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To:
General Practitioners
NHS Medical Directors
Cancer and Plastic Surgeons

Dear Colleagues

PIP SILICONE GEL BREAST IMPLANTS

I wrote to you on 6 January 2012 about the advice from Sir Bruce Keogh's expert advisory group. I asked you for your help in supporting the following model of care:

- All women who have received a PIP implant from the NHS will be contacted to inform them that they have a PIP implant and to provide relevant information and advice. If in the meantime NHS patients seek information about the make of their implant then this will be provided free of charge;
- Women who wish to will be able to seek a consultation with their GP, or with the surgical team who carried out the original implant, to seek clinical advice on the best way forward;
- If the woman chooses, this could include a non-urgent examination by imaging to see if there is any evidence that the implant has ruptured;
- The NHS will support removal of PIP implants if, informed by an assessment of clinical need, risk or the impact of unresolved concerns, a woman with her doctor decides that it is right to do so. The NHS will replace the implants if the original operation was done by the NHS.

For your convenience, a copy of the clinical guidance for GPs and surgeons from the expert group's report, is attached (Annex A). I am also attaching some more detailed guidance jointly prepared by the three main specialist organisations concerned (Annex B).

In the light of the feedback we have received since my first letter, I would like to take the opportunity of highlighting a number of points:

- i *GP referrals to specialist services:* if on clinical examination a GP finds symptoms which suggest the possibility of new breast disease, they should refer the patient urgently to a rapid access breast service, even if the original implant was from a private provider. Other referrals should be made to the regional breast reconstructive service or local equivalent (for patients who received implants as part of NHS treatment) or to the original clinic (for implants provided privately) and are unlikely to need fast track referral. Please refer to Annex A, paragraphs 6 and 7.
- ii *Patients of private providers:* if a GP is consulted by a woman who originally received an implant from a private provider, they should encourage them in the first instance to go back to the original provider for advice, scanning if appropriate, and removal or replacement of the implant if desired. However, if the original provider has gone out of business, or is unwilling to help, the GP should carry out a clinical examination and refer onwards to specialist NHS services as indicated above. They should make clear that the NHS is not offering to pay for a replacement implant.
- iii *Scanning:* scanning by ultrasound or MRI may be useful in helping to confirm whether or not the implant has ruptured. However, if the woman has already decided (after clinical advice) to have the implant removed, scanning is usually unnecessary.
- iv *Criteria for replacement of implants at NHS expense:* for patients who received the original implant from the NHS (eg as part of breast reconstruction surgery following breast cancer) the NHS will pay for removal and replacement. For patients who received the original implant from a private provider, the criteria for replacement at NHS expense should be the same as for a request for primary breast augmentation – see the excerpt at Annex C from the Modernisation Agency's 2005 guidance "Information for Commissioners of Plastic Surgery Services". As noted above, such patients should be encouraged wherever possible to go back to the original provider.
- v *Patients who are not eligible for replacement implants at NHS expense and who offer to pay for replacements as a private transaction:* we have received a number of queries from patients with PIP implants supplied by private providers where the provider has failed in its duty of care, causing these patients to turn to the NHS for removal of the implants. They have asked whether they can pay for the additional costs of a replacement as part of a single operation in which the NHS pays for the costs of removal. General guidance on this kind of "top up" payment was issued in 2009 (see excerpt at Annex D).
- vi *Information for patients:* an advertisement containing information for patients was published in national newspapers on 14 January, and a copy is attached as Annex E. GPs may wish to use this as the basis of a patient information leaflet to give to patients who are concerned about their

breast implants. A Word version will be available at <http://www.dh.gov.uk> for ease in adapting locally. I previously sent you the MHRA patient information sheet, which all patients should have been given prior to their original operation.

<http://www.mhra.gov.uk/Publications/Consumer/CON105954>

GPs may find it helpful to refer to the attached summary clinical pathways (Annex F), or to any more specific pathways which have been agreed locally and disseminated by their PCT or PCT cluster.

I would like to thank you for your continued support with this matter.

A handwritten signature in black ink that reads 'Sally C Davies'.

