

Intended Use

System User Manual

Addendum



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PN 554314-02 REV. C 2020.12

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System User Manual Addendum

This addendum to the da Vinci Xi System User Manual and the da Vinci X System User Manual provides an update to the Intended Use to add the nipple sparing mastectomy with reconstruction surgical procedure.

For full system information, including General Information and Professional Instructions for Use, see the applicable system user manual. Keep this addendum with your system documentation.

Intended Use

zakres zastosowania robota
chirurgicznego

The Intuitive Surgical Endoscopic Instrument Control System (da Vinci Surgical System Models IS4000 and IS4200) is intended to assist in the accurate control of Intuitive Surgical Endoscopic instruments during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general thoracoscopic surgical procedures, thoracoscopically-assisted cardiotomy procedures, nipple sparing mastectomy with reconstruction surgical procedures, and transoral otolaryngology surgical procedures restricted to benign tumors and malignant tumors classified as T1 and T2, and for benign base of tongue resection procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use (except for transoral otolaryngology surgical procedures). It is intended to be used by trained physicians in an operating room environment.

Additional Information for da Vinci Xi and da Vinci X System Use in Nipple Sparing Mastectomy with Reconstruction Procedures (RNSM):

- **Intended Population:**


- Patients undergoing prophylactic mastectomies with breast cup size C and below.
- RNSM is not approved for use in patients with cancer and precancer (ductal carcinoma in situ [DCIS]).

- **General Considerations:**

- The International Endoscopic and Robotic Breast Surgery Symposium (IERBS) has developed consensus statements that provide standardized guidelines on robotic-assisted mastectomy¹. These consensus statements should be reviewed and used as guidelines prior to using the da Vinci system in nipple sparing mastectomy with reconstruction surgical procedures.
- The long-term oncological outcomes related to the management of breast cancer following RNSM in patients with precancer (DCIS) and cancer have not been established. There is no published Level 1 evidence available (no randomized controlled trial).
- Operative time may be longer during the initial learning curve.

1. Lai H-W, Toesca A, Sarfati B, Park HS, Houvenaeghel G, Selber JC, Cheng FT-F, Kuo W-L, Peradze N, Song SY, Mok CW. Consensus statement on robotic mastectomy-expert panel from international endoscopic and robotic breast surgery symposium (IERBS) 2019. Ann Surg. 2020 Jan 17. doi: 10.1097/SLA.0000000000003789.

- **Training:**

 **WARNING:** Only trained users and those who have developed adequate robotic skills to perform the tasks associated with each procedure should use the system. Training provided by Intuitive Surgical is limited to the use of the da Vinci Xi system and da Vinci X system and does not replace the necessary medical training and experience required to perform RNSM surgery.

- **Contraindications:**

The same contraindications as for traditional NSM apply to the use of the da Vinci system in RNSM. RNSM is not recommended for use in nipple sparing mastectomy with reconstruction surgical procedures in the following patient population:

- Patients with thromboembolism, thrombose patients, patients at risk in relation to anesthesia.
- Patients with breast cup size D and above.
- Patients with cancer involving the nipple areolar complex (NAC), inflammatory breast cancer or T4d lesion, clinical evidence of skin involvement or T4b lesion, and clinical or radiological evidence of chest wall invasion.

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