**NEURAGEN® NERVE SIZER™**

**PRODUCT DESCRIPTION**

The NeuraGen Nerve Sizer is intended to determine the approximate diameter of peripheral nerves. The nerve sizer is a tool for the surgeon to easily identify the adequate size of Nerve Guide to be applied. The use of an instrument for a task other than that for which it is intended, as well as improper, ineffective and insufficient maintenance can greatly reduce the life of an instrument and will invalidate the instrument’s warranty.

**HOW SUPPLIED**

Integra’s instruments are supplied non-sterile and must be cleaned, lubricated and sterilized prior to use according to hospital protocol and the procedures outlined in this document. Failure to follow these procedures will invalidate the instrument’s warranty and can cause the instrument to fail.

**INSTRUCTIONS FOR USE**

The nerve sizer is designed to provide a rapid method of assessing the external diameter of a peripheral nerve in order to correctly determine the appropriate size product for entubulation repair or nerve wrapping. The gauges that are formed in each end of the nerve sizer correspond to the indicated dimension adjacent to each gauge. The surgeon should first choose a gauge that is obviously larger than the nerve. Place the gauge over the nerve so that the nerve sits between the parallel sides of the gauge. Choose successively smaller gauges and work down in steps until a gauge is found where the parallel sides of the gauge just touch the nerve on each side. Take precaution not to crush the nerve with the instrument. When the nerve diameter has been determined, it is suggested to use a nerve guide or nerve wrap of one size greater than that measured to prevent constriction of the nerve ends. For example, if the nerve measures as 4mm then use a 5mm ID nerve guide.

**CARE AND HANDLING**

After each use of an instrument, these critical processing steps must be followed:

1. Conduct a visual and mechanical inspection of each instrument. The importance of inspecting each instrument cannot be overemphasized.
2. Separate broken or malfunctioning instruments and send back to Integra for repair or replacement. (See Repairs and Maintenance.)
3. Hand wash nerve sizers in a neutral pH solution (7.0 to 8.5 pH).
4. Lubricate the instrument in a water soluble, antimicrobial lubricant after exposure to corrosive elements, and then clean in the usual manner.
5. Sterilize the nerve sizer prior to use. See Sterilization section for sterilization parameters.

**INSPECTION OF ALL INSTRUMENTS**

**Before Use.** Each instrument must be inspected after cleaning and before use and to ensure that the instrument is in proper operating condition. There should be no signs of rust or corrosion. Only fully cleaned, properly functioning instruments should be packaged for reuse.

**After Use.** Each instrument must be inspected immediately after use to ensure that the instrument is in proper operating condition.

**TROUBLESHOOTING**

Following are possible solutions to some common problems you may encounter with stainless steel surgical instruments:

**CORROSION (RUST)**

- **Cause:** Dried blood in gauges can look like rust after it has been baked on and may cause cracking.
- **Solution:** Clean instruments more thoroughly after each use.

- **Cause:** Excessive moisture left on the surface or crevices in sterile wrapped packs. Also, excessive moisture left in the autoclave during and at the completion of the cycle.
- **Solution:** Preheat the autoclave. Don’t rush the drying time - just open the door slightly. Properly maintain autoclave valves, as a leaking valve can cause moisture or permit the return of corrosive matter to the autoclave.

**PITTING**

- **Cause:** Exposure to saline solutions, blood, potassium chloride and a number of other compounds.
- **Solution:** Rinse with fresh running water as soon as possible after exposure to corrosive elements, and then clean in the usual manner.

**STAINING**

- **Cause:** Detergent residue, especially if not thoroughly rinsed from the instrument, contains chloride or has an acid base. The chloride in the cleaner unites with the steam in the autoclave to form hydrochloric acid.
- **Solution:** Avoid detergents with chloride bases.

**LIGHT COLORED SPOTTING**

- **Cause:** Condensation from the autoclave.
- **Solution:** Carefully follow the autoclave manufacturer’s recommendation, checking for loose fitting gaskets in the autoclave, and/or verifying proper weight limitations for each tray within the autoclave cycle.

**LIGHT BROWN SURFACE COATING**

A film-like coating can be deposited on the instrument through the sterilization process. This can be caused by high iron content in steam from the hospital water supply system used in the autoclave.

**STERILIZATION**

The NeuraGen® Nerve Sizer™ is provided NON-STERILE and must be decontaminated and sterilized prior to use.

Follow the sterilization parameters for sterilization of the NON-STERILE sizer as listed below:

Independent laboratory testing, conducted according to the F.D.A (21 CFR PART 58) and Good Laboratory Practice Regulations (G.L.P.), has validated steam sterilization as an effective process for reusable instruments. See also, AAMI Standards and Recommended Practices, “Steam Sterilization and Sterility Assurance in Health Care Facilities”, ANSI/AAMI ST46:2002; “Flash Sterilization _ Steam Sterilization of Patient Care Items for Immediate Use, ANSI/AAMI ST37:3ed. AAMI standards recommend that the sterilizer manufacturer’s written instructions for cycle parameters should also be followed.

Medical device manufacturer’s exposure times to sterilization temperature may need to be longer than the minimum indicated by the sterilizer manufacturer but must never be shorter.

Below are the recommended sterilization parameters:

<table>
<thead>
<tr>
<th>Sterilizer</th>
<th>Exposure Temperature</th>
<th>Exposure Time</th>
<th>Minimum Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-vacuum (wrapped)</td>
<td>121° C _ 250° F</td>
<td>20 min</td>
<td>20 min</td>
</tr>
<tr>
<td></td>
<td>132° C _ 270° F</td>
<td>4 min</td>
<td>20 min</td>
</tr>
<tr>
<td></td>
<td>134° C _ 273° F</td>
<td>3 min</td>
<td>15 min</td>
</tr>
<tr>
<td>Pre-vacuum (unwrapped)</td>
<td>132° C _ 270° F</td>
<td>4 min</td>
<td></td>
</tr>
<tr>
<td>Gravity Steam (wrapped)</td>
<td>132° C _ 270° F</td>
<td>18 min</td>
<td></td>
</tr>
</tbody>
</table>

These parameters are validated to sterilize only these instruments. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user.

As recommended by the AAMI Standards and Recommended Practices, Volume 1, 1992, the sterilizer manufacturer’s written instructions for cycle parameters should be followed.

**PRODUCT INFORMATION DISCLOSURE STATEMENTS**

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**RETURNED GOODS POLICY**

- Authorization, from customer service, must be obtained prior to returning product.
- Custom or special order products will not be accepted for credit.
- Credit will be issued for goods returned prior to ninety days from ship date with a restocking charge. This assumes that the product returned is not damaged and can be verified to have not been used or opened.

**SYMBOLS USED ON LABELING**

![Manufacturer](REF)  
![Catalog Number](Catalog Number)  
![Lot Number](LOT)  
![See Instructions for Use](See Instructions for Use)

**Distributed by:**

Integra LifeSciences Corporation  
311 Enterprise Drive • Plainsboro, NJ 08536 • USA  
(609) 275-0500 • Facsimile (609) 275-5363

Customer Service (USA Only) – (800) 654-2873

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