ACCUFIX
RESEARCH
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**Important Information about Telectronics**
**ACCUFIX and ENCOR Atrial 'J' Leads**

April 25, 2005

Dear Doctor,

Accufix Research Institute (ARI) has an ongoing commitment to provide information to facilitate the best care for patients. This is the tenth letter mailed to physicians since 1994 when the Accufix leads were withdrawn from the market based on mortality and morbidity from protrusion of the J retention wire. This letter presents the patient management guidelines recommended by the Physician Advisory Committee (PAC) at the November 7, 2004 meeting. Background information and clinical details supporting these recommendations can be found on the ARI website www.accufix.com.

- The overall recommendations for the ACCUFIX Bipolar Active Fixation leads ***have been modified*** based on the long implant duration of the currently implanted leads, the low probability of J wire injury projected over the next 20 years, and the increasing probability of a life-threatening or fatal extraction complication over time which is highest in the female patient.

  ***Conservative management is advised. Consideration for extraction is probably best reserved for leads with protrusion, or in young patients (age at implant less than 51) with Class II leads and implant durations less than 16 years (male); 13 years (female). While injury can only occur with protrusion, this condition does not mandate lead or wire extraction. Patient care should be individualized with attention to life expectancy and co-morbidities. Some patients with protrusion are being followed conservatively. If extraction is the treatment of choice for a protrusion, consider removing the J wire (proximal non-welded J wire) utilizing a snare, while leaving the lead intact as this procedure substantially reduces risk.***

  - The recommended fluoroscopic screening interval remains every 6 months as a starting point, but can reasonably be extended based on individual patient and lead factors (refer to page 2).

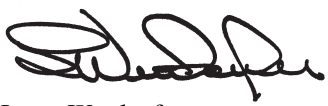
- The overall recommendations for the ENCOR Bipolar Passive Fixation leads **remain unchanged.**
  - Conservative management and less encouragement for extraction of non-protruding leads is advised based on the extremely low probability of J wire injury in the patients' remaining lifetime compared to an increasing combined life threatening/fatal extraction risk.
  - A fluoroscopic screening interval every 12 months is a starting point, but can reasonably be extended based on individual patient and lead factors (refer to page 3).

- Fluoroscopic screening and extraction are **still <u>not</u> recommended** for the ENCOR Unipolar leads. No protrusions or injuries have been reported and extraction risk is almost certainly greater than leaving the lead in-situ.

In order for ARI to provide the most informed patient management recommendations, please send to ARI all screening, explant and patient status information, and also return all explanted leads. Unless there is evidence of a change in clinical risk impacting patient management, this letter will likely be the last communication from ARI providing patient management recommendations.

Please call our toll free number (800-565-8656) if you have any questions or to request explant screwdriver stylets. Copies of Explant, J wire Injury and Fluoroscopic Screening Forms can be found on our website at www.accufix.com. Thank you for your continued help in the management of this situation.

Sincerely,



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# ACCUFIX Bipolar Active Fixation Atrial 'J' Leads
# 330-801 / 329-701 / 033-812

## Summary of Patient Management Guidelines

When determining the appropriate management options, consider the 'J' wire injury risk in the patient's lifetime, patient's medical history, patient requests based on informed decision, life expectancy, and extraction risk.

***Lead Extraction Considerations***

- All Accufix leads currently implanted have an implant duration of at least 10 years. An estimated 6400 leads remain implanted.
- For all patients, the time post implant at which the risk of extraction exceeds the probability of future J wire injury strongly depends on the patient's expected remaining lifetime, gender, implant duration and J wire status.
- Based on the current implant duration and the very low injury rate, consideration for extraction is probably best reserved for patients with a protruding J wire, or young patients (age at implant less than 51) with Class II leads and implant duration less than 16 years (males); 13 years (females).
- While injury can only occur with protrusion, this condition does not mandate lead or wire extraction. Patient care should be individualized with attention to life expectancy and co-morbidities. Some patients with protrusion are being followed conservatively. If extraction is the treatment of choice for a protrusion, consider removing the J wire (proximal non-welded J wire) utilizing a snare, leaving the lead intact. This approach substantially reduces extraction risk.
- For patients with age at implant less than 51 and Class I leads, the Life-threatening/Fatal extraction risk appears to be greater than the future probability of J wire injury over the next 20 years.
- For male patients with age at implant 51 to 70, and Class II leads the Life-threatening/Fatal extraction risk is greater than the future probability of J wire injury over the next 20 years since all leads have now been implanted at least 10 years and the risk is approximately equal at 10 years.
- For female patients with age at implant 51-70 and Class II leads, the Life-threatening/Fatal extraction risk is greater than the future probability of J wire injury over the next 20 years based on the higher extraction complication risk in female patients.
- For all patients with age at implant 71+, with Class I or Class II leads, the Life-threatening/Fatal extraction risk appears to be greater than the probability of J wire injury in the patients' remaining lifetime.
- Replacement of a pulse generator is not sufficient reason to remove the lead. The extraction risk should be the primary consideration in the decision to extract the lead.
- There is no evidence to suggest that new advances in lead extraction technology have reduced the risk of a Life-threatening/Fatal extraction complication.
- Only physicians who are experienced in the extraction procedure and who have immediate access to a surgical unit equipped for an emergency thoracotomy should attempt lead extraction. Please refer to the NASPE policy statement on lead extraction in PACE April 2000 vol. 23 pp. 544-551.
- When a thoracotomy with atriotomy is performed, strongly consider extracting the lead regardless of lead status.
- At all times, attention should be focused on the emotional and psychological impact on the patient when assisting him/her in the decision-making process, especially in light of the low risk of J wire injury compared to extraction risk. In some patients, if management of the emotional and psychological impact might eventually require extraction, it would be better to extract earlier rather than later.

