Capsule endoscope delivery device

INSTRUCTIONS FOR USE

STERIS™
US Endoscopy
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Mentor, OH 44060
800-548-4873
www.steris.com
A subsidiary of STERIS Corporation

Reorder No. HZ-711144
This device is not made with natural rubber latex.

**Intended Use:**
- The disposable AdvanCE® capsule endoscope delivery device is a 2.5 mm single sheathed device indicated for transendoscopic delivery of Capsule (with the dimensions of 10.5mm - 11.5mm in diameter and 23.5mm - 26.5mm in length) to the stomach or duodenum. This device is intended for patients who are either unable to swallow the capsule, or unable to pass the capsule beyond the pylorus in sufficient time to complete the desired diagnostic evaluation.

<table>
<thead>
<tr>
<th>Description</th>
<th>Product Number</th>
<th>Sheath Diameter</th>
<th>Sheath Length</th>
<th>Acceptable Capsule Sizes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advance® Capsule Endoscope Delivery Device</td>
<td>HZ-711144</td>
<td>2.5mm</td>
<td>180cm</td>
<td>Diameter: 10.5mm - 11.5mm Length: 23.5mm - 26.5mm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Capsule Cup - Outer Diameter (OD)</th>
<th>0.50 inches/12.7mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capsule Cup – Inner Diameter (ID)</td>
<td>0.46 inches/11.7mm</td>
</tr>
</tbody>
</table>

**Warnings and Precautions:**
- Endoscopic procedures should only be performed by persons having adequate training and familiarity with endoscopic techniques.
- Consult the medical literature relative to complications, hazards and techniques prior to the performance of any endoscopic procedure.
- For use of the video capsule, consult the Information for Use document from the video capsule manufacturer.
- Transendoscopic capsule placement requires skill and experience in endoscopic esophageal intubation with an accessory device seated at the distal tip of the endoscope. The use of this device is not recommended if the clinician lacks the required experience and proficiency.
- **This device is compatible with an endoscope that has an accessory channel of 2.8mm or greater.**
- Do not attempt to reuse, reprocess, refurbish, remanufacture, or resterilize this device. STERIS Endoscopy did not design this device nor is it intended to be reused, reprocessed, refurbished, remanufactured, or resterilized. Performing such activities on this disposable medical device presents a safety risk to patients (i.e. compromised device integrity, cross-contamination, infection).

**Contraindications:**
- Those specific to any GI condition that may hinder or prevent the endoscopic placement of the capsule.
- The Given PillCam® SmartPill Motility capsule is not compatible with the AdvanCE® Capsule Endoscope Delivery Device

**Prior to Use Instructions:**
1. Perform baseline EGD.
2. Assess if the patient is a candidate for capsule deployment (see contraindications).
3. Decompress the stomach upon completion of the baseline EGD (this can minimize gastric looping on the repeat EGD for capsule delivery).
4. Prior to clinical use, you should familiarize yourself with the AdvanCE® capsule endoscope delivery device.
5. Read this “Instructions for Use” and review the attached photographs.
6. Open and inspect the device for shipping or handling damage. If damage is evident (e.g. bends, kinks, cracks, misshaped cup), **do not use this device and contact your local STERIS Endoscopy product specialist.**

**Instructions for Use:**
1. Open the larger poly bag, remove the paper tape restraint from the coiled device, and gently uncoil the catheter assembly.
2. Remove the small capsule cup bag by sliding it over the end of the catheter.
3. Hold the proximal end in one hand and the distal sheath in the opposite hand, and drape in a “U” shape.
4. Open and close the finger rings on the handle two (2) times to make sure it moves smoothly. (Moving the finger rings away from the thumb ring is open, moving the finger rings towards the thumb ring is closed).
   - **Note:** The finger rings do not advance the full length of the handle shaft.
5. If this unit does not function properly, **do not use this product and please contact your local product specialist.**
6. Place the scope in a straight position prior to inserting the AdvanCE® capsule endoscope delivery device catheter.
7. Hold the finger rings on the AdvanCE® device handle in a closed position (see Fig. 1) to ensure that the deployment cable is maintained within the catheter.
8. Pass the catheter through the endoscope’s accessory channel (See Fig. 2) using short strokes (1”-1.5” length is recommended to avoid sheath kinking).
9. **Observe that the catheter assembly exits the distal end of the endoscope.**
10. **Remove capsule cup from the small bag.**
11. Hold the white portion of the capsule cup between thumb and forefinger, with clear end facing out.
12. Attach the clear end of the capsule cup onto the threaded end of the catheter by turning the capsule cup in a clockwise direction (see Fig 3).
13. Tighten capsule cup until it stops and the catheter begins to turn.
14. Pull gently on the capsule cup to confirm proper connection.
15. Hold the finger ring handle in a closed position (see Fig. 1).
16. Push the video capsule into the capsule cup with the optical dome of the video capsule facing out (see Fig. 4).
17. Listen for an audible click (This indicates that the capsule is appropriately seated within the capsule cup).
   **Caution:** Do not use the device if you experience any of the following:
   a. Failure to hear an audible click
   b. Capsule falls out of capsule cup
18. Seat the capsule cup against the endoscope’s distal tip by pulling the proximal end of the catheter (see Fig. 5).
19. Lubricate the outer surface of the capsule cup and endoscope with water soluble lubricant.
   **Note:** do not cover the endoscope lens or video capsule with lubricant
20. Hold the finger rings on the AdvanCE® capsule endoscope delivery device handle in a closed position (see Fig. 1).
21. Maintain tension on the catheter during intubation to keep the capsule cup against the end of the endoscope.
22. Advance the capsule cup and endoscope into the stomach or duodenum.
   **Note:** Patient condition may indicate the best location for capsule deployment.
23. Deploy the capsule by following these steps:
   a. Open the finger ring handle briskly until it stops (see Fig. 6).
   b. Confirm capsule delivery endoscopically by looking through the clear capsule cup and seeing the cable and the empty capsule cup.
   **Note:** Advancing the capsule cup from the distal tip of the endoscope may enhance the luminal field of view.
24. If the capsule does not fully deploy:
   a. Close the finger ring handle.
   b. Slightly alter the position/angulation of the endoscope.
   c. Straighten the handle and catheter
   d. Repeat step 23.
25. After capsule delivery, close the finger ring handle until the deployment cable is retracted into the catheter.
26. Maintain tension on the catheter to keep the capsule cup seated against the endoscope’s distal tip.
27. Remove the endoscope from the patient.
28. Remove the device from the endoscope:
   a. Hold the finger ring handle in a closed position,
   b. Loosen the capsule cup until it can be removed from the distal end of the catheter.
   c. Withdraw the device from the endoscope’s accessory channel.
   d. Dispose of device as per institutional guidelines.
Product Disposal:

