

4 November 2025

TruScreen appoints distributor to South Africa

- TruScreen appoints Johannesburg distributor AIR to distribute its AI enabled TruScreen cervical cancer screening system in South Africa
- South Africa has an extremely high cervical cancer mortality rate - 19.6 per 100,000, compared to New Zealand and Australia's 1.7 per 100,000¹, with an estimated 10,702 new cases of cervical cancer each year and 5,807 deaths annually¹
- South Africa had the 10th highest global cervical cancer incidence in 2022²
- South Africa has an estimated screening population of over 19 million women⁴

TruScreen Group Limited ("TruScreen" or "the Company") advises the appointment of South African medical products company AIR to distribute its unique AI enabled TruScreen cervical cancer screening system.

South Africa has an extremely high cervical cancer mortality rate - 19.6 per 100,000, compared to New Zealand and Australia's 1.7 per 100,000¹, with an estimated 10,702 new cases of cervical cancer each year and 5,807 deaths annually¹. South Africa had the 10th highest global cervical cancer incidence in 2022².

These statistics highlight persisting challenges South Africa faces with late diagnosis, limited screening coverage, and healthcare access. TruScreen, is a portable AI enabled, real-time, laboratory-free cervical cancer screening system that is ideally suited to meet these challenges.

The investigators of TruScreen's [most recently peer-reviewed study in Saudi Arabia concluded](#): ***"TruScreen represents a reliable, practical screening tool for cervical neoplasms and provides an evidence-based approach for policymakers when selecting the optimal cervical cancer screening strategy in countries without an established national screening program."***³

AIR will market and sell TruScreen in South Africa and will be supported by Evohealth, a Guateng-based manufacturer of pharmaceuticals and distributor of pharmacy products and medical devices. They will register and provide logistics support for TruScreen in South Africa.

Registration is expected to be completed in 3 months, with first sales expected to occur in January 2026.

South African distribution is a key market for TruScreen's African strategy. TruScreen has major public screening programs to recommence in Zimbabwe, a proposed local Public Screening program (in planning) for Eswatini, and early commercial sales in Rwanda. The addition of 19 million women in South Africa⁴ will grow TruScreen's African distribution reach to an addressable market of 30 million women.

¹ ICO/IARC HPV Information Centre (*ICO = Catalan Institute of Oncology and IARC = International Agency for Research on Cancer)

² World Cancer Research Fund [Cervical Cancer Statistics](#)

³ Majed Alhudhud, Shazia Maqsood, Maab El Hussein et al. Beyond Tradition: Investigating TruScreen's Performance Versus Pap Smear in Cervical Cancer Detection, 25 July 2024, PREPRINT (Version 1) available at Research Square [<https://doi.org/10.21203/rs.3.rs-4638793/v1>]

⁴ CIA World Factbook women aged 15-64

TruScreen CEO, Martin Dillon commented:

“Adding South Africa is a major milestone in our African distribution strategy. The majority of African nations are emerging economies with limited or no screening laboratory infrastructure. The TruScreen technology will assist to reduce deaths from cervical cancer. TruScreen is also well suited to increase the screening rates in 47 WHO member nations looking to achieve 70% screening rates by 2030.”

This announcement has been approved by the Board.

Ends

For more information, visit www.truscreen.com or contact:

Martin Dillon

Chief Executive Officer

martindillon@truscreen.com

Guy Robertson

Chief Financial Officer

guyrobertson@truscreen.com

About TruScreen:

TruScreen Group Limited (NZX/ASX: TRU) is a medical device company that has developed and manufactures an AI-enabled device for detecting abnormalities in the cervical tissue in real-time via measurements of the low level of optical and electrical stimuli.

TruScreen's cervical screening technology enables cervical screening, negating sampling and processing of biological tissues, failed samples, missed follow-up, discomfort, and the need for costly, specialised personnel and supporting laboratory infrastructure.

The TruScreen device, TruScreen Ultra®, is registered as a primary screening device for cervical cancer screening.

The device is CE Marked/EC certified, ISO 13485 compliant and is registered for clinical use with the TGA (Australia), MHRA (UK), NMPA (China), SFDA (Saudi Arabia), Roszdravnadzor (Russia), and COFEPRIS (Mexico). It has Ministry of Health approval for use in Vietnam, Israel, Ukraine, and the Philippines, among others and has distributors in 29 countries. In 2021, TruScreen established a manufacturing facility in China for devices marketed and sold in China.

TruScreen technology has been recognised in CSCCP's (Chinese Society for Colposcopy and Cervical Pathology) China Cervical Cancer Screening Management Guideline.

TruScreen has been recognised in a China Blue Paper "Cervical Cancer Three Stage Standardized Prevent and Treatment" published on 28 April 2023.

In Dec 2023 TruScreen technology was added to the Vietnam Ministry of Health approved National Technical List, for use in Vietnam's public and private healthcare sectors and in 2024 was added to the Russian guidelines for the screening of cervical cancer.

In financial year 2024 alone, over 200,000* examinations were performed with the TruScreen device. To date, over 200 devices have been installed and used in China, Vietnam, Mexico, Zimbabwe, Russia, and Saudi Arabia. TruScreen's vision is "A world without the cervical cancer"®.

To learn more, please visit: www.truscreen.com/.

**Based on Single Use Sensor sales.*

Glossary:

Pap smear (the Papanicolaou smear) test involves gathering a sample of cells from the cervix, with a special brush. The sample is placed on a glass slide or in a bottle containing a solution to preserve the cells. Then it is sent to a laboratory for a pathologist to examine under a microscope. <https://www.cancer.net/navigating-cancer-care/diagnosing-cancer/tests-and-procedures/pap-test>

LBC (the liquid-based cytology) test, transfers a thin layer of cells, collected with a brush from the cervix, onto a slide after removing blood or mucus from the sample. The sample is preserved so other tests can be done at the same time, such as the human papillomavirus (HPV) test <https://www.cancer.net/cancer-types/cervical-cancer/diagnosis>

HPV (human papilloma virus) test is done on a sample of cells removed from the cervix, the same sample used for the Pap test or LBC. This sample is tested for the strains of HPV most commonly linked to cervical cancer. HPV testing may be done by itself or combined with a Pap test and/or LBC. This test may also be done on a sample of cells which a person can collect on their own. <https://www.cancer.net/cancer-types/cervical-cancer/screening-and-prevention>

Sensitivity and specificity mathematically describe the accuracy of a test which reports the presence or absence of a condition. If individuals who have the condition are considered "positive" and those who don't are considered "negative", then sensitivity is a measure of how well a test can identify true positives and specificity is a measure of how well a test can identify true negatives:

- **Sensitivity** (true positive rate) is the probability of a positive test result, [conditioned](#) on the individual truly being positive.
- **Specificity** (true negative rate) is the probability of a negative test result, conditioned on the individual truly being negative ([Sensitivity and specificity – Wikipedia](#)).

For more information about the cervical cancer and cervical cancer screening in New Zealand and Australia, please see useful links:

New Zealand: [National Cervical Screening Programme | National Screening Unit \(nsu.govt.nz\)](#)

Australia: [Cervical cancer | Causes, Symptoms & Treatments | Cancer Council](#)