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Technical Sheet

MED-SOFT Suction System Disposable Soft Liner & Reusable Outer Canister

MED-SOFT is a closed suction system with a canister/liner combination for the collection of body fluids, liquids and aspiration waste. The outer canister is reusable (hardware) and the soft liner is single patient use (disposable):

MED-SOFT Canister: DYNDCLO1000, DYNDCLO1500, DYNDCLO3000 MED-SOFT T-Canister: DYNDCLO10T, DYNDCLO15T, DYNDCLO30T MED-SOFT Liner: DYNDSCL1000, DYNDSCL1500, DYNDSCL3000 MED-SOFT Liner + MED-GEL: OR1910PG, OR1920PG, OR1930PG MED-SOFT Liner +ORNEX Tubing: OR916K, OR926K, OR936K, OR929K, OR939K

MED-SOFT Liner + ORNEX + MED-Stop: OR53916, OR53926, OR53929, OR54916,

OR54926

More details in the Description part - page 2-3.

Reference(s)

Description

MED-SOFT Suction Canister (hardware-reusable) for inserting and connecting MED-SOFT single patient use suction liner:

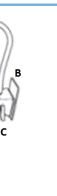
DYNDCLO1000: Reusable MED-SOFT Canister 1.0L DYNDCLO1500: Reusable MED-SOFT Canister 1.5L DYNDCLO3000: Reusable MED-SOFT Canister 3.0L

DYNDCLO10T: Reusable MED-SOFT T-Canister 1.0L **DYNDCLO15T**: Reusable MED-SOFT T-Canister 1.5L DYNDCLO30T: Reusable MED-SOFT T-Canister 3.0L

The MED-SOFT outer canister is composed of :

- A. a transparent recipient with graduations corresponding to the volume of liquids collected in the disposable MED-SOFT liner under suction,
- B. a short strong red backing to fix the MED-SOFT canister to a suitable support (wall or mobile) (not for DYNDCLO10T, DYNDCLO15T, DYNDCLO30T),
- a plain white ON / OFF valve to open or close the vacuum located on the white connector (under the red backing) (not for DYNDCLO10T, DYNDCLO15T, DYNDCLO30T),
- a reinforced red tube to connect vacuum to VACUUM port of the blue lid with intuitive and mistake-proof installation.

Cleaning the outer canister: Reusable canister can be wiped with disinfectant. Do not autoclave



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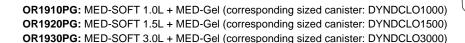
DYNDSCL1000: MED-SOFT Liner 1.0L (corresponding canister: DYNDCLO1000) **DYNDSCL1500**: MED-SOFT Liner 1.5L (corresponding canister: DYNDCLO1500) DYNDSCL3000: MED-SOFT Liner 3.0L (corresponding canister: DYNDCLO3000)

MED-SOFT liner is composed of :

- a translucent textured liner with "shape of the bottom of the bottle" for
 - More accurate volumes reading
 - Enabling liner standing straight when handling liner.
- a blue lid (sealed to the liner) with 4 ports of different diameters and their associated caps:
- VACUUM PORT: allows connection of the red vacuum tube from the reusable canister. To protect the vacuum source from contamination, each MED-SOFT liner is built with:
 - the Bacteriological filter protects vacuum source from aerosolized liquids and micro particulates generated by suction. (efficacy: 99.9% - Nelson Lab Study).
 - the Mechanical Shut-Off valve: to prevent overflow of liquids and foams into vacuum source when MED-SOFT liner is full. This mechanical protection system discontinues suction if canister is bumped or moved suddenly away from a vertical position (to continue suction, disconnect the vacuum tube from Vacuum Port and allow the shut-off valve to move back into the open position. Then reconnect the vacuum tube to Vacuum Port).
- PATIENT PORT: Allows connection of patient tubing. The patient port is equipped with a 90° elbow connector. It can be removed or used to facilitate the connection and avoid kinking of the patient tubing.
 - the Anti-reflux valve prevents backflow of liquids and aerosols when disconnecting the patient tubing.
- TANDEM PORT: allows connection of tandem tubing (ref: DYNDTND) with another MED-SOFT suction canister for higher volume fluid collection during specific surgeries.
- ACCESSORY PORT: Is the largest port of the lid. It allows connection of accessories like specimen socks (ref: OR123 / OR124 / OR125), or add MED-GEL doses (ref: RE2015 gelling agent) at the end of the procedure for a safe waste disposal.