After use, this product may be a potential biohazard which presents a risk of cross-contamination. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Issued Date: October 2019

Warning:
An issued or revision date for these instructions is included for the user’s information. In the event that two years have elapsed between this date and product use, the user should contact STERIS to determine if additional information is available.

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Serious incidents that have occurred in relation to this medical device should be reported to the manufacturer and competent authority in the country where the incident occurred.

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Made in the U.S.A
## Explanation of symbols used on Labels and Instructions for Use

<table>
<thead>
<tr>
<th>SDO (if applicable)</th>
<th>Symbol and Reference Number</th>
<th>Title of Symbol</th>
<th>Meaning of Symbol</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ISO 15223-1</strong></td>
<td>5.1.1</td>
<td>Manufacturer</td>
<td>Indicates the medical device manufacturer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>メーカー</td>
<td>医療機器の製造業者を示します</td>
</tr>
<tr>
<td></td>
<td>5.1.3</td>
<td>Date of Manufacture</td>
<td>Indicates the date when the medical device was manufactured</td>
</tr>
<tr>
<td></td>
<td></td>
<td>製造日</td>
<td>医療機器が製造された日付を示します</td>
</tr>
<tr>
<td></td>
<td>5.1.4</td>
<td>Use By</td>
<td>Indicates the date after which the medical device is not to be used.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>使用期限</td>
<td>医療機器が使用されなくなる日付を示します</td>
</tr>
<tr>
<td></td>
<td>5.1.5</td>
<td>Batch Code</td>
<td>Indicates the manufacturer’s batch code</td>
</tr>
<tr>
<td></td>
<td></td>
<td>パッチコード</td>
<td>メーカーのバッチコードを示します</td>
</tr>
<tr>
<td></td>
<td>5.1.6</td>
<td>Catalog Number</td>
<td>Indicates the manufacturer’s catalogue number</td>
</tr>
<tr>
<td></td>
<td></td>
<td>カタログ番号</td>
<td>メーカーのカタログ番号を示します</td>
</tr>
<tr>
<td></td>
<td>5.2.7</td>
<td>Non-Sterile</td>
<td>Indicates a medical device that has not been sterilized</td>
</tr>
<tr>
<td></td>
<td></td>
<td>非滅菌</td>
<td>滅菌されていない医療機器であることを示します</td>
</tr>
<tr>
<td></td>
<td>5.2.8</td>
<td>Do not use if package is damaged</td>
<td>Do not use if the product sterile barrier system or its packaging is compromised.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>包装が破損している場合は使用禁止</td>
<td>製品の無菌バリアシステムまたはその包装が破損している場合は使用しないでください。</td>
</tr>
<tr>
<td></td>
<td>5.3.4</td>
<td>Keep dry</td>
<td>Indicates a medical device that needs to be protected from moisture</td>
</tr>
<tr>
<td></td>
<td></td>
<td>湿気厳禁</td>
<td>湿気から保護する必要がある医療機器であることを示します</td>
</tr>
<tr>
<td></td>
<td>5.4.1</td>
<td>Biological Risks</td>
<td>Indicates that there are potential biological risks</td>
</tr>
<tr>
<td></td>
<td></td>
<td>生物学的リスク</td>
<td>潜在的な生物学的リスクがあることを示します</td>
</tr>
<tr>
<td></td>
<td>5.4.2</td>
<td>Do not reuse</td>
<td>Indicates a medical device that is intended for a single procedure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>再利用の禁止</td>
<td>単一の手順を対象とした医療機器でることを示します</td>
</tr>
<tr>
<td></td>
<td>5.4.3</td>
<td>Consult instructions for use</td>
<td>Indicates the need for the user to consult instructions for use</td>
</tr>
<tr>
<td></td>
<td></td>
<td>使用説明書の参照</td>
<td>使用説明書を参照する必要があることを示します</td>
</tr>
</tbody>
</table>
| 5.4.4 | Caution: Federal law (U.S.A.) restricts this device to sale or on the order of a physician.  
注意:連邦法(米国)により、本機器の販売先は医師の指示を受ける者のみに制限されています。 |
| 21 CFR 801.109 (b) (1) | N/A | Unique Device Identifier  
固有の機器ID | Indicates the unique device identifier  
固有の機器IDを示します |
| N/A | N/A | Medical Device  
医療機器 | Indicates the product is a medical device  
本製品は医療機器であることを示します |
| N/A | N/A | Contents  
内容物 | Number of devices/kits within packaging  
包装内の機器/キットの数 |
| N/A | N/A | Length  
長さ | Indicates length measurement  
長さ測定値を示します |
| N/A | N/A | O.D.  
外径 | Indicates outer diameter  
外径を示します |