



Gelfoam®

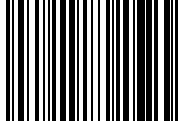
absorbable gelatin sponge, USP

PHARMACIA

DESCRIPTION

GELFOAM Dental Sponges are small, sterile, surgical sponges prepared from specially treated and purified gelatin solution which is beaten to desired porosity, dried, sectioned, packaged, sealed, and sterilized by dry heat. GELFOAM is pliable, and is capable of absorbing and holding within its meshes many times its weight in

Gelfoam
absorbable gelatin
sponge, USP



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whole blood. It is used as a hemostatic device.

ACTIONS

When implanted in tissues, GELFOAM Dental Sponges are completely absorbed within four to six weeks without inducing excessive scar tissue.

INDICATIONS AND USAGE

Hemostasis: In oral and dental surgery, GELFOAM Dental Sponges are an aid in providing hemostasis. GELFOAM may be used either dry or moistened, depending upon conditions present at operation and preference of the surgeon. Isotonic saline is suitable for use with GELFOAM. Although not necessary, GELFOAM can be used either with or without thrombin to obtain hemostasis.

DIRECTIONS FOR USE

When used dry, GELFOAM Dental Sponges, cut to desired size, are rolled between the fingers and lightly compressed to the approximate diameter of the cavity or socket to be filled. Following insertion of the rolled pack, light finger pressure should be applied for one or two minutes.

When used moistened, GELFOAM, cut to desired size, is immersed in the solution of sodium chloride. The piece is then removed from the solution, squeezed thoroughly to remove air bubbles present in the meshes, and replaced in the solution where it will swell to its original size. It is then taken from the solution, blotted on sterile gauze to remove excess fluid, and placed in the cavity or wound. For use with thrombin, consult the thrombin insert for complete prescribing information and proper sample preparation.

CONTRAINDICATIONS

GELFOAM Dental Sponges should not be used in closure of skin incisions because they may interfere with the healing of skin edges.

WARNINGS

This product should not be resterilized by heat, because heating may change absorption time. Ethylene oxide is not recommended for resterilization because it may be trapped in the interstices of the foam. Although not reported for GELFOAM Dental



Composition Unit 2566

COMPOSITION ORDER # 20964	PRODUCT GELFOAM (Dental Sponges)	COPY CODE # 812 243 512	
CCS # 0396-04	NDC #	EDP # 691320	
ITEM Insert	SIZE 2.5 x 12"	FOLDED SIZE 2.5 x 1"	DRAWING # PD1779 Rev. 1
ADDITIONAL INFORMATION		DATE 08/27/03	TYPESET BY DHUFF

Document Approval Record

Signed By:	Date (EST):	Action:
Joe Volpe	2004-04-13 15:37:37	Approved