NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

Microthane implants for breast reconstruction or breast augmentation

1 Technology

1.1 Description of the technology

The Microthane breast implant (Polytech Health & Aesthetic GmbH) is a silicone gel-filled mammary implant with a micropolyurethane foam coating. The micropolyurethane foam coating is vulcanised on the surface, to enable better adhesion to the surrounding breast tissue, reducing the movement of the implant and the risk of complications such as capsular contracture. The shell of the implant consists of silicone elastomers; a barrier layer made of polymethylphenylsiloxane reduces the diffusion of silicone gel from within the implant and a polydimethylsiloxane elastomer membrane is used to fix the foam coating.

The implant is available in four different shapes (Meme, Replicon, Opticon and Optimam) and selection depends on the size and shape of the breast base.

Patients are often advised to exchange their implants after 10 years whether or not there have been any problems. The company has a lifetime exchange warranty for the Microthane breast implant in the case of implant shell rupture.

In addition, an insurance backed warranty scheme is available for Microthane implants, free of charge for 2 years, to cover the cost of repeat surgery following common complications. The warranty schemes apply to patients undergoing breast augmentation and those having breast reconstruction following radiotherapy. The warranty will reimburse up to £1500 per implant in

the event of any of the following complications of breast reconstruction or augmentation surgery that requires repeat surgery:

- Capsular contracture either Baker scale III or IV
- Rotation dislocation and rupture
- Haematoma
- Post-operative infection
- Seroma.

This warranty is valid for 2 years after implantation but may be extended at additional cost by the hospital or patient if additional cover is purchased.

1.2 Regulatory status

The Microthane breast implant is a class 3 device which received a CE mark in 1998 as a permanent breast implant for use as part of reconstruction or augmentation surgery. In 2005, the Medicines and Healthcare Regulatory Agency (MHRA) issued a letter bringing the potential risks and claimed benefits associated with polyurethane-coated breast implants to the notice of plastic surgeons.

1.3 Claimed benefits

The benefits to patients claimed by the company are:

- Potential for lower rates of complications particularly capsular contracture Baker scale III or IV.
- Potential for lower reoperation rates due to reduced complications.
- Increased patient satisfaction as implants are claimed to feel more natural due to tissue integration.

The benefits to the healthcare system claimed by the company are:

- If improved complication rates are achieved there will be a reduced need for treatment of any associated symptoms and lower reoperation rates, which require a hospital stay, and staff and treatment resources.

- Potential for free positioning of breast implant due to improved integration with surrounding tissue.
- Cost effectiveness if lower rates of complications and reoperations are realised.
- Implant exchange and warranty schemes for registered patients.

1.4 Relevant diseases and conditions

The Microthane breast implants are intended for use for breast reconstruction following mastectomy, for breast augmentation, for implant replacement, and for the treatment of combined breast/thorax deformities.

In breast reconstruction, the need for an implant depends on the type of mastectomy performed, whether the patient will require chemotherapy or radiotherapy in the future and individual patient choice. In 2013–14, more than 19,000 mastectomies were performed in England. There were over 4,000 breast reconstruction procedures performed on women in the NHS during the same period.

Mastectomy can have a major psychological effect on some women and adversely affect their confidence and self-esteem. Breast reconstruction following mastectomy in patients with breast cancer allows women to regain a similar breast shape and eliminates the need for prosthesis. This may improve the patient's self-esteem and help them to feel more comfortable with their body image during recovery and eliminates the need for an external prosthesis.

Some women are offered breast augmentation in the NHS for cosmetic purposes if the appearance of their breasts causes them significant psychological distress. This includes women whose breasts have not developed normally (breast aplasia, hypoplasia or tuberous breasts), those with severe breast asymmetry, and those with deformations of the pectoral muscles, such as Poland's syndrome.

Some transgender people are also offered breast augmentation in the NHS. Many transgender people are satisfied with the natural breast tissue that grows in response to hormone therapy, however if this is inadequate they may decide to undergo augmentation surgery which may include the use of an implant.

It is estimated that 30,000 augmentation procedures occur in the UK each year. In 2012–13 fewer than 4,500 of these operations were carried out in the NHS.

Generally, breast implants for mainly cosmetic purposes are not funded by the NHS but significant abnormalities will be considered on a case by case basis.

1.5 Current management

For patients who undergo mastectomy during treatment for breast cancer there are a number of methods for breast reconstruction. The optimum method for each patient is dependent on the type of mastectomy (full, radical or skin-sparing mastectomy or breast-conserving surgery), the body type of the patient, expectations for further treatment, type and stage of breast cancer and patient preference.

In some patients, breast reconstruction is performed at the same time as the mastectomy. An immediate breast reconstruction means that the patient is less likely to need as many procedures to complete their reconstruction and there may also be less scarring and more breast skin saved. Implants are used in around 37% of all immediate reconstructions.

In other cases, breast reconstruction is delayed until adjunctive radiotherapy or chemotherapy is completed. This is because radiotherapy can damage the reconstructed breast and chemotherapy can cause tissues to heal much more slowly and leave them vulnerable to infection. Complications from the reconstruction procedure can also lead to a delay in starting adjunctive treatment. This delayed type of reconstruction may cause more scarring and requires the patient to spend a period of time without a reconstructed breast.

The size of the implant used in a reconstruction will depend on the amount of skin left behind after the mastectomy and the size of the original and any remaining breast. To avoid asymmetry in the breasts the unaffected breast may also require surgery so that it matches the reconstructed breast. This could involve reducing the size or changing the position of the breast. Breast implants are available in teardrop or round shapes and the best match for the contour of the breast area will be chosen. They may be filled with saline or silicone; the surface of the implant may be smooth, textured or polyurethane foam coated.

