AtriCure®

Instructions for Use
cryoLASE® cryosphere cryosurgical probe

CAT# CSY05; CSY05-L

INDICATION FOR USE

FOR ADULT PATIENTS

AtriCure® cryosphere cryosurgical probes are sterile, single-use devices intended for use performed by freezing target tissues, creating an inflammatory response (sympathetically) for blocking pain by temporarily ablating peripheral nerves.

FOR ADOLESCENT PATIENTS

The cryoLASE cryosphere cryosurgical probes are intended for use in temporarily block pain by ablating neural tissue anterior direct visualization in adolescent patients of at least 12 years of age.

Direct visualization, in this context, requires that the surgeon is able to see the targeted tissue for cryosurgical cryodestruction directly or with assistance from a camera, endoscope or other similar optical technologies.

CONTRAINdications

There are no known contraindications.

SYSTEM DESCRIPTION

The AtriCure cryospheric system creates cryosurgical lesions in tissue by delivering a cryogenic Nitrous Oxide (N$_2$O) energy source from the console to the tip of the connected probe. The system provides controlled tissue freezing temperatures that is below +4°C, with typical operating ranges being below +1°C to +3°C.

The system is comprised of the following components:

1. Single cryoLASE cryosurgical probe connected to the CONSOLE and the corresponding tool (referred to hereafter as TOOL).

2. AtriCure cryosphere cryosurgical probes are connected to the CONSOLE as an optional footswitch.

NOTE: The Shaft supports bending up to 180° in one direction. Successive bends will result in increased bend resistance.

NOTE: Repetitive bends in the same location could cause damage to the Rigid Shaft Probe.

1) Ensure the CONSOLE is in Ready Mode before attempting to connect the PROBE. The sudden release of pressurized gas may cause the tool to recoil, which may injure the operator or patient.

2) Verify the N$_2$O Cylinder pressure is at least 700 PSI after the appropriate warming period.

3) Charging the CONSOLE to +2°C or higher before connecting the PROBE to the CONSOLE will prevent the device from malfunctions.

4) Charging the CONSOLE to +2°C or higher before connecting the PROBE to the CONSOLE will prevent the device from malfunctions.

5) Prior to forming, ensure the CONSOLE is in Ready Mode per Figure 2.

6) Insert the PROBE Ball Tip into the TOOL Barrel in the direction of the Insertion Arrow, as illustrated in Figure 4.

7) Hold the TOOL or the Shaft is locked onto the Bonding Channel, as illustrated in Figure 4, and the desired bend angle is achieved.

NOTE: Repetitive bends in the same location could cause damage to the Rigid Shaft Probe causing device malfunction.

CAUTION: Repetitive bends in the same location could cause damage to the Rigid Shaft Probe.

NOTE: The Rigid Region of the Shaft can be formed by hand and supports bending two times with up to the deflections as illustrated in Figure 5.

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**WARNING**

Do not replace or reuse the PROBE. Failure can cause patient injury and for the communication of adverse events (AEs) from one patient to another.

**RETURN OF USED PRODUCT**

If for any reason this product must be returned to AtriCure, Inc., a return goods authorization (RGA) number is required from AtriCure, Inc. prior to shipping. If the product has been in contact with blood or body fluids, it must be thermally cleaned and disinfected before packing.

1. Thoroughly clean the product using the cleaning method described in these instructions for use, including, but not limited to, ensuring the product is not re-used.

2. 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.

3. 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.

4. Waste Electrical and Electronic Equipment (WEEE) and Waste Batteries and accumulators are indicated by the symbol below. These products and batteries should be treated and disposed of at designated collection points.

5. Caution: Federal Law (US) restricts this device to sale by or on the order of a physician.

6. Not made with natural rubber latex.

7. Do not use if package is damaged.

8. Do not use if sterilization cycle is not completed.

9. Use-by date.

10. Catalog number.

11. Made from non-pyrogenic materials.

12. Do not reprocess or reuse the PROBE. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another.

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**SYMBOLS GLOSSARY**

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<thead>
<tr>
<th>SYMBOL</th>
<th>MEANING</th>
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<tbody>
<tr>
<td>Manufacturer</td>
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<tr>
<td>Rx only</td>
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<tr>
<td>Lot</td>
<td>Batch scale</td>
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<tr>
<td>Sterile R</td>
<td>Sterilized using steam autoclave</td>
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<tr>
<td>Caution</td>
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<tr>
<td>Non-sterile</td>
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<tr>
<td>Non-ergonomic</td>
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<td>Acetylcholine</td>
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<td>Temperature LIMIT</td>
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<td>Humidity LIMIT</td>
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<td>Made in Electrical and Electronic Equipment</td>
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**CNS PROVIDER REFERENCE FOR NERVE BLOCK INDICATION**


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**CLINICAL STUDY REFERENCES FOR NERVE BLOCK INDICATION**


