



Food and Drug Branch – Device Recalls

**CALIFORNIA DEVICE RECALL INFORMATION SHEET**

**Intuitive Recalls Sterile Drapes for DaVinci Xi & X Surgical Robots for Incorrect Expiration Date**

Recall Date	Product Description	Recalling Firm	Recall Reason
11/19/2021	<p><b>X/Xi Instrument Arm Drape</b>            IS4000PC/IS4200PC            The da Vinci Xi and X surgical systems (IS4000 and IS4200) each consist of three main components: the Surgeon Console (SC), the Vision Cart (VC), and the Patient Cart (PC). The Patient Cart is the operative component of the system and its primary function is to support the instrument arms and camera arm. The X/Xi Instrument Arm Drape is intended to be used with the instrument arms of the PC as a sterile barrier during clinical procedures, and makes the instrument arms sterile and suitable for surgery. X/Xi Instrument Arm Drapes are sterile unless the package is opened or damaged, and are indicated for a single use. The drapes are placed onto the instrument arms by two users (one sterile and one non-sterile) in tandem, with the non-sterile user leading the placement via drape cuff pockets.</p>	<p><b>Intuitive Surgical Inc.</b>            Sunnyvale, California</p>	<p>Incorrect expiration date on its package labeling (shipper box and inner carton label).</p>

Recall Class	Product Identification	Distribution	Affected Dates
II	<p><b>X/Xi Instrument Arm Drape</b>            1 Part number: 470015-07; Lot number: DM4210309; REF: 470015; UDI # 00886874112199.</p>	<p>8 Boxes in California</p>	<p>9/2021 and prior</p>

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