DESCRIPTION:
A set of SOHN’S™ DILATORS includes (1) 30 mm, (1) 35 mm and (1) 40 mm dilators.

INDICATIONS:
SOHN’S™ DILATORS are intended for the treatment of persistent anal fissure, frequent fissure recurrences, or a severely painful or acute fissure.

CONTRAINDICATIONS:
Incontinence or high grade anal stenosis

INSTRUCTIONS FOR USE:

Treatment of anal fissure:
1. Perform under general, regional or local anesthesia. If using general anesthesia, use local also.
2. Consider prophylactic parental antibiotics for patients at risk for complications of bacteremia.
3. Perform a thorough rectal examination.
4. All dilators must be well lubricated when inserted.

For patients selected to receive the 40 mm anal dilator:
5. Insert the 30 mm dilator and hold in place for 1 minute.
6. Insert the 35 mm dilator and hold in place for 1 minute.
7. Insert the 40 mm dilator and hold in place for 6 minutes.

For other patients:
5. Gradually dilate the anus.
6. Insert the preferred maximum size dilator for 6 minutes.

WARNING:
Excessive force could result in damage to tissue and incontinence. Do not use the 40 mm dilator in women over 60 years old, in men over 65, in patients with anal stenosis that persists after regional or local anesthesia has been administered, or in any patient at high risk for incontinence.

CLEANING:
Do not use abrasive materials or brushes.

STERILIZATION:
Steam sterilize per ANSI/AAMI ST79:2006 “Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities” using ONE of the following methods:

<table>
<thead>
<tr>
<th>Method</th>
<th>Steam (Wrapped)</th>
<th>Steam (Wrapped)</th>
<th>Flash Steam (Unwrapped)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle</td>
<td>Gravity</td>
<td>Prevacuum</td>
<td>Gravity</td>
</tr>
<tr>
<td>Temperature</td>
<td>270°F/132°C</td>
<td>270°F/132°C</td>
<td>270°F/132°C</td>
</tr>
<tr>
<td>Exposure</td>
<td>15 mins</td>
<td>5 mins</td>
<td>3 mins</td>
</tr>
</tbody>
</table>

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