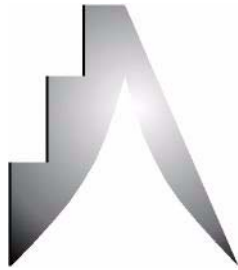


ASERNIP/ S



**Australian Safety
and Efficacy
Register of New
Interventional
Procedures-Surgical**

Clinical Practice Guidelines for the Advanced Breast Biopsy Instrument (ABBI)

ASERNIP-S CPG REPORT NO. 1

**Australian Safety & Efficacy Register of
New Interventional Procedures – Surgical
The Royal Australasian College of Surgeons**

Clinical Practice Guidelines for the Advanced Breast Biopsy Instrument (ABBI).

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Clinical Practice Guidelines for the Advanced Breast Biopsy Instrument (ABBI)

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Ratification

The Clinical Practice Guidelines for the Advanced Breast Biopsy Instrument (ABBI) were ratified by the:

ASERNIP-S Management Committee
May 6th 2000
Melbourne, Australia

Guidelines Development Process

An evidence-based approach was taken to the development of these guidelines.

The ASERNIP-S researcher conducted a review of the literature using search strategies and search terms developed with the assistance of the protocol surgeon. Four electronic databases (Medline, Current Contents, Embase and the Cochrane Library) were searched exhaustively for all research on the ABBI system up until December 1998.

A breast surgeon, familiar with the ABBI technique, drafted the clinical practice guidelines for ABBI, based on the evidence available in the literature. The guidelines' author was supplied with the literature collated by ASERNIP-S, where necessary, and also conducted his own literature searches. Grey literature sources were used to supplement the available material (i.e. conference abstracts and manufacturer trial and training information). All literature was critically appraised by the author, in terms of the level of evidence it represented.

In June 1999, these draft guidelines were sent to other centres that utilise the ABBI system for comment and revision.

ASERNIP-S formed a review group or panel of experts in the field of breast surgery, along with a surgeon from another specialty and a representative from ASERNIP-S to critique the guidelines. The review group was sent the draft guidelines, literature, and a modified assessment instrument to record their comments. A further questionnaire was included, inviting members to suggest methods or processes of further developing the guidelines. All responses were synthesised and summarised and a teleconference was held in February 2000 to amend the guidelines.

The clinical practice guidelines for ABBI were ratified by the ASERNIP-S Management Committee and then disseminated through the Section of Breast Surgery, Royal Australasian College of Surgeons, to practising breast-endocrine surgeons, as well as to all other stakeholders and interested parties.

Clinical Practice Guidelines for the Advanced Breast Biopsy Instrument (ABBI)

Introduction

Since 1995 the Advanced Breast Biopsy Instrument System has been available for the management of radiologically detected breast lesions. The ABBI system is a stereotactically guided procedure able to precisely localise and excise impalpable mammographic breast lesions in a single step.

The ABBI biopsy represents an alternative to open localised surgical biopsy for definitive diagnosis of impalpable mammographic lesions. It has diagnostic advantages over localised needle or fine core biopsies. For patients, undergoing an ABBI biopsy has potential benefits including:

- 1) A rapid, single stage procedure, to expedite the diagnosis of potentially malignant mammographic lesions (cf. open biopsy).
- 2) A day surgery procedure (cf. open biopsy).
- 3) A procedure performed under local anaesthesia (cf. open biopsy).
- 4) A tissue sample adequate for a formal histological diagnosis in all cases (cf. needle or small core biopsy).
- 5) Immediate confirmation of correct lesion removal (cf. open biopsy).
- 6) Minimisation of tissue removal, maximisation of cosmesis (cf. open biopsy).

For all new procedures it is important to consider possible risks to the patient. Possible problems or concerns regarding the safety of the ABBI system would include:

- 1) Wound haematomas, bleeding and infection (cf. open biopsy).
- 2) Discomfort during the procedure (cf. open biopsy).
- 3) Unnecessary procedures (cf. needle or small core biopsy).
- 4) Poor cosmesis (cf. needle or small core biopsy).
- 5) Failure to remove the target lesions (cf. open biopsy).
- 6) Failure to obtain a definitive histological diagnosis (cf. open biopsy).

