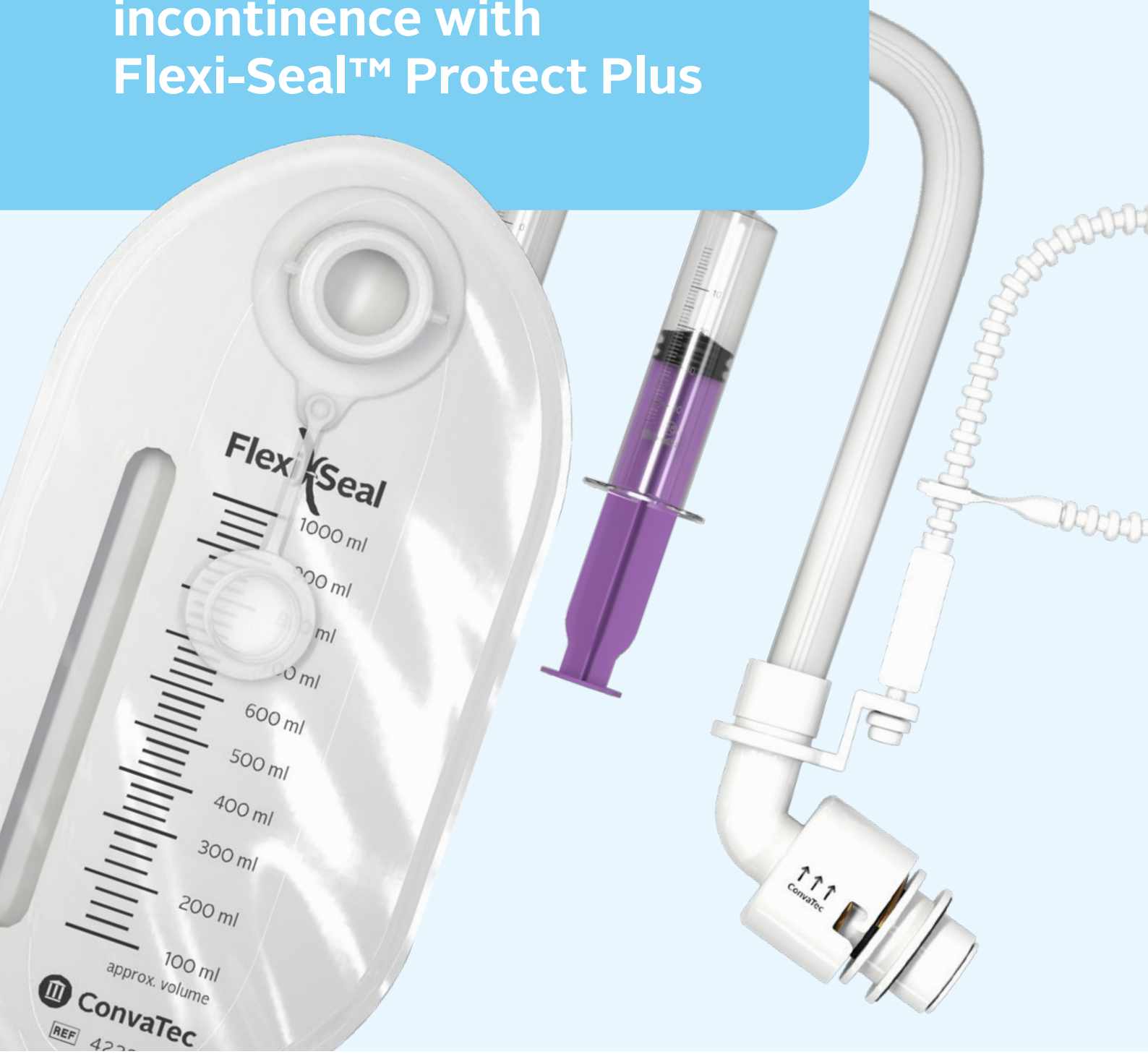
Flexi-Seal™ PROTECT PLUS

Guidelines for the management of fecal incontinence with Flexi-Seal™ Protect Plus



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OBJECTIVE

To effectively divert and contain liquid and semi-liquid stool away from the body.

OUTCOMES (GOALS)

- Reduce the risk of skin breakdown by helping to keep the skin clean, dry and free from contaminants.
- Reduce the risk of spread of infection by containing infectious body waste within a disposable, closed system.
- Help to protect wounds, surgical sites, and burns from contamination by stool.
- Help improve patient comfort.
- Help reduce the cost of managing fecal incontinence.
- Help maintain patient dignity.

