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Pleura-safe® Pleural puncture set

Item no.	Designation
27040	Pleura-safe® pleural puncture set, sterile

ACCESSORIES

Item no.	Designation
27041	Pleura-safe® replacement bag for Pleural puncture set, sterile

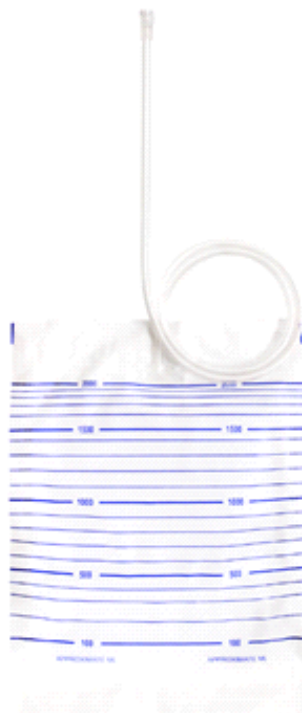
DESCRIPTION

The Pleura-safe® pleural puncture set consists of a catheter with an integrated safety puncture needle and a Luer lock syringe, an automatic three-way valve with extension tube and a drainage bag (2000 ml). The automatic three-way valve means fluid can be aspirated via the catheter using the supplied syringe without any adjustments having to be made to the system. Smaller quantities of effusions can be removed in advance via the safety puncture needle using the supplied syringe.

Pleura-safe® pleural puncture set are supplied as sterile.



REF 27040



REF 27041

Prepared

Department: VQ-RA

Date: 2023-10-18

Signature: *L. Sahaidachna*

Reviewed and Approved

Department: VQ

Date: 2023-10-20

Signature: *Jus Adami*

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CLASSIFICATION

The classification according to Annex VIII of regulation (EU) 2017/745 for the Pleura-safe® pleural puncture set is class IIa Rule 6.

The classification according to Annex VIII of regulation (EU) 2017/745 for the Pleura-safe® replacement bag for Pleural puncture set is class Is Rule 1.

INTENDED USE

Pleura-safe® pleural puncture set is designed for the diagnostic and therapeutic puncture of the pleural cavity. Pleura-safe® pleural puncture set is intended for one-time removal of secretions (e.g., in case of a pleural effusion). In addition, it can also be used for emergency pressure relief in the event of a pneumothorax. The

Pleural puncture set accessories are used to perform pleural puncture using a pleural puncture set.

PROPERTIES

Puncture needle (Veress needle)

The puncture needles are used to puncture the pleural space.

The Veress needle features an atraumatic tip, which is pushed backwards during insertion to expose a sharp hollow needle and springs forwards again automatically to cover the tip of the needle once the pleural space is reached.

Possibility for position control and option of taking a specimen directly with the needle.

Valve

Safety valve on the puncture needle automatically closes when the syringe is removed.

Reliably prevents air from entering the pleural space.

Self-closing safety valve on the catheter: closes automatically when the safety puncture needle is removed from the catheter.

Catheter (advance)

Special feature of the catheter: alternating perforation to avoid ingrowth of tissue and increase drainage performance. The catheter is made of radiopaque material for position control.

Automatic Three-way-valve

Automatic Three-way-valve: no risk of confusion, separate connection of syringe and drainage bag.

Now the effusion can be repeatedly aspirated with the catheter and transferred to the bag without switchovers – simply by pressing the syringe.

Automatic Three-way-valve makes switchovers unnecessary; air cannot be sucked back into the pleural space; no operating errors possible

Female Luer-Lock connector (blue-transparent)

The Female Luer-Lock connector enable a secure and firm connection between the individual components (drainage bag, three-way-valve, syringe, puncture needle) of the pleural puncture set.

Drainage bag

The drainage replacement bag for the Pleura-safe® pleural puncture set corresponds to the bag system (bag, tube and Luer connection) and is intended for connection. In case of an increased amount of drainage fluid, the replacement bag can be connected to the system. The drainage bag is used to collect the pleural fluid.



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MATERIALS

Product components	Material name
Body Pleura-safe	PC
Sealing plug (black)	TPE
Cap (blue-gray-transparent)	PC
Catheter	TPU
Puncture needle (Veress needle)	ABS, HDPE, SUS304
Pressure spring	Stainless steel
Protective sleeve	PE
Valve, luer activated, luer lock female	PC / Silicone
Hose (blue tinted)	PVC (DEHP-free)
Dual check valve	PC / Silicone
Drainage bag	PVC (contains DEHP)
Female Luer-Lock connector (blue-transparent)	PC
Disposable syringe with LL male connection	PP (barrel) / PS or ABS (plungers) / TPE (piston) / Stainless steel (needle) / PP or PE (protective cap for pluger and for cannula) / PP (hub)

- Latex-free
- Components of the medical device containing DEHP do not come into direct contact with the patient.

PACKAGING

Item no.	Primary packaging (single / sterile packaging)	Secondary packaging (packaging unit)	Tertiary packaging (shipping unit)
27040	1 pc.	-	20 pcs.
27041	1 pc.	50 pcs.	50 pcs.

Primary packaging: Peel packaging, sterile bag consisting of:
medical grade paper and PET/PP film

Secondary packaging: PE bag (only for REF 27041)

Tertiary packaging/Shipping unit: corrugated cardboard folding carton

STERILIZATION

Sterilization is carried out with ethylene oxide in accordance with EN ISO 11135:2014/A1:2019.
The method used for germ destruction satisfies the requirements of this standard.
The SAL (sterility assurance level) reaches a value of 10^{-6} .

STORAGE

Pleura-safe® pleural puncture set must be stored in a cool and dry place and protected from dust and sunlight according to requirements concerning "Medical Devices".
Store Pleura-safe® pleural puncture set neither below 10°C nor above 35°C.
When properly stored, sterile peel packaging maintains sterility of the device until the specified expiry date.

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SHELF LIFE

When properly stored, Pleura-safe® pleural puncture set have a shelf life of 5 years.

COMMENTS

Pleura-safe® pleural puncture set are for single use.
Therefore, reprocessing by cleaning, disinfection and / or resterilization for reuse are not allowed, as reuse of the device may change its mechanical or biological features. This can cause device failure, allergic reactions or bacterial infections.

Do not use the product if the packaging is damaged as sterility of the device could no longer be guaranteed.

REVISION HISTORY

Rev.	Date	Change
00	18.10.2023	New creation

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