Diagnosis and Treatment of Patients with early and advanced Breast Cancer

Guidelines Breast
Version 2023.1E

In collaboration with:

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Breast Cancer Surgery
Oncological Aspects

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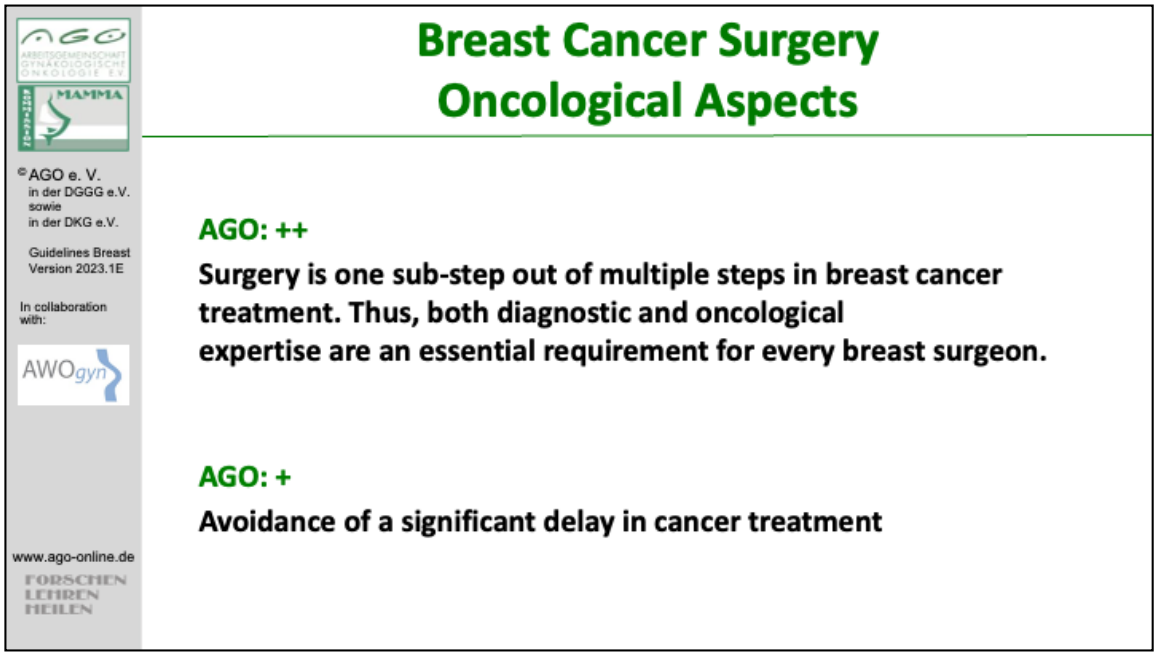
- **Versions 2002–2022:**
  Banys-Paluchowski / Bauerfeind / Blohmer / Böhme / Brunnert / Costa / Ditsch / Fallenberg / Fersis / Friedrich / Gerber / Hanf / Janni / Junkermann / Kaufmann / Kühn / Kümmel / Möbus/ Nitz / Rezai / Simon / Solomayer / Thomssen / Thill / Untch / Wöckel

- **Version 2023**
  Bauerfeind / Thill



Delay of surgical therapy:

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Surgeon:

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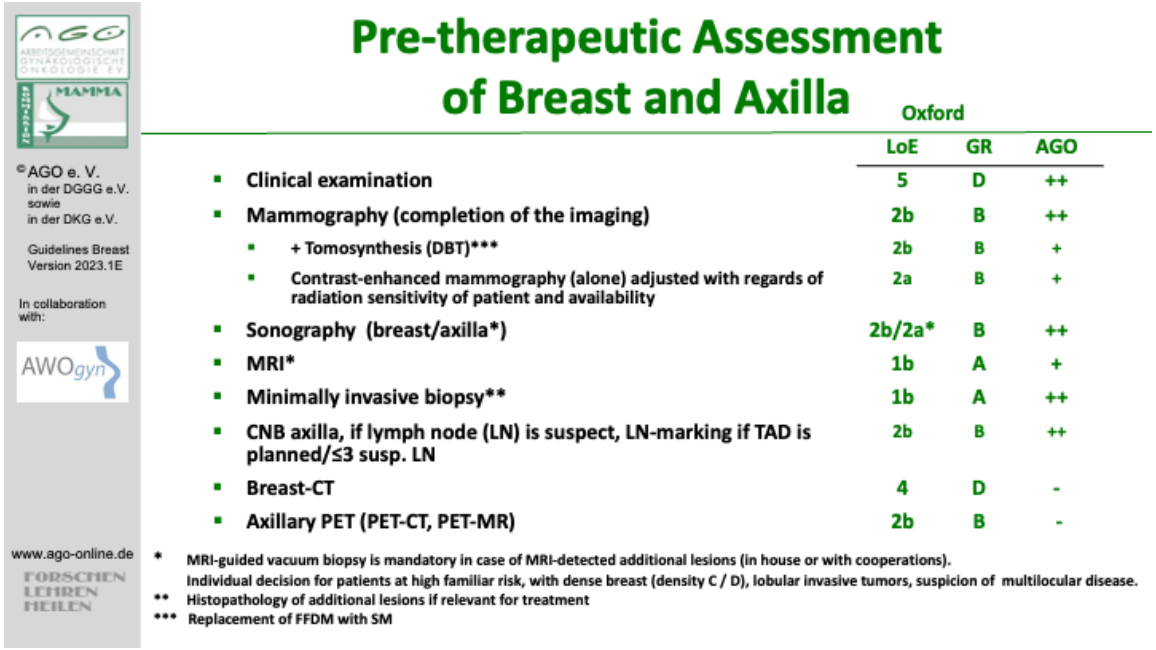

Combined DM + DBT + US + MRI

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US-Axilla +FNA/CNB

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Biopsie

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MRT

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<u>Reviews CESM:</u>

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2. Patel, B.K., M.B.I. Lobbes, and J. Lewin, Contrast Enhanced Spectral Mammography: A Review. Semin Ultrasound CT MR, 2018. 39(1): p. 70-79.
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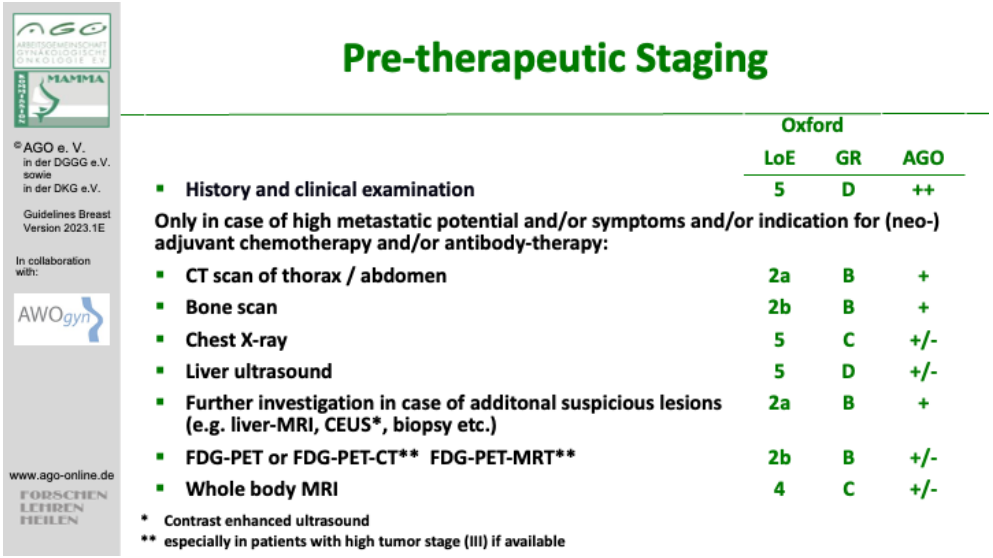
Brust-CT:

1. Uhlig, J. A.-O., A. Uhlig, L. Biggemann, U. Fischer, J. Lotz and S. Wienbeck "Diagnostic accuracy of cone-beam breast computed tomography: a systematic review and diagnostic meta-analysis." (1432-1084 (Electronic)).
2. Zhu, Y., A. M. O'Connell, Y. Ma, A. Liu, H. Li, Y. Zhang, X. Zhang and Z. Ye (2022). Dedicated breast CT: state of the art-Part II. Clinical application and future outlook. Eur Radiol. Germany. **32:** 2286-2300.