PATIENT ASSESSMENT

- Fecal incontinence management with Flexi-Seal™ Protect Plus is appropriate for patients with liquid and semi-liquid stool (flowing). When stool begins to become solid, use of the device should be discontinued.
- Prior to use of Flexi-Seal™ Protect Plus, a digital rectal assessment must be performed to rule out the possibility of a fecal impaction. If a fecal impaction is present, consult with patient's physician to determine if impaction removal is appropriate. The device can be inserted once the fecal impaction is removed.
- A digital rectal assessment should also confirm presence or absence of rectal tone, as poor or absent tone may increase leakage around the device or may contribute to the inability to retain the device.

Flexi-Seal™ PROTECT PLUS

RECTAL ASSESSMENT PROCEDURE

- Wash hands and put on gloves.
- Position patient on left side and flex hips.
- Separate buttocks and examine external area for fissures, skin tags, rectal prolapse, hemorrhoids or other abnormalities.
- Lubricate index finger of gloved hand.
- If patient is alert, ask patient to bear down for a moment or two to ease passage of index finger.
- Gently insert finger 3 centimeters and pause.

  TIP: 3cm equates to about halfway between most distal "crease lines" on index finger.

- At this point, rectal sphincter tone is determined.

  TIP: Good tone feels like a snug ring around the finger.

- Fair tone feels like a snug ring around the finger but quickly loses its "grip" on the finger.
- There is little or no resistance with poor or absent tone.
- Pause for a second or two, you should feel the sphincter relax somewhat.
- Continue insertion of index finger until well into the rectal vault.

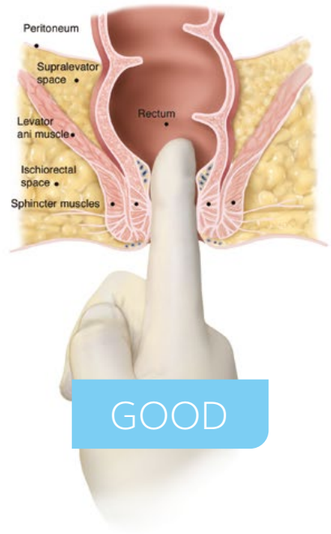
  TIP: If there is poor or absent rectal sphincter tone, the finger feels as if it was in a narrow passageway which then "opens up" into a cavern.

- Gently sweep the rectal vault.

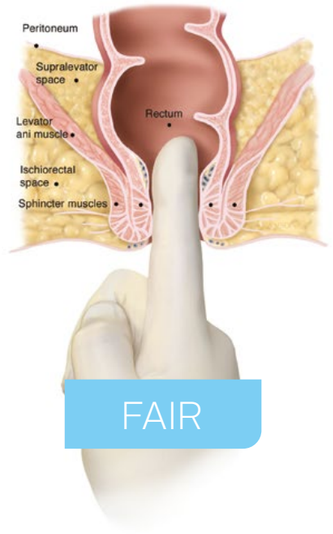
  TIP: Check for impacted stool.

- Remove finger and wipe anus and buttocks of excess lubricant.

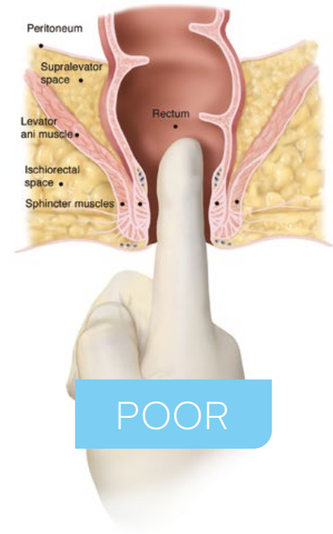
FEELS LIKE a snug ring around the finger



FEELS LIKE a snug ring around the finger BUT quicky loses its grip on the finger



FEELS LIKE there is little or no resistance



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Flexi-Seal™ PROTECT PLUS

CONTRAINDICATIONS

This product is not intended for use

- for more than 29 consecutive days
- for pediatric patients as its use has not been tested in this population

The Flexi-Seal™ PROTECT PLUS Fecal Management System with ENFit™ Connector should not be used on individuals who

