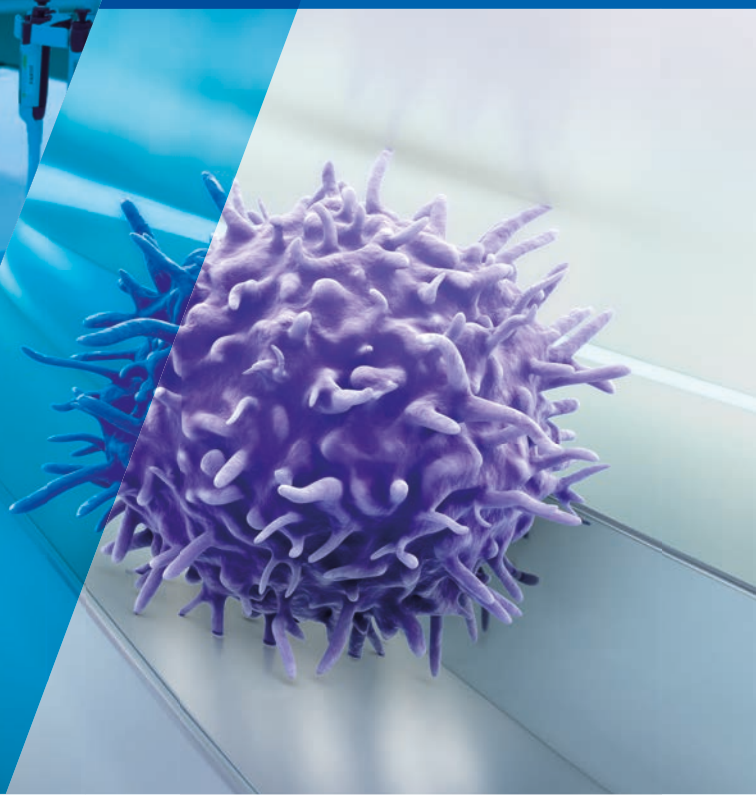
FDA cleared

ANGLE

The Parsortix® PC1 Clinical System

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



Recover the cells that matter with the Parsortix® PC1 Clinical System

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The first FDA product classification for a medical device that captures and harvests intact circulating tumor cells (CTCs) from metastatic breast cancer (MBC) patient blood for subsequent analysis.

Why CTC-based liquid biopsy?

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

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.[1] 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.[2]

For the same reasons, very few MBC patients will subsequently have a further biopsy of another metastatic site, despite it being well-established that cancer develops and changes over time and there is a clear medical need for up-to-date information on disease status.[2,3]

Benefits of Parsortix® technology

The Parsortix® PC1 Clinical System uses liquid biopsy for obtaining MBC cells for analysis, which is non-invasive and can be repeated as often as needed. Furthermore, unlike ctDNA which is limited to DNA analysis and is the focus for most of the liquid biopsy industry, a full range of analyses can be undertaken with CTCs including DNA, RNA and protein analyses giving a viable alternative to a tissue biopsy.[3,4]

Capture a wide range of cancer cells

CTCs are captured based on their size and deformability, enabling the isolation of live epithelial and mesenchymal CTCs and CTC clusters. Harvested CTCs can be used for imaging and a range of downstream analyses including:

- Cytological examination
- DNA, RNA and protein analyses
- Single cell picking and analyses

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.

Parsortix® PC1 Clinical System

The Parsortix® PC1 Clinical 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 K_2EDTA 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.

References:

1. 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.
2. 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.
3. Ring A, et al. Circulating Tumor Cell Transcriptomics as Biopsy Surrogates in Metastatic Breast Cancer. Ann Surg Oncol 2022. https://doi.org/10.1245/s10434-021-11135-2.
4. Alix-Panabieres C, Pantel K. Liquid Biopsy: From Discovery to Clinical Application. Cancer Discov 2021;11:858-73.

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