Statement: history and physical examination

1. GCP

Statement: high metastatic potential / symptoms

1. Rutgers, EJ et al: Quality control in the locoregional treatment of breast cancer (2001) EJC 37: 447-453
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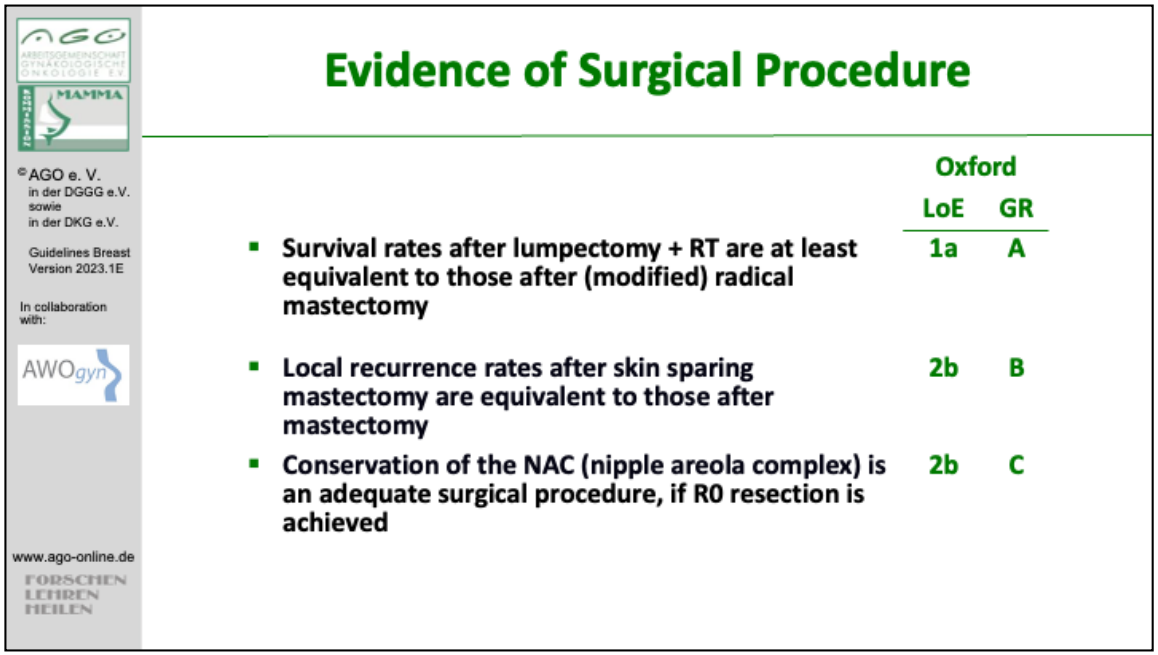

Statement: lumpectomy – mastectomy

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Statement: skin sparing mastectomy

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6. Foster et al. Skin-sparing mastectomy and immediate breast reconstruction: a prospective cohort study for the treatment of advanced stages of breast carcinoma. Ann Surg Oncol 2002 Jun;9(5):462-6
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indications Ann Surg. 2009;250(2):288-92

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Statement: Nipple sparing mastectomy

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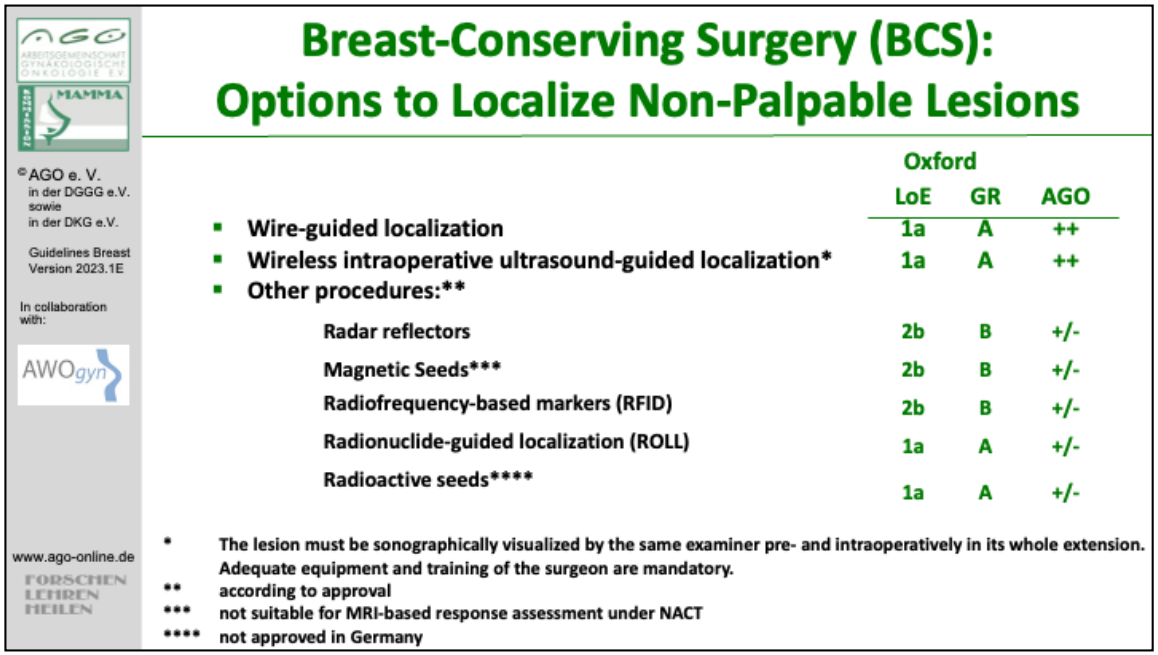

Meta-analyses of different techniques:

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3. Davey MG, O'Donnell JPM, Boland MR et al. Optimal localization strategies for non-palpable breast cancers -A network meta-analysis of randomized controlled trials. Breast. 2022 Apr;62:103-113. doi: 10.1016/j.breast.2022.02.004. Epub 2022 Feb 8

Meta-analysis WGL vs. ROLL:

1. Kiruparan N, Kiruparan P, Debnath D. Use of wire-guided and radio-guided occult lesion localization for non-palpable breast lesions: A systematic literature review and meta-analysis of current evidence. Asian J Surg. 2022 Jan;45(1):79-88.

