

Codman® Surgical Patties CODMAN Surgical Strips

ENGLISH
IMPORTANT INFORMATION Please Read Before Use
CODMAN® Surgical Patties CODMAN Surgical Strips
R[®] TM
STERILE EO
Description CODMAN® Surgical Patties and CODMAN Surgical Strips are manufactured of COTTONOID® Material with x-ray detectable markers. All patties have a suture string attached for ease in performing posturgical count verification.

This product is for SINGLE USE ONLY; DO NOT RESTERILIZE. Use aseptic technique in all phases of handling. Integra Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or resterilization, after a single patient use. These devices are intended to come into contact with the central nervous system and the ability does not currently exist to destroy possible contaminantes such as Creutzfeldt-Jakob Disease. Reuse can also compromise device performance and any usage beyond the design intent of this single-use device can result in unpredictable use hazards or loss of functionality.

Warnings
Do not leave patties or strips in situ. Failure to remove them may result in a foreign body reaction.

Avoid cutting the patties or strips because fragsments without x-ray detectable material may enter the surgical site. Fragments left in the surgical site may result in an unintended adverse reaction, including a foreign body reaction.

Precautions
The string attached to the patties is for identification purposes only. Do not use the string to pull the patty from the wound.

This device is considered radiopaque in accordance with ASTM Test Method F640 (Standard Test Methods for Radiopacity of Plastics for Medical Use). The device may not be visible under all radiographic conditions. The size and position of the marker may impact radiopacity. In addition, adjacent structures may inhibit visibility.

It is recommended that at least three views, using the optimal parameters for the imaging (x-ray) equipment, at a variety of angles (e.g., 45 degrees, 22.5 degrees, and 0 degree angles) for anterior and posterior, or the appropriate plane, be taken and examined for a missing device. If there are

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concerns regarding visualization, consult with your local imaging expert to establish the optimal radiographic parameters (e.g., kVp, mAs) for visualzation with the imaging equipment.

The locator strings attached to the patties will not be visible by x-ray as they are not radiopaque. The locator strings are for identification purposes only; avoid using the strings to remove the patties from the surgical site to prevent detachment.

Count all devices before and after the procedure prior to surgical closure. In the event a device cannot be located, an x-ray can be used to locate the device. Only the radiopaque markers are visible on imaging. The size and position of the radiopaque markers may impact their visibility.

Sterility
(2)

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