYNAS : lv SIMBOLU GLOSĀRIJS : nl VERKLARENDE LIJST MET
 S Y M B O L I E T P : pl SŁOWNIK SYMBOLIÓW : pt GLOSSÁRIO DE SÍMBOLOS : ro GLOSAR DE SIMBOLURI : sk SLOVNÍK
 S Y M B O L O V : sl SLOVAR SIMBOLOV : sr ZNAČENJE SIMBOLA : sv SYMBOLORDLISTA