A National Audit of Magseed® and wire localisation of breast lesions.

iBRA-net Study Group

Study Protocol Version 3
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1. Background

1.1 Localisation techniques

Excision of impalpable breast lesions is usually directed by preoperative wire placement into or adjacent to the target lesion. Wire localization has several disadvantages, most notably, displacement of the wire, and difficulty in the surgeon discerning accurately the position of the tip of the wire intraoperatively [1]. The entry point of the wire may be some distance from the wire tip, making optimal incision placement a challenge and leading to extensive dissection to remove the target lesion. Additionally, wire placement occurs on the day of surgery which can create problems for radiology and surgery scheduling and lead to delays in the operating theatre. However, it remains the default method of localization due to the limitations of other methods of localization and given the long term data supporting its effectiveness [2].

Iodine (^{125}I) radioactive seed localization is used in some centres to overcome many of the disadvantages of wire localization. It can be performed prior to the day of surgery and the surgeon can accurately localise the device in theatre using a hand-held gamma probe, providing major logistical advantages [3]. However, the radiation safety precautions required to set up and support this service limits its widespread implementation [4]. Radioactive seed localization and radiooccult lesion localization (ROLL) are equally reliable to wire localization [2]. ROLL offers less logistical advantage compared to seeds, because it still requires patient injection of radioisotope into the tumour bed to occur within 24 hours of surgery. Unless contrast is also given, ROLL does not offer the surgeon mammographic or ultrasound confirmation of the site of injection in relation to the lesion [5].

1.2 Magseed® localisation of breast tumours

Magseed® is an alternative method of localising breast lesions. It consists of a 5x1mm paramagnetic steel and iron oxide seed. The seed is cylindrical with no barbs and is readily visible on mammography and ultrasound. It is supplied in sterile packaging preloaded into an 18-gauge 20 cm long steel needle. The seed is retained by a wax plug and there is a steel obturator which is advanced to deploy the seed. The seed is detectable using the Sentimag probe in the same way as the Sienna dye [6] used in sentinel lymph node biopsy. The probe generates an alternating magnetic field which transiently magnetises the iron oxide particles within the Magseed®. The magnetic signature of the

Magseed® is then detected by the Sentimag probe. The Sentimag unit displays a numerical count and produces an audio tone, which are related to the strength of the magnetic field and therefore the distance of the seed from the detector probe. Magseed® offers the potential advantages of a radioactive seed without the onerous radiation governance requirements.

Magseed® has been validated in a two-centre open label cohort study to assess the feasibility and safety of magnetic seed (Magseed®) localization of breast lesions [7]. Magseed®s were placed under radiological guidance, into women having total mastectomy surgery. The primary outcome measure was seed migration distance. Secondary outcome measures included accuracy of placement, ease of transcutaneous detection, seed integrity and safety. Twenty-nine Magseed®s were placed into the breasts of 28 patients under ultrasound guidance. There was no migration of the seeds between placement and surgery. Twenty-seven seeds were placed directly in the target lesion with the other seeds being 2 and 3 mm away. All seeds were detectable transcutaneously in all breast sizes and at all depths. There were no complications or safety issues.

Magseed® was CE marked to localise breast cancers in 2018 and allows the device to be placed in a patient for up to 30 days before removal. Magseed® has been used in >5,000 cases worldwide but only one small study of its use in wide local excisions has been published using 73 seeds [8]. There is therefore a lack of available evidence on its efficacy.

1.3 Ibra-net research collaborative

There are a number of established barriers to the conduct of large prospective multicentre studies; they require significant organisation and collaboration between a large number of centres; they may be expensive to run and can be prohibitively time-consuming for surgeons.

Breast surgery has a long history of using implantable devices, with the recent history being the implementation of multiple different mesh and acellular dermal matrix devices. IBRA-net was designed to prospectively audit short term outcomes of these devices and to support breast surgery in conforming to the IDEAL guidelines for surgical trials of No Innovation without Evaluation [9]. The Association of Breast Surgery is committed to the community of breast surgeons evaluating new devices, a collaborative prospective collection of data is seen as a good way of approaching data collection on a new device without stifling Innovation. Ibra-net offers the opportunity for breast

surgeons to come together to design trials and ensure device safety and efficacy within the safe governance of a formalised evaluation.

