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INSTRUCTIONS FOR USE LEAFLET

adept®

(4% icodextrin solution)

Baxter

CB-30-02-441

DESCRIPTION
ADEPT® is a single use, sterile, clear, colourless to pale yellow fluid for intraperitoneal administration containing icodextrin at a concentration of 4% w/v in an electrolyte solution.

Each 1 litre of solution contains:

Icodextrin	40	g
Sodium Chloride	5.4	g
Sodium Lactate	4.5	g
Calcium Chloride	257	mg
Magnesium Chloride	51	mg

Theoretical osmolarity 278 milliosmoles per litre

Ionic composition (approximately) per litre:

Sodium	133	mmol
Calcium	1.75	mmol
Magnesium	0.25	mmol
Chloride	96	mmol
Lactate	40	mmol

PRESENTATION
ADEPT is packaged in single use, flexible polyvinylchloride bags, fitted with connecting ports, containing 1.5 litres of solution. The product is presented sterile (by heating in an autoclave). The bags are packaged in cartons of 5 x 1.5 litres.

STORAGE
ADEPT should be stored at 2° – 30°C (36° – 86°F). Do not freeze.

INTENDED USE
ADEPT is intended for use as an intraperitoneal instillate for the reduction of adhesions following gynecological laparoscopic surgery, and should be used as the irrigant during the course of that surgery.

INDICATIONS
ADEPT is indicated to be used in gynecological laparoscopic surgery of the abdominal-pelvic cavity in adults.

ACTIONS
ADEPT performs its function through a physical effect by providing a temporary separation of peritoneal surfaces by hydroflotation. This minimises tissue apposition during the critical period of fibrin formation and mesothelial regeneration following surgery, thereby providing a barrier to adhesion formation.
Icodextrin is an α-1,4-linked glucose polymer which, when administered intraperitoneally as a 4% solution, is capable of maintaining a reservoir of fluid within the peritoneal cavity for up to 3–4 days. A 7.5% solution of icodextrin has been used extensively on a daily basis as a peritoneal dialysis solution for the treatment of chronic renal failure.
When given intraperitoneally, the polymer is largely retained within the peritoneal cavity. Some absorption occurs from the peritoneum into the systemic circulation where it is metabolised by amylase to smaller oligosaccharides, ultimately maltose and by maltase to glucose.
ADEPT has been shown to reduce significantly the incidence, extent and severity of post surgical adhesions in animal models (rabbit double uterine horn and rabbit sidewall models) when used as a lavage during surgery and as an instillate post-operatively.

CONTRAINDICATIONS
ADEPT is contraindicated:
- In patients with known or suspected allergy to cornstarch based polymers, icodextrin, maltose or isomaltose intolerance, or in patients with glycogen storage disease.
- In the presence of frank infection (e.g. peritonitis) in the abdomino-pelvic cavity.
- In procedures with laparotomy incision. Serious post-operative wound complications including dehiscence and cutaneous fistula formation have been reported from clinical experience when ADEPT was used in surgical cases with laparotomy incision.
- In procedures involving bowel resection or repair, or appendectomy. Anastomotic failure, ileus, peritonitis and rare cases of serosal fibrosis following procedures involving bowel resection and instillation of ADEPT have been reported from clinical experience.

PRECAUTIONS

There are rare reports of pleural effusion from clinical experience with ADEPT. As a possible relationship to the use of ADEPT, in conjunction with inappropriate fluid monitoring during surgical procedure cannot be ruled out, the volume of ADEPT instilled should always follow the recommendations of the Instructions for Use.

Patient information
Self-limited vulvar swelling is a known side-effect of instilling large volumes of fluid into the abdomino-pelvic cavity. Most cases resolve within one week of surgery. When swelling is associated with urinary retention, catheterization may be necessary (see also undesirable effects).

Use in Children
ADEPT is not recommended for use in children.

