ArmourSorb™ neurosurgical device

Instructions For Use

DESCRIPTION
ArmourSorb™ is a pattie with a proprietary impermeable and pliable layer that imparts unique characteristics intended for use during neurosurgical procedures. ArmourSorb™ is manufactured from high performance materials and is supplied sterile. The actual size of ArmourSorb™ may vary slightly from the size shown on the label. All ArmourSorb™ devices are disposable and should never be reused.

INDICATIONS
ArmourSorb™ is indicated for use by trained physicians during neurosurgical procedures to protect neural tissues from drying, abrasion, or contamination and to absorb fluids.

WARNINGS
Teflon left inside the body may cause a granuloma.

Do not use ArmourSorb™ if received in an open or damaged package.

Do not use ArmourSorb™ if expiration date has passed.

Do not use ArmourSorb™ if damaged or discolored, placed on Mayo Stands, or exposed to contamination.

Do not leave ArmourSorb™ in situ. Failure to remove may result in foreign body reaction.

Do not cut ArmourSorb™. Fragments without X-ray detectable strips may enter the surgical site. Failure to remove these fragments may result in foreign body reaction.

Count all ArmourSorb™ devices prior to placing in the operational field and again after removal from the operational field. Failure to perform counts may result in additional procedures.

The threads attached to ArmourSorb™ devices are for identification purposes only. Avoid using threads to remove ArmourSorb™. Avoid drill burr contact with thread.

Do not place a dry ArmourSorb™ device in the field or permit the device to dry out.

Discard all unused ArmourSorb™ devices that are not contained in their original, intact package.

Particulate matter can be generated with drill burr contact on the device and thus, thorough irrigation of the surgical field is recommended after drilling of the calvarium or skull base.

Avoid direct contact with ArmourSorb™ device when using a high speed drill.

Discard ArmourSorb™ device if defective and absorbent layers begin to separate.

Do not resterilize. This product is disposable and should never be reused to prevent any contamination or cross-contamination from previous use.

STORAGE
Packages of ArmourSorb™ should be stored in a clean, uncontaminated area at a temperature between 4°C and 30°C (40°F to 86°F) and at a relative humidity level between 20% and 70%. If package becomes wet, it must be discarded.

PACKAGE OPENING
When opening the outer pouch to expose ArmourSorb™, observe standard aseptic practices approved by your institution.

WARRANTY
American Surgical Company warrants that these devices are of merchantable quality and free from defects. The user of these medical devices must determine their suitability for any medical procedure. American Surgical Company shall not be liable for any incidental or consequential damages. Manufactured in the USA subject to USFDA and ISO 13485:2012 control.

CONTROL OF MATERIALS
Count all devices to assure control. Count all devices before the procedure and again after the procedure prior to surgical closure. If there is a question about count, an X-ray can be used to locate the devices via their X-ray detectable strips. Take 3 pictures using predetermined strength at 45°, 22.5°, and 0° angles anterior and posterior or the appropriate plane. Establish X-ray strength and time by prior testing on equipment that will be used.

PREPARATION FOR USE
All ArmourSorb™ devices must be thoroughly soaked in sterile water or physiologic saline solution and squeezed thoroughly prior to use. Since the devices may initially resist wetting, the soaking and squeezing increases absorbency and softens the patties. Do not cut across the stitching of ArmourSorb™. Prior to placing ArmourSorb™ device on tissue, ensure that the deflective layer is facing up and absorbent layer is facing tissue.

CAUTION
Federal (USA) Law restricts ArmourSorb™ to sale by or on the order of a physician or his/her representative.

Sterilized by Ethylene Oxide in Accordance with BS EN ISO 11135-1; 2007

MANUFACTURED BY
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