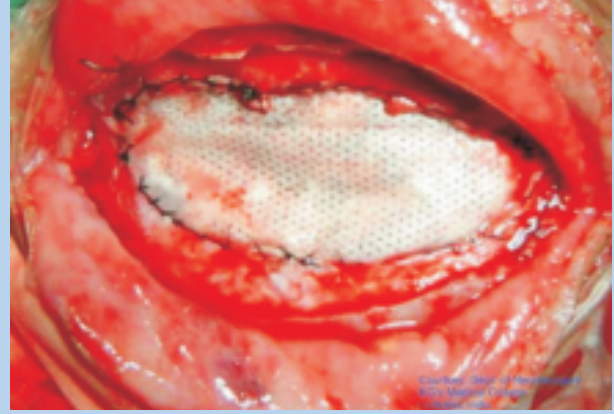


G-PATCH/ G-PATCH-2 SYNTHETIC FABRIC PATCH



d DESCRIPTION

The SURGIWEAR "SYNTHETIC FABRIC PATCH" is designed to repair defects in soft tissues & reinforcement of soft tissues such as DURAMATER, Peritoneal pleura etc. The patch is made of Poly Propylene (same as PROLENE Mesh). G-Patch-2 is made of High Density Polyethylene) Each pack contains one patch.

G-Patch is available in three sizes and custom sizes as well.

i INDICATIONS

G-Patch is indicated for repair of Duramater, repair of peritoneum or places, where ever soft tissue repair is required.

c CONTRAINDICATIONS

Presence of all kinds of infection (meningitis, ventriculitis, skin infection, bacteremia, septicemia and peritonitis etc.) whether local or general, prohibits all kind of implantation procedures. It is advisable to avoid implantation in such cases.

G-Patch is not a strong fabric. It should not be used in places where large tensile forces are expected. In such places stitch may not hold and it may give way and torn.

m METHOD OF USE

Surgical Procedure

The implantation of G-Patch is a simple procedure. The patch is shaped and cut as per requirement. It is stitched with the tissue around the defect. Special care is required to use it as dura substitute. Water tight stitching is required to avoid leakage of CSF.

It should not be used without reinforcement in repair of peritoneum. The choice of exact procedure depends upon the training of neurosurgeon, customs

in that hospital, country. Therefore the surgeon is best advised to use method, which his/her own practice and training dictate to be best for the patient.

h HOW SUPPLIED

G-Patch is supplied in three sizes. Custom sizes are also available. These are available sterile by EO gas in double peel open packing.

G-Patch

Small 8 x 10 cm	GP01
Medium 10 x 12 cm	GP02
Large 15 x 20 cm	GP03

G-Patch-2

Small 8 x 10 cm	GP01-2
Medium 10 x 12 cm	GP02-2
Large 15 x 20 cm	GP03-2

w WARNINGS

This device has not been tested for compatibility with all drugs and therefore should be used with caution.

Occasionally, fibrous adhesions or fibrosis will bind the patch with the adjacent tissues. Tissues may adhere with it. This adhesion may cause harm. Inflammation and or foreign body reaction may occur in surrounding tissues and organs. Excessive tension may tear the patch.

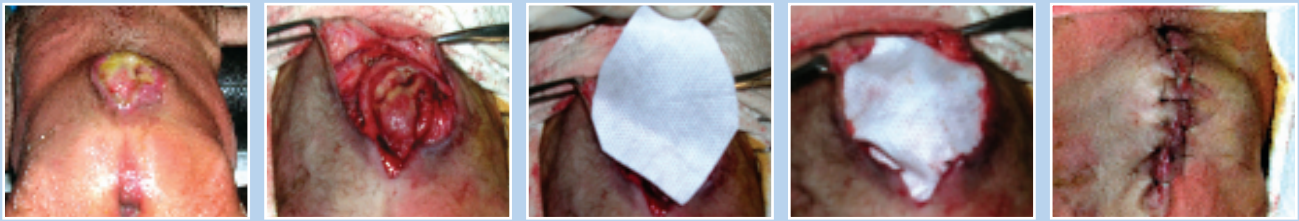
p PRECAUTIONS

Prior to surgery, prospective patients and or their representative should be informed of the possible complications associated with the use of this product.

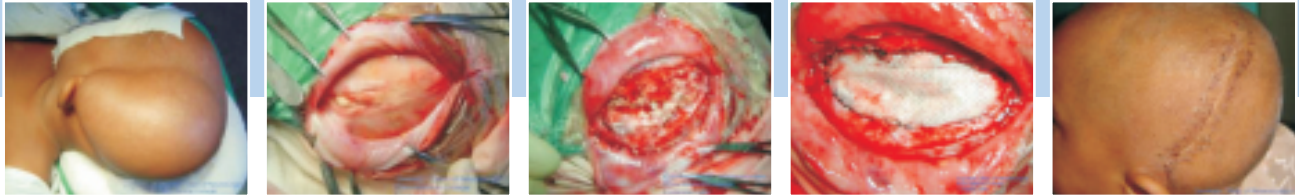
The patch should be carefully secured to the surrounding tissue with ligatures in such a manner as to avoid cutting or tearing the patch.

be all free from disease & sufferings

SURGIWEAR®
AN ISO 13485 : 2003 COMPANY



A case of Meningomyelocele



A case of growing skull fracture

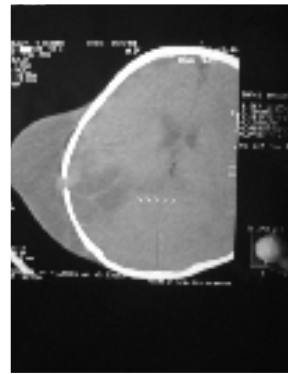
C COMPLICATIONS

Complications which may result from the use of this product include the risks associated with the medication and methods utilized in the surgical procedure, as well as patients response, reaction or degree of intolerance to any foreign object implanted into the body.

The principal complications associated with "Synthetic Fabric Patch" implantation are functional failure and infection.

Functional failure of "Synthetic Fabric Patch" due to separation of its component parts can result in serious complications.

Infection is a common and serious complication of implantation and is most frequently caused by skin contaminants. Septicemia, which occurs most frequently in debilitated infants, can result from infections anywhere in the body and may develop with few or no symptoms. It may occur as a result of a wound infection. The presence of a foreign body may trigger ventriculitis or a dormant meningitis. Lesions developing from the breakdown of tissue may also act as foci of serious infections. In the event of an infection, removal of "Synthetic Fabric Patch" is indicated in addition to appropriate therapy.



Pre operative CT Scan



Post operative CT Scan

PRODUCT INFORMATION DISCLAIMER

G. Surgiwear Limited has exercised reasonable care in the choice of materials and manufacture of this product. G. Surgiwear Limited excludes all warranties, whether expressed or implied by operation of law or otherwise, including, but not limited to any implied warranties of merchantability or fitness for a particular purpose. G. Surgiwear Limited shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from use of this product. G. Surgiwear Limited neither assumes nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this product.

Photo Courtesy : Dept. of Neurosurgery K G College, Lucknow

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