NZX/ASX Announcement

12 January 2026

Clinical study validates TruScreen's efficacy and safety for pregnant women

- **Leading Chinese medical publication *Family Doctor* confirms TruScreen's efficacy as a cervical cancer screening tool for pregnant women, in a 2,000-patient study conducted at Guilin People's Hospital**
- **This is the first clinical validation of TruScreen Ultra's use in pregnancy**
- **The Study confirms the use to include the screening of pregnant women**
- **TruScreen's AI-enabled, real-time, non-invasive device was determined to be a superior choice for pregnant women compared to TCT (ThinPrep Cytologic Test) due to:**
  - **better tolerance**
  - **lower rates of post-procedure bleeding**
  - **avoidance of sampling-related limitations**

TruScreen Group Limited ("TruScreen" or "the Company") advises that a new study has been published in the leading Chinese medical publication *Family Doctor,* validating TruScreen's efficacy as an initial screening tool for cervical lesions during pregnancy. This is the first study to focus on TruScreen's use in pregnancy. The study can be viewed at https://www.cnki-acc.net/wenzhang/37126.html (in Chinese).

In pregnancy, the cervix is fragile, increasing discomfort and bleeding risk and negatively affecting compliance and specimen quality during cervical cancer screening. The study retrospectively analyzed 2,000 pregnant women screened with TruScreen and 900 screened with TCT (ThinPrep Cytologic Test) at Guilin People's Hospital between January 2022 and December 2024. It compared baseline characteristics, discomfort during screening, post screening vaginal bleeding, and pathology from colposcopy directed biopsy.

The study concluded that ***TruScreen has a high clinical value in screening pregnant women****, with diagnostic performance overall similar to TCT but better tolerance and lower rates of post-procedure bleeding. The authors note that pregnancy-related cervical changes can impair cytology quality and increase the risk of bleeding, whereas TruScreen evaluates tissue characteristics non-invasively and avoids sampling-related limitations. They conclude that TruScreen improves safety, reduces anxiety and unnecessary interventions related to bleeding, and enhances follow-up compliance.*

The comparison between TruScreen and the Thin Prep liquid-based cytology was:

	Sensitivity	Specificity
TruScreen	73.7%	94.8%
TCT	71.4%	95.2%

The paper concludes that *TruScreen is simple to operate, safe, well-tolerated, and provides immediate results, making it a* ***valuable*** *supplementary and* ***initial screening method for cervical lesions during pregnancy*** *with* ***good prospects for wider clinical application****.*

The *Family Doctor* is a leading print publication in China which supports China's major health policy to establish a strong primary care system.

TruScreen CEO, Martin Dillon commented:

" We are delighted to see the clinical evidence for TruScreen's use for pregnant women presented so powerfully and its potential superiority as a screening choice. China is our largest market, with an estimated screening population of 467 million women, so it is highly encouraging to see TruScreen's efficacy reported by a widely circulated journal in the consumer channels in addition to our many academic clinical performance validations already conducted there and globally. "*

This announcement has been approved by the Board.

* CIA World Factbook (female population aged 15-64yrs)

Ends

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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-andprocedures/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