

## 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 the 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.**

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**Warning:**

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

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## Installation



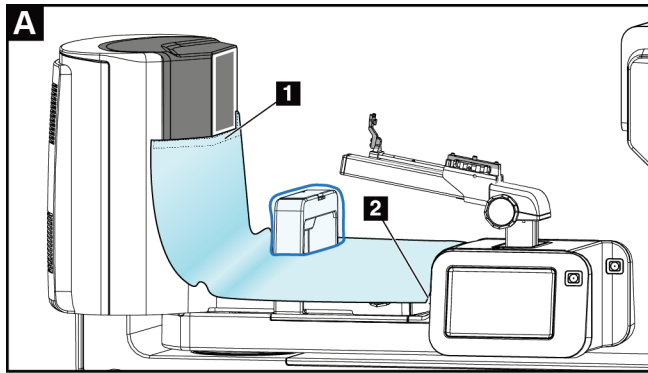
**Note**

Keep in mind the following when installing the drapes:

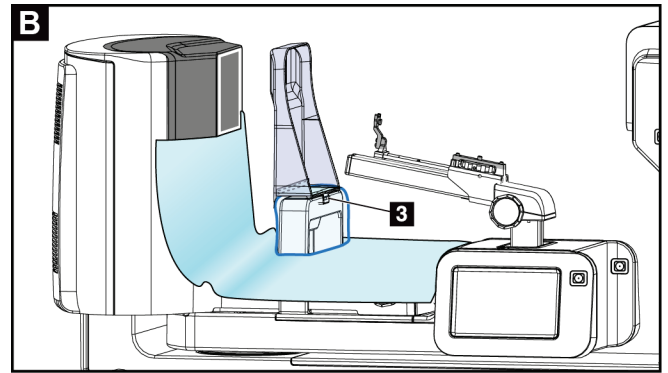
- Install the needle guide holder on the biopsy device mount *before* installing drapes.
  - Install the paddle and biopsy device in the order marked in these illustrations.
  - Place the blue (absorbent) side of the drape facing up.
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# Affirm Prone Biopsy System Equipment Drape Set

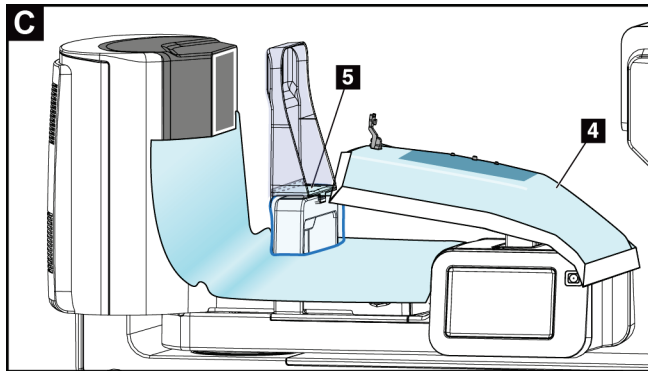
User Instructions



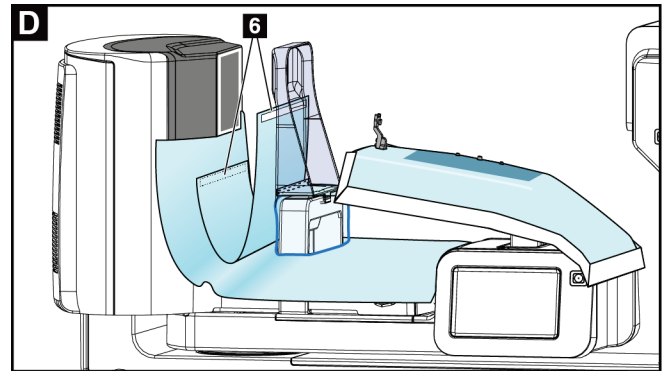
Install breast platform drape section on breast platform and over paddle mount. Peel off adhesive under drape (item 1) and attach to image receptor right below white square (do not cover white square area). Tear off excess drape at perforation (item 2) and save for later.



Attach paddle on the paddle mount (item 3) over the clear plastic pouch section of the drape.



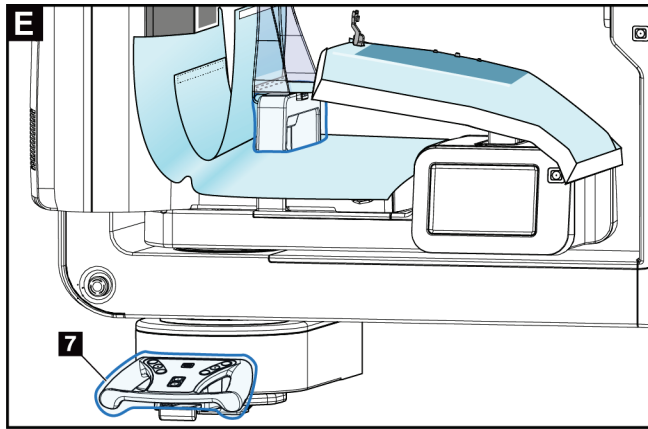
Install biopsy device mount drape section over biopsy device mount (item 4). Make sure the three protrusions and needle guide holder from the biopsy device mount line up with the respective openings in drape section. Peel off adhesive under drape flap (item 5) and attach to bottom of paddle.



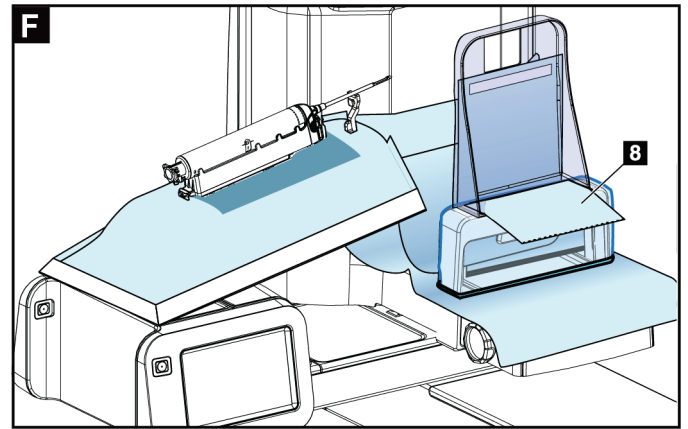
Locate previously torn off drape section and insert between paddle and breast platform to catch fluid leakage. Peel off adhesive on ends and attach to paddle and breast platform (item 6).

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## User Instructions










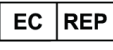








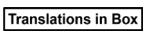
Install the clear cover (item 7) over the control panel.



When using a lateral needle approach, separate biopsy drape flap at perforation (item 8).

## Symbols

This section describes the Symbols on this Drape Set.

Symbol	Description	Symbol	Description	Symbol	Description
	Manufacturer		Quantity	 <a href="http://www.hologic.com/package-inserts">www.hologic.com/package-inserts</a>	Consult Instructions for Use (Hologic)
	Date of Manufacture		Batch code		Do not re-use
	Catalog number		Authorized representative in the European community		Non-sterile
	CE Mark European Conformity		Country of Manufacture		Prescription use only
	Medical device		Vendor Code		Caution
	Revision		Translations in Box		

