1. STANDARD SET LIST
This package includes the following items:
• PENTAX Medical Single Use Injection Needle
• Instructions for Use

NOTE:
• Read this manual before operating.
• Failure to read and thoroughly understand the information presented in this manual, as well as those developed for other endoscopic equipment, may result in serious injury to the patient and/or user. Furthermore, failure to follow the instructions in this manual may result in damage to, and/or malfunction of, this equipment.
• It is the responsibility of each medical facility to ensure that only well educated and appropriately trained personnel, who are competent and knowledgeable about the endoscopic equipment, antimicrobial agents/processes and hospital infection control protocol be involved in the use of these medical devices.
• Known risks and/or potential injuries associated with flexible endoscopic procedures include, but are not limited to, the following: hemorrhage, perforation, pleural effusion, hepatic failure, chest pain, ulcration after delayed injection, esophageal stenosis, aspiration pneumonia, dysphagia, septicemia, air embolism, and other respiratory tract problems.

2. INTENDED USE
This device is intended to be used with a flexible endoscope to assist physicians in performing an endoscopic injection for the treatment of esophageal and gastric varices and for submucosal injection in the digestive tract.

CAUTION:
Never use this device for any purpose other than that for which it has been designed. Since endoscopic accessories are designed to be used in conjunction with other medical devices, the effectiveness of an accessory is dependent upon a number of factors including the condition of the endoscope.

WARNING:
• This device has been ETO sterilized for single patient use. Never reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may lead to device failure, patient injury and/or illness. Reuse, reprocessing, or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection. Contamination of the device may lead to injury and/or illness of the patient.
• Never attempt to repair or modify this device. The use of repaired or modified device may result in patient injury.

3. CONTRAINDICATIONS
This device is contraindicated for injection and treatment in patients, including but not limited to those who are allergic to harderner and vasocostructor, and injured patients who are not suitable for injection of harderner and vasocostructor.

4. NOMENCLATURE

5. PREPARATION AND INSPECTION BEFORE USE

CAUTION:
Use sterilized surgical gloves when performing the pre-use inspection.

1) Prior to use, the endoscope with which this device will be used must be carefully and thoroughly inspected for cleanliness and proper function to determine that it is appropriate for patient use. Please refer to the manual supplied with the endoscope.
2) Select an appropriate device to satisfy the technical characteristics as well as the intended application of the endoscopic accessory.

<table>
<thead>
<tr>
<th>Model</th>
<th>Max Insertion Portion Width</th>
<th>Working Length</th>
<th>Needle</th>
<th># Compatible Endoscope</th>
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</thead>
<tbody>
<tr>
<td>N-ME-320</td>
<td>1.9</td>
<td>1650</td>
<td>4</td>
<td>1350 or less</td>
</tr>
<tr>
<td>N-ME-320</td>
<td>2.0</td>
<td>1650</td>
<td>4</td>
<td>1350 or less</td>
</tr>
<tr>
<td>N-ME-320</td>
<td>2.5</td>
<td>2300</td>
<td>4</td>
<td>2000 or less</td>
</tr>
<tr>
<td>N-ME-320</td>
<td>2.8</td>
<td>1650</td>
<td>4</td>
<td>28</td>
</tr>
</tbody>
</table>

* There is no guarantee that instruments selected solely using this minimum instrument channel width will be compatible in combination.

CAUTION:
Never use this device with an incompatible endoscope. It could result in endoscopy and/or accessory damage/failure.

CAUTION:
This device should only be used in an endoscope with forward viewing optics. Never use an endoscope with oblique or side viewing optics.

6. OPERATION

WARNING:
• The user must carefully read and follow all instructions in the operating manuals supplied with all the related equipment. The equipment should be carefully and thoroughly inspected to determine that it is appropriate for patient use.
• Technical criteria, clinical applications and accompanying risks shall be well understood before the use of this device.
• Physicians and assistants should wear protective garments such as gloves, gowns, face masks, goggles, etc. to minimize the risk of cross contamination.
• To avoid damaging the device, when inserting or withdrawing any device through the instrument channel insert of an endoscope, keep the endoscope in a straight position and slowly insert, advance, or withdraw the device and never apply excessive force. Do NOT twist, rotate, or bend any of the rubber strain reliefs of an endoscope as these areas are particularly susceptible to damage.

