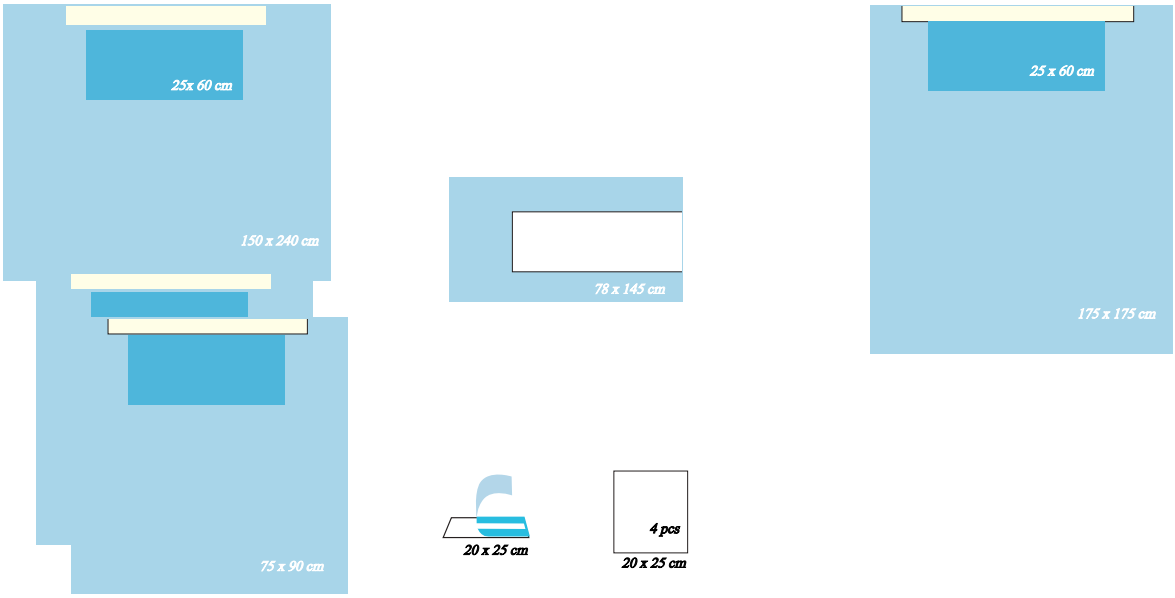
General Surgery Pack - Large



Contents and Description:

A)	1	145 X 80 cm	Mayo Stand cover
B)	1	150 X 240 cm	Instrument Table Cover
		40 X 40 cm	Extra absorbing
C)	1	175 X 175 cm	Adhesive Drape
		60 X 40 cm	Extra absorbing
D)	2	75 X 90 cm	Adhesive drape
		90 X 40 cm	Extra absorbing
E)	1	20 X 25 cm	Op-tapes
F)	4	20 X 25 cm	Hand towels

Use Destination:

- Sterile patient protection and surgical field isolation during General Surgery procedures.

Characteristics:

- Optimal drapery
- Anti-contamination wrapped drape
- Latex free
- Suitable bending to guarantee the total respect of the corrected aseptic technical in the creation Of the operating field.

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Date: 2022.11.24 13:16:10 EET
Reason: MoldSign Signature
Location: Moldova

Materials used:

- Patient drapes made of nonwoven chemical bonded viscose fabric 54 g/m²
- Op-Tape made of nonwoven azure hydro-repellant SMS 43 g/m²
- Instrument Table Cover; Instrument Table made of absorbent nonwoven 35 g/m² and PE film 45 g/m²
- Hand Towels; Scrim Thread Configuration-3''x2''/square inch
  Basis weight-65 GSM; (+/- 10%) Caliper –Embossed Color- White, virgin

Storage and dispose:

- The product is disposable.
- After use, the product should be disposed of in medical waste containers without contact with persons or persons.
- The product should be kept away from damp environment, away from direct sunlight.

Sterilization:

- The sterilization process is carried out with ETO according to EN 11135-1 standard.
- Shelf life 5 years.

Conformity:

- Medical Device Directive 93 / 42 / EEC
- CE Certificate no:2195-MED-1404008
- Notified Body SZUTEST UYGUNLUK DEGERLENDIRME A.S. /2195
- Conformıty Assesment: Annex II-Full Quality Assurance System
- Classification: Medical Device Directive-ANNEX IX, RULE 1, CLASS Is
- The product design works were carried out according to EN ISO 13485 standard.
- According to standard EN ISO 10993-1 biocompatibility tests were performed and the products were found to be biocompatible.
- Tests made according to EN 13795 indicate that the product has performance characteristics.

Packaging:

- Its packaging meets requirements of EN 11607-1.
- The packing process is carried out in a clean room designed according to requirements of EN 14644.
- Single packaging in sterile TYVEK bag.

Warnings / Precautions:

- The sterilized product must be opened in the operating room environment.
- The sterility of torn wrapped products is impaired. Please do not use.
- Do not use packages that do not have a chemical ethylene oxide indicator or whose indicator color does not change.