AMERICAN™ SURGICAL COMPANY
www.AmericanSurgical.com

Sterilized by Ethylene Oxide in Accordance with BS EN ISO 11135-1; 2014

STERILE	EO

Neurosurgical Patties:

Delicot, Uniqcot, Ray-Cot, Policot, Telfa® (TRADEMARK OF COVIDIEN PLC), Americot, Ultracot

Table 1 Neurosurgical Patties

Substrate	Product	Property	Additional layer
Cotton	Americot	Absorbency	None
Cotton	Ultracot	Moisture Retention	None
Cotton	Telfa®	Low adhesion	PET
Polyester	Policot	Strength	None
Rayon	Delicot	Pliability	None
Rayon	Uniqcot	Fluid Aspiration	None
Rayon	Ray-Cot	Strength	None

Instructions for Use:

DESCRIPTION:

Neurosurgical patties are intended to be used during neurosurgical procedures. They are manufactured from high performance materials. The actual size of the patty may vary slightly from the size shown on the label. All neurosurgical patties are disposable and should never be reused.

INDICATIONS:

Neurosurgical patties are indicated for use in the protection of neural tissue during surgery.

WARNINGS:

Do not use patties on patients that may have sensitivity to the sponge materials (cotton, rayon, polyester).

Do not use patties if expiration date has passed.

Do not use patties that are damaged, discolored, or exposed to contamination.

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

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

Count all patties 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 the patties are for identification purposes only. Avoid using threads to remove patties.

Discard all unused patties that are not contained in their original, intact package.

This product is disposable and should never be reused to prevent any contamination or cross-contamination from previous use.

PACKAGE OPENING:

When opening the outer pouch to expose the patties, observe standard aseptic practices approved by your institution.

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CONTROL OF MATERIALS:

Count all patties before the procedure and again after the procedure prior to surgical closure. Patties having attached strings are supplied with notched holders to aid in final counting. If there is a question about count, an x-ray can be used to locate the patties 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 neuropatties, whether constructed of cotton, rayon, polyester, Telfa® (TRADEMARK OF COVIDIEN PLC) or another material, must be thoroughly soaked in sterile water or physiologic saline solution and squeezed thoroughly prior to use. Since the patties may initially resist wetting, the soaking and squeezing increases absorbency and softens the patties. The washing of the sponge brings it to a neutral P.H. cleansing the sponges of any saline soluble residue and free fibers. Do not place a dry patty in the field or permit the patty to dry out. Do not cut across the stitching of the patty. Thorough irrigation and aspiration of the surgical field is recommended to remove any observable particulate matter.

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 13485:2016 control.

CAUTION:

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

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SYMBOLS:

Symbol	Description	Symbol	Description
	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.		Indicates a medical device that needs to be protected from moisture.
EC REP	Indicates the authorized representative in the European Community.		Indicates a medical device that should not be used if the package has been damaged or opened.
	Indicates the date after which the medical device is not to be used.	30°C 4°C	Indicates the temperature limits to which the medical device can be safely used.
LOT	Indicates the manufacturer's batch code so that the batch or lot can be identified.	70% 20%	Indicates the range of humidity to which the medical device can be safely exposed.
REF	Indicates the manufacturer's catalog number so that the medical device can be identified.	LATEX	Indicates the absence of natural rubber or dry natural latex as a material of construction within the medical device or the packaging of the medical device.
STERILE EO	Indicates a medical device that has been sterilized using ethylene oxide.	STERILIZE	Indicates a medical device that is not to be resterilized.
	Indicates the need for the user to consult the instructions for use.		Indicates the need for the user to consult the instructions for use for important cautionary information such as warning and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.		