- have suspected or confirmed rectal mucosal impairment, i.e. severe proctitis, ischemic proctitis, mucosal ulcerations
- have had rectal surgery within the last year
- have any rectal or anal injury
- have hemorrhoids of significant size and/or symptoms
- have a rectal or anal stricture or stenosis
- have a suspected or confirmed rectal/anal tumor
- have any in-dwelling rectal or anal device (e.g. thermometer) or delivery mechanism (e.g. suppositories or enemas) in place
- are sensitive to or who have had an allergic reaction to any component within the system

GENERAL GUIDELINES

If the device is expelled or requires repositioning, withdraw the fluid from the balloon and reposition the balloon in the rectal vault. After repositioning, fill the balloon as described in the IFU. Do not fill with more than 45ml fluid.

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PRECAUTIONS AND OBSERVATIONS

- Close attention should be exercised with the use of the device in patients who have inflammatory bowel conditions or who have had rectal surgery. The physician should determine the degree and location of inflammation or extent of surgery (e.g. location of anastomosis) within the colon/rectum prior to considering use of this device in patients with such conditions.
- Care should be exercised in using this device in patients who have a tendency to bleed from either anti-coagulant / antiplatelet therapy or underlying disease. If signs of rectal bleeding occur, remove the device immediately and notify a physician.
- The device should be used with caution in patients with spinal cord injury because of the possibility of the development of autonomic dysreflexia.
- Remove any indwelling or anal device prior to insertion of the Flexi-Seal™ PROTECT PLUS FMS with ENFit™ Connector and do not insert any other devices into the rectum while the Flexi-Seal™ PROTECT PLUS FMS with ENFit™ Connector is in place.
- Ensure that the patient does not lie or sit on the catheter as this could lead to localised pressure damage and contribute to the development of anal skin breakdown and/or restrict fecal flow.
- Solid or soft-formed stool cannot pass through the catheter and will obstruct the opening. The use of the device is not indicated for solid or soft-formed stool.
- Small amounts of moisture or seepage around the catheter is anticipated. To avoid skin irritation, initiate an appropriate institutional skin care protocol. At a minimum, the skin should be kept clean, dry and protected with a moisture barrier product.
- If the catheter becomes blocked with feces, it can be rinsed with water using the irrigation port only (see “Irrigation, Maintenance & Removal of Device”). Do not use the white inflation port (marked “≤45ml”) to irrigate. If obstruction of the catheter is due to solid stool, use of the device should be discontinued.
- Clinicians should take extra care to use the purple ENFit™ irrigation/medication port only when irrigating and delivering medication. DO NOT irrigate or administer medication through the white inflation port (marked “≤45ml”).
- Discontinue the use of the device if the patient’s bowel control, consistency and frequency of stool begin to return to normal.
- If the patient is regularly and closely monitored, patients may be seated for short periods i.e. for up to 2 hours, as part of daily nursing care. During this period of seating, regular monitoring should be made to ensure the tubing is never blocked or kinked and to check for and avoid pressure damage to the anal/peri-anal region. Clinicians should be alert that for some patients seating time needs to be reduced due to the possibility of pressure damage to the anal/peri-anal region - Adjust balloon fill volume in case the red indication dome pops.

As with the use of any rectal device, the following adverse events could occur:

- Leakage of stool around the device
- Rectal/anal bleeding due to pressure necrosis ulceration of rectal or anal mucosa
- Peri-anal skin breakdown
- Temporary loss of anal sphincter muscle tone
- Infection
- Bowel obstruction
- Perforation of the bowel
- This device is for single use only and should not be re-used. Re-use may lead to increased risk of infection or cross contamination. Physical properties of the device may no longer be optimal for intended use.
- If there is no flow of stool in a 24hr period then the following actions should occur: irrigation (see “Irrigation, Maintenance & Removal of Device”), or removal of the device.
- The collection bag should be coupled to the catheter in the correct orientation as shown on the previous page. Reading measurements of the collection bag is approximate only.
- Do not use if package is damaged. Do not use Diamonds™ sachets if sachets are significantly broken.

Preparation of Device & Patient

- In addition to the device kit, gloves and lubricant will be required.
- Using the syringe provided, remove the air that is in the balloon by attaching the Luer syringe to the white inflation port (marked "≤45ml") and withdraw the plunger.

- Remove the supplied Luer syringe and fill it with only 45ml of water or saline and connect the syringe to the white inflation port of the catheter.

