# Bracco Imaging Receives Regulatory Approval in China for sulphur hexafluoride (SF6) in the Assessment of Fallopian Tube Patency

*New indication of SF6 microbubbles supports non-invasive assessment of female infertility through contrast-enhanced ultrasound in China*

**August 5, 2025, MILAN** – Bracco Imaging, a global leader in diagnostic imaging, today announced that its ultrasound contrast agent has been approved by the China's National Medical Products Administration (NMPA) for use in hysterosalpingo-contrast-sonography (HyCoSy).
HyCoSy is a contrast-enhanced ultrasound (CEUS) procedure that helps identifying potential causes of female infertility related to blockage of the fallopian tubes or uterine abnormalities with a high level of diagnostic accuracy (1,2). Fallopian tube conditions, such as blockages, scarring, or other damage, are a leading cause of infertility, contributing to approximately 25–35 percent of cases of infertility among women in China (3).
This regulatory approval represents an important milestone in the management of infertility because, unlike laparoscopic assessment of tubal patency with use of a dye, HyCoSy is a non-invasive procedure, and, unlike traditional X-ray hysterosalpingography, HyCosy does not expose to radiation the genital tract of women in their reproductive years (4-6).

"The NMPA approval of SF6 use with HyCoSy marks an important step in expanding access to non-invasive, radiation-free detection of tubal issues and uterine problems that often cause infertility in women" said Alberto Spinazzi, Chief Medical and Regulatory Officer, Bracco Group. "We strive to provide healthcare professionals in China with solutions that advance standards of care, reflecting our commitment to advancing diagnostic precision and improving the patient experience through contrast-enhanced ultrasound."

"We are proud to support China's healthcare priorities through solutions like the ultrasound contrast agent that may help address important diagnostic needs," said Valtero Canepa, Head of APAC, Bracco Imaging. "This new indication advances Bracco's role in delivering meaningful innovation in support of the Healthy China 2030 initiative, which prioritizes earlier detection, clinical precision, and broader access to reproductive health services."

The high diagnostic performance of HyCoSy with SF6 microbubbles has been confirmed by a recent systematic review and meta-analysis of 24 clinical studies (total of 1358 women with infertility and 2661 fallopian tubes). Using laparoscopic chromotubation dye test as the standard of truth for the assessment of fallopian tube patency, the pooled estimates of sensitivity, specificity, and accuracy of HyCoSy with the contrast agent were 93%, 90%, and 96%, respectively (1).

Backed by over 20 years of clinical use, sulphur hexafluoride is the ultrasound contrast agent with the largest number of approved indications in the largest number of countries worldwide. The newly approved HyCoSy indication reinforces Bracco Imaging's commitment to expanding non-invasive, high-quality diagnostic tools aligned with evolving clinical standards and national health objectives in China and beyond.


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2) Wang T, Dong T, Nie F. Clinical applications, advances, and future directions in hysterosalpingography. Front Med 2025; 12:1537506
3) Reproductive Health Branch of Chinese Preventive Medicine Association. Chinese Expert Consensus on Holistic Management of Tubal Factor Infertility (2023 edition) [J]. Chinese Journal of Practical Gynecology and Obstetrics 2023; 39:318-324
4) Roy KK, Gajapathy SR, Rai R, Zangmo R, Das A, Singhal S. Assessment of Tubal Patency with Selective Chromopertubation at Office Hysteroscopy versus Modified Minilaparoscopy in Infertile Women. Gynecol Minim Invasive Ther 2021; 10:159-165
5) Perisinakis K, Damilakis J, Grammatikakis J, Theocharopoulos N, Gourtsoyiannis N. Radiogenic risks from hysterosalpingography. Eur Radiol 2003; 13:1522-1528
6) Sulieman A, Theodorou K, Vlychou M, Topaltzikis T, Roundas C, Fezoulidis I, Kappas C. Radiation dose optimisation and risk estimation to patients and staff during hysterosalpingography. Radiat Prot Dosimetry 2008;128:217-226


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Bracco Imaging S.p.A. ("Bracco Imaging"), part of the Bracco Group, is an innovative world leader delivering end-to-end products and solutions through its comprehensive portfolio across diagnostic imaging modalities. Headquartered in Milan, Italy, Bracco Imaging's purpose is to improve people's lives by shaping the future of prevention and precision diagnostic imaging. The Bracco Imaging portfolio includes products and solutions for all key diagnostic imaging modalities: X-ray imaging, magnetic resonance imaging (MRI), Contrast Enhanced Ultrasound (CEUS), and Nuclear Medicine through radioactive tracers and novel PET imaging agents. Bracco Imaging has 3,800 employees and operates in more than 100 markets globally. Bracco Imaging has a well skilled and innovative Research and Development (R&D) organization with an efficient process-oriented approach and track record in the diagnostic imaging industry. Discover Bracco at https://www.bracco.com/.

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LIFE FROM INSIDE

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Bracco is an **international Group** active in over 100 countries worldwide in the healthcare sector and a leader in **diagnostic imaging**. It has 3,700 employees and annual total consolidated revenues of around 1,8 billion euros, 88% of which from international sales. In the Research and Development area, the company invests approximately 10% of reference turnover in the imaging diagnostics and medical devices sectors and has a portfolio comprising over 2,600 patents.

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