**PROFESSOR DAME SALLY C DAVIES
CHIEF MEDICAL OFFICER
CHIEF SCIENTIFIC ADVISER**

ANNEX A: CLINICAL GUIDANCE FROM THE EXPERT GROUP REPORT

[Originally Annex E of *Poly Implant Protheses (PIP) breast implants: interim report of the expert group* (DH 2011), slightly reordered for greater clarity.]

Patients

1. Any patient with breast implants is advised to check the details of their implant with their surgeon or clinic.

GPs

2. GPs consulted by patients with PIP implants should explore the patient symptoms and examine the breast and locoregional lymph nodes.
3. Patients with local signs and symptoms should be referred for a specialist opinion.
4. Signs will include
 - Lumpiness of the breast
 - Lumpiness/ swelling of the regional lymph nodes
 - Change in shape of the breast
 - Deflation of the breast
 - Redness
 - Tenderness of the breast
 - Swelling of the breast
5. Symptoms may include
 - Pain
 - Hyperaesthesia

Guidance for GPs for NHS specialist referrals

6. **Patients with PIP implants who experience lumpiness within the breast and lymph nodes** : In cases where there is concern regarding the nature of the lumpiness, referral should be made to a rapid access breast service. In cases where the practitioner is happy that the lumps are associated with the implant or gel, referral should be made to the regional reconstructive breast surgery department.

7. **Patients with changes in shape or feel of the breast**, for instance discomfort, deflation or asymmetry should be referred to their regional breast reconstructive unit. These patients do not require fast track referral.

Guidance for GP referrals for private patients

8. General Practitioners may be approached by patients who underwent their surgery in the private sector. These patients should be advised to contact their original provider. It is expected by the expert group and the professional bodies represented on it that these providers will offer the same service as the NHS without cost to the patient.

Surgeons

9. Surgeons and hospital specialists reviewing patients with PIP implants should carefully assess the patient for the possibility of rupture or leak. Those patients who have evidence of implant rupture should be advised regarding the implications of implant removal/ exchange. If it is felt that the risk benefit ratio favours explantation/ exchange then this procedure should be advised. For NHS patients the patient may be offered re-implantation. For patients from the private sector who have been unable to secure help from their original provider, the NHS will offer implant removal where it is felt to be clinically appropriate, but no re-implantation will be offered.

Ongoing review

10. Where a patient decides, after consultation with her GP or specialist, not to have an explantation, she should be followed up on an annual basis. This review would normally be carried out by the GP (for NHS patients) or by the clinic which carried out the original implant (for private patients).

Possible updates to guidance

11. This guidance may change after consultation with relevant parties.

The full report is available at

<http://www.nhs.uk/news/2012/01January/Documents/pip-report.pdf>

ANNEX B: JOINT SURGICAL STATEMENT ON CLINICAL GUIDANCE FOR PATIENTS, GPs AND SURGEONS

January 2012

Poly Implant Prothèse (PIP) breast implants

Joint surgical statement on clinical guidance for patients, GPs and surgeons

The Association of Breast Surgery, the British Association of Plastic and Reconstructive Aesthetic Surgeons, the British Association of Aesthetic Plastic Surgeons, the Federation of Surgical Speciality Associations and the Royal College of Surgeons participated in the expert group convened by Professor Sir Bruce Keogh to review policy in relation to breast implants from the French company Poly Implant Prothèse (PIP). All organisations have endorsed the findings of the interim report published on 6 January 2012.

These five professional surgical organisations are now independently publishing further clinical guidance for GPs and surgeons regarding the care of patients who have received PIP breast implants.

Guidance for patients

If you have breast implants and do not have details of your implant manufacturer, you are advised to check the details of your implant with the surgeon or surgical provider responsible for your care. The surgeon or provider should have a record of the implants used (including the make and size). We would expect this information to be provided free of charge. If you are unable to access your surgeon or provider you should contact your GP for advice regarding an alternative referral.

We recommend that you discuss your options with your surgeon first of all. The decision on whether a scan will be required will only be made after consultation with a surgeon.