Meta-analysis intraoperative ultrasound vs. wire-guided localization:

1. Ahmed M, Douek M. Intra-operative ultrasound versus wire-guided localization in the surgical management of non-palpable breast cancers: systematic review and meta-analysis. Breast Cancer Res Treat. 2013 Aug;140(3):435-46.
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RCTs intraoperative ultrasound vs. wire-guided localization:

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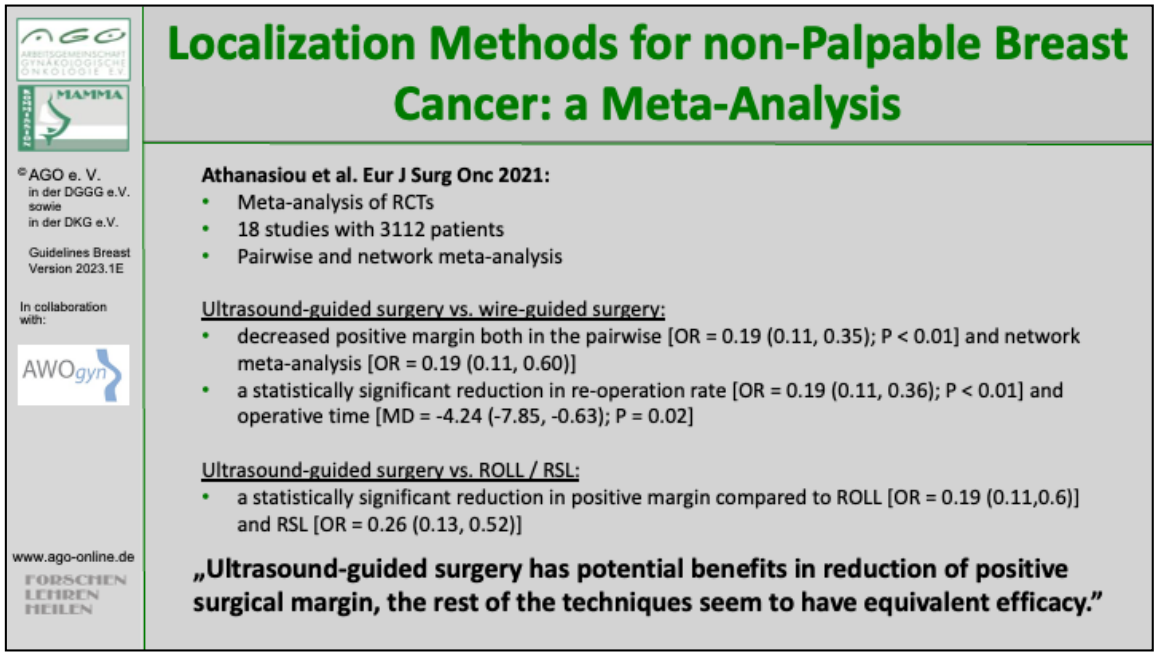

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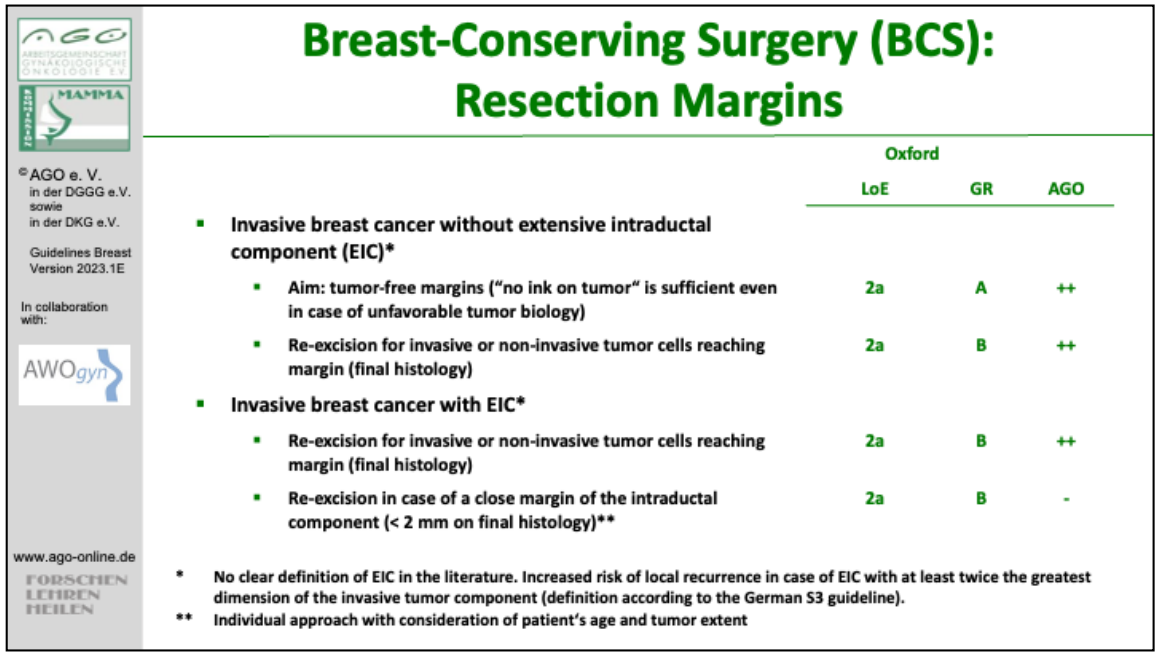

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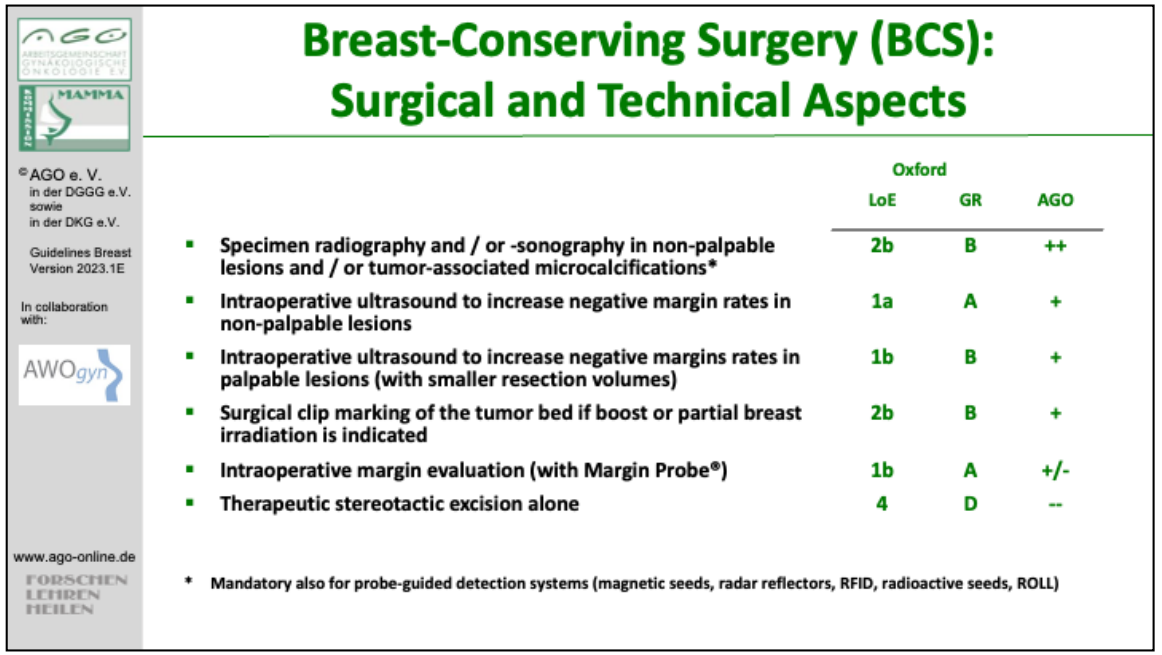