Aims

The aim of these clinical practice guidelines is to summarise the current reported experience with the ABBI system. These guidelines are aimed specifically at health care professionals preparing to perform ABBI biopsies, rather than consumers. They are designed to help standardise the use of the procedure across Australasia, to facilitate assessment of this technique. It is hoped the guidelines may shorten the learning curve for new ABBI centres.

The ABBI system is a sophisticated tool in the management of breast disease, and as such should be employed by professionals experienced in breast disease. An understanding of breast disease, particularly the diagnosis and management of mammographically detected breast cancer, is assumed in the preparation of these guidelines.

Methods

In preparing these guidelines a keyword Medline search was performed. Other sources of information include training materials from the Autosuture/USSC Company and personal experiences from individual ABBI centres. More weight was given to material published in refereed journals and to reports with larger case numbers.

Most of the available data regarding the ABBI system was in the form of case series and case reports. Under NHMRC definitions such evidence is designated level IV (see Table 1). There has been considerable experience with the procedure, particularly in the USA, and this will eventually be reflected in the literature regarding ABBI. When such data is available these guidelines will need to be reviewed and revised accordingly. The formal review of these guidelines is planned for February 2001.

Table 1 Designation of levels of evidence

I	Evidence obtained from a systematic review of all relevant randomised controlled trials.
II	Evidence obtained from at least one properly designed randomised controlled trial.
III-1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method).
III-2	Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case-control studies or interrupted time series with control group.
III-3	Evidence obtained from comparative studies with historical control, two or more single arm studies or interrupted time series without a parallel control group.
IV	Evidence obtained from case series, either post-test or pre-test and post-test.

Source: National Health and Medical Research Council. *A guide to the development, implementation and evaluation of clinical practice guidelines*. Canberra: NHMRC, 1999

Guidelines

1. Lesion Selection

1.1 ABBI biopsy is appropriate only for impalpable breast lesions.²⁻¹³

Palpable lesions are generally best dealt with by alternative means for both diagnosis and treatment. A rare exception may be a palpable lesion where a particular area of mammographic concern was selectively sampled.

1.2 The lesion must be clearly visible on a diagnostic mammogram.^{1,3,4,10-12}

It is important to note that the digital mammography image quality produced by the ABBI system means that lesions may be more difficult to visualise. This is particularly so for diffuse densities. This problem is a persistent factor in the failure of ABBI biopsies in reported series.

1.3 ABBI is currently recommended only for the diagnosis of malignant lesions.^{2,5-7,12-13}

At present in the USA the Federal Drug Administration has only approved ABBI for the diagnosis of malignant breast lesions. Therefore all lesions that have proven malignant in published series have undergone re-excision. The significance of clear ABBI margins is therefore largely anecdotal and should at this time be considered unknown. It is unknown whether the technique is associated with tumour implantation and whether the method of excision can produce a falsely clear margin. This information will not be known unless re-excision on the biopsy sites is routinely performed as part of the procedure evaluation. Local recurrence rates after ABBI biopsy are not established. Hence, ABBI should not be considered a therapeutic device whilst the maximal cannula size is 20 mm and whilst more experience with the significance of clear specimen margins is accrued.

1.4 Proven malignant lesions should not routinely undergo ABBI biopsy.^{2-9,12}

Where a malignant diagnosis has been proven by other diagnostic modalities a therapeutic procedure rather than ABBI biopsy is recommended. The ABBI system may be employed to provide pathological information that would influence subsequent surgical procedures, for example the evaluation of second breast lesions or the discrimination between *in situ* versus invasive malignant lesions. Reported series show that the large ABBI core reliably discriminates between DCIS (ductal carcinoma *in situ*) and invasive tumours.

1.5 ABBI is indicated as the primary diagnostic procedure for impalpable mammographic lesions in certain situations.¹⁰⁻¹³

These may include centres where other localised breast biopsy techniques are not available, or where expertise in performance and pathological interpretation of such results is limited.

