IRIS Program DIRE Committee Results

DIR #: 20799 **File No:**

Device Name: Femoral Component **File Location:**

Classification: Urgent: ☐ Expedite: ☐ Routine: ☐ Not Investigated: ☑

Resolution: Investigate ☐ Referral to……..

Information Only ☑ Await sponsor response and review ☐

Attendees: AECS ☐ MDAS ☑ LABS ☑ CLINICAL ☑ MVMS ☑

Investigator: **Competitor report** (do not send letters) ☐

Letters: Yes ☐ No ☐

Is the sample going to be tested by Lab staff? Yes ☐ No ☐

Name of person testing the sample: _____

Special Instructions on Letters: (to be completed by / /)

(Please provide any additional questions for letters and tick in the brackets if you require any of the information below)

- Sample of product ( ) – if requesting samples please tick above if they will be tested by Lab staff or not.
- Product Specifications ( )
- Descriptive product promotional documentation ( )
- Instructions for use, as supplied with the device ( )
- Device Packaging with printed instructions ( )
- Operator's manual ( )
- Technical Service Manual ( )
- Clinical training manual in printed or video form ( )
- In-house training documentation ( )
- Evidence of compliance with the Essential Principles ( )
- A summary of risk management activities performed by the manufacturer for the device, e.g. Risk Management Report required by Clause 8 of ISO 14971:2000 ( )

DIRE Committee comments for the investigator or rationale for not investigating:

- being looked at by the orthopaedic expert working group.

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Cause of Incident	Result of Investigation
☐ Biocompatibility	☐ Bulletin Article
☐ Component Failure	☐ Company Warned
☐ Contamination	☐ Compliance Testing
☐ Design	☐ No Further Action
☐ Diagnostic Inaccuracy	☑ Not Investigated
☐ Electrical	☐ Other
☐ Inadequate Instructions	☐ Problem Not Confirmed
☐ Labelling	☐ Product Improvement
☐ Maintenance	☐ Recall / Hazard Alert
☐ Manufacture	☐ Refer to ADRAC
☐ Material / Formulation Deficiency	☐ Refer to GMP
☑ Mechanical	☐ Refer to Surveillance
☐ Not Applicable - ADR	☐ Safety Alert
☐ Not Device Related	☐ User Education
☐ Other	
☐ Packaging / Sterility	
☐ Quality Assurance	
☐ Unknown	
☐ Wear / Deterioration	

Recommendation (please circle the appropriate recommendation):

1. The cause of this problem has not been conclusively determined; however the low level of occurrence is not currently cause for concern.
2. No further investigation will occur at this time, however the TGA will continue to monitor the rate and pattern of occurrence and may re-open the file as appropriate.
3. Available frequency and severity data do not indicate further investigation is appropriate at this time. The TGA will continue to monitor for similar incidents and may re-open the file if appropriate.
4. This product is not a therapeutic device within the meaning of the Therapeutic Goods Act 1989. This report will not be investigated.
5. The framework for the regulation of disinfectants and sterilants is not fully implemented. Sponsors have until October 1998 to fully comply with labelling requirement.
6. This report is entered for the record, and is not investigated at this time. The incidence of failure with this device is reviewed regularly for changes in trending or significant failure modes.
7. The information is entered for the record. This report is not being investigated at this time.

Other recommendations:

Form completed by: [redacted]