

PETIPAD™ (NEUROSURGICAL SPONGES)**MATERIAL SAFETY DATA SHEET****Product name:** Petipad™ neurosurgical sponges**Ref nos. of sets containing Petipad:** 06130 - 06220**Product and Company Identification****Product name:** Petipad™ neurosurgical sponges, other companies supplying similar product under the following names: Paddies, Neurosponge, neurosurgical pads, compressed cotton, patties, Cottoniod®**Intended Use:**

1. It protects the brain and other tissues against injury by contact from instruments during surgical procedures.
2. It absorbs fluids during surgical procedures.
3. It acts as a filter for aspiration during surgery.
4. It helps to control bleeding during surgical procedures.

Supplier: Manufacturer:

Pollak (International) Ltd

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Indications

Protects the brain and other tissues against injury by contact from instruments during surgical procedures. Absorbing fluids during surgical procedures. Filter for aspiration during surgery. Controlling bleeding during surgical procedures.

Composition/Information on Ingredients:

pad	Viscose fibers (Rayon) Polyester fibers Polyurethane coating	79.97032 % 19.99258 % 0.03709 %
Blue coated X-Ray Thread	Textile thread – polyester280 dctx Barium Sulphate P.V.C Color Phtalocyanine Blue	60.0000 % 39.9999 % 0.0001 %

Properties:

Compressed non-woven material cut into various rectangular or round sizes into which is incorporated X-Ray detectable guiding thread that does not protrude over the surfaces of the pad permitting the use of both surfaces.

When washed in Saline water, the debris in the water does not exceed 0.05% of the weight of the pad when dry.

Both surfaces of Petipad™ are smooth preventing adherence to human tissue when covered by dry blood.

APPLICATION OF PETIPAD™

Sponges are wet with saline or sterile water prior to use. They are then squeezed and placed onto the brain tissue for absorption of fluids, or to protect the tissue. In certain procedures, a suction tube is placed over the sponge to absorb fluids that gather within the treated area, thus facilitating cleaner and clearer access without interference of excess fluids which may hamper the surgeon's visibility. During surgery, soiled sponges are removed and replaced with fresh ones. In some cases, whilst infected tissues are removed, the surgeon uses PETIPAD™ to cover & protect cleaned areas, and continues to work in another affected area. Larger sized PETIPAD™ sponges are used to protect the skull walls during neuro-surgical procedures. Prior to use, the original pack should be delivered to the operating theater. The first pack should be opened in aseptic conditions, and sponges are then removed from the second inner pack in sterile and aseptic conditions.

Hazards Identification:**Emergency Overview:**

PETIPAD™ is removed before the end of the surgical procedure.

PETIPAD™ is very small, and the surrounding areas where they are used during surgery are saturated with blood and other fluids. Sponges can easily be forgotten or lost in the brain or surrounding areas. The

sponge has an X-Ray detectable thread and extending guiding thread, to ensure that it is completely X-Ray detectable and cannot be lost or forgotten during/after surgery.
PETIPAD™ must be removed by means of forceps only. The guiding string is not meant for pulling/removing the pad.

Contraindication:

PETIPAD™ are packed in packs of 10. If a pad is missing after completion of surgery, the operated area must be X-Rayed.

Do not use if pack is damaged or open.

Signs and Symptoms of Overexposure - N.A

First Aid Measures

If a sponge is missing - X-Ray the operated area.

Fire Fighting Measures – N.A

Autoignition temperature: N.A.

Hazardous combustion Products: - N.A

Accidental Release Measures:

Material is compressed to solid, no spillage measures are required.

Caution; take care not to cut X-Ray guiding thread.

Caution; when loosening guiding thread from cardboard, take care not to peel away blue coating (rare phenomena).

Handling and Storage:

PETIPAD™ sponges are double packed in a sterile rigid transparent tray, 10 sponges per pack, - 20 packs per carton. PETIPAD™ should be stored in its original carton. Prior to use, the original pack should be delivered to the operating theater. The first pack should be opened in aseptic conditions, and sponges are then removed from the second inner pack in sterile and aseptic conditions.

Storage Precautions: Store in cool, dry place.

Exposure Control/Personal Protection

Engineering Controls: General exhaust is adequate

Eyes: None necessary under normal conditions of use.

Respirator: None necessary under normal conditions of use.

Skin: None necessary under normal conditions of use.

Other: None necessary under normal conditions of use.

Work/Hygienic Practices: Practice good personal hygiene.

SHELF LIFE

Following sterilization (PETIPAD™ is supplied only in sterile form) the product has an unlimited shelf life, provided that it is stored in the original packaging. Pollak (International) Ltd. manufacturers of PETIPAD™ has a policy of limiting the shelf life of PETIPAD™ to a period of FIVE (5) years after the date of sterilization, provided that the packs are not damaged or opened or tampered with in any way.

PETIPAD™ STERILIZATION INFORMATION

PETIPAD™ is sterilized by ETO (Ethylene Oxide 20% and Carbon Dioxide CO₂ 80%)

ETO sterilization is conducted according to ISO –11135 standards and has been validated and approved by the USA FDA and our CE Competent Authority.

Microbial Tests: according to USP 24, page 1816.

Results: Products were found sterile.

Stability and Reactivity

General: Stable

Incompatible Materials: Strong Oxidizing Agents

Conditions to Avoid: Exposure to excessive Heat.

Hazardous Decomposition/Hazardous Combustion: N/A

Hazardous Polymerization: In temperature exceeding 60°C

BIOCOMPATIBILITY TESTS

Biocompatibility Tests: conducted according to the relevant paragraphs in USP 24, page 861 – “ Absorbent Gauze” - replacing “gauze” by “sponges”.

The results were in the requested limits, as follows:

Acid/Alkali	Neutral
Absorption per second	2 sec.
Water extract	0.8%
Starch – Dextrin	none
Ether Soluble substances	0.21%
Water holding capacity of own weight	6.9 minimum up to 12.1 maximum
Surface active substances	OK

Physical and Chemical Properties

Appearance: Smooth cut edges with no debris.

Vapor Pressure: N.A.

Solubility in Water: NO

Melting point: N.E.

Boiling Point: N.A.

Odor: No discernable odor

Vapor Density: N.A.

Specific Gravity: N.E.

Percent Volatility (by wt): N.A.

Toxicological Information:

Carcinogenicity:

IARC: no

NTP: no

OSHA: no

LD50: N.E.

LC50: N.E.

Ecological Information:

NE

Disposal Considerations:

Dispose or incinerate in accordance with all applicable regulations for disposed medical products.

Transportation Information:

No specific requirements to be met; not regulated as a hazardous material.

Regulatory Information:

USA – FDA – 510K # K914600

CE =Class III device

Other Information:

Legends: NA= not applicable NE = Not Established ND = Not Determined

Approved by:

POLLAK (INTERNATIONAL) LTD – Quality Assurance

Approval Date : March 2nd 2010

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