In situations where the management of impalpable breast lesions does not include guided fine needle aspiration biopsy (FNAB), 14g-core etc, then ABBI may be used as the primary diagnostic step. In certain lesions, that have characteristics likely to lead to the eventual recommendation of open localised excision biopsy (e.g. radial scar/complex sclerosing lesions), ABBI may provide a definitive pathological diagnosis when used as a primary or sole diagnostic procedure.

2. Patient Selection

2.1 *The patient should not be anti-coagulated.*^{1,13}

Formal anti-coagulation (warfarin, heparin therapy) should not be given perioperatively, as for any surgical breast biopsy. The possibility of co-existent bleeding disorders or liver disease should be considered. Most centres performing the procedure would recommend withholding aspirin therapy for 1 week prior to the procedure, in order to lessen the risk of haematoma. The evidence for this practice is anecdotal.

2.2 *The patient must weigh less than 130 kg.*¹

The ABBI system table cannot be safely raised with a patient who weighs in excess of 130 kg.

2.3 *The patient must be able to lie immobile in the prone position.*^{3-6,12-13}

The ability to assume this position comfortably for the expected duration of the procedure is crucial to patient selection. The average on table time is around 60 minutes in most centres. In particular, cardiac failure, chronic pulmonary disease, neck pain, back pain and hip replacements are recognised problem areas.

2.4 *The mammographic lesion may be too close to the chest wall.*^{1,13}

The nature of the stereotactic table and the necessary patient positioning will make it difficult to visualise some lesions that are located too far posteriorly. Likewise the patients breasts must be big enough to visualise the lesion on the ABBI system table while the breast hangs pendulant.

2.5 *The mammographic lesion behind the nipple should be approached with caution.*^{3,4,15}

Large cannula biopsy of a subareolar lesion may compromise the blood supply to the nipple. Attempts at excision in this area have been avoided in some reported series.

2.6 *The compressed breast may be too small to allow ABBI biopsy.*^{1,6,7,12,13}

The minimum breast compression for the safe use of the ABBI system is 20 - 25 mm. If the breast compresses to less than this, it becomes impossible to perform an adequate dissection safely, as there will not be enough of a safety margin beyond the lesion to avoid passing the cannula through the other side of the breast. This problem is a persistent factor in the failure of ABBI biopsies in reported series.

3. Technical Factors

3.1 *ABBI biopsy is a day patient procedure.*²⁻¹³

All centres routinely perform ABBI biopsies as a day surgery procedure. As for other day surgery procedures, and particularly when sedation is employed, the patient should be escorted home and remain in the company of a responsible adult for 24 hours.

3.2 *Orally administered premedication appears to facilitate the procedure.*^{6,10-13}

Many centres report the practice of performing ABBI biopsies after the oral administration of a benzodiazepine (typically diazepam) and an analgesic agent (typically codeine phosphate). Facilities for patient resuscitation should be available as for any procedural unit. Intravenous sedation is generally not required, and has additional hazards and safety requirements. These are a particular concern given the prone position and difficulty with full patient access on the imaging table.

3.3 *Post biopsy mammography and specimen radiology should be routinely performed.*^{2-9,12}

Immediately after the procedure, confirmation of lesion excision should be obtained by performing both a mammogram of the patient's biopsy site and an X-ray of the specimen removed. The patient mammogram can be performed prior to releasing the breast from the imaging table compression plates. If necessary more tissue can be excised when the patient is turned supine and the biopsy cavity explored prior to skin closure. A copy of the specimen X-ray should accompany the specimen to facilitate pathological assessment.

3.4 *The ABBI room must meet appropriate radiological and surgical standards.*¹

The area used to house the ABBI system must be equipped adequately for both the radiological and surgical aspects of the procedure, e.g. radiation shielding, electrical insulation, lighting, diathermy, washing, suction etc. Standard surgical practices such as scrubbing, gowning and gloving, sterile technique, counting swabs and instruments etc. should be employed where appropriate during the procedure. The installation, operation and maintenance of the ABBI system must comply with the appropriate hospital and regulatory body standards.

4. Credentialling

4.1 *The ABBI system should be operated by practitioners specifically trained and accredited in its use.*^{1,13}

That training should include participation in a formal program of familiarisation with the functions of the ABBI system, both imaging and biopsy aspects. The training should include attendance at a "hands on" workshop. The first 2 - 5 procedures should be performed under the supervision of an experienced ABBI proceduralist.