The NICE guideline on Early and locally advanced breast cancer recommends discussing immediate breast reconstruction with all patients who are being advised to have a mastectomy, and to offer it except where significant comorbidity or (the need for) adjuvant therapy may preclude this option. The guideline recommends that all appropriate breast reconstruction options should be offered and discussed with patients, irrespective of whether they are available locally.

2 Reasons for developing guidance on Microthane breast implants for breast reconstruction or breast augmentation.

The Committee considered that the Microthane breast implants may offer benefits to patients and the healthcare system by leading to reduced rates of capsular contracture.

The Committee was advised by experts that data from studies using implants that are coated with micropolyurethane foam other than Microthane, are potentially relevant to this evaluation.

The Committee noted that the evidence presented in the notification had been published more than ten years ago, and wished to encourage identification of more recent evidence in any form.

3 Statement of the decision problem

	Scope issued by NICE
Population	People requiring breast reconstruction following mastectomy and those requiring breast augmentation for breast abnormalities or gender reassignment
Intervention	Microthane breast implants
Comparator(s)	• Textured silicone implants • Smooth silicone implants (see also 'Cost analysis' below)
Outcomes	The outcome measures to consider include: • Capsular contracture rate • Re-operation rate • Incidence of rotations / dislocations • Time to removal of polyurethane implants • Difficulty in removing polyurethane implants • Device-related adverse events (e.g. rashes and skin wrinkling) • Quality of life and patient satisfaction • Length of hospital stay • Staff and operative resource utilization (including benefits of ease of positioning of implants)
Cost analysis	Comparator(s): Textured or smooth silicone implants The cost analysis will include an examination of the company warranty schemes for the implants and their impact on overall cost: • Lifetime warranty for shell rupture • Warranty for complications of breast reconstruction or augmentation surgery that require repeat surgery (including where additional cover is bought after the 2 years of free cover). Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which should include scenarios in which different numbers and combinations of devices are needed.
Subgroups to be considered	•Transgender people •People having breast augmentation
Special considerations, including those related to equality	Breast reconstruction following mastectomy is part of the breast cancer pathway. People with breast cancer and transgender people are protected groups under the Equality Act 2010.
Special	

considerations, specifically related to equality issues	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No
	* Delete as appropriate, if yes please provide further details here:	

4 Related NICE guidance

Published

- Advanced breast cancer (update): Diagnosis and treatment. NICE clinical guideline 81 (July 2014). Available from www.nice.org.uk/guidance/CG81
- Familial breast cancer: Classification and care of people at risk of familial breast cancer and management of breast cancer and related risks in people with a family history of breast cancer. NICE clinical guideline 164 (June 2013). Available from www.nice.org.uk/guidance/CG164
- Advanced breast cancer. NICE Pathway (2014). Available from http://pathways.nice.org.uk/pathways/advanced-breast-cancer
- Early and locally advanced breast cancer. NICE Pathway (2014). Available from http://pathways.nice.org.uk/pathways/early-and-locally-advanced-breast-cancer
- Familial breast cancer. NICE Pathway (2013). Available from http://pathways.nice.org.uk/pathways/familial-breast-cancer
- Breast reconstruction using lipomodelling after breast cancer treatment. NICE technology appraisal guidance 417(January 2012). Available from www.nice.org.uk/guidance/TA417
- Breast cancer quality standard. NICE quality standard 12 (September 2011). Available from http://www.nice.org.uk/guidance/qs12
- Endoscopic mastectomy and endoscopic wide local excision for breast cancer. NICE technology appraisal guidance 296(April 2009). Available from www.nice.org.uk/guidance/TA296

- Early and locally advanced breast cancer: Diagnosis and treatment. NICE clinical guideline 80 (February 2009). Available from www.nice.org.uk/guidance/CG80
- Laparoscopic mobilisation of the greater omentum for breast reconstruction. NICE interventional procedure guidance 253(February 2008). Available from www.nice.org.uk/guidance/IPG253
- Improving outcomes in breast cancer. NICE cancer service guidance breast cancer. Available from http://www.nice.org.uk/guidance/csgbc

Under development

NICE is developing the following guidance (details available from www.nice.org.uk):

None identified

5 External organisations

5.1 Professional organisations

5.1.1 Professional organisations contacted for expert advice

At the selection stage, the following societies were contacted for expert clinical and technical advice:

- BASO - The Association for Cancer Surgery
- Royal College of Surgeons of England
- Association of Breast Surgery
- British Association of Aesthetic Plastic Surgeons

5.1.2 Professional organisations invited to comment on the draft scope

The following societies have been alerted to the availability of the draft scope for comment:

- BASO - The Association for Cancer Surgery
- Royal College of Surgeons of England

- Association of Breast Surgery
- British Association of Aesthetic Plastic Surgeons
- British Association of Plastic Reconstructive and Aesthetic Surgeons

5.2 Patient organisations

At the selection stage, NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- BME cancer communities
- Breakthrough Breast Cancer
- Breast Cancer Campaign
- Breast Cancer Care
- Breast Cancer UK
- Cancer Black Care
- Cancer Equality
- Help Adolescents With Cancer (HAWC)
- Independent Cancer Patients' Voice
- Macmillan Cancer Support
- Tenovus
- Equalities National Council
- Muslim Council of Britain
- South Asian Health Foundation