General Instructions for Vented Instrument Guards-Translucent

EN **INTENDED USE:** Vented Instrument Guards are accessories intended to minimize the risk of mechanical damage to medical instrument tips during routine handling, transport, sterilization, and storage.
This device is SINGLE USE.

KEY SPECIFICATIONS OF PRODUCT:
- Compatible with steam sterilization.
- Translucent Blue color.
- Vented, and Cylindrical styles.

INSTRUCTIONS FOR USE:
- To be placed on the tip of the instrument.
- Fit each instrument with the appropriate size tip.

1. Place Vented Instrument Guard on the appropriate size instruments prior to sterilization.
2. Package instruments in sterile barrier system as detailed in the instrument's Instructions for Use.
3. Process as indicated in the instrument's Instructions for Use.

STERILIZATION:
- *Pre-vacuum Sterilizer:* Vented Instrument Guards have been validated and should be exposed to:

Steam Sterilization			
Cycle Type	***Temperature***	***Minimum Time - Full Cycle***	***Minimum Validated Dry Time***
Pre-Vacuum	132° C(270 °F)	4 minutes	20 minutes
Pre-Vacuum	134° C(273°F)	18 minutes	20 minutes
Pre-Vacuum	135° C(275°F)	3 minutes	20 minutes

- *Gravity Steam Sterilizer:* Vented Instrument Guards have been validated and should be exposed to:

Gravity Displacement Sterilization			
Cycle Type	***Temperature***	***Minimum Time - Full Cycle***	***Minimum Validated Dry Time***
Gravity	121° C (250° F)	30 minutes	20 minutes

PERFORMANCE CHARACTERISTICS: Compatible with standard steam sterilization cycles (pre-vacuum and gravity) without material degradation. Provides physical protection for instrument tips during sterilization, transport, and storage. Vented design allows sterilant penetration to instrument surfaces. Maintains secure fit on compatible instrument tips.

CONTRAINDICATIONS: No contraindications for this device.

WARNINGS/PRECAUTIONS:
- Tip protectors must be **removed prior to clinical use**. Failure to remove the device may result in interference with instrument function or contribute to a retained surgical item (RSI).
- **Single use only:** This device is intended for single use. Reuse may result in contamination, material degradation, or compromised protection.
- **Fit matters:** Ensure the protector is appropriately sized and fully seated on the instrument. An improper fit may reduce protective function or fail to prevent tip damage.
- Use outside of validated cycles (e.g., excessive time or temperature) may lead to material degradation or loss of function.

REPROCESSING INSTRUCTIONS: No reprocessing is possible for this family of **SINGLE USE** products. Single use only. Do not re-use.

STORAGE AND HANDLING:
- Store in a clean, dry environment at room temperature.
- Avoid exposure to direct sunlight or extreme temperatures.
- Do not use if the device is damaged, deformed, or visibly contaminated prior to use.
- Do not use if package is damaged.

LATEX FREE: not made with natural rubber latex

DISPOSAL REQUIREMENTS: Dispose of the products according to your facility's waste protocols and local, state and federal regulations.

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

This product is intended for use only by qualified healthcare professionals, such as sterilization technicians, sterilization managers, or other personnel trained in instrument reprocessing.

REF 09-2-011, 09-2-012, 09-2-013, 09-2-014, 09-2-015, 09-2-016, 09-2-017, 09-2-018, 09-2-019, 09-2-020

Symbols Used	
REF	Catalog Number
MD	Medical Device
UDI	Unique Device Identifier
LOT	Lot Number
eIFU	Consult Instructions for Use
	Caution/ Warning
	Expiration date. Do not use after the expiration date.
	Single use
	Do not use if package is damaged.
	Date of Manufacture
CC e.g. US, MX	Country of Manufacture
	Manufacturer healthmark Healthmark Industries Company, Inc 18600 Malyn Blvd. Fraser, MI 48026, USA
	Keep dry
	Keep away from sunlight
	Storage Temperature
LATEX	Latex Free
CE	CE Mark – Indicates compliance with the requirements of the Medical Device Regulation
	Importer
EU REP	EU Authorized Representative
UK REP	UK Authorized Representative

IFU-EDU-000569, V3 SAUDI, 8-SEP-2025