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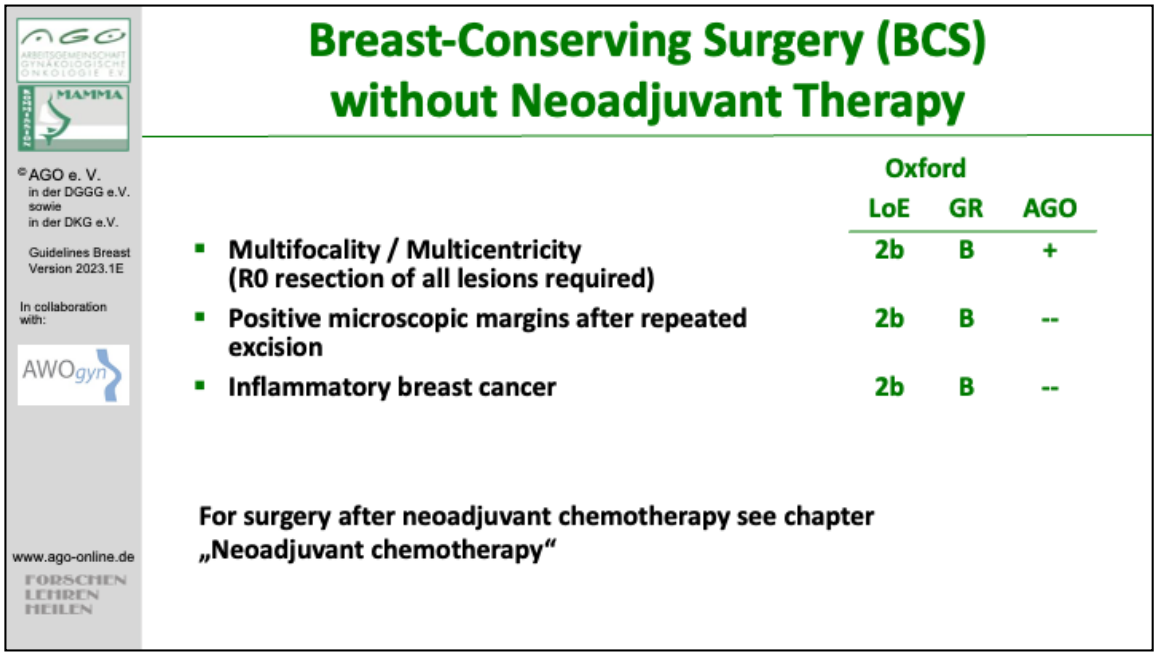

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Statement: general

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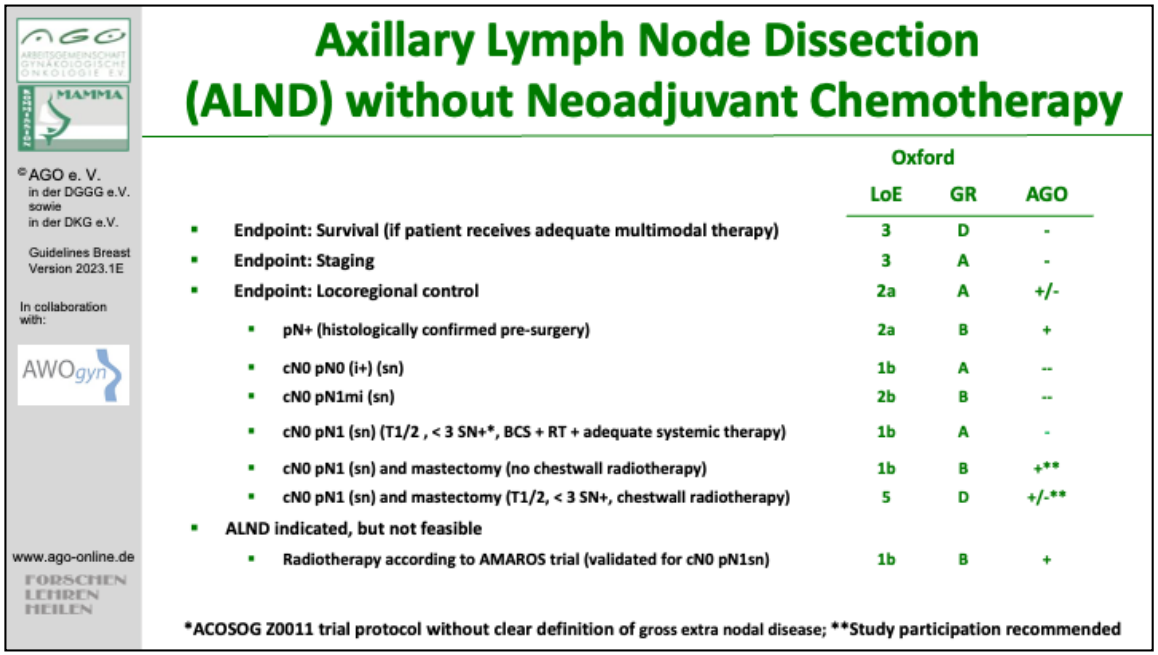

Statement: Axillary lymph node dissection

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pN+ (pre-surgery) without neoadjuvant systemic therapy LoE 2a B AGO +

1. Euhus DM. Management of the clinically positive axilla. Breast J. 2020 Jan;26(1):35-38.

cN0 pN0(sn)(i+)LoE 1b A AGO –

1. Rutgers EJ. Sentinel node biopsy: interpretation and management of patients with immunohistochemistry-positive sentinel nodes and those with micrometastases. J Clin Oncol. 2008 Feb 10;26(5):698-702.
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cN0 pN1 (mi) LoE 2b B AGO --

1. Mamtani A, Patil S, Stempel M, et al. Axillary Micrometastases and Isolated Tumor Cells Are Not an Indication for Post-mastectomy Radiotherapy in Stage 1 and 2 Breast Cancer. Ann Surg Oncol. 2017 Aug;24(8):2182-2188.
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cN0 pN 1(sn) (cT1/2 , < 3 SN +, BCS + tangential radiation field, adequate systemic therapy) LoE 1b A AGO -

1. Giuliano AE, Ballman KV, McCall L, et al. Effect of Axillary Dissection vs No Axillary Dissection on 10-Year Overall Survival Among Women With Invasive Breast Cancer and Sentinel Node Metastasis: The ACOSOG Z0011 (Alliance) Randomized Clinical Trial. JAMA. 2017 Sep 12;318(10):918-926.
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cN0 pN1 (sn) and mastectomy (no chestwall radiotherapy) LoE 1b B AGO +*

1. Cody HS 3rd1. Extending ACOSOG Z0011 to Encompass Mastectomy: What Happens Without RT? Ann Surg Oncol. 2017 Mar;24(3):621-623.

ALND indicated, but not feasible – Radiotherapy according to AMAROS-trial (validated for cN0 pN1sn) LoE 1b B AGO +

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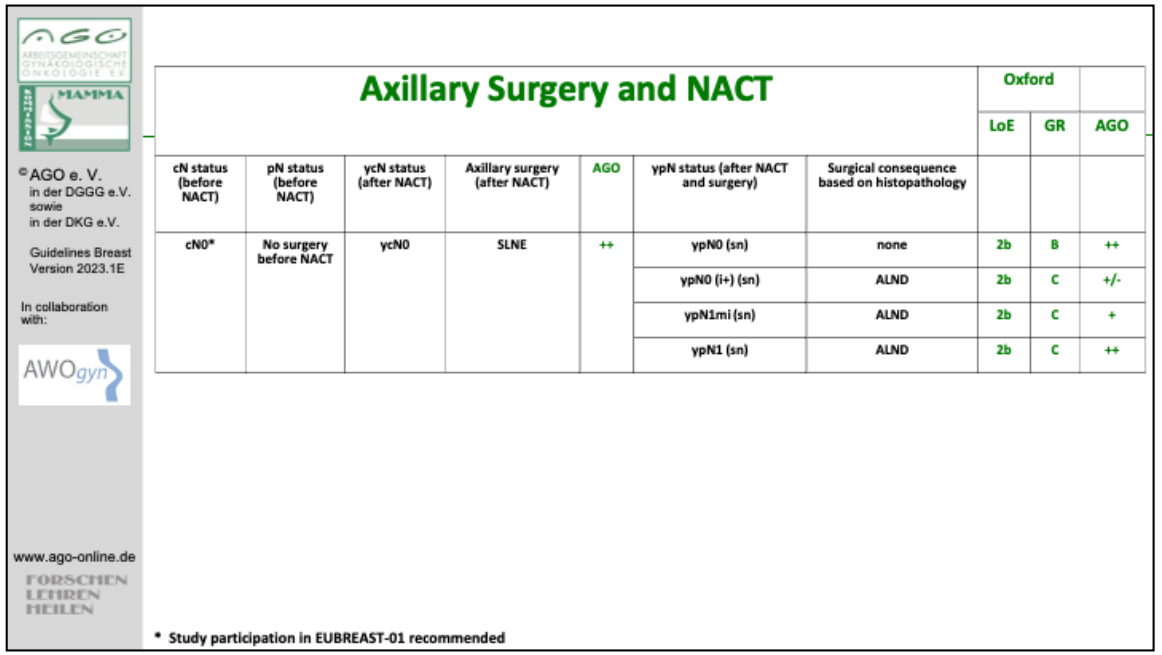
ACOSOG Z0011 gross extra nodal disease was not clearly defined in the protocol: A, Giuliano: personal email communication January 2023