It is expected that the provider of the initial procedure, either private sector or the NHS, will offer the same information and where necessary implant removal and replacement without cost to you.

Guidance for GPs

The purpose of this guidance is to ensure patients who seek advice are assessed and managed in an agreed and standardised fashion, and that they have appropriate access to specialist advice.

All NHS patients who have undergone aesthetic or reconstructive surgery with PIP implants will be contacted by their local hospital. If they do not hear from their original provider they may contact their GP or their surgeon.

It is expected that private providers will follow the example of the NHS and call their patients for consultation. The first port of call for all patients who have undergone breast augmentation in the private sector is their original provider.

At present the government has decided that private patients referred to the NHS will be entitled to explantation and not re-augmentation. Patients planning re-augmentation soon after explantation should be advised of the increased risk associated with having two operations.

GPs are advised that patients should not be referred for scanning (USS/MRI) before receiving a specialist surgical opinion.

GPs consulted by patients with PIP implants are advised to assess the patient for the following signs and symptoms.

Symptoms that may be associated with rupture/gel leak:

- localised pain and discomfort
- axillary pain/discomfort
- persistent burning sensation

Signs of rupture/ gel leak:

- lumpiness of the breast
- regional swelling of the lymph nodes/glands (lymphadenopathy) – this may be in the absence of other breast signs/symptoms
- change in the shape of the breast
- hardening or firmness of the breast
- tenderness of the breast
- swelling of the breast

GP referral pathways through the NHS

1. If breast change or lymphadenopathy raises concerns of breast disease requiring urgent investigation:

Patients with significant new breast symptoms or signs should be referred to an NHS Rapid Access Breast Unit. This 'fast track' should ONLY be used when there is a need to exclude serious breast disease. It is not anticipated that this group of patients will be large.

2. If breast lumpiness/lymphadenopathy is felt to be related to problems with implants/gel, but signs or symptoms do NOT raise concerns of breast disease:

In cases where the practitioner has reasonable confidence that the breast lumps or lymphadenopathy are associated with the implant rupture or gel leak, or when patients report changes in shape, size or feel of the breast without raising concerns of breast disease, referral should be made to the regional plastic and reconstructive surgery breast service. These patients do NOT require fast-track referral to the NHS Rapid Access Breast Unit.

3. If there are no signs or symptoms:

For patients without physical signs or symptoms, we feel that there is a duty of care on the part of the original surgical providers to reduce anxieties about the long-term health consequence of these implants. For many women, reassurance and confidence will only be achieved once the implant has been removed.

In these cases referral may be made to the regional plastic and reconstructive surgery breast service.

It is understood that the government's policy explicitly offers these services without the need for specific clearance from the local commissioner (ie the primary care trust).

Guidance for all clinicians regarding scanning

Patients should not be referred for scanning (USS/MRI) before receiving a specialist surgical opinion.

In patients without signs or symptoms of rupture, scanning should only be used to assist decision making where the patient is uncertain of whether to have the implant removed or where rupture is identified. For all patients who have already decided to undergo explantation, scanning is unnecessary.

Caution is urged in interpreting ultrasound or MRI imaging information, owing to the available evidence offering conflicting advice about false positive and negative detection rates for implant rupture and leaks.

Guidance for surgeons

Surgeons and hospital specialists reviewing patients with PIP implants should carefully assess the patient for the possibility of rupture or gel leak.

For patients who have evidence of implant rupture/gel leak

Patients should be advised of the surgical implications of implant removal/exchange. If it is felt that the risk–benefit ratio favours removal or exchange, then this procedure should be strongly advised.

For patients without symptoms or signs of leak or rupture

If a patient requests it, removal should be offered in cases where the surgeon considers that the benefits outweigh the risks. If a patient is unable to come to a decision immediately, arrangements should be made for regular review and follow-up. We understand that the current offer to remove and/or replace PIP implants is not time-limited and can be reviewed at future follow-up appointments.

Surgical procedure

Surgeons removing an implant should do so using conventional techniques. Where possible the implant should be removed or exchanged through the original incision.