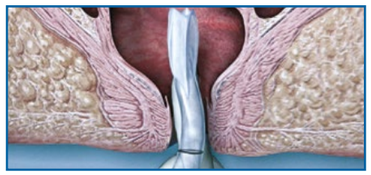
- Insert 3 or 4 ConvaTec Diamonds™ sachets, one at a time, into the bag opening. Do not tear open the sachets. Do not force the sachets, if resistance is met then gently move the sachet sideways ensuring they are placed at the bottom of the bag. (WARNING: DO NOT use the bag content for source of clinical information on stool color or consistency as it is modified by the gelling agent. Do not open sachet.).

- Position the catheter connector at a 90 degree angle to the bag connector opening and gently insert the catheter connector into the bag connector. Do not trap the bag against the bag connector.
- Locate the two pins on the bag connector and align them to the two corresponding slots on the catheter connector.
- Gently push the catheter connector into the bag connector and twist clockwise to securely couple the two parts.
- Use your date printed labels to write insertion date and time. Place on the allocated space at the end of bead strap.

- Position the patient in left side-lying position; if unable to tolerate, position the patient so access to the rectum is possible.
- Perform a digital rectal exam to evaluate suitability for insertion of device.
- The rectum should have adequate anal tone and be free of solid stool or any in-dwelling or anal device prior to insertion.

Insertion of Device

- Unfold the length of the catheter to lay it flat on the bed, extending the collection bag toward the foot of the bed.
- Insert a lubricated gloved finger into the blue finger pocket for digital guidance during device insertion (the finger pocket is located above the position indicator line).
- Coat the balloon end of the catheter with lubricant.



- Grasp the catheter and gently insert the balloon end through the anal sphincter until the balloon is beyond the external orifice and well inside the rectal vault.
- The finger may be removed or remain in place in the rectum during initial balloon inflation.

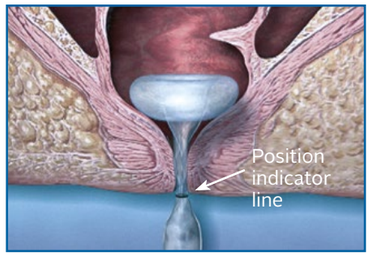
- Inflate the balloon with up to 45ml of fluid by slowly depressing the Luer syringe plunger.
- Never inflate the retention balloon with more than 45ml of water.

- With the insertion finger removed, the green dome will indicate once the balloon has reached the optimal fill level for the anatomy. Stop inflation once the green dome has signalled optimal fill. Under no circumstances should the balloon be inflated with more than 45ml of fluid.

- If the green dome indicates at less than 30ml of fluid, withdraw the fluid and reposition the balloon in the rectal vault.
- After repositioning, fill the balloon as described above. DO NOT fill with more than 45ml of fluid.
- The red indication dome will start to indicate if the balloon is overfilled beyond the maximum 45ml of fluid. If the red indication dome starts to inflate, assess patient's position, fully deflate the balloon and repeat the balloon inflation process. Stop inflation once green dome has signalled optimal fill.

- Remove the Luer syringe from the inflation port, and gently pull on the soft catheter to check that the balloon is secure in the rectum and that it is positioned against the rectal floor.
- Take note of the position indicator line relative to the patient's anus.
- Regularly observe changes in the location of the position indicator line as a means to determine movement of the retention balloon in the patient's rectum. This may indicate the need for the balloon or device to be repositioned.

Insertion of Device *Continued*



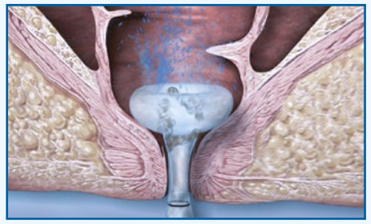
- In the event of expulsion of the device, deflate the balloon fully; rinse the balloon end of the catheter and reinsert following the instructions for 'Insertion of Device'.
- A rectal exam should be conducted prior to re-insertion to verify that no stool is present.
- If expulsion continues for more than three episodes discontinuation of the device should be considered.

- Position the length of the flexible catheter along patient's leg avoiding kinks and obstruction.

- Hang the bag by the bead strap on the bedside at a position lower than that of the patient.

