

Global Report

> KINETIC CONCEPTS INC.

COMPANIES DISCUSSED: KCI

TOP STORY

KCI: V.A.C. Growth Still Sluggish

SOURCES & BACKGROUND

79 U.S. and European wound care professionals

United States 34 sources (20 nurses, 7 podiatrists, 6 physicians and 1 podiatric aide in 8 wound care centers, 5 hospitals, 5 home health centers, and 1 extended care center) who collectively treat more than 1,500 wound-care patients weekly; **Europe** 45 sources (20 tissue viability nurses, 9 wound physicians, 7 surgical nurses, 4 surgeons, 3 home health care nurses and 2 dermatologists – 18 in the United Kingdom, 10 each in France and in Germany and 7 in Italy) treating more than 2,700 wound-care patients weekly

Repeat Sources 25 U.S. and 18 European sources from OTR's March report

Interviews Mid- to late May

Averages Weighted

- OTR's read on KCI's V.A.C. remains negative, as in the March report
- Midyear and year-end V.A.C. growth below WS expectations; KCI reports 7/22 (est.)

- V.A.C. usage up 1%-4% in the United States and Europe during 2Q05 qq [> page 2](#)

- Few nonusers plan adoption by midyear [> page 3](#)

- V.A.C. usage in non-hospital settings based on reimbursement eligibility [> page 2](#)

- Expanded KCI sales force barely noticeable; no real impact [> page 4](#)

- Blue Sky Medical's Versatile 1 system not yet competitive [> page 5](#)

Executive Summary

Growth expectations for **Kinetic Concepts Inc.**'s (KCI) Vacuum Assisted Closure (V.A.C.) system remain low in the United States and Europe, consistent with OTR's prior findings. While seasonal factors are expected to account for some sluggishness during 3Q05, sources continue to cite cost and reimbursement hurdles as the primary stumbling blocks to increased uptake. In addition, virtually no increased sales activity from KCI's recent sales force expansion was noted. In the United States, the less expensive but controversial **Blue Sky Medical Group Inc.**'s wound closure system poses little competition because of sources' limited familiarity and the company's apparent lack of promotional efforts.

Key data

Single-Digit V.A.C. Growth Expected for 2H05
(number of sources)

	U.S.	France	Germany	Italy	U.K.	Europe
Up 11%-20%	-	-	1	-	-	1
Up 6%-10%	3	-	-	-	4	4
Up 1%-5%	9	-	-	4	2	6
Up	-	-	-	-	2	2
Flat	16	6	5	3	2	16
Down	-	-	1	-	-	1
Down 11%-15%	-	-	1	-	-	1
Don't know	3	-	-	-	2	2
No response	2	-	-	-	-	-
Not applicable	1	4	2	-	6	12
Weighted average	1%-4%	0%	2%-5%	0%-3%	4%-7%	3%-6%

"If reimbursement were not a role, I would use the V.A.C. liberally."

– U.S. plastic surgeon

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Growth Slow Overall

"V.A.C. use will increase marginally [3% to 5%] during the second half of 2005 because summer is a time of low patient census, although census will pick up in the fall and winter."

Consistent with OTR's March report and April monitoring, U.S. sources anticipate a modest 4% to 7% average growth in V.A.C. usage during 1H05 compared with usage at year-end 2004. Some said the growth rate may be related to how long the V.A.C. has been in use in a facility. "I expect a 1% increase in V.A.C. use by mid-2005 because the V.A.C. heals the wounds in a cost-effective manner by decreasing hospitalization time," one established user said. A podiatric aide anticipates a larger increase. "I expect a 30% increase in V.A.C. use by mid-2005, but we just started using the V.A.C. [in 2005]," she said.

U.S. sources anticipate only a 1% to 4% increase on average in V.A.C. usage during 2Q05 qq and during 2H05 compared with 1H05. While very satisfied with outcomes, more than one-half of sources expected use to be steady during 2Q05, with a few attributing modest usage growth to increasing case loads, new physician awareness through colleague recommendation and seasonal adjustments. One hospital source said. "V.A.C. use will increase marginally [3% to 5%] during the second half of 2005 because summer is a time of low patient census, although census will pick up in the fall and winter."

European sources slightly lowered their expectations for V.A.C. treatments compared with OTR's March findings and anticipate an increase of only 2% to 5% on average during 1H05 compared with usage at year-end 2004. German sources expect the strongest uptake, at 9% to 12%, with two relatively new users expecting a significant uptake before usage levels off. One surgeon said, "I think [V.A.C. usage] will increase another 20%, but then we will reach saturation and everybody who can be treated with the V.A.C. will be treated." U.K. and Italian sources expect marginal increases of 1% to 4% and flat to up 3% respectively, while French sources expect usage to remain flat. "Differentiated programs and various types of dressings make the V.A.C. pump a valuable treatment; however, reimbursement issues and a general lack of awareness over the problems involved in wounds management place V.A.C. use as a niche treatment," an Italian source said.

