

Recover the cells that matter with the Parsortix[®] PC1 system



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The Parsortix® PC1 system

The first FDA cleared medical device for the capture and harvest of intact circulating tumor cells (CTCs) from metastatic breast cancer (MBC) patient blood for subsequent user-validated analysis.

Why liquid biopsy?

Liquid biopsy is an emerging approach to cancer management that provides repeatable access to a tumor sample without the need for an invasive, and potentially dangerous solid tissue biopsy procedure.¹

The current National Comprehensive Cancer Network (NCCN) Guidelines for the treatment of metastatic breast cancer (MBC) patients require a tissue biopsy of the metastatic site to support clinical decision-making. Cancer is a dynamic disease that changes over time and there is a clear need for up-to-date information on disease status.²

Despite being recommended in the NCCN Guidelines, many patients are not eligible for biopsy as a result of patients being too sick for the invasive procedure, the inaccessibility of the metastatic site or other organ-specific complications associated with the procedure.^{3,4}

The ability to monitor and analyze CTCs may transform the treatment of MBC, providing patients with personalized cancer care through a non-invasive, repeat liquid biopsy with the power of Parsortix® technology.

Benefits of the Parsortix PC1 system

- Provides access to biologically and clinically relevant, viable CTCs, including epithelial and mesenchymal phenotypes
- Captures CTC and CTC clusters from whole blood, eliminating the need for sample pre-processing
- Easy to operate system requiring minimal user intervention
- Allows comprehensive analysis options, including cell morphology, DNA, RNA and protein analysis
- Provides a CTC enriched sample compatible with single cell sorting for subsequent molecular analysis

“*The first medical device to receive FDA clearance for the harvest of intact CTCs*”

Karen Miller
Chief Scientific Officer



“As a breast cancer surgeon, I am very enthusiastic about the potential of liquid biopsy. Our pilot data shows that potentially the same information can be obtained from a simple blood test using the Parsortix® system as from an invasive tissue biopsy and indeed may be advantageous over invasive tissue biopsies in regard to the diverse sites of metastatic disease.”

Julie E. Lang

Chief of Breast Surgery, Cleveland Clinic. Formerly, Director, USC Breast Cancer Program, Associate Professor of Surgery, Norris Comprehensive Cancer Center, University of Southern California





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2. Carlson RW, et al, Metastatic breast cancer, version 1.2012: featured updates to the NCCN guidelines. *Journal of the National Comprehensive Cancer Network*. 2012 Jul 1;10(7):821-9
3. Criscitiello C, et al. Biopsy confirmation of metastatic sites in breast cancer patients: clinical impact and future perspectives. *Breast Cancer Res* 2014; 16(2):205-12
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Parsortix® PC1 system

The Parsortix® PC1 system is cleared by the FDA only when used with the MBC-01 Metastatic Breast Cancer Kit and ICT-01 Instrument Control Test kit in compliance with the approved instructions for use.

Product Intended use:

The Parsortix® PC1 system is an in vitro diagnostic device intended to enrich circulating tumor cells (CTCs) from peripheral blood collected in K2EDTA tubes from patients diagnosed with metastatic breast cancer. The system employs a microfluidic chamber (a Parsortix® cell separation cassette) to capture cells of a certain size and deformability from the population of cells present in blood. The cells retained in the cassette are harvested by the Parsortix® PC1 system for use in subsequent downstream assays. The end user is responsible for the validation of any downstream assay. The standalone device, as indicated, does not identify, enumerate or characterize CTCs and cannot be used to make any diagnostic/prognostic claims for CTCs, including monitoring indications or as an aid in any disease management and/or treatment decisions.