We aim to design a study around Key Performance Indicators for Breast localisation devices with defined outcome measures. This should enable us to compare similar devices in the future, using the datasets on localisation devices collected as part of this study.

2. Aims and objectives

The iBRA-net study of Magseed® and wire localisation aims to:

i. Set up Key Performance Indicators to compare the outcomes of breast localisation devices.
ii. Describe the current practice of breast localisations.
iii. Evaluate the outcomes of Magseed® and Wire localisation including;

Primary outcome – Identification rate of index lesion

Secondary outcomes include

Margin status

Accuracy of placement

Pathological weight of specimen

Transcutaneous detection rate

Reoperation rate

Complications

Cancellation rate on day of surgery

Reason for cancellation on day of surgery

Time of day of start of surgery

Learning points from surgery

Sensitivity of Magseed® for bracketing lesions.

Healthcare professional (Surgeon and radiology) qualitative outcome of use Magseed® compared with current practice.

iv. To inform a future prospective trial in breast localisation surgery

v. To identify and disperse any learning points on use of Magseed® device

3. Definitions

The following definitions of complications will be used for this audit. Slight modifications will be made to the patient-reported complication section to provide more accurate estimations of associated morbidity (e.g. major vs minor infection; number of seromas drained).

Haematoma - A collection of blood in the breast

- **Minor –** managed conservatively, or by aspiration in clinic or
- **Major –** requiring surgical evacuation.

Infection - A hot, red swollen breast associated with one of the following; a temperature, pus at the wound site, a raised white cell count; a positive wound culture within the first 3 months following surgery. This will be further classified as:

- **Minor** – requiring oral antibiotics only;
- **Major 1** – requiring admission for IV antibiotics and/or debridement;
- **Major 2** – requiring surgical drainage/debridement

Wound dehiscence – separation of the skin edges at the wound site.

- **Minor** – treated conservatively;
- **Major** – requiring return to theatre for re-suturing under GA

In hospital complication – any complication that occurs during the patient's initial hospital stay at the time of their surgery. This includes systematic complications such as DVT/PE and procedure specific complications such as haematoma.

Readmission to hospital – any re-admission to hospital in the 30 days following surgery directly related to the procedure but excluding re-excision of margins (e.g with infection requiring antibiotics or systemic complications including pulmonary embolus)

Return to theatre – Return to the operating theatre at any time during the first 30 days to deal with any complications directly related to the breast surgery.

Major complication - Any complication requiring readmission to hospital or return to theatre

Minor complication - Any other complication

Cancellation of surgery – patient has breast localisation operation (wide local excision or localised diagnostic excision biopsy) cancelled in the 24 hours prior to the time of the scheduled operation.

4. Magseed® Ibra-net phases

4.1 Phase 1 –Practice survey

i. Current localisation technique

Baseline questionnaire on current practice of localisation, logistics of current method of localisation. Distributed October 2018- January 2019.

4.2 Phase 2 - Prospective Audit

a) Local audit of the outcomes of wire localisation

Audit of current practice using wire localisation. This can be prior to adoption of Magseed®, or current practice whilst changing practice to Magseed® or whilst trialling Magseed® device.

b) Local audit of Magseed® breast localisation cases

Key Performance Indicators - Identification rate of index lesion, unplanned readmission

i. Identification rate of index lesion

>98% of impalpable lesions should be correctly identified at the first operation [ABS guideline surgeons best practice in breast screening 2018]. This index lesion (cancer/lesion/clip) should be removed or partially removed at surgery.

ii. Unplanned readmission

<5% of patients require re-admission to hospital within 3 months (QC17 ABS/BAPRAS Oncoplastic guidelines 2012)

Other outcome data collected include;

Margin status – is disease (DCIS/ invasive) <1mm from nearest margin, which margin

Weight of specimen – weight of wide local excision specimen (g)

Transcutaneous detection rate – proportion of localisations where the Magseed® can be detected transcutaneously prior to the first incision being made

Reoperation rate – planned and unplanned reoperation rate to the breast.

Complications – proportion of patients having a complication and reporting of any complications related to the device.