European sources expect V.A.C. usage to increase an average 3% to 6% during 2H05 compared with 1H05. U.K. sources are more optimistic, while some German specialists expect the number of treatments to decrease after previous years of good growth. "We had an exploding increase [compared with] the last [few] years, but cost [concerns] force us to decrease usage," a German source said. In France and Italy, sources do not anticipate any change during the next six months.

Reimbursement Eligibility Key Part of Decision-Making

U.S. sources generally agreed that documenting medical necessity was critical to obtaining reimbursement for V.A.C. use, and some added that patients without insurance would not receive the V.A.C. "The patient must meet the medical-necessity criteria established by Medicare or another payer," one wound-care source said. A home-health source said, "The V.A.C. gets reimbursed for the right patient, which is why we must be selective." Another said, "We use the wound V.A.C. only for selected patients because it's expensive."

Operating under the Diagnosis Related Groups (DRG) system, U.S. hospital sources are less concerned with reimbursement. "Reimbursement is not a problem because it's cost effective," one hospital-based nurse said. No hospital source has felt any pressure to use the V.A.C. for a shorter duration. In contrast,

> KINETIC CONCEPTS INC.**European Reimbursement Varies**

“The outpatient treatment with the miniV.A.C. is not paid, which is very bad. We have to check out the patient because we can’t justify a stay any longer, but the wound is not completely healed and in a couple of weeks he returns again.”

extended-care facilities face greater hurdles to V.A.C. use. “Most of our extended-care facilities do not use V.A.C. Therapy because they cannot absorb the cost of the V.A.C., and I doubt that will change,” one source said. A plastic surgeon agreed, saying, “If reimbursement were not a role, I would use the V.A.C. liberally.” None of the five U.S. home-health sources was familiar with upcoming changes in the Durable Medical Equipment Regional Carrier (DMERC) situation.

Throughout Europe, V.A.C. reimbursement varies, even within a single country, and still is the main obstacle to more widespread use. Italian insurance covers V.A.C. Therapy only in some regions. “Piedmonte is one of the few Italian regions that reimburse the V.A.C. Therapy for outpatient treatment. The reimbursement policy varies among different districts. We can say not all Italians have access to the same quality healthcare,” an Italian source said. Many U.K. sources reported severe reimbursement limitations because of strict National Healthcare Service (NHS) and private insurance guidelines for the V.A.C. “No one covers [it] in our experience. We have to eat the cost and provide it on humanitarian or practical grounds,” a U.K. source said. In France, although the treatment is not reimbursed at all, hospitals offer it and cover the cost. “We rent the V.A.C. systems on the global hospital budget,” a French source said. Most German sources do not have serious reimbursement problems for the V.A.C. within hospital settings, but private practices struggle to get paid. A German source said, “I’ll stop offering the treatment because I’m tired of the fight with insurance.”

Across Europe, outpatients face serious difficulties obtaining coverage for home treatment with KCI’s miniV.A.C. This is the main reason European nursing homes and home care services generally are unable to offer the system. “The outpatient treatment with the miniV.A.C. is not paid, which is very bad. We have to check out the patient because we can’t justify a stay any longer, but the wound is not completely healed and in a couple of weeks he returns again,” a German source said.

Sources also said KCI may be capitalizing on its European market monopoly and keeping prices artificially high. “We need a competitor to enter the European market. It is so frustrating to have a wonderful device that you can see brings great benefit to the patient in terms of comfort, pain relief and faster healing, but you cannot use it as often as you would like due to cost,” a U.K. source said.

Wide Application Well Established

Twenty-nine of 34 U.S. sources use the V.A.C. system and treat a wide variety of wounds – especially those associated with diabetes, ulcers, trauma, surgery and the abdomen. “We use the V.A.C. on nonhealing surgical wounds and deep ulcer wounds,” one source said. Another said, “Surgical wounds are the most common type of wound we use the V.A.C. for, followed by pressure ulcers.” No source plans to use the V.A.C. for additional types of wounds during 2005.

U.S. sources initiate V.A.C. treatment on up to three patients a week on average. “We start one or two patients on the V.A.C. each week,” said one source who treats 40 wound patients weekly. The duration of V.A.C. use for each patient ranges from less than one week to four months among sources, with most averaging three to four weeks. No U.S. V.A.C. users reported any pressure to shorten treatment time to cut costs.

Among the five nonusers, two expect to begin using the V.A.C. by mid-2005. “I would like to try the V.A.C.,” said one podiatrist. “My partner and I would probably use the V.A.C. in the hospital.” One nonuser was uncertain and two others have no plans to start using the V.A.C. “I used the V.A.C. a couple of times in the

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"I have chased KCI's reps during conferences, and it seems that the prices won't go down and that the V.A.C. will not be reimbursed any time soon. I have little hope that independent practices will be able to use the V.A.C. system in the near future."

past, but I prefer to clean, cut and close quickly, followed by stretching the skin and using Apligraf [artificial skin] by **Organogenesis Inc.** I heard about a death that recently occurred when a patient with an abdominal wound was on V.A.C. for three months. That's too long," a plastic surgeon said.

