

Value Analysis Committees: Preparation & Submission Process

Value Analysis Committees (VACs) have been implemented by hospital systems to establish a balance in providing cost-effective care and utilizing emerging medical technologies. VACs are comprised of decision makers in various roles and are responsible for evaluating the clinical efficacy and financial impact of requested products before they are approved for use at the facility. VAC processes and requirements are unique to each hospital system with a significant variation in the amount and type of documentation requested. Therefore, it is important that we prepare VAC submissions in an organized, consistent and professional manner.

Please follow the process outlined below when you receive a request for a VAC submission:

1. Research - Identify Basic Information

Identify basic information that is unique to each hospital system.

- Name & address of hospital/hospital system
- Pricing information
- Name & title of surgeon champion
- VAC contact name & information
- VAC request packet & submission form
- Documentation requirements
- VAC submission deadline
- VAC meeting date
- Timeline for VAC decision

2. Communication – Identify Specific Information

Communicate with your surgeon champion or VAC contact to identify specific information needed for the VAC submission. It is important to ask probing questions to uncover all needs for the VAC submission well in advance of any deadlines.

Examples of probing questions:

- “Which characteristics of STIMULAN would you like further information on?”
 - *This question helps to identify information needed that is specific to STIMULAN.*
- “What information would be helpful to support how STIMULAN is intended to be used at your institution?”
 - *This general question helps to uncover supporting information needed regarding how STIMULAN is being used at the hospital (procedural or volume related).*
- “What procedures will you be using STIMULAN in and require further information for?”
 - *This question helps to identify information needed to support the use of STIMULAN in specific procedural areas.*

*If you receive a request for information related to off-label use of the product, notify your surgeon champion or VAC contact that the request relates to a physician directed usage of the product. Inform your contact that you will need to follow the Biocomposites’ process to relay the question to the Compliance Department.

This document is confidential. Please do not distribute.

3. Internal Process for VAC Submissions

An internal process has been created to ensure that adequate preparation has been conducted and that VAC submissions are as organized, consistent and professional as possible.

- Obtain a copy of the hospital VAC request packet & VAC submission form.
- Complete the Biocomposites VAC Submission Request Checklist.
 - A draft of the checklist is located on the next page.
 - An approved copy of the VAC Submission Request Checklist is located on the Distributor Hub for download.
- Submit the following documents to Al Todd (mat@biocomposites.com):
 - Copy of the hospital VAC request packet.
 - Copy of the hospital VAC submission form.
 - A completed Biocomposites VAC Submission Request Checklist.
- Al will oversee all VAC submissions to ensure that they are organized, correct, consistent, professional, and trackable.
- Al will submit the VAC paperwork and the Biocomposites information package to the hospital facility directly.

**Please allow as much time as possible for review and submission of the VAC paperwork and Biocomposites information package.*

VAC Submission Request Checklist (Draft Copy)

Requested Information	Identified Information	
Name of Hospital/Hospital System		
Address of Hospital/Hospital System		
Pricing Information		
Name & Title of Surgeon Champion		
VAC Contact Name and Information (email address and phone number)		
VAC Submission Deadline		
VAC Meeting Date		
Timeline for VAC Decision		
Information Identified from Probing Questions (specific needs)		
VAC Documentation Requirement Checklist (please check all that apply)		
Digital Brochures/Presentations	Product Specific Documents	Additional Documents
<input type="checkbox"/> Biocomposites digital brochure	<input type="checkbox"/> Current 510(k) K141830	<input type="checkbox"/> Vendor Setup Form
<input type="checkbox"/> STIMULAN digital brochure	<input type="checkbox"/> Latex Declaration	<input type="checkbox"/> HCPCS Code Letter
<input type="checkbox"/> STIMULAN Case Studies Presentation	<input type="checkbox"/> STIMULAN Kit IFU	<input type="checkbox"/> Insurance Liability Letter
<input type="checkbox"/> STIMULAN Clinical Presentation	<input type="checkbox"/> STIMULAN Rapid Cure IFU	<input type="checkbox"/> New Hospital Account Form
External Requirements	<input type="checkbox"/> Other (please specify)	<input type="checkbox"/> W-9
<input type="checkbox"/> VAC Request Packet Obtained		<input type="checkbox"/> Other (please specify)
<input type="checkbox"/> VAC Submission Form Obtained		

Please complete and submit VAC Submission Request Checklist to Al Todd (mat@biocomposites.com) for review and processing of VAC submission.