Axillary Surgery and NACT

cN status (before NACT)	pN status (before NACT)	ycN status (after NACT)	Axillary surgery (after NACT)	AGO	ypN status (after NACT and surgery)	Surgical consequence based on histopathology	Oxford LoE	Oxford GR	AGO
cN0*	No surgery before NACT	ycN0	SLNE	++	ypN0 (sn)	none	2b	B	++
					ypN0 (i+) (sn)	ALND	2b	C	+/-
					ypN1mi (sn)	ALND	2b	C	+
					ypN1 (sn)	ALND	2b	C	++

* Study participation in EUBREAST-01 recommended

1. Giuliano AE, Ballman KV, McCall L et al. Effect of axillary dissection vs no axillary dissection on 10-year overall survival among women with invasive breast cancer and sentinel node metastasis: The acosog z0011 (alliance) randomized clinical trial. JAMA 2017, 318, 918-926
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cancer according to molecular subtype. Gynecologie, obstetrique, fertilite & senologie 2017, 45, 535-544.

8. Gustavo Werutsky G, Untch M, Hanusch C, Fasching PA, Blohmer JU, Seiler S, Denkert C, Tesch H, Jackisch C, Gerber B et al. Locoregional recurrence risk after neoadjuvant chemotherapy: A pooled analysis of nine prospective neoadjuvant breast cancer trials. Eur J Cancer 2020, 130, 92-101.
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13. Tee, S.R.; Devane, L.A.; Evoy, D.; et al. E.W. Meta-analysis of sentinel lymph node biopsy after neoadjuvant chemotherapy in patients with initial biopsy-proven node-positive breast cancer. Br J Surg 2018, 105, 1541-1552.
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15. Barron AU, Hoskin TL, Day CN et al. Association of low nodal positivity rate among patients with erbb2-positive or triple-negative breast cancer and breast pathologic complete response to neoadjuvant chemotherapy. JAMA surgery 2018.
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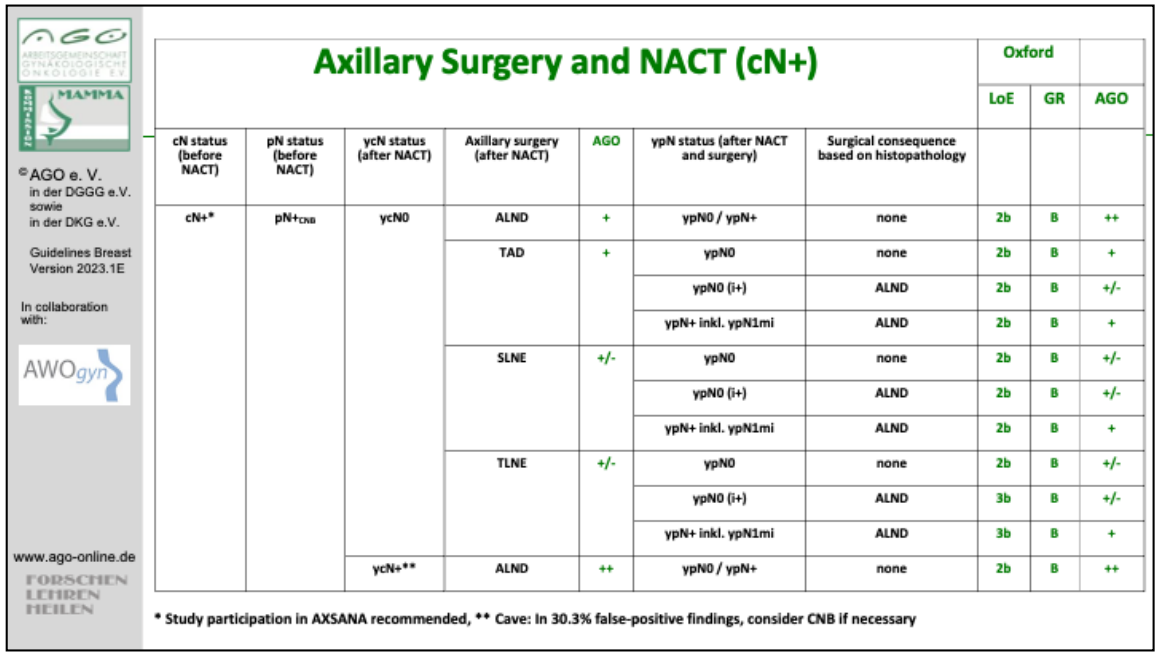
32. Kantor, O.; Sipsy, L.M.; Yao, K.; et al. A predictive model for axillary node pathologic complete response after neoadjuvant chemotherapy for breast cancer. Ann Surg Oncol 2018, 25, 1304-1311.

Statement: SLNE after NACT

1. El Hage Chehade H, Headon H, El Tokhy O et al. Is sentinel lymph node biopsy a viable alternative to complete axillary dissection following neoadjuvant chemotherapy in women with node-positive breast cancer at diagnosis? An updated meta-analysis involving 3,398 patients. Am J Surg. 2016 Nov;212(5):969-981.



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Axillary Surgery and NACT (cN+)

cN status (before NACT)	pN status (before NACT)	ycN status (after NACT)	Axillary surgery (after NACT)	AGO	ypN status (after NACT and surgery)	Surgical consequence based on histopathology	Oxford LoE	Oxford GR	AGO
cN+*	$pN+_{CNB}$	ycN0	ALND	+	ypN0 / ypN+	none	2b	B	++
			TAD	+	ypN0	none	2b	B	+
					ypN0 (i+)	ALND	2b	B	+/-
					ypN+ inkl. ypN1mi	ALND	2b	B	+
			SLNE	+/-	ypN0	none	2b	B	+/-
					ypN0 (i+)	ALND	2b	B	+/-
					ypN+ inkl. ypN1mi	ALND	2b	B	+
			TLNE	+/-	ypN0	none	2b	B	+/-
					ypN0 (i+)	ALND	3b	B	+/-
					ypN+ inkl. ypN1mi	ALND	3b	B	+
		ycN+**	ALND	++	ypN0 / ypN+	none	2b	B	++

* Study participation in AXSANA recommended, ** Cave: In 30.3% false-positive findings, consider CNB if necessary