Use in Diabetics
Maltose metabolites of icodextrin may interfere with blood glucose measurement in diabetic patients who use rapid blood glucose systems that are not glucose specific.

Pregnancy and Lactation
There are limited data available from animal studies on the effects of icodextrin on reproduction or lactation and therefore ADEPT should not be used during pregnancy or lactation.
Women of childbearing potential should be treated with ADEPT only when adequate contraceptive precautions have been taken.

Phthalates
Only PVC bag contains DEHP, 4% Icodextrin solution itself is DEHP free.

Interactions with Other Medicaments
The primary intended function of ADEPT is not to administer medicinal products. However, the bag has an injection port, which may be used for administration of drugs, if required.
A range of antibiotics, including vancomycin, cephazolin, ampicillin, flucloxacillin, ceftazidime, gentamycin and amphotericin, have shown no evidence of incompatibility with ADEPT.

UNDESIRABLE EFFECTS
Undesirable effects are those typically seen following abdominal-pelvic or laparoscopic surgery, like rare reports of aseptic peritonitis in patients treated with ADEPT. In patients receiving icodextrin 7.5% solution as part of a peritoneal dialysis regimen and on multi therapy, there have been common reports of skin reactions, including rash and pruritus. Occasionally these rashes have been associated with exfoliation or rare cases of bruising. There have been rare reports of hypersensitivity reactions, pleural effusion or urinary retention in patients treated with ADEPT. There have been rare reports of vulval oedema following the administration of ADEPT. The reaction generally resolves spontaneously within a few days. Oedema is a recognised event associated with the use of fluids for irrigation and instillation in laparoscopic surgery.

DIRECTIONS FOR USE
ADEPT is administered into the peritoneal cavity during abdominal surgery, being used as an irrigant solution during the course of surgery. Once the surgeon has completed the surgical procedure(s) and removed all packs and sponges, the cavity is aspirated of all remaining fluid. A final volume of at least 1 litre of ADEPT is then introduced into the cavity before closure of the cavity/removal of the scope.
ADEPT should be warmed to approximately body temperature prior to use, using a device specifically intended for warming solutions in operating theatres. ADEPT can be kept in a warmer at 37°C (99°F) for up to 14 days, provided it is not removed and then replaced.

Using standard operating room technique:
1. Remove the outer wrap from the ADEPT bag and hang the sterile bag of solution on a stand.
2. Remove the twist-off tab from the spike port and insert a sterile solution/ administration set for connection to a laparoscopic port.
3. ADEPT should be used intra-operatively as an irrigant solution, and as a post-operative instillate. The solution will flow through a sterile solution/administration set and through laparoscopic ports.
4. When used as an intra-operative irrigant solution, 100ml of ADEPT should be introduced to the cavity every 30 minutes up to a volume of 500 mL.
5. Remove remaining fluid and exsufflate before introducing the final instillation of ADEPT.
6. For the final instillation of ADEPT, prior to removal of the laparoscope, one litre should be used. Direct the solution at the operative sites in the first instance, the remainder being distributed throughout the cavity.
7. Dispose of the bag and any unused portion of the solution following normal operating room biological hazard procedures.

PRECAUTIONS FOR USE
ADEPT must be used as directed by a physician. It must not be used unless the solution is clear and the container undamaged.
Any unused portion of solution should be discarded. Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient. ADEPT is not to be used for intravenous infusion.

Baxter Healthcare SA
8010 Zurich
Switzerland

Made in Ireland

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SYMBOLS

2°C 36°F 30°C 80°F	Temperature limitation
	Consult instructions for use
	Single use
	Do not use if package is damaged
	Not made with natural rubber latex
STERILE	Sterilized using steam or dry heat
	Keep dry
	Manufacturer
LOT	Batch number
	Use by
REF	Catalogue number
	Twist off administration port
PHT DEHP	Contains or presence of Phthalate: Bis(2-ethylhexyl) phthalate (DEHP) *Refer to Phthalate paragraph in the Precautions section for further clarification.*