4.2 *The ABBI technique requires both radiological and surgical skills.*^{7,9-13}

The reported literature shows that the ABBI has been operated successfully by both radiologists and surgeons trained in the procedure. However, as the technique requires skills from both fields of practice, the ABBI team should involve radiological and surgical input in the pre-operative assessment, selection and performance of the biopsy and the post-operative care. As the procedure is an operative process, it is prudent to have a surgeon immediately available to assist with the patient's care should problems arise during or after the ABBI biopsy. An experienced breast surgeon should manage any procedural complications. Facilities should be available on site for formal surgical exploration, should the system fail or a major complication develop.

4.3 *The ABBI procedure should be subject to surgical audit.*¹⁴

As ABBI is a surgical biopsy, morbidity, complications and overall outcome data should be included in each proceduralist's audit of operative practice.

4.4 *ABBI biopsies should be viewed by a multidisciplinary team.*¹⁵

It is recommended that all biopsies performed are reviewed by a multidisciplinary management team, especially for malignant lesions.

4.5 *A patient database should be established at all ABBI centres.*¹²

Currently, the ABBI is defining its role in breast surgical practice. It is therefore recommended that all ABBI centres be involved in a common audit of procedural usage and outcome.

This audit should include:

- a) patient demography
- b) characteristics of the mammographic lesion

- c) pre-procedure investigations
- d) technical aspects of the procedure - e.g. cannula size, anaesthesia, duration, hardware problems, post-operative mammogram and specimen X-ray, immediate complications
- e) final pathological diagnosis
- f) follow-up data - e.g. patient appraisal, scar appearance, late complications, follow-up mammogram.

An ABBI audit proforma has been developed at the NSW Breast Cancer Centre, and is in use at the Westmead Hospital in Sydney, Queen Elizabeth Hospital in Adelaide and Aust Path Breast Centre in Sydney (see Attachment 1).

5. Pathological Specimens

5.1 *The ABBI biopsy specimen should always be submitted for histopathological examination.*^{2-9,12}

As for any breast biopsy, the ABBI specimen should be processed as a formal histological specimen. After appropriate fixation and staining, a histopathologist experienced in breast pathology should interpret the sections. In cases where malignancy is discovered, it is routine to submit appropriate tissue samples for hormone receptor studies. Margins of clearance should be reported for ABBI biopsies, but as stated previously their significance is unproven at this time.

5.2 *A copy of the specimen X-ray should be sent with the ABBI specimen.*^{2-9,12}

As discussed previously, a specimen X-ray should accompany the specimen to the pathology laboratory. The X-ray should be appropriately marked to assist the pathologist with orientation and lesion identification.

5.3 *Frozen sections are not routinely recommended for ABBI specimens.*^{2-9,12}

In general, paraffin fixed, transversely cut sections are the method of choice for ABBI specimens. Some centres report the use of frozen sections to obtain a rapid diagnosis, and to facilitate re-excision of the ABBI cavity. This is not a routinely recommended practice in most centres performing ABBI biopsies.

5.4 *The localisation and fixation “T” bar should remain in the specimen.*^{1,6,10,13}

Removal of the localisation wire and “T” bar from the specimen prior to submission for pathological examination is not recommended. The wire acts to help orientate the specimen (representing the superficial aspect), and acts as a marker for the lesion of interest, especially useful for correlation with the specimen X-ray. Removal of the localisation wire is also likely to considerably distort and disrupt the specimen.

5.5 *Orientation sutures should be placed in the specimen.*^{1,6,9,10,12,13}

It is routine practice to employ surface sutures to be used in association with the localisation wire and specimen X-ray. The accepted practice is to place a suture at 12 o'clock on the ABBI cylinder to represent the deep margin.

6. Financial Considerations

The MSAC has declined to allocate a specific MBS item number for ABBI system procedures.

The Medicare Services Advisory Committee (MSAC) is an independent committee which has been established to provide advice to the Commonwealth Minister for Health and Aged Care on the strength of evidence available on new medical technologies and procedures in terms of their safety, effectiveness and cost-effectiveness. This advice will help to inform Government decisions about which new medical services should attract funding under Medicare.