1. Giuliano AE, Ballman KV, McCall L et al. Effect of axillary dissection vs no axillary dissection on 10-year overall survival among women with invasive breast cancer and sentinel node metastasis: The acosog z0011 (alliance) randomized clinical trial. JAMA 2017, 318, 918-926
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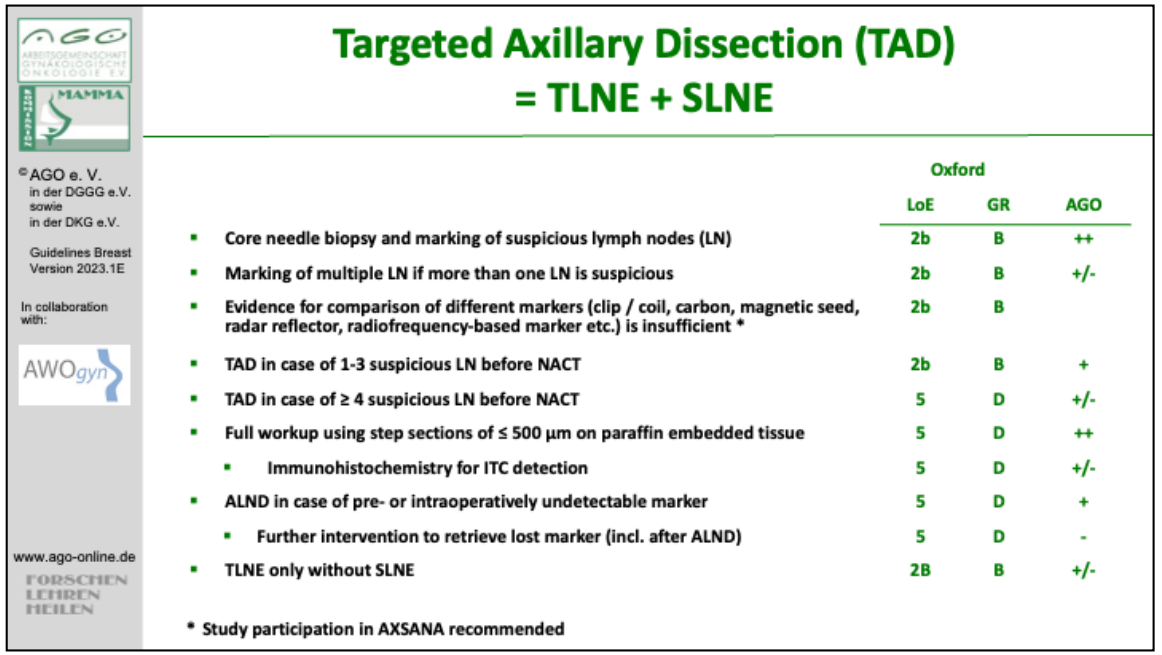
Statement: False-positives in ALND after ycN+

1. Hartmann S, Kühn T, Hauptmann M et al., Axillary staging after neoadjuvant chemotherapy for initially node-positive breast carcinoma in Germany. Geburtsh Frauenheilk 2022, online

Statement: TLNE alone:

1. Swarnkar PK, Tayeh S, Michell MJ et al., The Evolving Role of Marked Lymph Node Biopsy (MLNB) and Targeted Axillary Dissection (TAD) after Neoadjuvant Chemotherapy (NACT) for Node-Positive Breast Cancer: Systematic Review and Pooled Analysis. Cancers (Basel) 2021; 13(7):1539



1. Kümmel S, Heil J, Rueland A, et al: A prospective multicenter registry study to evaluate the clinical feasibility of targeted axillary dissection (TAD) in node-positive breast cancer patients. Ann Surg. 2020 Nov 4. doi: 10.1097/SLA.0000000000004572
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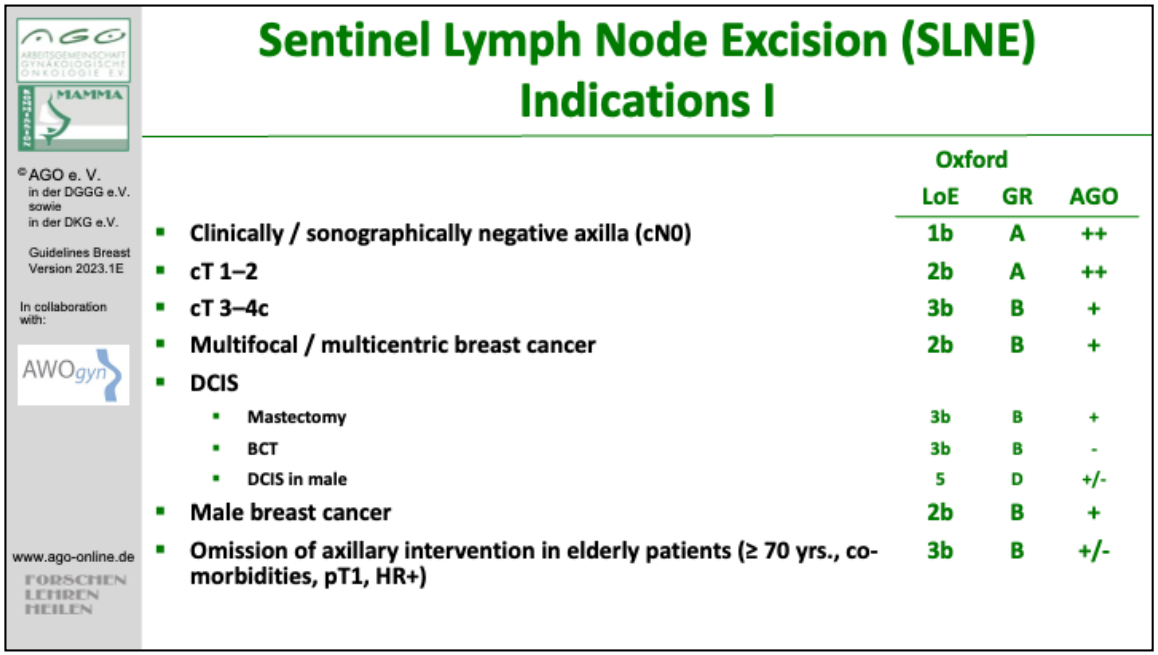
Statement: TLNE alone:

1. Swarnkar PK, Tayeh S, Michell MJ et al., The Evolving Role of Marked Lymph Node Biopsy (MLNB) and Targeted Axillary Dissection (TAD) after Neoadjuvant Chemotherapy (NACT) for Node-Positive Breast Cancer: Systematic Review and Pooled Analysis. Cancers (Basel) 2021; 13(7):1539



Statement: SLNE

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12. Lyman GH, Somerfield MR et al. Sentinel Lymph Node Biopsy for Patients With Early-Stage Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Oncol*. 2017;35(5):561–564.
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<u>Statement: preoperative FNA / CNB (core needle biopsy) of suspicious lymph nodes</u>

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<u>Statement: Multifocal / multicentric MaCa</u>

1. Ferrari A, Dionigi P, Rovera F. Multifocality and multicentricity are not contraindications for sentinel lymph node biopsy in breast cancer surgery. World J Surg Oncol. 2006 Nov 20;4:79.