In cases with a soft 'quiet' capsule without evidence of silicone impregnation/local inflammation or contracture the capsule and immediate pericapsular tissues should be biopsied, but a capsulectomy will usually be unnecessary.

In cases of extensive capsular thickening/inflammation/contracture a complete capsulectomy should be performed. The capsule and biopsies from areas of pericapsular thickening should be sent for histology.

In patients with breast cancer who have undergone implant-based breast reconstruction, any suggestion of capsular thickening should prompt consideration of full capsulectomy and excision biopsy of areas of thickening. All specimens must be sent for histology.

Patients with extensive lymphadenopathy or extensive parenchymal swelling and lumpiness should be discussed in a breast multi-disciplinary meeting. Where lymph node removal may be clinically indicated, it should only be carried out in patients who are fully informed about the risks of additional axillary surgery.

Specific considerations for PIP-related explantation

Reports have suggested that in cases of PIP implant rupture/leak the inflammatory reaction may be more intense than usual, making a conventional capsulectomy more difficult. Washing or wiping the cavity with diluted aqueous povidone-iodine (PVPI) topical antiseptic solution or aqueous chlorhexidine appears to help dislodge and remove residues of the silicone gel from the surface of the cavity. In cases of extreme contamination where re-augmentation had been planned, a decision to defer replacement should be considered. Surgeons are advised to discuss this possibility with patients in advance.

Dealing with the implant

A ruptured implant should be discarded unless arrangements for examination have been made with the Medicines and Healthcare products Regulatory Agency.

We would advise surgeons to collect all available data at the time of consultation and surgery. Further advice regarding data collection will be made available shortly by the relevant surgical organisations.

Implant replacement

Patients from the private sector who have been unable to secure help from their original provider will be eligible for help from the NHS. The government has offered implant removal but implants will not be replaced in these patients. Surgeons are advised to make this clear at the initial consultation.

We would encourage all surgeons and surgical providers responsible for breast augmentations using PIP implants to undertake replacement surgery without making a charge to the patients.

Professional conduct

It is expected that all surgeons will offer advice and care based on these guidelines. We hope and expect that a compassionate and caring attitude will be shown to all patients.

Future monitoring

Patients who have undergone explantation following rupture/gel leak of PIP implants should be advised to attend annual follow-up for at least two years.

Patients who underwent a 'clean' explantation or re-implantation should be advised about normal follow-up procedures.

Where a patient decides, after consultation with specialist, not to have their PIP implants removed, they should be followed up on an annual basis. In the case of NHS patients this review would normally be carried out by the GP; private patients should be followed up by the surgeon or provider responsible for the original implantation. Patients with PIP implants should be made aware of the signs and symptoms of implant rupture and gel bleed.

This guidance may change after consultation with relevant parties.

ANNEX C: CRITERIA FOR BREAST IMPLANTATION IN THE NHS

[Excerpt from *Action on plastic surgery: Information for commissioners of plastic surgery services* (Modernisation Agency, 2005)]

Breast enlargement (Augmentation mammoplasty)

Will only be performed by the NHS on an exceptional basis and should not be carried out for “small” but normal breasts or for breast tissue involution (including post partum changes).

Exception should be made for women with an absence of breast tissue unilaterally or bilaterally, or in women with of a significant degree of asymmetry of breast shape and/or volume. Such situations may arise as a result of:

- Previous mastectomy or other excisional breast surgery
- Trauma to the breast during or after development
- Congenital amastia (total failure of breast development)
- Endocrine abnormalities
- Developmental asymmetry

Patients who are offered breast augmentation in the NHS should be encouraged to participate in the UK national breast implant registration system and be fully counselled regarding the risks and natural history of breast implants. It would be usual to provide patients undergoing breast augmentation with a copy of the DoH guidance booklet “Breast implants information for women considering breast implants”.

It is important that patients understand that they may not automatically be entitled to replacement of the implants in the future if they do not meet the criteria for augmentation at that time.

The full guidance document is available at

<http://www.bapras.org.uk/page.asp?id=719>

ANNEX D: GUIDANCE ON “TOP UP” PAYMENTS

[Excerpts from *Guidance on NHS patients who wish to pay for additional private care* (DH 2009)]

General principles

4.1 This guidance establishes that, where a patient opts to pay for private care, their entitlement to NHS services remains and may not be withdrawn.