A report was prepared by the MSAC on the ABBI system in May 1999.¹⁶ It was considered that there existed insufficient evidence to conclude that ABBI is superior to existing diagnostic tests that are on the Medicare Benefits Schedule (MBS).

MSAC therefore recommended that additional funding is not warranted at this time, and that ABBI should continue to be funded under the existing MBS item numbers (30363, 30345G/30346S, 59312, 59314). The report was endorsed by the Commonwealth Minister for Health and Aged Care on 11 May 1999.

One of the key findings in the report was that from the literature available on ABBI, the sensitivity and specificity of the procedure from the studies retrieved was unclear, most of the studies being quasi-experimental in design and providing limited detail on patient selection, blinding and randomisation. The future importance of clinical practice guidelines, standardised techniques, accurate audit and data collection for the ABBI system is highlighted by these findings, particularly if ABBI is to eventually gain specific and appropriate MBS status.

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Attachment 1

Sticky Label: _____

Name: _____

UR No: _____

ABBI EVALUATION FORM - IMAGING PAGE 1

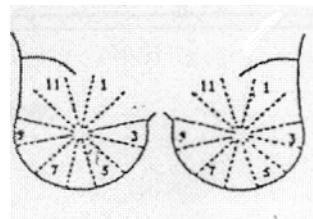
Examination Normal Abnormal

Draw and number lesions on diagram:

Lesion Size (cm) Distance from nipple (cm)

1. x

2. x



Investigations – correlate mammogram, US & biopsy

Mammogram

Date: ___/___/___

Not done

Q.E.H. BreastScreenSA

Other _____

Westmead

Lesion 1

Lesion 2

Side

R

L

R

L

Position

_____ clockface or

Subareolar

Central

Axillary tail

_____ clockface or

Subareolar

Central

Axillary tail

Lesion depth

Anterior

Middle

Posterior

Anterior

Middle

Posterior

Distance nipple

___cm

___cm

Lesion size

___mm

___mm

Mass

Not present

Round / oval

Lobular

Irregular

Not present

Round / oval

Lobular

Irregular

Margins

Circumscribed

Microlobulated

Indistinct

Spiculated

Partially obscured

Circumscribed

Microlobulated

Indistinct

Spiculated

Partially obscured

Density

High

Equal to FG

Low

Fat containing

High

Equal to FG

Low

Fat containing

Calcifications

Not present

Benign type

Amorphous Indistinct

Pleomorphic

Fine or branching

Not present

Benign type

Amorphous Indistinct

Pleomorphic

Fine or branching

Sticky Label: _____

Name: _____

UR No: _____

ABBI EVALUATION FORM
- IMAGING PAGE 2

Distribution

- | | |
|--|--|
| <input type="checkbox"/> Grouped / clustered | <input type="checkbox"/> Grouped / clustered |
| <input type="checkbox"/> Linear | <input type="checkbox"/> Linear |
| <input type="checkbox"/> Segmental (ductal) | <input type="checkbox"/> Segmental (ductal) |
| <input type="checkbox"/> Regional | <input type="checkbox"/> Regional |
| <input type="checkbox"/> Diffuse / scattered | <input type="checkbox"/> Diffuse / scattered |
| <input type="checkbox"/> Multiple groups | <input type="checkbox"/> Multiple groups |

Assessment

- | | |
|---|---|
| <input type="checkbox"/> No sig abnormality | <input type="checkbox"/> No sig abnormality |
| <input type="checkbox"/> Benign lesion | <input type="checkbox"/> Benign lesion |
| <input type="checkbox"/> Equivocal lesion | <input type="checkbox"/> Equivocal lesion |
| <input type="checkbox"/> Suspicious lesion | <input type="checkbox"/> Suspicious lesion |
| <input type="checkbox"/> Malignant lesion | <input type="checkbox"/> Malignant lesion |

Ultrasound:

Not done

Date: ____/____/____

Q.E.H. BreastScreenSA_____ Other_____ Westmead

Lesion 1

Lesion 2

Side

- | | |
|----------------------------|----------------------------|
| <input type="checkbox"/> R | <input type="checkbox"/> R |
| <input type="checkbox"/> L | <input type="checkbox"/> L |

Position

_____ clockface _____ clockface

Lesion depth

- | | |
|------------------------------------|------------------------------------|
| <input type="checkbox"/> Anterior | <input type="checkbox"/> Anterior |
| <input type="checkbox"/> Middle | <input type="checkbox"/> Middle |
| <input type="checkbox"/> Posterior | <input type="checkbox"/> Posterior |

Distance nipple

_____ cm _____ cm

Lesion size

_____ mm _____ mm

Description

- | | |
|--|--|
| <input type="checkbox"/> Normal breast | <input type="checkbox"/> Normal breast |
| <input type="checkbox"/> Cystic | <input type="checkbox"/> Cystic |
| <input type="checkbox"/> Solid, prob benign | <input type="checkbox"/> Solid, prob benign |
| <input type="checkbox"/> Indeterminate | <input type="checkbox"/> Indeterminate |
| <input type="checkbox"/> Solid, prob malignant | <input type="checkbox"/> Solid, prob malignant |
| <input type="checkbox"/> Other | <input type="checkbox"/> Other |

Margins

- | | |
|--|--|
| <input type="checkbox"/> Smooth / Oval | <input type="checkbox"/> Smooth / Oval |
| <input type="checkbox"/> Lobulated | <input type="checkbox"/> Lobulated |
| <input type="checkbox"/> Slight irregular | <input type="checkbox"/> Slight irregular |
| <input type="checkbox"/> Irregular, spiculated | <input type="checkbox"/> Irregular, spiculated |

Echotexture

- | | |
|--|--|
| <input type="checkbox"/> Anechoic | <input type="checkbox"/> Anechoic |
| <input type="checkbox"/> Hyperechoic | <input type="checkbox"/> Hyperechoic |
| <input type="checkbox"/> Heterogeneous | <input type="checkbox"/> Heterogeneous |
| <input type="checkbox"/> Calcification | <input type="checkbox"/> Calcification |

Attenuation

- | | |
|---|---|
| <input type="checkbox"/> Decreased transmission | <input type="checkbox"/> Decreased transmission |
| <input type="checkbox"/> Unchanged | <input type="checkbox"/> Unchanged |
| <input type="checkbox"/> Increased transmission | <input type="checkbox"/> Increased transmission |

Sticky Label: _____
Name: _____
UR No: _____

ABBI EVALUATION FORM
- IMAGING PAGE 3

Assessment:

- | | |
|---|---|
| <input type="checkbox"/> No sig abnormality | <input type="checkbox"/> No sig abnormality |
| <input type="checkbox"/> Benign lesion | <input type="checkbox"/> Benign lesion |
| <input type="checkbox"/> Equivocal lesion | <input type="checkbox"/> Equivocal lesion |
| <input type="checkbox"/> Suspicious lesion | <input type="checkbox"/> Suspicious lesion |
| <input type="checkbox"/> Malignant lesion | <input type="checkbox"/> Malignant lesion |

Pre-ABBI biopsy:

FNAB	Lesion 1	Side <input type="checkbox"/> R <input type="checkbox"/> L	N	B	PB	PM	DM	Inadequate	Clock or _____	S	C	A
<input type="checkbox"/> Not done	2	<input type="checkbox"/> R <input type="checkbox"/> L	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Date: ___/___/___		<input type="checkbox"/> Q.E.H.	<input type="checkbox"/> BreastScreenSA _____		<input type="checkbox"/> Other _____		<input type="checkbox"/> Westmead					

Core Biopsy	Lesion 1	Side <input type="checkbox"/> R <input type="checkbox"/> L	N	B	PB	PM	DM	Inadequate	Clock or _____	S	C	A
<input type="checkbox"/> Not done	2	<input type="checkbox"/> R <input type="checkbox"/> L	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Date: ___/___/___		<input type="checkbox"/> Q.E.H.	<input type="checkbox"/> BreastScreenSA _____		<input type="checkbox"/> Other _____		<input type="checkbox"/> Westmead					

