***Device Feedback Tool***

Any Biocomposites employee may collect feedback details using the method that works best for you:

* Use page 1 of the Feedback Information Form (QOP5.0)
* Use this tool as questionnaire
* Use a draft email
* Connect the rep or customer directly to Wilmington office Quality/Compliance:

[complianceus@biocomposites.com](mailto:complianceus@biocomposites.com)

Office: 910-350-8015

Fax: 910-350-8072

\*\* ALWAYS alert Compliance promptly, even if you are waiting on further details! \*\*

**Sample Scenarios**

Setting Issue

* Does the surgeon have any concerns about the device?
* Has this event been reported to the hospital’s Risk Manager?
* Has this event been reported to FDA?
* Was the device used in the patient?
* Hospital name, surgeon name, and sales rep/distributorship info
* Procedure date
* Device Name / Lot #
* Volume of device used
* Other devices / substances used
* Describe the process of mixing, including order of introducing all elements.
* How much time was spent mixing at each step?
* Was the device powder stirred first to ensure any clumps were broken down? (if applicable)
* Were any extra elements added to the mixture (describe all liquids, powders, volumes, brands – if known)?
* If any additional liquid was added, how was the liquid measured?
* Was the device mixing solution used?  If so, what is the method used to ensure all mixing solution is extracted? (For example, was the mixing solution tube held upright and flicked to ensure no water remains in the cap, then was the tube squeezed down several times over the powder to ensure all water is extracted?)
* At what point in the process was the mixture noted to not be setting up as expected?
* Was distributor rep present to witness mixing?
* Was the surgeon/hospital staff experienced with mixing? If so, did they do anything outside of their ordinary routine?
* If product could not be used, was another box used successfully in the case? If so:
  + What was the lot#?
  + Was this mixture prepared in the same manner?
  + How long did 2nd mixture take to set?
  + Any other feedback about differences observed between the two mixtures?

Drainage

* Does the surgeon have any concerns about the device?
* Has this event been reported to the hospital’s Risk Manager?
* Has this event been reported to FDA?
* Hospital name, surgeon name, and sales rep/distributorship info
* Procedure date
* Device Name / Lot #
* Volume of device used
* Other devices / substances used
* Placement of device / for what procedure?
* Surgical technique used for closure?
* What is the surgeon’s experience level with the device / overall experience with this procedure?
* What was the host type / comorbidities & patient demographics?
* How long after surgery did the drainage occur?
* Was the drainage expected?
* Was the drainage better or worse than normal for this procedure or compared to use of a similar device?
* Has the drainage been resolved / how?  (i.e., Did they re-operate?  Did they put in a drain?)
* What was the final outcome / current patient status?
* Are there other factors the surgeon is considering that may have caused or contributed to the issue?

Hypercalcemia

* Does the surgeon have any concerns about the device?
* Has this event been reported to the hospital’s Risk Manager?
* Has this event been reported to FDA?
* Hospital name, surgeon name, and sales rep/distributorship info
* Device Name / Lot #?
* Procedure date
* Volume of device used?
* Other devices / substances used
* Placement of device / for what procedure?
* What is the surgeon’s experience level with the device / overall experience with this procedure?
* What was the host type / comorbidities & patient demographics?
* How was patient’s renal function? Any history of dehydration?
* How long after surgery did the hypercalcemia occur?
* Was the hypercalcemia expected?
* Has the hypercalcemia been resolved / how?  (For example: Did they prescribe bisphosphonates?)
* What was the final outcome / current patient status?
* Are there other factors the surgeon is considering that may have caused or contributed to the issue?

Abnormal Lab Values or Renal Failure

* Does the surgeon have any concerns about the device?
* Has this event been reported to the hospital’s Risk Manager?
* Has this event been reported to FDA?
* Hospital name, surgeon name, and sales rep/distributorship info
* Device Name / Lot #?
* Procedure date
* Volume of device used?
* Other devices / substances used
* Placement of device / for what procedure?
* What were the total dosages of antimicrobials given: pre-surgery, during surgery, and post-surgery? (IV antibiotics, PMMA spacer, etc.)
* What is the surgeon’s experience level with the device / overall experience with this procedure?
* What was the host type / comorbidities & patient demographics?
* Is there a patient history of renal insufficiency?
* What were the specific lab values in question / any other relevant lab results?
* How long after surgery did the issue occur?
* Was the issue anticipated?
* Has the issue resolved / how?  (i.e., Were there any interventions?)
* What was the final outcome / current patient status?
* Are there other factors the surgeon is considering that may have caused or contributed to the issue?

References:

*QAP8.0 – Complaints & Regulatory Reporting*

*QOP5.0 –Feedback Information Form*