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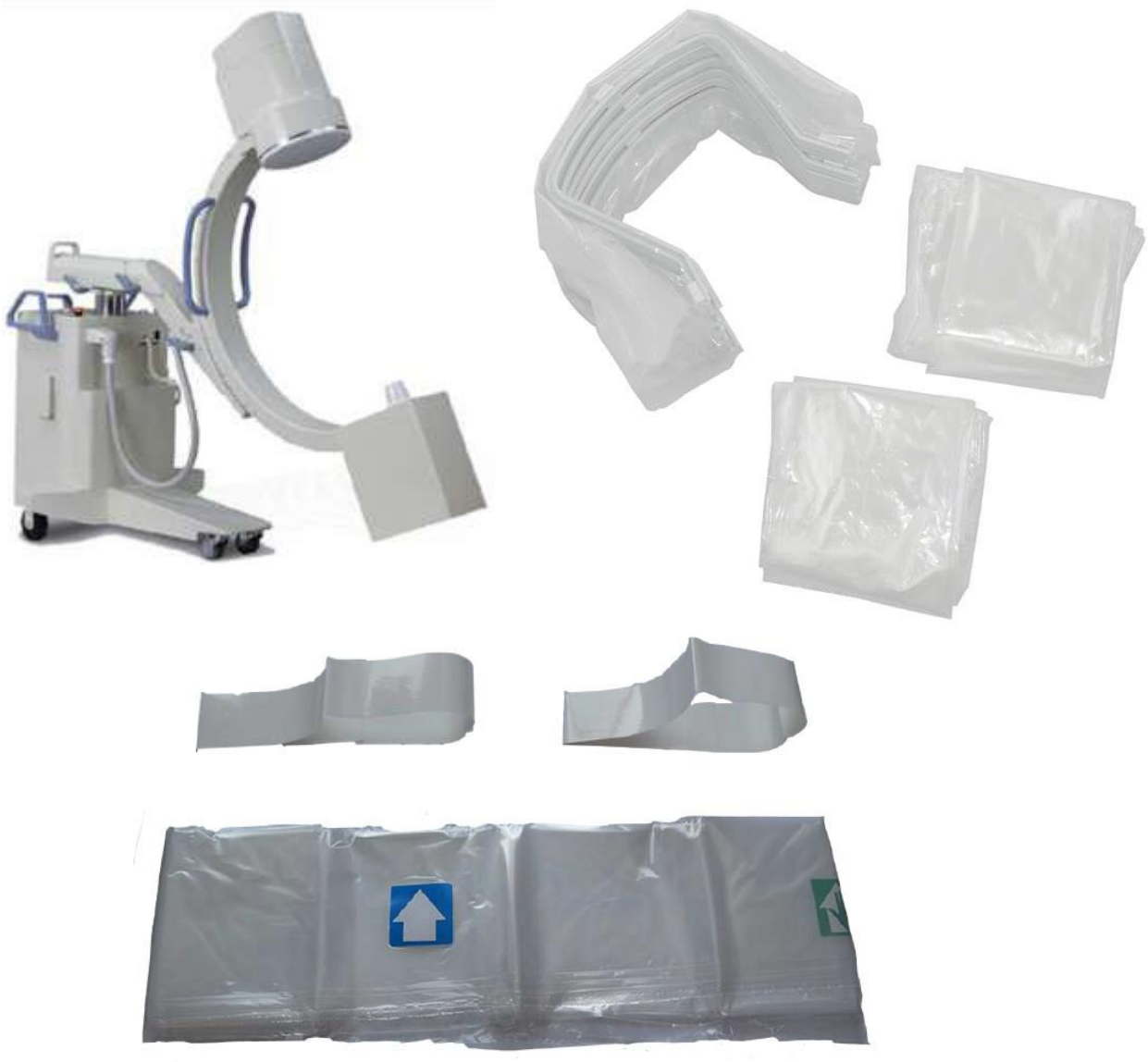
DATASHEET

QwikCover C-Arm set covers

Intended Use

C-Arm Cover is used for isolating the contamination source to prevent contamination risk coming from hospital devices to media, patient or personnel during the surgical operations from contamination. C-Arm Covers are sterile/non-sterile and disposable medical devices with transient use. The devices are intended for single use.

Main performance indicators for C-Arm Covers are sterility, to cover the device without preventing device use and to provide sterile media by preventing the contamination from the device to media.



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Models

TC55130C	QwikCover C-Arm set cover (3 parts) - Siemens Siremobil
TC55150C	QwikCover C-Arm set cover (3 parts) - Siemens Arcadis
TC55220C	QwikCover C-Arm set cover (3 parts) - Philips
TC55320C	QwikCover C-Arm set cover (3 parts) - Ziehm 1
TC55340C	QwikCover C-Arm set cover (3 parts) - Ziehm 2
TC55350C	QwikCover C-Arm set cover (3 parts) - Ziehm 3
TC55550C	QwikCover C-Arm set cover (3 parts) - GE/OEC
TC55600C	QwikCover C-Bow cover - 3 parts
TC55602C	QwikCover C-Bow cover - 2 parts
TC55227C	QwikCover C-Arm cover 90x225cm
TC55400C	QwikCover C-Arm long cover 115x180cm
TC55433C	QwikCover C-Arm long cover 90x250cm with strips
TC55466C	QuickCover Mini C-Arm Cover with Band 138x160cm
TC55476C	QuickCover Mini C-Arm Cover with Band 138x220cm

Applied Standards:

EN ISO 13485:2016 Quality Management Systems - Requirements for Regulatory Purposes

TS EN ISO 11135-2014 Sterilization of health care products

ASTM F-1980-02 Standard Guide for Accelerated Aging of Sterile Medical Device Packages

EN ISO 14971 Application Of Risk Management To Medical Devices

EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

ISO1924-2 Paper And Board-Determination Of Tensile Properties Part 2-Constant Rate Of Elongation Method

ISO1974_2012 Paper - Determination Of Tearing Resistance - Elmendorf Method

ISO11607 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

EN868 Packaging materials and systems for medical devices which are to be starilized-Part 5: Heat and self- sealable pouches and reels of paper and plastic film construction-Requirements and test medhods

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Classification:

Class I others

6. Storage:

All Pergo products should be stored in a closed and warm environment. All products should be protected from damp, dirty and dusty environments.

7. Shelf Life:

5 years from production date.

8. Cleaning and Disposal:

All disposable products used in the Pergo Surgical Equipment Drapes should be replaced for every patient change. The products to be destroyed should be disposed of in accordance with hospital disposal policy.

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