Statement: DCIS

1. Tuttle TM, Shamliyan T, Virnig BA, et al. The impact of sentinel lymph node biopsy and magnetic resonance imaging on important outcomes among patients with ductal carcinoma in situ. J Natl Cancer Inst Monogr. 2010;2010(41):117-20.
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Statement: Male

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Statement: Elderly

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Statement: Lymphedema

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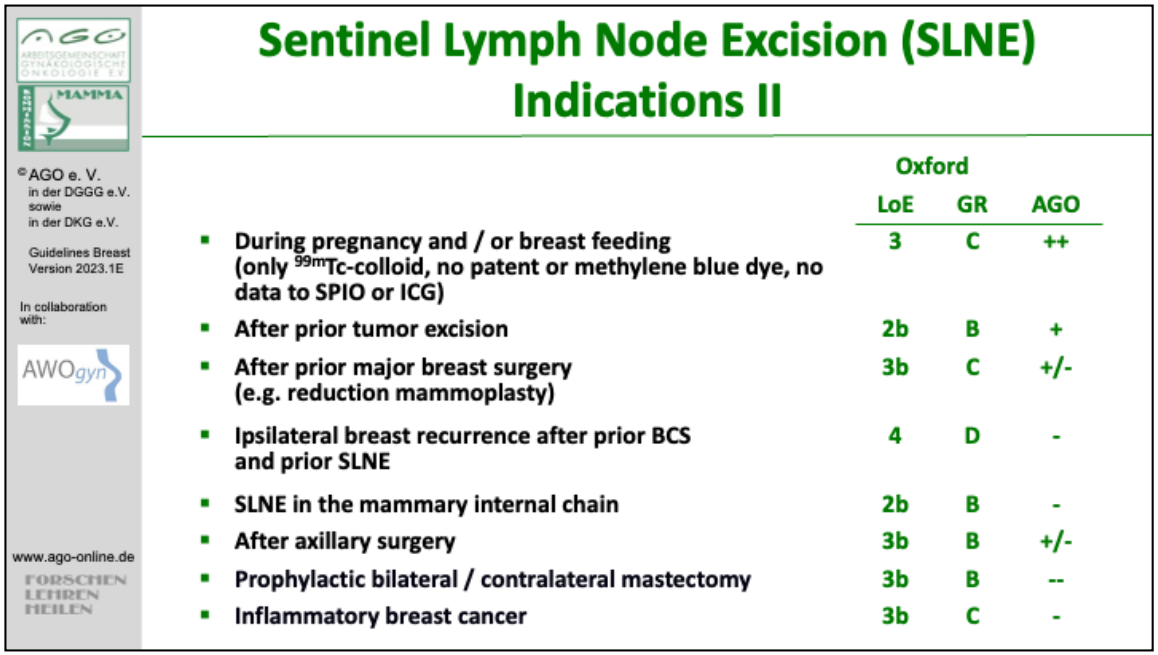

Statement: pregnancy

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2. Bergkvist L. Resolving the controversies surrounding lymphatic mapping in breast cancer. Future Oncol. 2008 Oct;4(5):681-8.
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Statement: internal mammarian

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Statement: prophylactic mastectomy

1. Dupont et al. The role of sentinel lymph node biopsy in women undergoing prophylactic mastectomy. Am J Surg 2000 Oct;180(4):274-7
2. Soran A et al.: Is routine sentinel lymph node biopsy indicated in women undergoing contralateral prophylactic mastectomy? Magee-Womens Hospital experience. Ann Surg Oncol 2007 Feb;14(2):646-51.
3. Boughey JC et al.: Decision analysis to assess the efficacy of routine sentinel lymphadenectomy in patients undergoing prophylactic mastectomy. Cancer 2007 Dec 1;110(11):2542-50

Statement: After previous tumor excision

1. Celebioglu et al.: Sentinel node biopsy in non-palpable breast cancer and in patients with a previous diagnostic excision. Eur J Surg Oncol 2007 Apr;33(3):276-80.

Statement: previous major breast surgery

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Statement: Ipsilateral breast recurrence after prior BCS and prior SLNB

1. Mattia Intra M,Triro G, Viale G: Second Biopsy of Axillary Sentinel Lymph Node for Reappearing Breast Cancer After Previous Sentinel Lymph Node Biopsy. Ann Surg Oncol. 2005;12(11):895-9
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Statement: inflammatory breast cancer

1. Fayanju OM, Ren Y, Greenup RA, et al. Extent of axillary surgery in inflammatory breast cancer: a survival analysis of 3500. Breast Cancer Res Treat. 2020 Feb;180(1):207-217.
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Statement: Others

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2. Kuehn T, Bembenek A, Decker T. A concept for the clinical implementation of sentinel lymph node biopsy in patients with breast carcinoma with special regard to quality assurance. Cancer. 2005 Feb 1;103(3):451-61
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4. Schrenk et al. Symmetrization reduction mammaplasty combined with sentinel node biopsy in patients operated for contralateral breast cancer. J Surg Oncol 2006 Jul 1;94(1):9-15.
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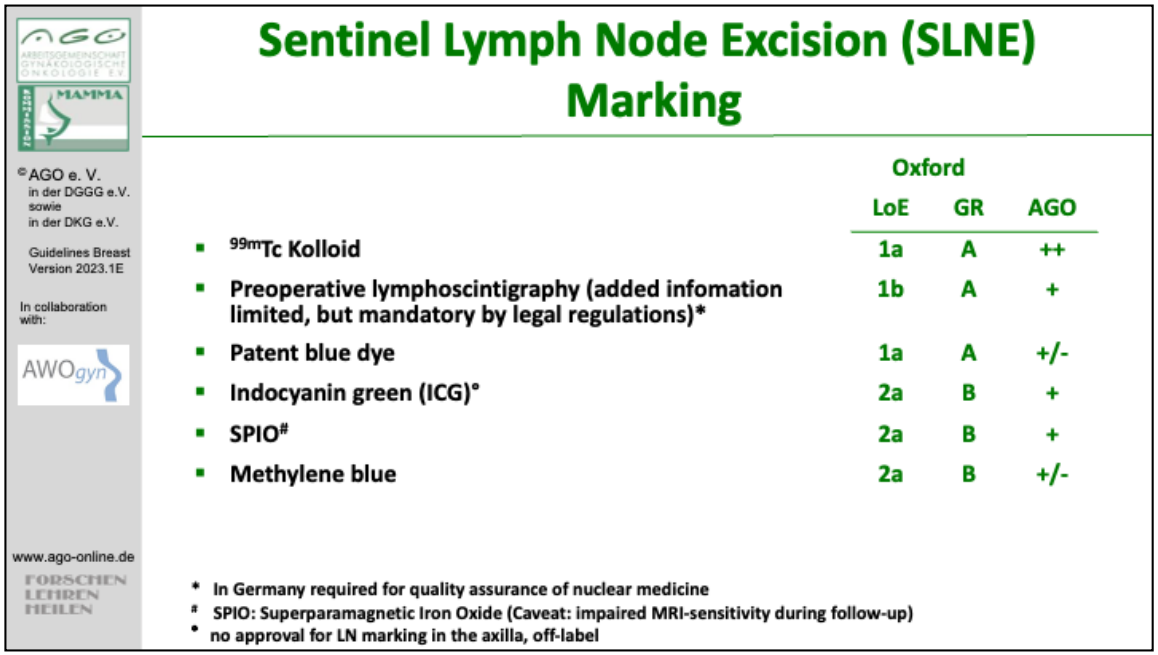

Statement radiotracer/blue dye:

1. Shams S, Lippold K, Blohmer JU, et al. A Pilot Study Evaluating the Effects of Magtrace® for Sentinel Node Biopsy in Breast Cancer Patients Regarding Care Process Optimization, Reimbursement, Surgical Time, and Patient Comfort Compared With Standard Technetium99. Ann Surg Oncol. 2021 Jun;28(6):3232-3240. doi: 10.1245/s10434-020-09280
2. Lyman GH, Somerfield MR et al. Sentinel Lymph Node Biopsy for Patients With Early-Stage Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline Update. J Clin Oncol. 2017;35(5):561–564.
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Statement Magnetic Tracer

1. Shams S, Lippold K, Blohmer JU, et al. A Pilot Study Evaluating the Effects of Magtrace® for Sentinel Node Biopsy in Breast Cancer Patients Regarding Care Process Optimization, Reimbursement, Surgical Time, and Patient Comfort Compared With Standard Technetium99. Ann Surg Oncol. 2021 Jun;28(6):3232-3240. doi: 10.1245/s10434-020-09280
2. Thompson W, Argáez C. Ottawa (ON): Magnetic Localization System for Sentinel Lymph Node Biopsy: A Review of the Diagnostic Accuracy, Cost-Effectiveness, and Guidelines. Canadian Agency for Drugs and Technologies in Health; 2020

Statement: pre-operative lymphoscintigraphy

1. Kummel S, Holtschmidt J, Gerber B et al. Randomized surgical multicenter trial to evaluate the usefulness of lymphoscintigraphy (LSG) prior to sentinel node biopsy (SLNB) in early breast cancer: SenSzi (GBG80) trial. Journal of Clinical Oncology 35, no. 15_suppl (May 2017) 555-555.