Cancellation rate on day of surgery – proportion of patients cancelled within 24 hours of time of surgery and the reason for cancellation

Time of day of surgery – HH:mm of starting time of the operation (check anaesthetic chart or ORMIS)

Learning points from surgery – qualitative feedback on learning points from the use of Magseed® which may benefit others.

Sensitivity of Magseed® for bracketing lesions – number of seeds used, distance apart, were the seeds' signals distinctly separate.

Healthcare professional (Surgeon and radiology) qualitative outcome of use Magseed® compared with current practice.

5. Methods

This is a research collaborative led project with 2 phases:

1. A national practice survey
2. A prospective audit of the outcomes of current technique of breast localisation and a prospective audit of Magseed® localisation of breast lesions

Trainees will be invited to participate in the study through the Mammary Fold and the National Research Collaborative network. A local Trainee Lead; ideally a higher surgical trainee with a special interest in breast surgery will be identified at each centre. Trainee leads will be responsible for identifying a supervising consultant and obtaining the support of other consultants in the department and to register the audit locally with their institution.

Support has been forthcoming from the Association of Breast Surgery (ABS). We will ask that they encourage all Consultant members who are carrying out Magseed® localisation to support their trainees in this audit and to enter all their patients undergoing Magseed® and wire localisation in to the study.

5.1 Phase 1 - National practice questionnaire

A questionnaire has been devised by members of the steering group to provide a summary of the current practice of breast localisation; types of localisation offered and to document the current localisation process for a patient.

All breast and plastic surgical units offering care to women over the age of 16 will be encouraged to participate, by direct contact and by the professional associations. Sysmex, the distributors for Magseed® will be asked to contribute a list of current Magseed® centres to ensure all units are offered participation.

Local Trainee Leads will be responsible for completing the national practice questionnaire with the support of their supervising consultants and returning them. No formal approvals are required for Phase 1 of the study.

5.2 Phase 2 - Prospective audit of the outcomes of current technique of breast localisation and a prospective audit of Magseed® localisation of breast lesions

5.2.1 Logistical and clinical governance issues

The named supervising consultant will act as the principal investigator for each unit (although trainees can be responsible for data collection). Patient recruitment and data collection will be completed by the local trainee lead who will also be responsible for seeking local Clinical Audit Department approval for the project prior to commencing data collection.

It is anticipated that each Trainee lead will identify a small team of 2-3 people to help conduct the audit and will liaise with the wider surgical team including the breast care and reconstructive nurses.

5.2.2 Patient inclusion and exclusion criteria

Inclusion criteria

All female patients over the age of 16 electing to undergo a breast conserving localisation procedure will be eligible for inclusion in the study.

Exclusion criteria for Magseed localisation

i. Patients who have received Sienna (iron oxide) injection in the previous six months.
ii. Patients who have a pacemaker or implantable electronic device in their chest wall.

5.2.3 Participation identification and recruitment

It is expected that participating centres will recruit consecutive patients into the audit.

Potential participants will be identified prospectively by the local audit team via clinics, local MDTs, consultant surgeons and clinical nurse specialists. Simple demographic, procedure and process data will be contemporaneously collected for each participant. Data will be recorded in an anonymised format using a unique alphanumeric study identification number on a secure web-based database (REDCap) designed by Vanderbilt University[89-91] (http://www.projectredcap.org/).

5.2.4 Unit inclusion criteria for Phase 2

To ensure consistent quality in localisation and excision, the study requires a minimum standard of the individual performing the localisation procedure. This is to ensure the individual has received adequate training and is experienced in the technique.

Wire localisation surgery – The operating surgeon must have completed a minimum of 10 wire guided wide local excisions in the last year. The operator can be a trainee with less experience as long as a suitably experienced Consultant is supervising the surgery in an appropriate manner.

Magseed® localisation surgery – The unit must have adopted Magseed® as their method of localisation and not still be within their trial period, this is to ensure that there is adequate expertise in both radiological placement and surgical removal of the Magseed®. Individual surgeons must have completed a minimum of FIVE Magseed® localisation cases successfully and have completed their training requirements with Sysmex.