4.2 Patients may pay for additional private healthcare while continuing to receive care from the NHS. However, in order to ensure that there is no risk of the NHS subsidising private care:

- It should always be clear whether an individual procedure or treatment is privately funded or NHS funded.
- Private and NHS care should be kept as clearly separate as possible.
- Private care should be carried out at a different time to the NHS care that a patient is receiving.
- Private care should be carried out in a different place to NHS care, as separate from other NHS patients as possible. A different place would include the facilities of a private healthcare provider, or part of an NHS organisation which has been permanently or temporarily designated for private care, such a private wing, amenity beds or a private room. Trusts may also want to consider using the services of a home healthcare provider where this is clinically appropriate. Putting in place arrangements for separation does not necessarily mean running a separate clinic or ward. As is the case now, specialist equipment such as scanners may be temporarily designated for private use as long as there is no detrimental effect to NHS patients.

4.3 Departing from these principles of separation should only be considered where there are overriding concerns of patient safety, rather than on the basis of convenience. Such decisions should usually be agreed in advance with the Medical Director or equivalent. Where a decision has to be made without gaining prior approval from the Medical Director on the grounds of clinical urgency, the Medical Director should be informed as soon as possible afterwards. A record should be kept of all decisions to depart from these principles.

Allocation of costs

8.2 Additional private care may be provided by the NHS Trust or Foundation Trust, as a service provided by their organisation, or by individual consultants who have agreed this with their employer. In either case, in developing charges for NHS patients who are having additional private care, NHS organisations and staff should use the following principles:

- The NHS should not subsidise the private element of care
- The patient should meet any additional costs associated with the private element of care, such as additional treatment needed for the management of side effects.

- Any care which would normally have provided in the course of good NHS practice should continue to be offered free of charge on the NHS.
- Where the same diagnostic, monitoring or other procedure is needed for both the NHS element of care and the private element, the NHS should provide this free of charge as part of the patient's NHS entitlement and share the results with the private provider if necessary. Patients should not be unnecessarily subjected to two sets of tests or interventions.
- The private provider should normally deal with non-emergency complications resulting from the private element of care.
- The NHS should never refuse to treat patients simply because the cause of the complication is unclear.
- The NHS should continue to treat any patient in an emergency.

This guidance should be read in conjunction with the examples included in the original guidance document – see

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_096428

ANNEX E: GUIDANCE FOR PATIENTS

[This was issued as an advertisement in national papers on 14 January. It may be freely adapted for local use as a patient information leaflet]

THE NHS WILL SUPPORT WOMEN WITH PIP BREAST IMPLANTS

The latest advice from the NHS and plastic surgery experts is that women with PiP breast implants do not need to have them removed unless they have symptoms such as pain and tenderness.

There is no link to cancer and there is no clear evidence of an increased risk of harm compared to other brands of breast implants.

However, if you are concerned, you should:

- **Find out** if you have PiP implants by checking your medical notes. You can get this information for free from your clinic or through your GP. If you had PiP implants on the NHS, you will receive a letter in the next few weeks.
- **Speak** to your specialist or GP, if you had them done on the NHS, or your clinic if you had them done privately.
- **Agree what's best for you** Get advice on whether or not you need a scan then discuss appropriate action with your doctor.

If you decide you want your implants replaced, the NHS will do it for free if your original operation was done on the NHS.

