

# HaloShield™

## NIPPLE PROTECTOR

FP0112-01B



 MANUFACTURER

 TEMPERATURE LIMIT

 USE-BY-DATE

 DO NOT REUSE

 ATTENTION, SEE INSTRUCTIONS FOR USE

 KEEP DRY

 STERILE  EO STERILIZED USING ETHYLENE OXIDE

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## HALOSHIELD™ NIPPLE PROTECTOR

### PRODUCT DESCRIPTION

The HaloShield™ Nipple Protector is a skin-adhering, compression resistant device composed of a transparent plastic dome and form fitting base.

### INTENDED USE

The HaloShield™ Nipple Protector is intended to be used as a wound cover protector for the areola and nipple in breast reconstruction or surgery.

**Rx ONLY** This symbol means the following:

**CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.**

**NIPPLE PROTECTOR** This symbol means the following: Nipple Protector.

### PRECAUTIONS

- This device is designed for single use only. Attempts to reprocess, resterilize and/or reuse may lead to device failure and/or transmission of disease.
- Do not resterilize.
- The protector is sterile if the packaging is dry, unopened and undamaged. Do not use if the package seal is broken.
- Discard the protector if mishandling has caused possible damage, contamination, or if the protector is past its expiration date.
- The protector should not be placed in direct contact with breached or compromised tissue.

### POTENTIAL COMPLICATIONS

Complications that can occur with use of the protector include, but are not limited to:

- Inflammation
- Abrasion
- Skin Irritation
- Pain
- Infection
- Tissue Necrosis
- Wound Dehiscence
- Allergic Reaction
- Nipple Compression

If infection, acute or chronic inflammation, or allergic reaction occur and cannot be resolved, protector removal and discontinuation should be considered.

### STORAGE

The protector should be stored in a clean, dry environment at room temperature.

### STERILIZATION

The protector has been sterilized with ethylene oxide.

### INSTRUCTIONS FOR USE

#### Procedure

1. Measure nipple projection to ensure that the protector can accommodate the nipple.  
**NOTE:** The protector is available in two configurations:
  - a. HaloShield™ Nipple Protector (G46289) has a maximum clearance of 10 mm.
  - b. HaloShield™ Nipple Protector Extended (G46290) has a maximum clearance of 20 mm.
2. Measure nipple diameter.
3. Remove the sterile protector from the product pouch.
4. If the nipple diameter is larger than 12mm then remove the perforated inner section of the protector base. This will make the protector compatible with the larger diameter.
5. Prior to securing the protector to the breast mound, place silicone tape, 3M™ Steri-Strip™, or other appropriate barrier to prevent direct contact of the protector with breached or compromised tissue.  
**NOTE:** Consider wrapping the nipple with a non-adherent dressing to prevent any direct contact between the protector dome and the nipple.
6. Remove the protector adhesive release liner from the protector base using the provided tab, exposing the adhesive.
7. Orient the dome vents vertically to prevent moisture from collecting during use.
8. Adhere the protector to dry skin around the nipple.
9. Once the protector is adhered, press lightly on the protector base to ensure complete and even contact of the adhesive to the breast mound.
10. If the protector loses its adhesive properties, becomes disassembled, or acquires a crack in the dome, discard and replace it with a new one.  
**NOTE:** To ensure best outcomes, advise the patient on the proper post-operative use and application of the HaloShield™ Nipple Protector according to these instructions.