5.2.5 Protocol for Magseed® use

To ensure consistent quality in localisation and excision, there is a recommended Protocol for use of the Magseed® device (Appendix 1, 2), this does not have to be followed if this does not fit with the local requirements. We are keen that different practices occur and that the relative merits of these practices can be compared. One major outcome of the study is to improve practice and ensure Quality and Governance. As patients are recruited and as sites and individuals learn to use the Magseed® we would envisage the Protocol for Magseed® use to be updated and distributed to units participating in the study.

All patients should receive an information leaflet about Magseed® prior to insertion (Appendix 3).

6. Data management and storage

Data collection will occur in accordance with Caldicott II principles. Data for each patient will be anonymised using a unique alphanumeric study identification number. No patient identifiable data will be recorded for the purpose of the audit.

Study data will be collected and managed using REDCap electronic data capture tools hosted at University of Edinburgh and made freely available to research collaboratives in the UK[89]. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

REDCap is run by Clinical Surgery, University of Edinburgh under licence from Vanderbilt University. REDCap was developed specifically around HIPAA-Security guidelines. It is hosted within the University of Edinburgh Virtual Machine architecture which is physically secured. A linux web server running apache2/php5 hosts the application. Web browser communication to the server is SSL-encrypted by default. All other ports are firewall protected. Data is stored in MySQL databases on a separate server. This server is behind a firewall and can only be accessed from the IP address of the web server. An SSL-tunnel encrypts communication between the web and databases servers. File upload is secured between servers using theWebDAV protocol with SSL. "At rest" encryption is in place on the database server (aes-xts-plain64:sha256 with 512-bit keys). Daily back-ups are made of both servers and stored for two weeks prior to being deleted. Operating security updates are installed automatically. Antivirus software runs to a scheduled protocol on the web server. User passwords are managed directly. Accounts are disabled after 5 failed login attempts. Users are auto logged out after 30 mins of no activity. Users are forced to change password after 90 days. Daily audit tracking of users is in place with removal of unused user accounts. REDCap servers are housed at the University of Edinburgh and all web-based information transmission is encrypted.

REDCap has been disseminated for local use at more than 1,005 other academic/non-profit consortium partners in 79 countries. Vanderbilt leads the REDCap Consortium, which currently supports more than 99,000 projects and 128,000 users. More information about the consortium and system security can be found at http://www.projectredcap.org/.

7. Data analysis

All data analysis will occur centrally and will be led by The University of Manchester and the lead statistician Julie Morris.

Full details of the analysis can be found in the Statistical Analysis Plan (SAP).

7.1 National Practice Questionnaire

Simple summary statistics will be calculated to describe the parameters identified in the questionnaire and the data will be used to describe variations in the provision of care and practice. Categorical data will be summarised by counts and percentages. Continuous data will be summarised by mean, SD and range if data is normally distributed. Median, IQR and range will be reported if the data is skewed. No formal statistical testing will be undertaken.

Qualitative data, which comprises representatives' free text responses to open ended items, will be presented where appropriate according to overall themes within the responses. Where necessary, qualitative findings will be presented alongside those from the quantitative analysis to help contextualise and illuminate the quantitative responses. All text extracts will be anonymised.

7.2 Prospective audit

7.2.1 Calculation of internal audit standards

Simple summary statistics will be calculated for each of the main clinical audit standards (unplanned readmission and identification of the index lesion for individual localisation subtypes).These will be compared with targets from the Association of Breast Surgery and NHSBSP.
Initial calculations will be made when a total of 400 patients from a minimum of 10 centres have been recruited to the study.

7.2.2 Full analysis

Simple summary statistics will be calculated for each outcome and regression analysis used to control for predictive variables. Data will be tested for distribution and differences between groups using unpaired t-tests, Mann-Whitney U tests and Chi squared tests as appropriate.

Power Calculation - with n=1000 patients per group, the upper limit of the observed one-sided 95% confidence interval for the difference between failure rates (seed vs wire) is expected to be less than 0.9% with 80% power, assuming the two methods both have an expected failure rate of 0.6%.

Hence, if a 0.9% difference is considered an acceptable equivalence margin (eg. 0.6% for wire and 1.5% for seed), 1000 patients per group should be sufficient to establish equivalence.

8. Publication and authorship policy

All presentations and publications will be made on behalf of the Trainee Research Collaborative and the iBRA-net Study Group.