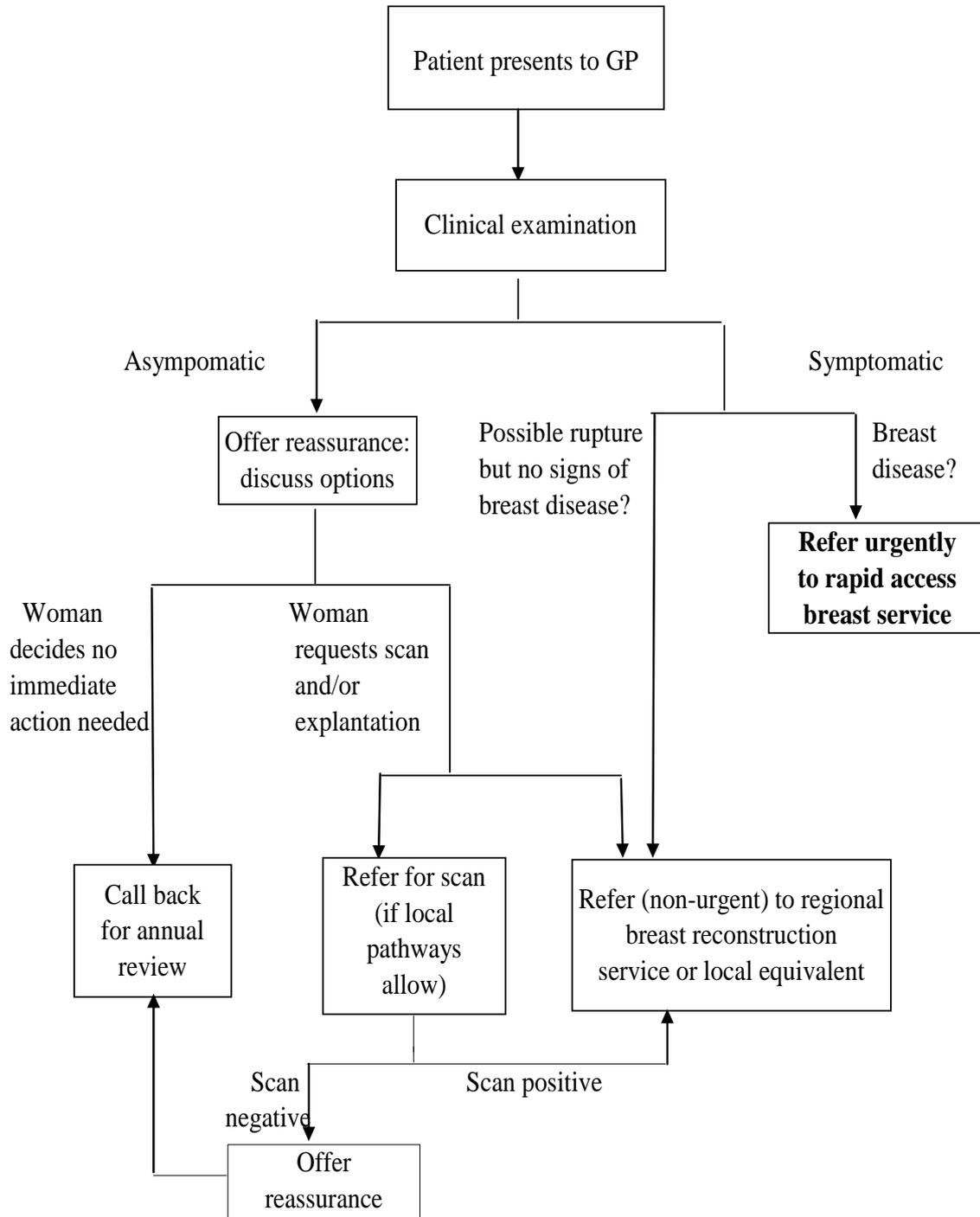
The following organisations have said they will replace PiP implants for free if clinically necessary: Holly House, Highgate Hospitals, Make Yourself Amazing, Ramsay Health Care, Spire Healthcare, BMI Healthcare, Nuffield Healthcare and HCA International.

If your private clinic no longer exists or refuses to remove your PiP implants, speak to your GP. The NHS will remove your implants if your doctor agrees, but the NHS will not replace implants unless it is clinically necessary.

For further information visit www.nhs.uk/implants

ANNEX F: OUTLINE CLINICAL PATHWAYS

OUTLINE PRIMARY CARE CLINICAL PATHWAY: (i) ORIGINAL IMPLANT NHS



OUTLINE PRIMARY CARE CLINICAL PATHWAY: (ii) ORIGINAL IMPLANT PRIVATE