Sticky Label: _____
Name: _____
UR No: _____

ABBI Procedure Report Form
Page 1 of 2

GENERAL

1. Patient Name: _____
 2. Date of Birth: ___/___/___
 3. Surgeon: VH RP DW Other _____
 4. Radiologist: _____
 5. Radiographer: _____
 6. Location: The Q.E.H. Westmead AustPath
 7. Date of Procedure: ___/___/___
 8. Pre-Op lesion size on imaging: _____mm
- OR
9. Lesion not visible on digital imaging (procedure abandoned)

PROCEDURE DETAILS

10. ABBI cannula size 5 mm
 10 mm
 15 mm
 20 mm
 Other – Specify _____
11. Localisation needle depth setting: _____mm
12. Compression: _____mm
13. Coordinates of needle tip: X = ___ mm Y = ___ mm Z = ___mm
14. Additional depth of cannula penetration: 15 mm
 Other – specify _____
15. Was the snare fired successfully? Yes No
16. Was *additional* local anaes. administered? Yes No
17. Total anaesthetic volume used _____ml

(continued over page)

Sticky Label: _____
Name: _____
UR No: _____

ABBI Procedure Report Form
Page 2 of 2

PROCEDURE OUTCOME

18. Blood loss: negligible
 required intervention – specify _____
19. Method of skin closure: routine (subcuticular absorbable monofilament)
 Other – specify type and reason _____
20. Was lesion identified on specimen x-ray? Yes No Indeterminate
21. Was lesion excised on post-procedure x-ray? Yes No Indeterminate
22. Was immediate re-excision done? Yes No Indeterminate
If yes, Specify _____
23. Radio tracer for sentinel node biopsy? Yes No Indeterminate
24. Any other adverse events or complications:

25. Any device or equipment malfunctions:

PATIENT APPRAISAL

26. Patient rating of pain PREVIOUS mammogram: _____
(0 to 10 where 0 is no pain, 10 is worst pain imaginable)
27. Patient rating of pain of ABBI procedure: _____
(0 to 10 where 0 is no pain, 10 is worst pain imaginable)
28. Patient opinion:
"Compared to your last mammogram, was the pain of this procedure ..."
 worse
 about the same
 better

Surgeon / Radiologist Name: _____

Signature: _____

Sticky Label: _____

Name: _____

UR No: _____

PATIENT EVALUATION FORM

ABBI Procedure

Page 1 of 2

1. How did you feel when you were first told that you needed the ABBI procedure?

- Not at all anxious or concerned
- Somewhat anxious
- Extremely anxious

2. How well did you understand why you were having the ABBI procedure?

- Very well
- Reasonably well
- Not completely
- Not at all

3. Have you visited another medical practitioner since the procedure because of your treated Breast?

- Yes
- No

If yes, what was the problem, and what treatment did you receive?

4. Have you had any concerns as a result of the procedure that you did NOT seek medical attention for?

- Yes
- No

If yes, what were the concerns?

5. How did you feel when you were waiting for your ABBI results?

- Not at all anxious or concerned
- Somewhat anxious
- Extremely anxious

6. How noticeable is the scar from your ABBI procedure when you stand in front of a mirror?

- Not noticeable at all
- Hardly noticeable
- Obvious
- Very obvious

7. Does the appearance of the scar on your breast concern you?

- No, not at all
- Somewhat
- Very much

(continued over page)

Sticky Label: _____

Name: _____

UR No: _____

PATIENT EVALUATION FORM
ABBI Procedure

Page 2 of 2

8. If you gave your other, non-treated breast 10 out of 10, in comparison, how would you score your treated breast? Please circle your answer

1-----2-----3-----4-----5-----6-----7-----8-----9-----10

9. Overall, how do you feel about the appearance of your treated breast since the ABBI procedure?

- Very happy
- Reasonably happy
- Satisfied
- Unsatisfied
- Very unhappy

10. Has the ABBI procedure caused any discomfort to your breast? (e.g. tender with pressure)

- No discomfort at all
- Some discomfort
- Significant discomfort

11. Has there been any bruising near the scar site since the ABBI procedure?

- No bruising
- Some blue skin
- A lot of bruising

12. Has there been any swelling of the treated breast since the ABBI procedure?

- No swelling
- A small amount of swelling
- Considerable swelling

13. Did the wound bleed after you arrived home from the procedure?

- No bleeding
- A small amount of bleeding
- Considerable bleeding

14. On a scale of 0 to 10, how would you rate the pain you experienced during the ABBI procedure?

no pain 0-----1-----2-----3-----4-----5-----6-----7-----8-----9-----10 *worst pain imaginable*