***Screening Interval and Technique Considerations***

A screening interval of every 6 months is generally recommended with considerations for longer intervals noted below. Based on prospectively followed multi-center (MCS) data, the protrusion risk is low (1.3% per year) and the worldwide overall injury rate in the registry is even lower (0.05% per year). Screening is a tool primarily designed to identify protruded leads. Continued screening allows for identification of protrusion; a situation where the J wire can be removed leaving the lead intact.

Fluoroscopic screening intervals greater than every 6 months should be considered based on:

- Patient informed decision regarding the risks.
- Risk of Fracture - Patients with closed J Shape, No J Swing or Prior Cardiac Surgery are at lower risk.
- Risk of Injury - Older patients are at lower risk of injury than younger patients ($p<0.001$). Median age at implant for injured patients = 67 years.
- Suitability of patient as an extraction candidate - The option of no further fluoroscopic screenings should be considered in patients who are not potential candidates for any form of extraction.

J wire screening using cinefluoroscopy provides the greatest flexibility in identifying J wire classification and motion, a predictor of fracture. High quality chest x-ray (PA, lateral and oblique) can generally identify protrusion.

Patients should be informed that protrusion of the J wire can manifest as chest pain and should be instructed to communicate the possibility of J wire protrusion to the attending physician.

# ENCOR Bipolar Passive Fixation Atrial 'J' Leads

**330-854 / 033-856 / 327-747 / 327-754 / 329-749 / 329-754 / 330-848**

## Summary of Patient Management Guidelines

When determining the appropriate management options, consider the 'J' wire injury risk in the patient's lifetime, patient's medical history, patient requests based on informed decision, life expectancy, and extraction risk.

### *Lead Extraction Considerations*

- All Encor leads currently implanted have an implant duration of at least 9 years. An estimated 6200 leads remain implanted.
- Based on the current implant duration of these leads, and the extremely low injury rate (0.02%/year) and the estimated extraction risk with current implant durations, consideration for extraction is probably best reserved for patients with a protruding J wire. Despite the high extraction complication risk, extraction should be strongly considered in patients with a straight J wire protrusion in the inter-electrode region due to the injury potential from this type of protrusion
- The Life-threatening/Fatal extraction risk for all Class I and Class II patients and all implant durations appears to be greater than the future probability of J wire injury.
- Replacement of a pulse generator is not sufficient reason to remove the lead. The extraction risk should be the primary consideration in the decision to extract the lead.
- There is no evidence to suggest that new advances in lead extraction technology have reduced the risk of a Life-threatening/Fatal extraction complication. There is also no evidence to suggest success in removing the protruding J wire (leaving the lead intact) for Encor Bipolar leads.
- Only physicians who are experienced in the procedure and who have immediate access to a surgical unit equipped for an emergency thoracotomy should attempt lead extraction. Please refer to the NASPE policy statement on lead extraction in PACE April 2000 vol. 23 pp. 544-551.
- When a thoracotomy with atriotomy is performed, strongly consider extracting the lead regardless of lead status.
- At all times, attention should be focused on the emotional and psychological impact on the patient when assisting him/her in the decision-making process, especially in light of the low risk of J wire injury compared to extraction risk. In some patients, if management of the emotional and psychological impact might eventually require extraction, it would be better to extract earlier rather than later.

### *Screening Interval and Technique Considerations*

An annual screening interval is generally recommended with considerations for different intervals noted below. Based on prospectively followed MCS data, the protrusion risk is low (0.2% per year) and the worldwide injury rate in the registry is even lower (0.02% per year). Screening is now a tool primarily designed to identify patients with protrusion. A program of continued screening allows identification of protrusion; a situation where extraction should be strongly considered due to the often-straight J wire projection in the inter-electrode region.

Fluoroscopic screening intervals greater than every 12 months should be considered based on:

- Patient informed decision regarding the risks.
- Risk of Fracture - Patients with closed J Shape, no motion in the inter-electrode region and age at implant greater than 50 are at lower risk of fracture. Conversely patients with open J Shape, inter-electrode motion (kink) and age at implant less than 50 are at higher risk of fracture which should be considered when establishing screening intervals. No predictive variables of protrusion have been identified.
- Risk of Injury - Older patients are at lower risk of injury than younger patients (p=0.006). Median age at implant for injured patients = 55 years versus median age at implant for non-injured patients = 74 years.
- Suitability of patient as an extraction candidate - The option of no further fluoroscopic screenings should be considered in patients who are not potential candidates for any form of extraction.

Fluoroscopic screening should occur if any of the following are observed:

- Changes in lead electrical parameters - Dramatic changes in impedance could indicate a severed or partially severed inter-electrode region (an area on the lead containing the straight portion of the J wire).
- Chest pain - Patients should be informed that protrusion of the J wire can manifest as chest pain and should be instructed to communicate the possibility of J wire protrusion to the attending physician.

J wire screening using cinefluoroscopy provides the greatest flexibility in identifying J wire classification and inter-electrode motion, a predictor of J wire fracture. However, high quality chest x-ray can generally identify protrusion. If a decision is made to use x-ray, then PA, lateral and oblique views are recommended.