

Advance Medical Design's Probe Cover Equipment Cover

General Description

AMD's Probe Cover Equipment Cover product family is intended to be used to maintain a sterile field or barrier by covering equipment such as microscopes, ultrasonic probes and tables that may be used by or within the area while a health care worker performs an operation or procedure. Equipment covers come in various widths and lengths. The intended user of this product is a nurse, technician, or physician and the intended patient population is any individual of the general public, undergoing a medical procedure. They are not intended for use by lay persons. The equipment cover product family is intended for single use, to cover a variety of different pieces of equipment in a vast array of surgical or radiological settings.

Materials

The Equipment Cover family consists of 340 covers that are predominately thin and flat sheets that are folded multiple times. Construction materials include Low Density Polyethylene, Polyethylene, Polypropylene, Polyurethane, Polyethylene Vinyl Acetate, EVA Foam, Metallocene, and Non-woven Rayon. The equipment cover family is designed to cover a large range of equipment, from a complex camera to a tabletop. Products can consist of a single bag that covers a simple piece of equipment to a bag that contains a lens, tie straps, and elastic band, but all serve the same function.

Warnings

- Do not use and dispose of properly if the package appears opened or damaged.
- Do not re-sterilize.
- Do not use and dispose of properly if the package opening is after the expiration date.
- Dispose of single-use components as infectious waste.
- Do not allow sharp objects to come in contact with this product.
- Do not operate equipment without proper medium required for the equipment cover product's intended use.

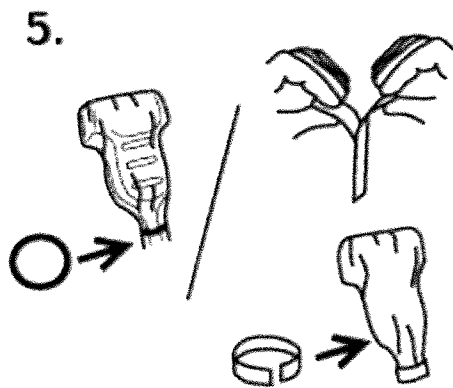
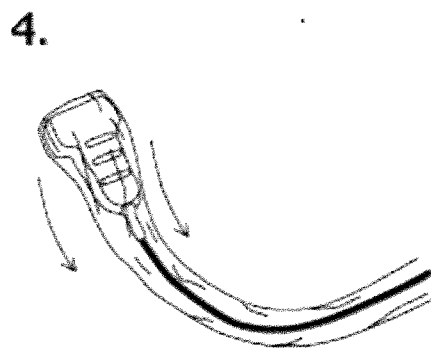
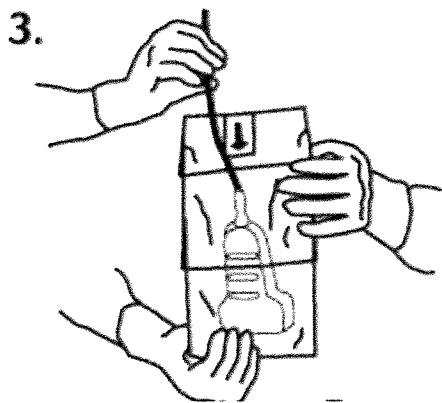
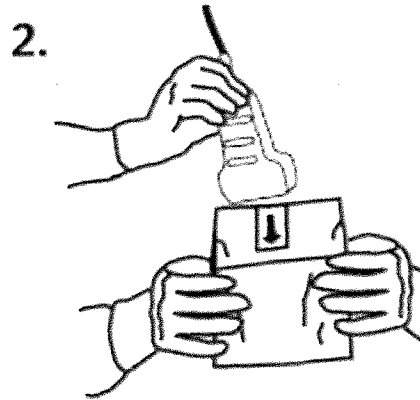
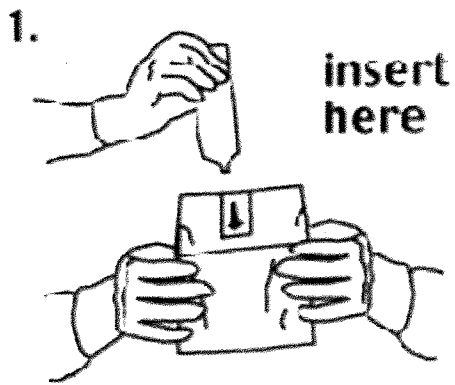
Intended Use

The Equipment Covers product family is intended to be used to maintain a sterile field or barrier by covering equipment such as microscopes, ultrasonic probes and tables that may be used by or within the area while a healthcare worker performs an operation or procedure.

Indications for Use

1. The sterile cover has been removed from the packaging using aseptic technique.
2. Unfold the product and affix/cover to the probe transducer equipment.
3. The procedure occurs.
4. Dispose of the product as infectious waste.

AMD PROBE COVER



Contraindications and Prohibitions

The equipment cover product family helps to maintain a clean working environment for the medical professionals. AMD's equipment cover product family has no pharmacological, immunological, nor metabolic mode of action. There are no contraindications for use.

Potential Risk of Reuse

The Probe Cover Equipment Cover is a single use disposable medical device. If the Device were to be reused there would be a risk of contamination of the Sterile Field and potential risk to health and safety of the patient.

Disposal

The Probe Cover Equipment Cover is a single use disposable device. The device is to be disposed of as infectious waste after use.

Notice to User

Any serious incident should be reported to the manufacturer and the Competent Authority of the member state.

Sterility

AMD's Equipment Covers are sterilized by ethylene oxide [EO].














Storage and Handling

Standard Warehouse Conditions

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Visit AMD's Website for a full list of Products and Information for Users

www.advancemedicaldesigns.com

SYMBOL	DEFINITION
	Reference number
	Do not Re-Sterilize
	Expiration date
	Caution, consult accompanying documents
	Manufacturer
	Do not Reuse for single use only.
	Sterilized with Ethylene Oxide
	Lot number/batch code
	Do not use if package is damaged.
	Latex-Free.
	Medical Device
	Single Sterile Barrier
	Prescription Use Only