15. Was the ABBI procedure

- Better than expected
- As expected
- Worse than expected

Thank you for completing this questionnaire. If you have any questions or concerns, please talk to your doctor about these.

Sticky Label: _____
Name: _____
UR No: _____

ABBI Procedure Time & Consumables Report Form

TIME SPENT

1. Patient into ABBI room / on table (time) -----:----- AM / PM
2. First local anaesthetic (time) -----:----- AM / PM
3. Patient off table (time) -----:----- AM / PM
4. Present at procedure: Surgeon Radiologist Radiographer
 Other(s)
- Who? _____

CONSUMABLES

CONSUMABLE NAME	QUANTITY	DEVIATIONS / COMMENTS
	USED	
ABBI device & Standard tray (contents listed on back of form)		
Extra Items		
Chlorhexidine		
1% lignocaine with adrenaline 5mls		
Saline 30ml sachet		
22G spinal needle		
Raytec gauze swabs (pack of 5)		
Moynihans forceps		
Small sponges		
Suction bottle		
Yankauer sucker		
Frasier sucker		
Diathermy pencil		
Diathermy tip		
Suture – 3/0 CCG		
Ligaclips (small) (pack of 5)		
Ligaclips applicator		
Protective gloves		

Surgeon / Radiologist Name: _____

Signature: _____

Sticky Label: _____
Name: _____
UR No: _____

ABBI Procedure Pathology Form
Page 1 of 2

SPECIMEN QUALITY

1. Lesion found on specimen x-ray at pathology? Yes No
Comments / describe _____
2. Orientation markings adequate? Yes No
If no, comment _____
3. Margins able to be identified macroscopically? Yes No
If no, comment _____

PATHOLOGY RESULTS

4. Lesion classification benign / ADH
 malignant
- If malignant, please complete questions 5 to 11
5. Tumour type(s) DCIS
 infiltrating ductal NOS
 lobular
 tubular
 medullary
 mucinous
 cribriform
 mixed
 other, specify _____
6. Percentage of DCIS _____ %
7. EIC+? Yes No
8. Vessel invasion? Yes No
If yes, specify _____
9. Lymphatic invasion? Yes No
If yes, specify _____

(Continued over page)

Sticky Label: _____
Name: _____
UR No: _____

ABBI Procedure Pathology & Treatment Recommendations Form

Page 2 of 2

Malignant lesions (continued)

10. Histological Grade (modified Bloom & Richardson) Grade 1
 Grade 2
 Grade 3
11. ER +? Yes No Not Done
12. PR +? Yes No Not Done

All lesions (benign and malignant):

13. Lesion size (maximum diameter) _____ mm
14. Clear margins? Yes No
- If yes, distance to closest margin _____ mm
- If no, extent of margin involvement _____ mm

Pathologist Name _____

Signature: _____

Date: _____ / _____ / _____

Sticky Label: _____
Name: _____
UR No: _____

ABBI Procedure Follow Up and Recommendations Form

1. Date of follow up: _____ / _____ / _____

2. Number of days since ABBI procedure: _____ days

3. Patient has completed evaluation from Yes No

If no, reason _____

COSMESIS

4. Length of scar _____ mm

5. Scar separation? Yes No

If yes, specify _____

6. Infection? Yes No

If yes, specify _____

7. Haematoma or bruising? Yes No

If yes, specify _____

8. Other notes on scar or appearance of breast tissue:

RECOMMENDATIONS

9. Primary Benign – no further surgery
 Malignant – no further surgery
 Re-excision
 Mastectomy

10. Nodes No surgery
 Sentinel node biopsy
 Dissection

Surgeon / Radiologist Name: _____

Signature: _____