The safety features of VACUUM PORT (mechanical shut-off valve & bacteriological filter) and PATIENT port (anti-reflux valve) classify MED-SOFT as a closed suction system with optimal protection for patients and healthcare professionals.

MED-SOFT Suction Liner + MED-GEL is pre-gelled liner with a granular substance which jellifies the suctioned fluids for a safe waste disposal. The gelling agent is contained in a water-soluble sachet and inserted directly into the liner.



It is not recommended to use solidifier prior to suction during tandem configuration, as fluid will solidify; volume expands and suction is altered in the tandem tube during procedures.

MED-SOFT Suction Liner + ORNEX is a kit composed of MED-SOFT liner with an ORNEX tubing.

ORNEX is low memory flexible transparent tubing with ribbed external surface to increase resistance to severe depressions avoiding kinking and enabling higher grip. At each extremity, a blue ribbed connector is sealed. The inside of the connector is conical and notched in order to ensure a secure leak-free connection







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Corresponding sized

MED-SOFT Suction liner + ORNEX + MED-Stop is a MED-SOFT Suction Liner with ORNEX non sterile suction tubing pre-connected to MED-Stop Fingertip control vacuum valve (adult or pediatric) to control

6mm x ←→ 1.80M

OR916K

OR926K

OR936K

Liner/Tubing

1.0L

1.5L

3.0L

suction.



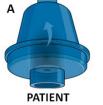
Liner/Tubing	⊘ 6mm x ⊬→1.80M		⊘6mm x ⊬→3.00M	Corresponding sized
Fingertip	Adult	Pediatric	Adult	canister
1.0L	OR53916	OR54916	-	DYNDCLO1000
1.5L	OR53926	OR54926	OR53929	DYNDCLO1500

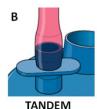
6 mm x ←→

3.00M

OR929K

OR939K





<u>MED-SOFT Tandem Tube</u> **DYNDTND** is designed to maintain closed suction system in tandem configuration. It connects two MED-SOFT liners enabling fluids to overflow from one liner to the next. The MED-SOFT tandem tube is intuitive and mistake-proof installation with:



- A. the female connector must be connected to PATIENT port of the MED-SOFT liner. To maintain safety during disconnection, the female connector is built with:
 - o an anti-backflow valve avoiding spillage of liquids from the tandem tube,
 - o a droplet proof system avoiding leakage of the residual liquids from the connector. At the end of the procedure, disconnect and securely close the cap.
- B. the male connector must be inserted in the TANDEM port of the next MED-SOFT liner. At the end of the procedure, the liner/tandem tube assembly remains together for disposal.

For best results, solidifiers should be added after the procedure and before shutting off the vacuum source to prevent risk of fluid leaking from the accessory port when the solidifier is added.

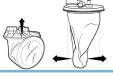
Materials

<u>Canister</u>: Transparent recipient (Polycarbonate), Red Backing and white ON/OFF valve (Acrylonitrile Butadiene Styrene plastic - ABS plastic), Red vacuum tubing (PVC Nylon)
<u>Liner</u>: Transparent pouch (Polyethylene transparent), Blue lid & accessories (Polypropylene), Antireflux/backflow patient Valve (TPE - Thermo plastic elastomer)
<u>MED-GEL Gelling Agent</u>: Sodium Polyacrylate, Water

ORNEX Tubing & Med-Stop Finger Control Valve: Transparent PVC and blue PVC – with DEHP.



<u>Canister</u>: each canister is wrapped in a polystyrene foam protective paper. <u>Liner</u>: each liner is individually packed in a sealed notched polyethylene film to ease opening. The liners are gathered in large PE bag for optimized transport and storage.



Pack Factor

Canister: 8 canisters per case.

Year and Month of manufacturing engraved on the bottom of the canister.

Liner: 50 liners per case (except OR1910PG/OR1920PG/OR1930PG: 45ea per case).

Volume, Lot number and Expiry date printed on the blue lid.

Manufacturer

Medline Industries, Inc. Northfield, IL 60093 USA. EN ISO 13485

Regulation

In compliance with Medical Device Regulation (EU) 2017/745
Conforms to EN10079-3 "Medical suction devices - Part 3: Devices su

Conforms to EN10079-3 "Medical suction devices - Part 3: Devices supplied by a source of vacuum or pressure".

MD Class: I Non sterile

Please refer to complete labeling and instruction for use before using the product.









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