Device Description:

The EASYGRIP FLO-41 Precision MIS Delivery System ("EASYGRIP FLO-41 System") is a sterile, single-use device that consists of two components:
- 1 x applicator device with a 41cm long cannula (5mm outer diameter)
- 1 x empty 1.5 mL syringe.


Indications:
The EASYGRIP FLO-41 Precision MIS Delivery System is indicated for delivering compatible hemostatic agents to bleeding sites through a 5mm or larger trocar.

Intended Purpose / Intended Use:
The EASYGRIP FLO-41 Precision MIS Delivery System is intended for delivering compatible hemostatic agents to bleeding sites through a 5mm or larger trocar.

Contraindications:
None

Warnings:
- Single use only. Do not reuse. Do not resterilize. Reuse or reprocessing of a single use device may lead to contamination and compromised device function or structural integrity.
- Do not use the EASYGRIP FLO-41 System if the tray, tray seal, or contents are damaged or open, as this could lead to compromised device function.
- Do not use air as a propellant to extrude hemostatic agent from the EASYGRIP FLO-41 System.
- Do not use the EASYGRIP FLO-41 System to manipulate or retract organs or tissue.
- Do not bend the malleable tip against organs or tissue.

Precautions:
Read the hemostatic agent's instructions prior to using this device.

How Supplied:
The EASYGRIP FLO-41 System is supplied sterile in a sealed plastic tray packed in a product box. The tray contains one (1) applicator device and one (1) empty 1.5 mL syringe. One (1) shipping carton contains six (6) EASYGRIP FLO-41 Systems.

NOTE: The provided syringe is used for optional residual product application; do not use prior to complete application of hemostatic agent.

Directions for Use:

Assembly:
1. Prepare the hemostatic agent per its instructions for use.
2. Inspect the integrity of the EASYGRIP FLO-41 System packaging. If the tray, tray seal, or contents have been opened or damaged, do not use.
3. Using aseptic technique, open tray lid where indicated and transfer contents into the sterile field.
4. Attach the hemostatic agent syringe to the EASYGRIP FLO-41 System fill port, taking care not to overtighten.
5. Taking care not to pull the device trigger, fill the reservoir completely with hemostatic agent.

NOTE: Syringe may be removed if desired.

6. Prime cannula by repeatedly pulling trigger (approximately 2-3 pulls) until hemostatic agent is visible in clear malleable tip. The EASYGRIP FLO-41 System is now ready to use.

NOTE: Once primed, take care not to depress trigger prior to application.

7. Ensure the malleable tip is straight before introducing the cannula into a trocar.
**Initial Product Application:**
8. Carefully approximate the distal end of the malleable tip to the treatment site; use appropriate endoscopic instruments to bend the malleable tip as required for application.
9. Pull the trigger of the EASYGRIP FLO-41 System to apply the hemostatic agent per its instructions. Multiple pulls may be required to apply desired amount of hemostatic agent.  
**NOTE:** For ease of application, apply the hemostatic agent within two (2) hours of reconstitution of the hemostatic agent.

Repeat Product Application (as needed):
1. If additional hemostatic agent is required during the same surgical procedure:
   - fill the reservoir with remaining hemostatic agent, taking care not to depress trigger  
   - or -  
   - attach new syringe of hemostatic agent and fill the reservoir
2. Priming is not needed.
3. Repeat steps 8 and 9 for product application.  
**NOTE:** Do not connect the empty syringe or use the saline prior to complete application of the hemostatic agent.

Residual Product Application (optional):
1. If application of residual hemostatic agent is needed, fill the provided 1.5 mL syringe with non-heparinized saline.
2. Attach saline syringe to EASYGRIP FLO-41 System and fill the reservoir with only 1.5 mL of non-heparinized saline.

For Disposal:
1. After application of the hemostatic agent straighten the malleable tip with appropriate endoscopic instruments prior to removing the applicator from the trocar.
2. Dispose of the EASYGRIP FLO-41 System according to local regulations. **Do not resterilize.**

Storage:
Store between 2°C (36°F) - 25°C (77°F). Store in original packaging.

**Symbols Used in Labeling:**

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Symbol Title and Description</th>
<th>Symbol Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="http://edocs.baxter.com">http://edocs.baxter.com</a></td>
<td>Consult instructions for use; e.g., indicator; indicates the need for the user to consult the instructions for use electronic location.</td>
<td>ISO 15223-1:2016, 5.4.3</td>
</tr>
<tr>
<td></td>
<td>Do not use if package is damaged; indicates a medical device that should not be used if the package has been damaged or opened.</td>
<td>ISO 15223-1:2016, 5.2.8</td>
</tr>
<tr>
<td></td>
<td>Sterile using irradiation; indicates a medical device that has been sterilized using irradiation.</td>
<td>ISO 15223-1:2016, 5.2.3</td>
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<td>Do not resterilize; indicates a medical device that is not to be resterilized.</td>
<td>ISO 15223-1:2016, 5.2.6</td>
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<td>Temperature limit; indicates the temperature limits to which the medical device can safely be exposed.</td>
<td>ISO 15223-1:2016, 5.3.7</td>
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<td></td>
<td>Do not re-use; indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.</td>
<td>ISO 15223-1:2016, 5.4.2</td>
</tr>
<tr>
<td></td>
<td>Not made with natural rubber latex; indicates no presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device.</td>
<td>ISO 15223-1:2016, 5.4.5 and Annex B, Section B2</td>
</tr>
<tr>
<td>Ref</td>
<td>Catalogue number; indicates the manufacturer’s catalogue number so that the medical device can be identified.</td>
<td>ISO 15223-1:2016, 5.1.6</td>
</tr>
<tr>
<td>Lot</td>
<td>Batch code; indicates the manufacturer’s batch code so that the batch or lot can be identified.</td>
<td>ISO 15223-1:2016, 5.1.5</td>
</tr>
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<td></td>
<td>Use-by date; indicates the date after which the medical device is not to be used.</td>
<td>ISO 15223-1:2016, 5.1.4</td>
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<td></td>
<td>Fragile, handle with care; indicates a medical device that can be broken or damaged if not handled carefully.</td>
<td>ISO 15223-1:2016, 5.3.1</td>
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<td></td>
<td>Keep away from sunlight; indicates a medical device that needs protection from light sources.</td>
<td>ISO 15223-1:2016, 5.3.2</td>
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<tr>
<td></td>
<td>Keep dry; indicates a medical device that needs to be protected from moisture.</td>
<td>ISO 15223-1:2016, 5.3.4</td>
</tr>
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<td>This way up; To indicate correct upright position of the transport package.</td>
<td>ISO 7080 - 9623</td>
</tr>
</tbody>
</table>

**U.S. Only:** Rx Only
U.S. Only: 1-888-229-0001  
Other Countries: Contact your local Baxter representative.

Baxter Healthcare Corporation  
One Baxter Parkway  
Deerfield, IL 60015, USA

U.S. Only: These instructions are available electronically at http://edocs.baxter.com. To request a paper copy of this document at no additional cost, call 1-888-229-0001.

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