NuStat®
hemostatic dressing

DESCRIPTION

NuStat® consists of a sterile X-Ray detectable hemostatic dressing and is packaged for aseptic removal.

INDICATIONS

NuStat® is indicated for temporary control of internal organ space bleeding for patients displaying class III or class IV bleeding. It may also be used for control of severely bleeding wounds such as surgical wounds and traumatic injuries.

CONTRAINDICATIONS

- Do not leave NuStat® in place for more than 48 hours
- NuStat® is not indicated for intraluminal vascular use

WARNINGS

- NuStat® is not absorbable and must be removed from the wound prior to wound closure
- Adhesion formation associated with NuStat® dressing use was noted in preclinical studies; adhesions were also observed with control materials. It is not known whether adhesion elicited by NuStat® dressings are equivalent to those caused by control materials
- Long-term implantation of silica in the human abdominal cavity is unknown. When used in animal studies, no adverse events related to the silica particulates have been identified, and tissue response was comparable to control devices. To minimize the number of particulates in the body, ensure that copious irrigation and lavage of the abdominal cavity should be performed at the time NuStat® is removed
- Results of bench testing showed that both NuStat® product and QuikClot Control+® had particulate levels that were too numerous to count. The Lap Sponge device in low particulate water (LPW) had particulate counts of 1008, 2042, and 2756 that were ≥10 um and particulate counts of 392, 702 and 1160 that were ≥25 um. When tested in acidified water, the particulate counts for the Lap Sponge were TNTC at both size ranges. This testing demonstrated that NuStat® product and the predicate QuikClot Control+® were equivalent in the shedding of particulates over a 48-hour period. In addition to particulate counts, further testing (characterization) of the particulates from each of the three devices has been performed using Fourier Transform Infrared Spectroscopy to determine the characterization of the particulates. The results of the FTIR are as expected for all three devices; FTIR has identified materials that are constituents of the devices, or materials associated with their manufacture. The FTIR demonstrated NuStat® particulates were comprised of silica and cellulose and rare contaminants. The FTIR demonstrated the QuikClot Control+® particulates were comprised of kaolin, rayon, polyester and rare contaminants. The FTIR results for particulates from the Lap Sponge were primarily rayon with some calcium salts and other rare contaminants.

SUMMARY OF PARTICULATE COUNT DATA

TEST ARTICLE	PARTICLES PER DEVICE	
	≥ 10 µm	≥ 25 µm
NuStat® LPW #1	TNTC	TNTC
NuStat® LPW #2	TNTC	TNTC
NuStat® LPW #3	TNTC	TNTC
NuStat® Acid #1	TNTC	TNTC
NuStat® Acid #2	TNTC	TNTC
NuStat® Acid #3	TNTC	TNTC
QuikClot Control+® LPW #1	TNTC	TNTC
QuikClot Control+® LPW #2	TNTC	TNTC
QuikClot Control+® LPW #3	TNTC	TNTC
QuikClot Control+® Acid #1	TNTC	TNTC
QuikClot Control+® Acid #2	TNTC	TNTC
QuikClot Control+® Acid #3	TNTC	TNTC
Lap Sponge LPW #1	~2,042	~702
Lap Sponge LPW #2	~1,008	~392
Lap Sponge LPW #3	~2,756	~1,160
Lap Sponge Acid #1	TNTC	TNTC
Lap Sponge Acid #2	TNTC	TNTC
Lap Sponge Acid #3	TNTC	TNTC

PRECAUTIONS

If bleeding persists, additional product may be applied to the wound

STERILITY AND EXPIRATION

- Product is sterilized by exposure to gamma radiation and is intended for single use only
- Do not attempt to re-sterilize the device by any means
- Do not use if the sterile pouch is damaged or opened
- Do not use the device after the expiration date listed on the package

STORAGE CONDITIONS

Keep dry. Keep away from heat, including storage in direct sunlight or in direct contact with heat sources.

INSTRUCTIONS FOR USE

1. Verify the expiration date on the package labels prior to using the product. Open package and remove NuStat® dressing.
2. Apply NuStat® dressing to the wound and apply pressure until bleeding is controlled. More than one dressing may be required. **NOTE:** If needed, additional gauze or a pressure dressing may be applied to maintain pressure. The time for formation of a stable clot may vary depending on several patient factors.
3. If required by the patient's condition, NuStat® may be left at the site of application for up to 48 hours.
4. Remove the dressing and repair the wound, if necessary.
5. **Copiously irrigate the NuStat® dressing application sites as well as the entire abdominal cavity and completely suction irrigation fluid prior to wound closure.**

PRODUCT NAME	SIZE	UNITS PER BOX	ORDER NUMBER
NuStat Trauma Pad® XR	8" x 12"	10	XR-0812
NuStat Trauma Pad® XR (5-Pack)	8" x 12"	25	XR-0812-5

See IFU

Do not use if package is damaged

Keep dry

Do not reuse

STERILE R Sterilized using irradiation

Do not resterilize

℞ ONLY Caution: U.S. Federal law restricts this device to sale by or on the order of a physician

Not made with natural rubber latex

Developed and manufactured by:

BEEKEN BIOMEDICAL®

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