CAUTION:
Avoid tight coiling or bending of the insertion portion where the diameter is smaller than 15mm. Doing so could damage the insertion portion of the device.

1) Slowly insert the endoscope under direct vision.
2) Insert the device through the silt into the rubber inlet seal with the endoscope in a straight position. Be certain to hold the slider in such a way to ensure that the needle is in a retracted position during insertion.

NOTE:
• When the distal end of the device is first passed through the inlet seal, a temporary resistance will be encountered. Hold the tube tightly at about 5cm from the distal end of the device and push it through.
• During insertion, if the device is found hard to advance further due to resistance, decrease the deflection of the bending section to a level suitable for smooth insertion and insert the device again. Alternately, withdraw the device, and then attempt to insert it again.

NOTE:
• When resistance is encountered, do not attempt to force the device further. Any resistance encountered should be thoroughly to be examined. If the resistance persists, do not attempt to further advance the device. Any resistance encountered during a patient procedure could result in serious injury to the patient.

3) Check the sterilization expiration date printed on the package labeling and confirm that the product has not expired. Make sure that there are no signs of abnormalities such as stains, wrinkles, tears or any other indications that the packaging has previously been opened or compromised.

CAUTION:
Always maintain a view of the device during advancement of the device beyond the scope tip.
4) For injection purposes, when the distal portion of the needle becomes visible in the viewing field, attach a syringe filled with medication to the injection port and inject the medication into the needle fully to expel air out of the device.

5) Carefully advance the device onto the target area and slowly expose the distal needle.

**WARNING:**
- NEVER withdraw the device quickly. It could result in the potential cross-contamination due to the possible scatter of patient debris.

6) Carefully place the device onto and into the target tissue as necessary. Always maintain a clear view during advancement of the device.

**CAUTION:**
- The actual projected or exposed length of the needle will vary during use depending on the degree of bends or curves to the insertion portion (protective tube).

**CAUTION:**
- The injection needles are available in various lengths. Always ensure that appropriate size has been chosen to satisfy the clinical requirements of the particular patient and procedure. Exercise extreme caution, especially when using longer length needles to avoid inadvertent perforation/puncture of untargeted tissues/organisms.

**WARNING:**
- If the needle does not move forth/back smoothly, never apply excessive force. Reduce the angulation of the endoscope.
- Always ensure that the distal needle is completely retracted within the protective tube during passage of the needle through the endoscope channel.

7) After injection, move the slider back to retract the needle.

8) Slowly withdraw the device with the needle tip retracted.

**WARNING:**
- If the needle cannot completely be retracted into the outer tube, safely position the endoscope to be in the possibly straight position, and repeat the above step.
- If the needle still can not be retracted into the tube, pull the needle to the distal end of the endoscope until the tip is invisible in the endoscope. In this way, the needle is stored completely in the working channel to prevent patients from injury.

**CAUTION:**
- Always maintain a clear view during advancement of the device.

**7. CARE AFTER USE**

**WARNING:**
- This device is for single patient use. Never reuse or resterilize the device. For disposal, follow the applicable protocol at your medical facility as well as local or national regulations.

**Operation Environment**
- Ambient temperature: 10°C - 40°C
- Relative humidity: 50% - 60%
- Atmospheric pressure: 700hPa - 1060hPa

**Storage Environment**
- Temperature: 0°C - 70°C
- Relative humidity: 50% - 85%
- Atmospheric pressure: 700hPa - 1060hPa

**WARNING:**
- Store this device inside the sealed sterilization package in a clean and dry place. Avoid high humidity, high temperature and areas exposed to the direct sunlight.

**CAUTION:**
- Always maintain a clear view of the device during advancement of the device beyond scope tip.

**Manufacturer**
- PENTAX Medical

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