Three levels of authorship are proposed based on degree of study participation:

8.1 Named authors

Named authors will be required to meet the International Committee of Medical Journal Editors (ICMJE) criteria (www.icmje.org) for authorship based on the following four criteria:

1. Substantial contribution to the conception or design of the work; or the acquisition, analysis or interpretation of the data for the work and
2. Drafting the work or revising it critically for important intellectual content and
3. Final approval of the version to be published and
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

The ICMJE states '*when submitting a manuscript authored by a group, the corresponding author should specify the group name if one exists and clearly identify the group members who can take credit and responsibility for the work as authors. The byline of the article identifies who is directly responsible for the manuscript and MEDLINE lists authors whichever names appear on the byline. If the byline includes a group name, MEDLINE will list the names of individual group members who are authors or who are collaborators, sometimes called non-author contributors, if there is a note associated with the byline clearly stating that the individual names are elsewhere in the paper and whether those names are authors or collaborators*.'

It is anticipated that between six and eight individuals will be named on each publication followed by the wording 'on behalf of the Trainee Research Collaborative and the iBRA-net Study Group'. All citable collaborators will be listed at the end of the paper and their roles identified.

Collaborators will be invited to sit on the iBRA-net Writing Group which will be responsible for drafting manuscripts and preparing them for publication.

8.2 Citable collaborators

Citable collaborators will have made a considerable contribution to the study, but will not have met the ICMJE criteria for authorship (non-author contributors). These will include trainee leads at each centre and other trainees or team members (including consultant surgeons, clinical nurse specialists or research nurses) who have recruited at least 10 patients to the study. Recruitment in this context includes submission of at least 10 completed data sets. Judgement may be used to determine participation according to local centre practice. Trainee leads will be asked to provide details of their local team and whether individuals fulfil the criteria for citable or acknowledged collaborator status.

8.3 Acknowledged collaborators

Acknowledged collaborators will include consultant surgeons who contributed patients to the audit, but did not personally collect data or recruit patients to receive PROMS and trainees who have made a lesser contribution to patient recruitment and data collection than that required for citable collaborator status. Trainees who are acknowledged contributors will also receive a certificate of participation for inclusion in their portfolios.

Local collaboratives and hospital Trusts will have ownership of their own data and will be able to present it locally if they wish.

The final reports will be prepared in accordance with the STROBE[92] (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines.

9. Research Governance

The main aim of the audit is to determine the safety of Magseed® localisation for breast lesions.

Summary statistics will be calculated for each participating Trust and fed back to individual units to allow comparison with national averages and ranges

This study is assessing the feasibility and safety of widespread use of Magseed® as a device to localise breast lesions. If any learning points are identified during the course of the study this information or recommendation will be shared with each contributing site as well as with the product distributor Sysmex.

Any centres or surgeons whose overall identification rate is identified as being an outlier will be contacted by a member of the study Executive Committee to inform them of this finding, check the validity of the results and explore reasons for this finding (e.g learning curve; complex caseload). If a Unit is found to be an outlier in 2 consecutive analyses, these results will be fed back to the Unit, the Clinical Director and local clinical governance lead for that Trust.

Overall audit results and results from individual centres will be fedback to ABS and compared with audit outcomes to complete the audit cycle and determine whether standards of care are being achieved.

10. Study Management

Oversight of the audit will be by the Audit Steering Group which will have wide representation from surgeons, trainees, the professional societies, patient representative and those with experience of study management and statistics. This group is expected to meet twice per year, but may also meet more frequently if necessary.

There will in addition be a smaller executive group for day to day audit management. It is expected that most of this work will be done as a 'virtual group' by e mail.

A writing and data analysis group will also be convened.

10.1 Shared learning

Incident/event reporting centrally is encouraged for any unexpected problems with their localisation technique during the course of the study, this should be done using Section 7 of the Case Report Form. Safety issues that we would recommend reporting would be; failure to remove the index lesion, failure to identify a Magseed transcutaneously at time of surgery, displacement of the localisation device from the index lesion, insertion of the localisation device >2cm from the index lesion, and conversion of one localisation technique to another. If safety points are raised during the study they will be disseminated to all units via their lead and also to the manufacturer Endomag and to the distributor Sysmex. The Trial steering committee will review the event reports and will be responsible for updating the Magseed® User Guide and Magseed® Protocol Guidance so that best practice is disseminated.

