

# INSTRUCTION FOR USE DISPOSABLE HOT BIOPSY FORCEPS

## DEVICE DESCRIPTION

- Horizons Disposable Hot Biopsy Forceps are a monopolar electrosurgical unit for endoscopic polypectomy.

## INTENDED USE

- Horizons Disposable Hot Biopsy Forceps is intended to be used in the flexible endoscope for Transendoscopic, dissecting and grasping tissue for biopsy.
- The device is intended to be used for patients with polyps in the gastrointestinal tract
- The device is intended to be used by licensed physicians with adequate training and experience in the removal of polyps from the gastrointestinal tract under endoscopic visualization.

## INTENDED USERS

The device is intended to be used by licensed physicians only (excluding non-physician specialists) with adequate training and experience in collect tissues samples, from the gastrointestinal tract under endoscopic visualization.

## INDICATIONS

The Biopsy Forceps (Hot) is indicated for endoscopic procedures when the doctor needs to be able to collect tissue from within a patient's body or body cavity.

When selecting the Biopsy Forceps (Hot) for use, the physician shall the suitability of the device for the patient age and anatomy. In general, a 2.5mm diameter device is designed for adults (aged 21 or over). A 1.7mm diameter device is indicated for pediatrics (excluding neonates and infants).

## ENVIRONMENT OF USE

The intended environment of use is at a physician's office or hospital operating room

## CONTRAINDICATIONS

- General medical condition that would not allow tolerance to endoscopy and/or other manipulation required.
- Patients demonstrating resistance.
- The device may not be used for applications other than for which it is intended.
- The device must not be passed through an incompatible endoscope (colonoscopy, gastroscopy and bronchoscopy).
- The device must not be re-sterilized and reused.
- The device is not intended to be implanted.

## WARNINGS

- It is suggested that the operator and the assistant wear protective gloves to prevent accidental burns. Universal precautions should be used in all cases. While operating the device avoid contact with the patient.
- Warning: This device is not intended to be used in the presence of flammable liquid, in an oxygen enriched atmosphere or in the presence of explosive gases.
- Any electrosurgical device constitutes a potential electrical hazard to the patient and/or the operator.
- No modification of this device is allowed.

- Fluid or flammable agents that may poll under the patient or in body depressions or cavities should be mopped prior to electro surgery.

## CAUTION

- Endoscopy should only be performed by a physician who has adequate experience and training.
- 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.
- Monopolar diathermy or electrosurgical cautery in patients with pacemaker or implantable cardiac defibrillators can result in electrical reset of the cardiac device, inappropriate sensing and/or therapy, tissue damage around the implanted electrodes, or permanent damage to the pulse generator. A cardiologist should be consulted prior to using Hot Biopsy Forceps in these patients.

## PRECAUTIONS

### For Hot Biopsy Forceps

- 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.
- Hot Biopsy Forceps must be used in conjunction with a Type BF or CF generator. The active cord (sold separately) is connected to the snare handle by a plug pushed onto the connector as far as possible so that none of the connecting pin is visible. The other end of the active cord is inserted into the generator. Always follow the manufacturer's suggestions for the operation of the unit to prevent unnecessary hazard to the operator and/or the patient. Consult the neutral electrode manufacturer about the proper grounding of the patient. It is recommended that a monitoring neutral electrode be used, if a contact quality monitor is available, or built into the generator. The entire area of the neutral electrode should be attached reliably to the patient's body, and as close to the operating field as possible. The patient should not come into contact with metal parts or objects that may be grounded to earth. The use of antistatic sheeting is recommended for this purpose.
- When using Hot Biopsy Forceps, Skin-to-skin contact should be avoided (for example between the patient's arms and body) by way of dry cloth or gauze. Monitoring electrodes should be placed as far from the surgical area as possible. Needle monitoring electrodes are not recommended. Avoid incidental contact between Active Cords and the patient's body, or any

other electrodes. In order to ensure that the insulating properties of the Hot Biopsy Forceps are not compromised, do not exceed the maximum rated peak voltage of 2500 for cut mode and 2500 for coagulation mode. The output power setting selected should remain under 50 Watts, yet be as low as possible for the intended purpose.

- When using Hot Biopsy Forceps, flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the procedure. It is very important if the proper setting of the generator is not known one should set the unit at a power setting lower than the recommended range and cautiously increase the power until the desired effect is achieved. Based on the medical literature, a power setting of 40 to 50 watts is typically achieved.
- Possible safety hazards may result from gas embolism caused by over-insufflation of air, inert gas prior to high frequency surgery, etc. Endogenous gases should be sucked away if possible prior to procedure. Patient leakage currents from endoscope, as well as energized hot Biopsy Forceps, are additive.
- Please review the operations and service manuals of the electro-surgical generator for the proper set and operation prior to using Hot Biopsy Forceps.
- Monopolar diathermy or electro-surgical cautery in patients with pacemaker or implantable cardiac defibrillators can result in electrical reset of the cardiac device, inappropriate sensing and/or therapy, tissue damage around the implanted electrodes, or permanent damage to the pulse generator. A cardiologist should be consulted prior to using Hot Biopsy Forceps in these patients.
- Should be used with caution and only after careful consideration in patients who are at risk for bleeding complications.

#### INSTRUCTIONS FOR USE

- For Hot Biopsy Forceps
- Follow steps 1 to 4 above.
- Attach the correct active cord to the handle and plug into generator. Set the generator to the pre determined settings.
- Maneuver the forceps towards the targeted site. Open the cups by activating the handle. Advance the opened forceps over the targeted site and close the forceps. Use only enough pressure to bite the tissue. Over-exertion could cause forceps to become misaligned or to fail.
- The time and power settings should be determined clinically to control hemostasis.
- Once the biopsy has been completed and hemostasis has been attained, the procedure can continue to the next step.
- Continue to apply gentle pressure on the handle as the forceps are withdrawn from the channel.
- Remove and prepare the tissue specimen according to standard technique for histologic evaluation.

#### REPORTING

- Customer in the EU shall report any serious incident associated with the device to their National Competent Authority, distributor, and Horizon International Corporation.
- 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>.
2. Once the website loads, you will be directed to the main page, which features various tabs and options. Look for the tab labeled "Products."
3. 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
4. Within your chosen product category, you will find a list of individual devices or models. Select the specific device that corresponds to your needs.
5. 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."
6. 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
7. 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.
8. 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		Refer to instruction manual/ booklet
	Sterile Barrier		