Statement: methylene blue

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Statement: Methylen blue / patent blue and anaphylactic reactions:

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Systematic Review and Meta-analysis. Ann Surg. 2021 Jun 1;273(6):1087-1093.
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Statement: ICG

1. Mok CW, Tan SM, Zheng Q, Shi L. Network meta-analysis of novel and conventional sentinel lymph node biopsy techniques in breast cancer. BJS Open. 2019 Mar 25;3(4):445-452.
2. Sugie T, Ikeda T, Kawaguchi A, et al. Sentinel lymph node biopsy using indocyanine green fluorescence in early-stage breast cancer: a meta-analysis. Int J Clin Oncol. 2017 Feb;22(1):11-17.
3. Zhang X, Li Y, Zhou Y, et al. Diagnostic Performance of Indocyanine Green-Guided Sentinel Lymph Node Biopsy in Breast Cancer: A Meta-Analysis. PLoS One. 2016 Jun 9;11(6):e0155597.
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6. Kedrzycki MS, Leiloglou M, Ashrafian H et al. Meta-analysis Comparing Fluorescence Imaging with Radioisotope and Blue Dye-Guided Sentinel Node Identification for Breast Cancer Surgery. Ann Surg Oncol. 2021 Jul;28(7):3738-3748.

Statement: SPIO

1. Shams S, Lippold K, Blohmer J et al. A Pilot Study Evaluating the Effects of Magtrace® for Sentinel Node Biopsy in Breast Cancer Patients Regarding Care Process Optimization, Reimbursement, Surgical Time, and Patient Comfort Compared With Standard Technetium ^{99}. Ann Surg Oncol. 2021;28(6):3232-3240. doi: 10.1245/s10434-020-09280-1
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Statement: General

1. Ahmed M, Purushotham AD, Douek M. Novel techniques for sentinel lymph node biopsy in breast cancer: a systematic review. Lancet Oncol. 2014 Jul;15(8):e351-62.
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Statement: Comparisons

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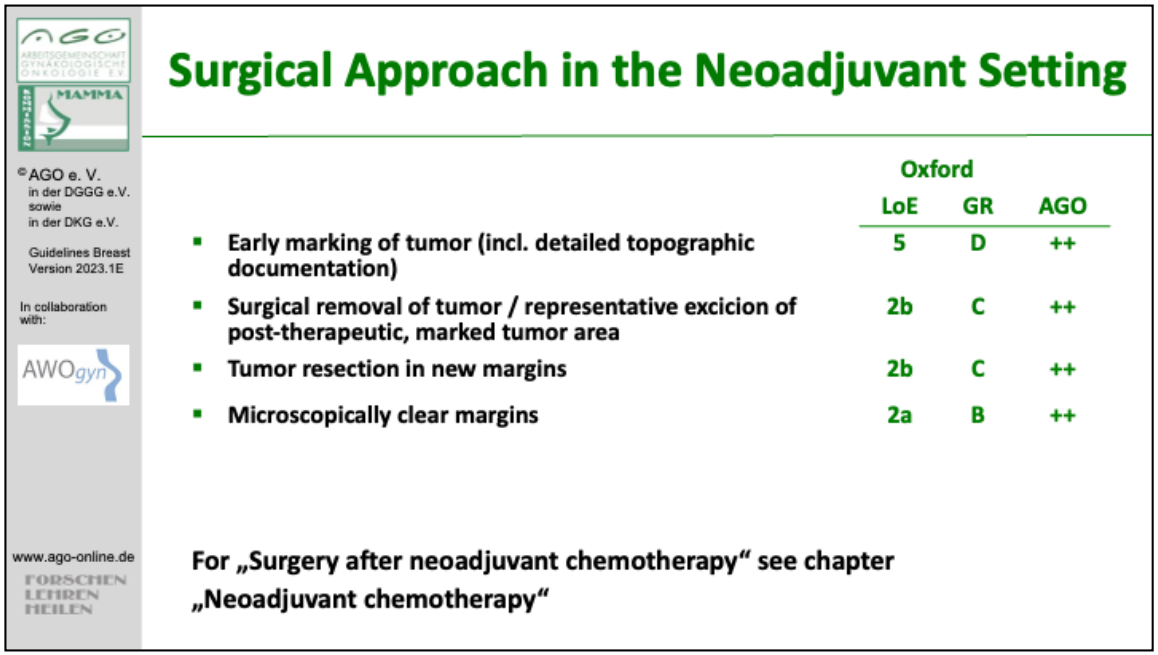

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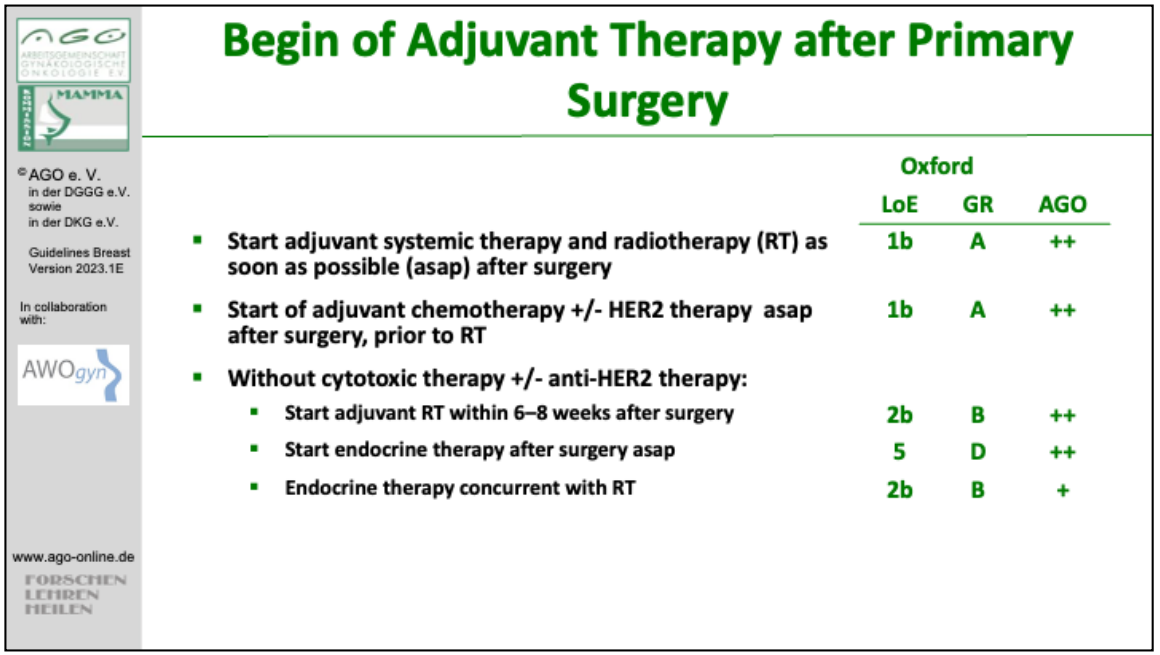

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