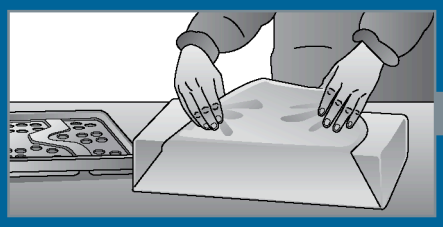

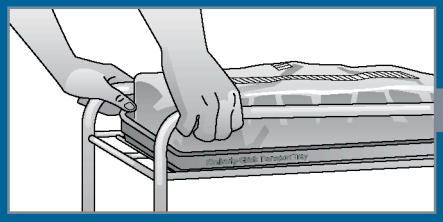

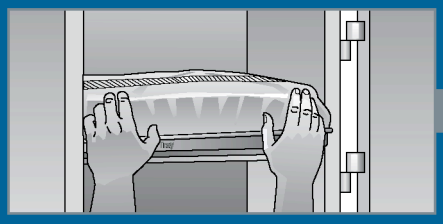

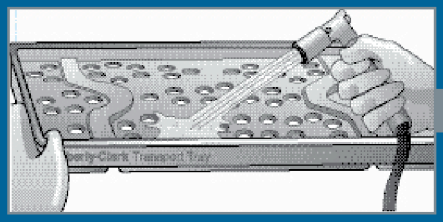

How to Use the KIMBERLY-CLARK* Transport Tray:

1 Identify set on which Transport Trays will be used. (The inner measurements of Transport Trays are either 11.5" wide x 21.5" long to correspond to full-size instrument baskets or 17" wide x 27.5" long to accommodate larger baskets.)

2 Wrap instrument set according to your normal procedure.

3 Place wrapped set into Transport Tray. (Until set is ready to be unwrapped in the O.R., it should always be transported in Transport Tray.)

4 Using Transport Tray to lift and support wrapped set, move entire unit to the sterilizer per normal hospital procedure. (Transport Trays can be used in both steam autoclave and ethylene oxide sterilizers.)

5 After cool down, move wrapped set and Transport Tray to sterile storage area to await use in the O.R.

6 As trays are needed in the O.R., place wrapped set and Transport Tray on case cart for transport. If you do not have a case cart system, move set and Transport Tray per your normal procedure.

7 In the O.R., remove wrapped set from Transport Tray prior to unwrapping.

8 Return Transport Tray to sterile processing area.

9 Reprocess Transport Tray in same manner as your instrument sets.

10 After cleaning and decontamination, Transport Trays can be reused.

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KIMBERLY-CLARK* Transport Tray

Test: Pre-Vacuum Steam Penetration Study

Methodology[1]

Four full-size surgical instrument sets, containing 16 pounds of instruments and five biological indicators each, are double-wrapped with KIMGUARD* Heavy-Duty Sterile-Wrap and placed in KIMBERLY-CLARK* Transport Trays. As controls, four duplicate sets are also assembled but not placed in transport trays. Each set is then exposed to a sublethal/fractional high-vacuum steam sterilization cycle with no drying time. After each fractional cycle, the biological indicators are cultured to verify organism kill.

Interpretation of Results

Results are expressed as percentage of biological indicators sterilized at specific time intervals.

Pre-Vacuum Steam Penetration Study Results

Exposure Time	Wrapped Set Without Transport Tray	Wrapped Set With Transport Tray
1 minute	100%	100%
2 minutes	100%	100%
3 minutes	100%	100%
4 minutes	100%	100%
5 minutes	100%	100%

Conclusion

KIMBERLY-CLARK* Transport Trays allow for acceptable steam penetration and sterilization.

Test: Ethylene Oxide Penetration Study

Methodology[2]

Two full-size surgical instrument sets, containing 16 pounds of instruments and five biological indicators each, are double-wrapped with KIMGUARD* Heavy-Duty Sterile-Wrap and placed in KIMBERLY-CLARK* Transport Trays. As controls, two duplicate sets are also assembled, but not placed in transport trays. Each set is then exposed to a minimum ethylene oxide sterilization cycle: 105 minutes exposure with 12 hours aeration.[3] After sterilization, the biological indicators are cultured to verify organism kill.

Interpretation of Results

Results are expressed as percentage of biological indicators sterilized.

Ethylene Oxide Penetration Study Results

Exposure Time	Wrapped Set Without Transport Tray	Wrapped Set With Transport Tray
105 minutes	100%	100%

Conclusion

KIMBERLY-CLARK* Transport Trays allow for acceptable ethylene oxide penetration and sterilization.

Test: Ethylene Oxide Residual Analysis

Methodology[4]

A KIMBERLY-CLARK* Transport Tray is cut into 4"x s6" pieces and placed into the standard AAMI test pack for EO residual testing and sterilized in an ethylene oxide gas sterilizer.[5] Immediately following sterilization, the transport tray pieces are tested for the amount of residual ethylene oxide (EO), ethylene chlorohydrin (ECH) and ethylene glycol (EG). Additional samples are allowed to aerate for 8 and 12 hours and then tested.

Interpretation of Results

The test results are expressed as parts per million (ppm) retained after the specified amount of aeration time. Low retention levels are desirable.

Ethylene Oxide Residual Analysis Results

	KIMBERLY-CLARK* Transport Tray Sterilant Residual Level (ppm)		
Aeration time	EO	ECH	EG
0 hours	98.6	ND	73.8
8 hours	43.1	ND	31.2
12 hours	24.9	ND	10.0
Maximum limit proposed by 1978 FDA guidelines for sterile medical devices contacting skin[6].	250	250	5,000

Conclusion

KIMBERLY-CLARK* Transport Trays retain a very low level of EO residuals, well below the maximum limits proposed by the 1978 FDA guidelines.

References

1 Nelson Laboratories, Inc., Salt Lake City, Utah, "Pre-Vacuum Steam Penetration Study," Protocol No. 931203-2, Laboratory No. 52631.
2 Nelson Laboratories, Inc., Salt Lake City, Utah, "Ethylene Oxide Penetration Study," Protocol No. 931205-2, Laboratory No. 52630.
3 "Good Hospital Practice: Ethylene Oxide Sterilization and Sterility Assurance," ANSI/AAMI ST41-1992, AAMI, July 13, 1992, Section 5.9.1, p.11.
4 Nelson Laboratories, Inc., Salt Lake City, Utah, "Ethylene Oxide Residual Analysis," Protocol No. 930201-3, Laboratory No. 53153.
5 "Good Hospital Practice: Ethylene Oxide Sterilization and Sterility Assurance," Section 7.6.1, p. 18.
6 "Ethylene Oxide, Ethylene Chlorohydrin, and Ethylene Glycol: Proposed Maximum Residue Limits and Maximum Levels of Exposure," 43 Federal Register, June 23, 1978, p. 27474.

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