

Introduction

This document provides instructions for installing the Equipment Drape Set for the Affirm™ prone breast biopsy guidance system. The Drape Set is used to prevent fluids from contaminating portions of the C-arm assembly.

The Drape Set consists of three sections:

- drape for breast platform (with a clear plastic pop-up section to cover the paddle mount)
- drape for the biopsy device mount (with a flap section for inside the paddle)
- clear cover for the control panel



Warning:

Change the drapes and the control panel cover after each patient.



Warning:

Discard the materials as you would any other potentially contaminated material.

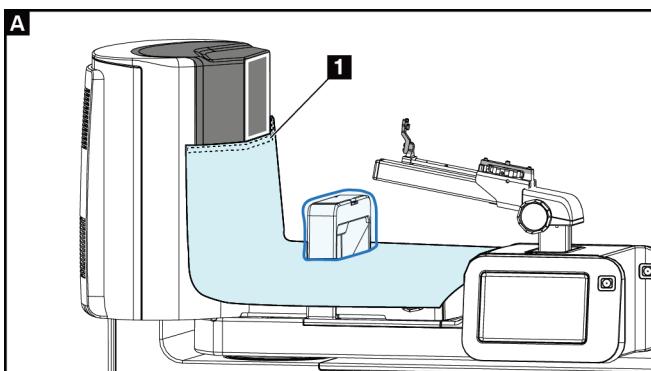
Installation

Note

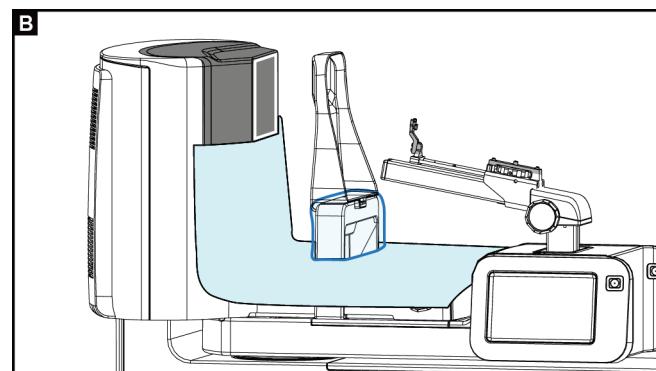


Install the drapes *before* attaching a biopsy device.

Place the blue (absorbent) side of the drape facing up.



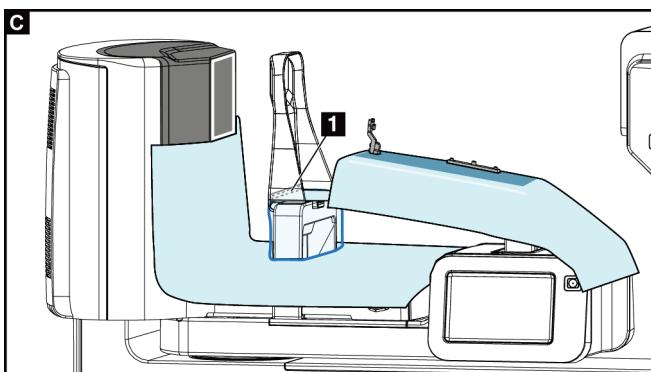
Install drape on breast platform and over paddle mount; peel off adhesive under drape (item 1) and attach to image receptor right below white square (do not cover white square area)



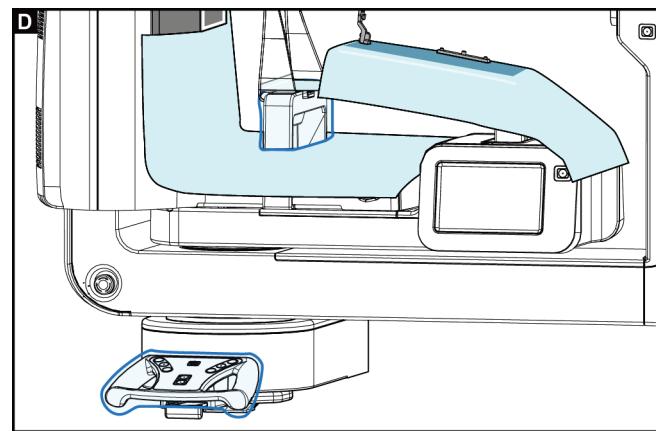
Reach under drape and attach paddle

Affirm Prone Biopsy System Equipment Drape Set

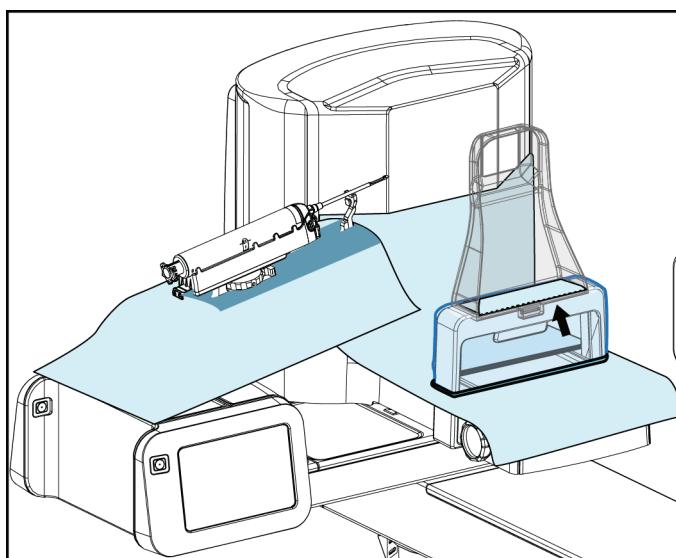
User Instructions



Install drape over biopsy device mounting assembly;
peel off adhesive under drape flap (item 1) and attach
to paddle bottom



Wrap clear cover over the control panel



When using a lateral approach, separate drape flap at perforation (arrow)

Symbols

This section describes the Symbols on this Drape Set.

| Symbol | Description | Symbol | Description | Symbol | Description |
|--------|---------------------|--------|-----------------------------------------------------|--------|-------------------------------|
| | Manufacturer | | Quantity | | Follow operating instructions |
| | Date of Manufacture | | Batch code | | Do not re-use |
| | Catalog number | | Authorized representative in the European community | | Non-sterile |