

INSTRUCTION FOR USE DISPOSABLE BASKETS/GRASPERS

DEVICE DESCRIPTION

Horizons Baskets/Graspers is intended to be used in the flexible endoscopes as a retrieval device for foreign body objects.

INTENDED USE

The Device is intended to be passed through an endoscope's working channel to remove foreign body objects, such as polyps and food boluses.

WARNINGS

- Physicians who have adequate experience and training should only perform endoscopy.
- Please read these instructions carefully, failure to follow these instructions may lead to serious medical consequences.
- This device is for single use only. Do not reuse, reprocess or re-sterilize. Reuse, re-processing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection including, but not limited to, transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury illness or death of patient.
- Used product and packing should be disposed of in accordance with hospital, administrative and/or local government policy.

PRECAUTIONS

- The device is ETO sterile. Do not use this device if there is any evidence of damage to the sterile package.
- Do not use this device for any purpose other than the stated intended use.
- Verify the expiration date on the package label of sterile devices prior to using the product. If the expiration date has lapsed, do not use or re-sterilize the device.

CONTRAINDICATIONS

- 1-General medical condition that would not allow tolerance to endoscopy and/or other manipulation required.
- 2-Patients demonstrating resistance.
- 3-The device may not be used for applications other than for which it is intended.
- 4-The device must not be passed through an incompatible endoscope.
- 5-The device must not be re-sterilized and reused.
- 6-The device is not intended to be implanted.

PREPARING FOR USE

1. Open and remove the Basket/Grasper from the pouch. Note: Uncoil the Basket/Grasper before continuing with preparation to avoid damage.

2. The Basket/Grasper should be visually inspected for kinks and complete product integrity. If any damage is observed, do not use the Basket/Grasper.
3. The Basket/Grasper should be tested prior to being passed through the endoscope's working channel. Test the device by sliding the finger grip forward and backward. The flexible wire and Basket/Grasper should completely extend from and retract back into the tip of the catheter.
4. Verify the working channel of the endoscope is a minimum of 2.8 mm to ensure compatibility with the Basket/Grasper.
5. The Basket/Grasper is now ready for clinical use.

INSTRUCTIONS FOR USE

Note: The Basket/Grasper should be advanced through the endoscope's working channel using short and precise movements to mitigate potential unintended damage to the device or endoscope.

1. Identify the foreign body endoscopically and advance the Basket/Grasper through the endoscope's working channel until the distal end of the catheter is endoscopically visible.
2. The distal end of the catheter should be advanced slightly distal to the foreign body however it is not recommended to advance the device if the foreign body has blocked the entire lumen. The Basket/Grasper should be opened completely by advancing the handle forward until it stops. Endoscopically confirm the net is fully open.
3. The Basket/Grasper should be positioned over the foreign body and rotated into position by rotating the device handle. For best results, the foreign object should be centered or proximal in the net prior to closure.
4. To secure the foreign body, retract the handle until the net closes around the foreign body. The Basket/Grasper should be carefully opened and closed with gentle traction applied until the entire foreign body is retrieved. Excessive traction may cause damage to the device and/or the foreign body.
5. The Basket/Grasper should then be retracted toward the endoscope so that it is visible, yet not compromising the endoscopic view to ensure visibility during removal of the device and foreign body.
6. Once the scope, device and foreign body have been removed, the foreign body can be collected from the Basket/Grasper by advancing the handle forward to open the net. The foreign body should be processed per procedural standards.
7. Once retrieval is complete, the device should be closed by advancing the handle and removed from the endoscope's working channel.

Any serious incident that has occurred in relation to the device must be notified to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

Accessing Electronic Versions of IFU - Step-by-Step Guide

1. Start by opening a web browser on your device and enter the official website URL for Horizons Corp: <https://www.horizonscorp.com>.

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- Once the website loads, you will be directed to the main page, which features various tabs and options. Look for the tab labeled "Products."
- Click on the "Products" tab to access a dropdown menu that categorizes different product options. Within this tab, you can choose the specific product category that aligns with your requirements. Alternatively, you can enter the following URL <https://www.horizonscorp.com/products> which will take you directly in the product pages
- Within your chosen product category, you will find a list of individual devices or models. Select the specific device that corresponds to your needs.
- After selecting the device, the main page will load with comprehensive information about the chosen product. At this point, you will have multiple options to explore, including "Specifications," "IFU," "Brochure," or "Video."
- To access the Instructions for Use (IFU), click on the "IFU" option. This will lead you to a section where the latest revision of the readable IFU is presented in an electronic format

- In the IFU section, you will have the opportunity to view and read the most recent version of the IFU directly on the webpage. Additionally, if you prefer, you can choose to download a PDF copy of the IFU for offline reference.
- If you are interested in accessing previous revisions of the IFU, you can find these versions within the same IFU section. Look for the category labeled "Previous Versions."

By following these steps, you will be able to access and utilize electronic versions of the Instructions for Use (IFU) for Horizons Corp products. Remember to make use of the IFU to ensure the proper and safe use of the products as intended.



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Symbol	Description	Symbol	Description
	Contry of manufacture		Translation
	Date of manufacture		Do not use if package is damaged
	Use by date		Do not re-use
	Batch Code		Consult instructions for use
	Catalogue number		Important cautionary information
	Sterilized using ethylene oxide		Do not re-sterilize
	Caution Federal (USA) law restricts this device to sale by or on the order of a physician		Latex Free
	Keep Away from Sunlight		Keep Dry
	Type BF applied part		Medical Device
	Importer		Authorized Representative
	Unique device identifier		Sterile Barrier