

GAZE

With X-ray detectable thread / Without X-ray detectable thread
INTENDED PURPOSE AND CLINICAL BENEFIT
Ribbon gauze is intended to be used for:
- For packing natural body orifices and surgical wounds.
- Mode of action: includes absorption of drainage and fluids, support, application of pressure to achieve haemostasis or as a carrier for administration of medications.

INDICATIONS
- For nasal packing (treatment of epistaxis; for administration of medicinal substances).
- For ear packing (for administration of medicinal substances e.g. treatment of otitis externa).
- For use in otitis media (e.g. for absorption of body fluids; for post-surgical packing; for stabilization of bony pieces).

INSTRUCIONES DE ESTERILIZACIÓN
The device must be packaged within a sterile barrier system (SBS), permeable and compatible with Moist Heat and/or Ethylene Oxide (EO) gas sterilization and with the packaging materials used for the sterilization process. The system shall comply with EN ISO 16067-1/2 and EN ISO 15765-2:2021. It is the responsibility of the processor to ensure the appropriate and effective packaging under controlled environmental conditions. The below Moist Heat and EO sterilization process parameters have been validated for the device (e.g. for absorption of body fluids; for post-surgical packing; for stabilization of bony pieces).
- Maximum density of the sterilization load must be 100kg/m³.
- Packaging comprising a maximum of 3 levels, being paper/film peel-pack the SBS (acc. to EN ISO 16067-1/2 and EN 868-5), card and carton box the protective packaging; sterility assurance level of 10⁻⁶.

CYCLE PARAMETERS	SPECIFICATION	DURATION
Vacuum/Air removal	100mbar x 3 cycles	-
Exposure temperature	121-124°C	5min. OR 20min.

CYCLE PARAMETERS	SPECIFICATION	DURATION
Minimum temperature during pre-conditioning	20 °C	-
Temperature	33 - 46 °C	-
Humidity	50 ± 15 %RH	22-27h

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RIBBON GAUZE

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- Mode of action: includes absorption of drainage and fluids, support, application of pressure to achieve haemostasis or as a carrier for administration of medications.

INDICATIONS
- For nasal packing (treatment of epistaxis; for administration of medicinal substances).
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- Maximum density of the sterilization load must be 100kg/m³.
- Packaging comprising a maximum of 2 levels, being paper/film peel-pack the SBS (acc. to EN ISO 16067-1/2 and EN 868-5), card and carton box the protective packaging; sterility assurance level of 10⁻⁶.

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MECHA DE GAZE

Com fio raiável a raios X / Sem fio raiável a raios X
INTENDED PURPOSE AND CLINICAL BENEFIT
A mecha de gaze destina-se a ser utilizada:
- Para tamponamento de orifícios corporais naturais e de feridas cirúrgicas.
- Modo de ação: inclui drenagem e absorção de fluidos, suporte, aplicação de pressão para atingir a hemostase ou como portador para administração de medicamentos.

INDICAÇÕES
- Para tamponamento nasal (ex. tratamento de epistaxis; para administração de medicamentos).
- Para tampão de ouvido (para administração de medicamentos e.g. tratamento de otite externa).
- Para tamponamento de feridas cirúrgicas (e.g. para curar feridas abertas, para estabilização de ossos).

INSTRUCIONES DE ESTERILIZACIÓN
O dispositivo deve ser embalado num sistema de barreira estéril (SBS), permeável e compatível com calor húmido por calor húmido e/ou gás de óxido de etileno (EO) e com os parâmetros de esterilização que serão descritos no presente documento. O sistema deve estar embalado de acordo com as normas EN ISO 16067-1/2 e EN ISO 15765-2:2021. É da responsabilidade do processador seleccionar um SBS adequado e proceder ao processo de embalagem em condições ambientais controladas. Os seguintes parâmetros do processo de esterilização por calor húmido e EO foram validados de acordo com a EN ISO 16067-1/2 e EN ISO 15765-2:2021, para calor húmido e EO, para EO.
- Densidade máxima da carga de esterilização deve ser 100kg/m³.
- Embalagem composta por no máximo 2 níveis, sendo o papel/filme peel-pack a SBS (de acordo com a EN ISO 16067-1/2 e EN 868-5) e a caixa de cartolina a embalagem de protecção.
- Nível de garantia de esterilidade de 10⁻⁶.

PARÂMETROS DO CICLO	ESPECIFICAÇÕES	DURAÇÃO
Temp. durante a exposição	121-124°C	5min. OR 20min.

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