



# adept<sup>®</sup>

Adhesion Reduction Solution  
[4% Icodextrin]



## Consider ADEPT<sup>®</sup> For Reducing Adhesions

ADEPT Adhesion Reduction Solution is indicated for use intraperitoneally as an adjunct to good surgical technique for the reduction of post-surgical adhesions in patients undergoing gynecological laparoscopic adhesiolysis.

Please see Detailed Important Risk Information on back.

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# ADEPT®

## Reduce the potential for adhesions after gynecologic laparoscopic adhesiolysis.<sup>1</sup>

“...An effective, broad-coverage adhesion-reduction agent that is easy to apply during laparoscopic procedures.”

*Fertility and Sterility, April 2007<sup>2</sup>*

### **ADEPT® Adhesion Reduction Solution [4% Icodextrin]**

ADEPT® Adhesion Reduction Solution is indicated for use intraperitoneally as an adjunct to good surgical technique for the reduction of post-surgical adhesions in patients undergoing gynecological laparoscopic adhesiolysis.

\*Clinical success was defined as a reduction in adhesions of at least 3 or 30% of sites lysed (whichever was greater) between the initial surgery and the follow-up laparoscopy.

- Unlike site specific site barriers, ADEPT® provides simple temporary hydroflotation within the peritoneal cavity.<sup>1</sup> It's the first FDA-approved device as an adjunct to good surgical technique for reduction of post-surgical adhesions in patients undergoing gynecological laparoscopic adhesiolysis<sup>2</sup>
- ADEPT® keeps the peritoneal surfaces apart for 3-4 days during the critical post-operative period when the patient is at greatest risk of adhesion formation<sup>1,3</sup>
- A randomized, double blind trial of ADEPT® demonstrated that ADEPT® is a safe and effective anti-adhesion agent in laparoscopy<sup>2</sup>
- The Pivotal study showed ADEPT® provided:<sup>1</sup>
  - Significant improvement in clinical success\* compared to lactated Ringer's solution (LRS) (45.4% vs 35.6%,  $p=0.016$ )
  - A reduction in sites with adhesions at second look vs. first look laparoscopy ( $p<0.001$ ). There was greater reduction in the number of sites with adhesions in the ADEPT® group vs. the LRS group ( $p=0.047$ )
  - A reduction in dense adhesions at second look in 50% of patients (mean reduction 1.19,  $p<0.001$ ); in the LRS group, the figure was similar (49%). There was no statistically significant difference between treatments

### **Selected Important Risk Information**

- ADEPT® is contraindicated in laparotomy, in cases involving bowel resection or repair, or appendectomy and in surgical cases with frank abdomino-pelvic infection
- In the Pivotal study, the most frequently occurring treatment-related adverse events between surgeries were post procedural leaking from port sites, labial, vulvar or vaginal swelling and abdominal distention

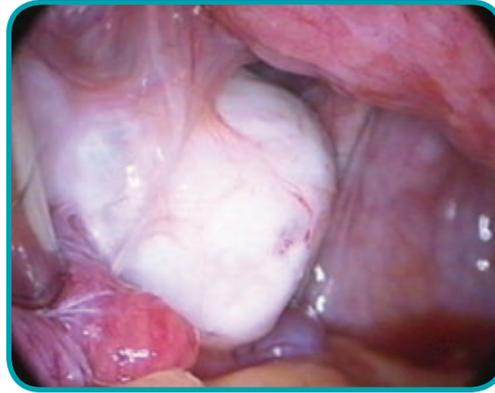
**Please see Detailed Important Risk Information on back.**

## Pivotal Study: 1st and 2nd look Laparoscopy photos

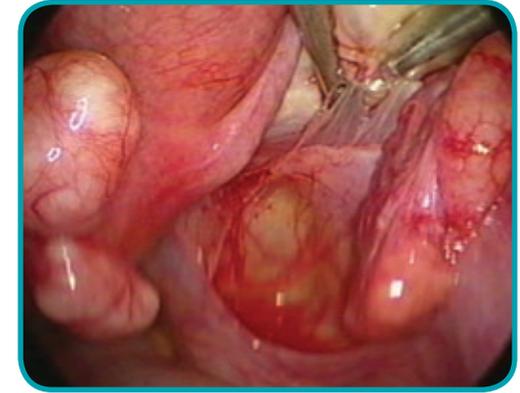
ADEPT® Adhesion Reduction Solution is for direct intraperitoneal administration only. **NOT** for intravenous (IV) administration.