Learning will be shared by updates to Principle Investigators and via Trial Newsletters.

11. References

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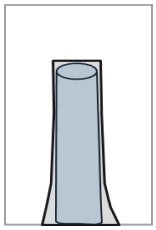
Appendix 1 – Ibra-net Magseed® User Guide

Customer Sentimag/Magseed® User guide

1. **Connect** the probe with the base unit – ensuring that the arrows on the probe connectors are at the top of the connectors
2. **Switch on** the Sentimag at least **15 – 20 minutes** prior to use – the dial needs to be set at position **2** throughout the procedure.
3. **Cover** the probe with a sterile single-use sheath
4. **Balance** the Sentimag using the balance button or the footswitch

Probe Connections

Sentimag Base Unit



Probe

Balance Button

Base Footswitch

Balance Function

The operator should at all times hold the probe behind the black ring – The internal workings of the probe contain a maze of coils. The Sentimag probe generates a magnetic field, when that field is passed over a Magseed®, the iron in the Magseed® becomes temporally magnetised. Once the magnetic field from the probe is removed, this effect disappears.

To perform a balance of the base unit, the operator should either press the button marked on the base unit or press the footswitch

Base unit then performs balance function. The LCD display will change to show a sequence in which the scales symbol rocks back and forth

After ~ five seconds the scales symbol will stop rocking. The Sentimag® should then display a value close to zero and is ready to use.

Make sure all metal including rings, retractors, lights, name badges are out of the range of the probe.

When to balance the scales

- When the stationary balance symbol is displayed e.g. after start-up
- When the sensitivity setting of the Sentimag® is changed. Dial Button 1-2-3
- Before starting use after a minimum of 15 minutes warm-up
- Before taking any measurements on the patient.

Probe Phantom Testing

To check system performance with the probe test phantom:

- Connect and allow the unit to warm up for at least 15 minutes
- Adjust the sensitivity setting to level 3

1. Balance the unit whilst the probe is being held away from any magnetic sources and then quickly place the phantom on top of the probe

Sentimag® system should display a similar value to ±10%

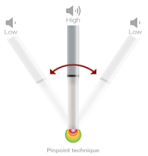
Technique 1: displays yellow counts / Technique 2: displays red counts

Sentimag® – Transcutaneous measurement

- Detect: Sweep the probe and apply some pressure around the breast until the Magseed®® is located (**to get a signal from Sienna/Magseed®® the probe must be within 3cm**)
- Pinpoint: Pivot the probe around the hotspot to maximize the signal - Always keep the probe moving.
- Confirm: Palpation of the skin should result in a rise and fall in the signal = a characteristic change in Sentimag® value and audio frequency

Confirming a lesion in vivo

Listen:
The signal will increase when the probe is pointing directly at a Magseed®® lesion, and decrease when angled away. This is known as the 'pinpoint' technique.



Pin point technique

- Balance in air:
  Remove probe from incision, balance in air and recheck suspect lesion
- Balance in-vivo:
  From within the incision, withdraw 2-3cm from the suspect lesion and re-balance. A clear positive signal should be seen when you examine the Magseed®® lesion again

Appendix 2 Magseed® localisation protocol guidance

Summary

- Magseed® should only be placed for up to 30 days in advance of operation date
- Magseed® should not be placed until all investigations including MRI have been completed.
- Patients should receive an information leaflet about Magseed® prior to insertion
- Prospective outcomes of Magseed® localisation should be audited
- Exclusion criteria for using Magseed® are; Patients with a Pacemaker or implanted device in the chest wall; patients requiring an MRI scan between Magseed® placement and surgery, patients who have received Sienna (iron oxide) injection in the previous six months, caution - metal coronary stents.
- Check in anaesthetic room prior to anaesthetic induction that Magseed® can be located and if bracketing that both Magseed®s can be differentiated.
- Caution when using Magseed® for bracketing lesions that are close together.
- Caution- ensure Magnetometer device is switched on in theatre AT LEAST 20 minutes prior to first use
- Wire localisation can continue to be available when clinicians feel that this would be preferable for an individual patient