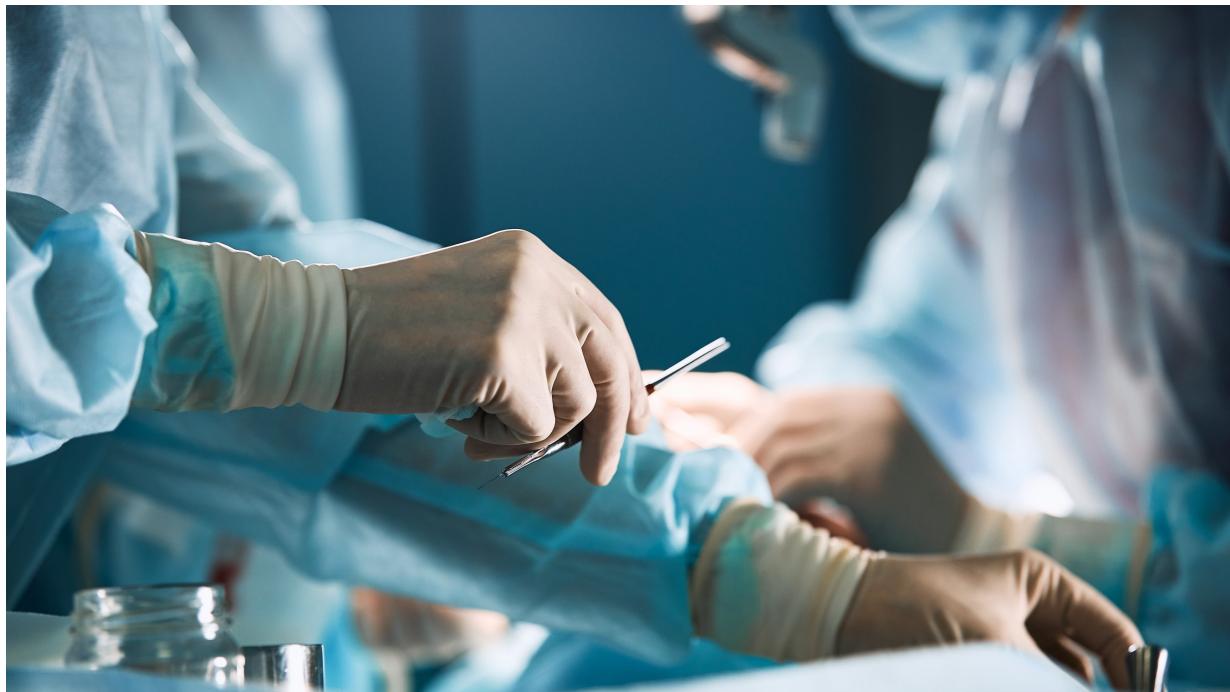


Appendices to the report





MAINTAINING PATIENT SAFETY WITH NEW SURGICAL AND INVASIVE METHODS

Appendices to the report

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Appendix 1

Template for information from HF to patients (PDF)

Appendix 2

Introduction of other surgical and invasive methods (PDF)

Appendix 3

Letter from NGICG-CR to the regional medical directors (PDF)

Appendix 4

Process chart – New methods (PDF)

Appendix 5

Questions from NHIB to the seven relevant hospitals

Below are the questions NHIB sent to the relevant hospitals.

Topic	Question
1. Introduction of taTME	<p>What was the decision-making process on the introduction of taTME? When was the first patient operated using taTME?</p> <p>When was the last patient operated using taTME? What was the reason that you suspended use of this procedure?</p>
2. Training	<p>How was the training and guidance of surgeons in the taTME method arranged?</p> <p>Was there a proctor scheme at the hospital in connection with implementation of the method? How was this carried out?</p>
3. Clinical trial	<p>Were the patients who underwent taTME surgery included in a clinical trial? Attach documentation/protocol</p> <p>Was any data sent to foreign trials? Attach documentation/protocol</p> <p>Was the trial registered in REK? Was it also registered anywhere else? Attach documentation</p> <p>Was the trial reported to the data protection officer (DPO)? Attach documentation</p>
4. Information for patients	<p>Did the patients who underwent surgery using the taTME method receive information that this is a technique in a developmental phase? Attach documentation</p> <p>Did the patients receive an information letter and/or consent form about this? Attach documentation</p> <p>Were the patients who underwent surgery using taTME at your hospital subsequently informed that the method had been suspended due to complications and oncological results? Attach documentation</p> <p>Did patients have a choice between surgery using taTME or the traditional method?</p> <p>Was it registered in the medical records that the patients were informed that they were to be operated on using a new technique that is subject to development?</p>

5. Quality improvement	<p>Did the hospital perform an internal review/internal scrutiny of the introduction of the taTME method after it was suspended? Attach documentation</p> <p>If the patients you operated on were among those who suffered a recurrence or complications after the taTNME surgery – was notification of this sent to the supervisory authorities?</p>
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