**1st Look Laparoscopy**, Pre-Adhesiolysis of Right Tubo-Ovarian Adhesions



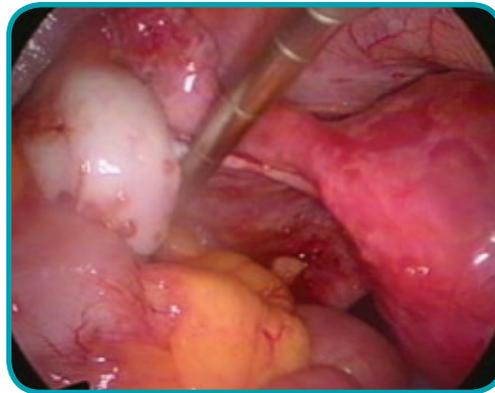
**1st Look Laparoscopy**, Pre-Adhesiolysis of Left Adnexal Adhesions



**1st Look Laparoscopy**, Pre-Adhesiolysis of Right Ovarian Fossa Adhesions



**2nd Look Laparoscopy**, Status Post Right Tubo-Ovarian Adhesiolysis



**2nd Look Laparoscopy**, Status Post Adhesiolysis of Left Adnexal Adhesions



**2nd Look Laparoscopy**, Status Post Adhesiolysis of Right Ovarian Fossa Adhesions

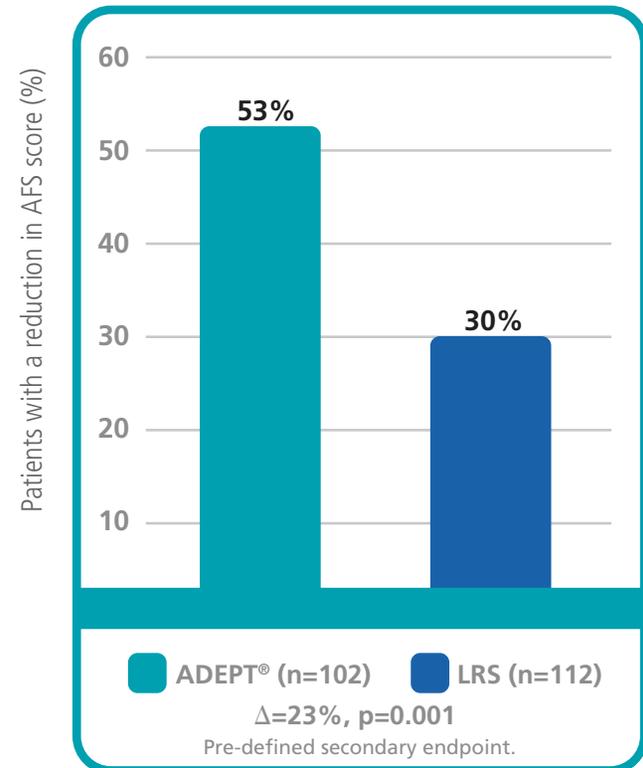
In the Pivotal study, the most frequently occurring treatment-related adverse events between surgeries were post procedural leaking from port sites, labial, vulvar or vaginal swelling and abdominal distention.

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In the sub-group of patients from the Pivotal study, presenting with a primary diagnosis of infertility, significantly more infertility patients (53%) had a reduction in AFS\* score compared with the LRS group (30%)  $p=0.001$ .<sup>1</sup>

Patients with reduction in AFS Score



The effectiveness of ADEPT® has not been established for longer term clinical outcomes following gynecological surgery, e.g. pregnancy and pain.

\*American Fertility Society

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A copy of the pivotal study is enclosed in this pocket.



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# adept®

**Adhesion Reduction Solution  
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## **ADEPT® Adhesion Reduction Solution [4% Icodextrin] Indications**

ADEPT Adhesion Reduction Solution is indicated for use intraperitoneally as an adjunct to good surgical technique for the reduction of post-surgical adhesions in patients undergoing gynecological laparoscopic adhesiolysis.

### **Important Risk Information for ADEPT®**

ADEPT® is for direct intraperitoneal administration only. NOT for intravenous (IV) administration.

ADEPT® is contraindicated in patients with known or suspected allergy to cornstarch based polymers e.g. icodextrin, or with maltose or isomaltose intolerance, or with glycogen storage disease.

ADEPT® is contraindicated in laparotomy, in cases involving bowel resection or repair, or appendectomy and in surgical cases with frank abdomino-pelvic infection.

There have been rare reports of sterile peritonitis following the use of icodextrin.

#### References

1. ADEPT® Adhesion Reduction Solution [4% Icodextrin] [Instructions for Use]. Deerfield, IL: Baxter Healthcare Corporation; 2006.
2. Brown CB, Luciano AA, Martin D, et al; Adept Adhesion Reduction Study Group. Adept (icodextrin 4% solution) reduces adhesions after laparoscopic surgery for adhesiolysis: a double-blind, randomized, controlled study. *Fertil Steril*. 2007;88(5):1413-1426.
3. Sutton C, Minelli L, Garcia E, et al. Use of icodextrin 4% solution in the reduction of adhesion formation after gynaecological surgery. *Gynecol Surg*. 2005;2(4):287-296.

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**BioSurgery**

## **ADEPT® Adhesion Reduction Solution**

<b>Reorder #</b>	<b>Description</b>
0600041	Box of 5 bags, 1.5L each

Leakage of ADEPT® from port sites may lead to wound healing complications; meticulous fascial closure may reduce leakage through laparoscopic port sites post-operatively.

There have been rare reports of hypersensitivity reactions, pulmonary edema, pulmonary effusion and arrhythmia.

Anaphylaxis has been reported in a few patients.

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

In the pivotal study, the most frequently occurring treatment-related adverse events between surgeries were post procedural leaking from port sites, labial, vulvar or vaginal swelling and abdominal distention.

**Rx Only:** For safe and proper use of this device, please refer to full device Instructions For Use.

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