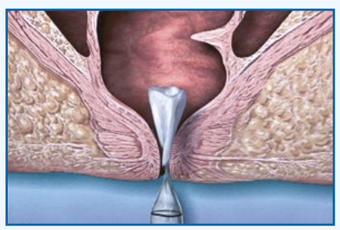
Irrigation, Maintenance & Removal of Device

- To irrigate the device, fill the syringe with water at room temperature, attach the purple ENFit™ syringe to the purple ENFit™ irrigation/medication port (marked "IRRIG./Rx") and slowly depress the plunger.
- Clinicians should take extra care to use the purple ENFit™ irrigation/medication port only when irrigating.
- DO NOT irrigate through the white inflation port (marked "≤45ml") as this would lead to over inflation of the retention balloon and the device would not be irrigated as intended.



- If repeated flushing with water does not return the flow of stool through the catheter, the device should be inspected to ascertain that there is no external obstruction (i.e. pressure from a body part, piece of equipment, or resolution of diarrhea).
- If no source of obstruction of the device is detected, use of the device should be discontinued.

- To remove the collection bag, push the catheter connector into the bag connector and then twist counter-clockwise to disengage. Gently pull the catheter connector from the collection bag. Use the thumb to push the back of the cap into the bag connector which is to be held in place from the rear of the collection bag using the fore and index fingers. Use thumb to press around the cap to ensure full bag closure.
- Discard used bags according to institutional protocol for disposal of medical waste.
- Observe the device frequently for obstructions from kinks, solid fecal particles or external pressure.



- To remove the catheter from the rectum, the retention balloon must first be deflated.
- Attach the Luer syringe to the white inflation port (marked "≤45ml") and slowly withdraw all fluid from the retention balloon.
- Disconnect the Luer syringe and discard.
- Grasp the catheter as close to the patient as possible and slowly remove from the anus.
- Dispose of device in accordance with institutional protocol for disposal of medical waste.

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Medication Administration

- Attach the supplied purple ENFit™ syringe and flush the irrigation line with 10ml of water.
- Prepare a new purple ENFit™ syringe with prescribed medication.
- Position the cinch clamp loosely on the catheter at the black indicator line. Connect syringe to the purple ENFit™ irrigation/ medication port ("IRRIG./Rx") and administer medication.
- Clinicians should take extra care to use the purple ENFit™ irrigation/medication port only when delivering medication.

- DO NOT administer medication through the white inflation port (marked "≤45ml") as this would lead to over inflation of the retention balloon and the patient would not receive medication as intended.
- To ensure delivery of medication into the rectum immediately flush the irrigation line with at least 50ml of water.
- Tighten the cinch clamp on the catheter to ensure no flow through the catheter (ensure the second notch is engaged; squeeze tightly using forefinger and thumb of both hands to ensure a good seal).

- Allow the medication to dwell in the rectum for the desired amount of time as dictated by the prescribing physician.
- Remove the cinch clamp.
- Flush the irrigation line with 10ml of water.
- Dispose of the syringe according to institutional policy.

Sampling

- To collect a sample from the catheter, open the dark blue sample port cap.
- Press the tip of a Luer-slip syringe (aka catheter tip or "Toomey" syringe) through the slit inside of the sampling port to access the interior of the catheter.
- Withdraw the Luer-slip syringe plunger to collect the sample.
- Withdraw the Luer-slip syringe and close the dark blue sampling port cap.

Product Information

Flexi-Seal™ Protect Plus

Flexi-Seal™ Protect Plus
(1 kit/box, 3 bags)

Collection Bag Information

Charcoal Filter Collection Bag
(10/box)

Privacy™ Collection Bag
with APS Filter

Non-Sterile | Single-Use Only | Does not contain natural rubber latex components

For inquiries on ConvaTec products including Flexi-Seal® and Faecal Collectors

Tel No 01244 284882
Hours of Trading 9am to 4pm.
Email: uk.customerservice@convatec.com

For inquiries on Unomedical products including UnoMeter®

Tel No 01244 832206
Hours of Trading 9am to 4pm.
Email: unomedical-uk.customerservice@convatec.com

ConvaTec is a global medical products company focused on therapies within advanced wound care, ostomy care, continence care, critical care, and infusion care.

Our most prominent products within critical care are Flexi-Seal®, UnoMeter®, CareLine®, and Unomedical branded products.

ConvaTec Ltd. and Unomedical Ltd. are subsidiaries of ConvaTec Group that market and distribute products of ConvaTec.

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