

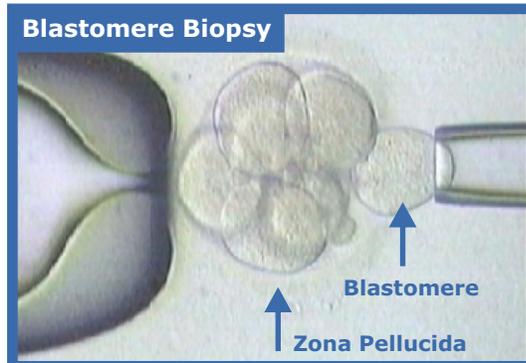


Caution: Federal law restricts this device to sale by or on the order of a physician or a practitioner trained and certified in its use. Assisted Hatching and/or laser biopsy is not recommended for routine use in all IVF patients.

## FREQUENTLY ASKED QUESTIONS ABOUT LASER-ASSISTED BIOPSY

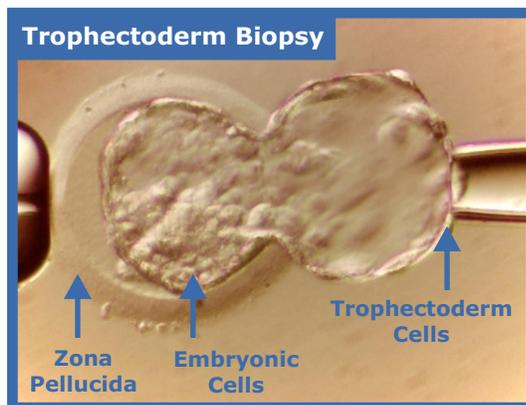
### Q: What is blastomere biopsy?

A: Blastomere biopsy is one method used for embryo biopsy. When an embryo reaches the third day of development, it normally has eight cells. One or two of these cells, called "blastomeres," can be removed from the embryo. The embryo can go on to develop just as though the one cell or two cells were never removed.



### Q: What is trophoctoderm biopsy?

A: Trophoctoderm biopsy is another method used for embryo biopsy. Trophoctoderm cells are extra-embryonic tissue; this means that it does not become part of the fetus but becomes part of supporting structures, such as the placenta and membranes. Trophoctoderm biopsy takes place at the 16-32 cell "blastocyst" stage of development, as the trophoctoderm is beginning to herniate through the zona pellucida. Instead of removing individual blastomeres, several trophoctoderm cells are removed.



### Q: Why is embryo biopsy performed?

A: The cells removed during the biopsy procedure are used to perform pre-implantation genetic diagnosis (PGD), which shows the chromosomal composition of the embryos, and if they carry a specific disease-producing mutation. One or more embryos free of conditions that would cause serious disease may then be implanted in a woman's uterus.

### Q: What are the different ways of performing the embryo biopsy procedures?

A: There are three methods of biopsy procedures: mechanical, chemical, and laser zona drilling. With mechanical methods, an incision or hole is made in the zona pellucida (the outer layer) using a tool such as a microsurgical knife or a special glass needle. The chemical method directs a stream of acidic solution to digest a portion of the zona pellucida. Laser zona drilling uses a highly focused laser beam to remove the zona pellucida in very precise increments.

### Q: How is the laser used during the embryo biopsy procedures?

A: For blastomere biopsy, the laser is used to drill an opening in the zona pellucida to facilitate insertion of the pipet used to remove the blastomere.

For trophoctoderm biopsy, the laser is first used to create an opening in the zona to promote herniation of the trophoctoderm. After the trophoctoderm has protruded, the laser is also used to help separate the trophoctoderm cells.

**FREQUENTLY ASKED QUESTIONS ABOUT LASER-ASSISTED BIOPSY (continued)****Q: What type of conditions can PGD detect?**

A: To date, PGD has been most widely used to enable the birth of children free from diseases such as Down's Syndrome, Tay-Sachs disease, Beta-thalassemia, Cystic Fibrosis, and Duchenne Muscular Dystrophy. Any gene disorder in which the DNA base pairs or code is known can be detected by PGD.

**Q: What are the indications for embryo biopsy for PGD?**

A: The most commonly used indications for PGD are:

✓ **Carriers of single gene disorders**

These patients benefit from PGD by reducing the risk of conceiving an affected baby.

✓ **Recurrent Miscarriage**

Fertile couples with repeated miscarriages should be evaluated for the presence of a chromosomal abnormality. The female or male partner may be a carrier of a balanced translocation or be an aneuploid mosaic.

✓ **Unsuccessful IVF cycles**

Couples with repeated unsuccessful IVF cycles should be evaluated for the presence of a chromosome abnormality. The female or male partner may be a carrier of a balanced translocation or be an aneuploid mosaic.

✓ **Unexplained Infertility**

The most probable cause of unexplained infertility or history of habitual miscarriage is a chromosome abnormality. The male OR female partner may be a carrier of a translocation or be an aneuploid mosaic.

✓ **Aneuploidy and Advanced Maternal Age**

Women of advanced maternal age (> 35) are at a higher risk of producing aneuploid embryos, resulting in implantation failure, a higher risk of miscarriage or the birth of a child with a chromosome abnormality (e.g. Down syndrome).

**Q: What are the risks of embryo biopsy using the laser?**

A: The risks of embryo biopsy using the laser are similar to the risks when using chemical or mechanical methods. These risks include possible damage / destruction to the embryo and a possible increased chance of monozygotic (identical) twinning.

**Q: What are the benefits of embryo biopsy using the laser?**

A: Using the laser for embryo biopsy requires less embryo handling, allows for more precision and control, is less traumatic, and reduces technician variation as compared to chemical and mechanical methods. Because laser embryo biopsy is faster than the other methods, the embryo spends less time outside the incubator and is less likely to be harmed.