Only one of 13 European nonusers plans to use the V.A.C. by mid-2005 if he is able to get funding. Eleven sources do not plan to use the therapy this year. "I have chased KCI's reps during conferences, and it seems that the prices won't go down and that the V.A.C. will not be reimbursed any time soon. I have little hope that independent practices will be able to use the V.A.C. system in the near future," a French source said. Another said her institution had ceased using the V.A.C. because of cost, but if reimbursement came through, her institution would pick it up again.

European sources start an average three to six patients a week on the V.A.C. treatment, and just over one-third of sources using the V.A.C. system use it for one to two weeks; slightly less than one-third use the V.A.C. for three to four weeks, and slightly less than one-fourth use the system for two months. Most sources are free to use it as long as necessary. However, in contrast to U.S. sources, some European specialists feel compelled by insurance and administration to shorten the therapy to save money. "There is considerable pressure to reduce duration of treatment because of cost," a U.K. source said.

Sales Force Expansion Still Not Felt

Twenty of 29 sources using the V.A.C. Therapy in the United States – including most physician sources – have noticed no increase in sales activity since KCI expanded its sales force. "The last time I talked with a KCI rep was one year ago," an extended-care source said. One home-health source said, "This week our KCI reps introduced me to their new district manager, but that was it. They made no sales pitches." Sales activity increases were noted by five wound-care sources and two podiatrists, all of whom are established V.A.C. users. No responding source using the V.A.C. has been notified of pricing flexibility or discount deals with the V.A.C. or its dressings.

Of the five nonusers, four had not experienced any increase in KCI sales activity, and one was unsure. "Maybe a little bit. They may have contacted my partner," a podiatrist said.

Most European sources also have not noticed any increase in KCI sales activity, but many consider KCI's support very good, and sources praised the helpful and well-trained representatives. "KCI already provides optimal support. If I call them, I get the V.A.C., dressings or the rep within 24 hours," a German source said.

Virtually no source reported pricing flexibility or discounting for V.A.C. consumables. Only one U.K. source received some dressings for free, and two Italian sources were loaned the device to establish the V.A.C. system in their institutions. "KCI is trying to increase the diffusion of V.A.C. use nationwide. The hospital received the equipment for free, and they sent a technician to train our staff," an Italian source said.

U.S. High-Volume Prefer Purchase

Although U.S. sources were evenly divided about preference for renting or purchasing a V.A.C. system, high-volume users generally preferred to purchase. "Because we use the V.A.C. so frequently, we would like to make a purchase,"

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one wound-care source said. Yet, U.S. sources consistently said the option of purchasing a V.A.C. system has not been offered to them. A hospital source said, "We've tried to buy the V.A.C., but KCI won't allow us to."

In Europe, where purchasing the V.A.C. system is available, more than one-half of users prefer to rent one, while slightly less than one-half opt for a combination of purchasing some devices and renting others as needed. A U.K. surgeon said, "It is always good to have one or two on standby in case you might need one in a hurry. For example, if I need one in the theater at 4 a.m., it isn't practical to call a KCI rep and expect it to be delivered within half an hour."

Blue Sky Little Known, Controversial

Thirteen sources were somewhat to very familiar with Blue Sky Medical's Versatile 1 Wound Vacuum System. One extended-care source uses the Blue Sky system because it is less expensive than the V.A.C. "The Blue Sky system works as well as the V.A.C., and I use it for the same wounds," the source said. "We are contacted regularly by Blue Sky reps." A hospital source said, "We once used the Blue Sky for 10 hours on a patient with a very deeply embedded fistula. It worked when nothing else would."

Other sources were less positive. "The Blue Sky is a wound drainage device, and I don't think it is as good as the V.A.C.," one wound-care source said. A surgeon said, "The Blue Sky and the V.A.C. are apples and oranges." A podiatrist said, "The Blue Sky is not nearly as good as the V.A.C." A plastic surgeon said, "The manufacturer would have to show me that the Blue Sky is better than the V.A.C."

Only two sources plan to use the Blue Sky system during 1H05, and most sources who responded have not been contacted by a Blue Sky sales representative.

This report was researched and written by **Fred Wilson** and **Robert Fischer**, with additional reporting by **Marie Gethins**, **Aude Lecrubier**, **Julie Remington**, **Violetta Signore**, **Charlotte Waterworth** and **Miriam Widman** for Off The Record Research LLC.

For more information, please contact your Off The Record Research representative:

NY (800) 444-9097 • SF (415) 675-7660 • CHI (847) 283-9152 • BOS (617) 878-2184

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ADDITIONAL QUOTES

On V.A.C. Usage ...

"I doubt if primary-care doctors will use the V.A.C.; they run away from wounds." *United States*

"The main problem is that you will not find real experts in the decision-making bodies of the insurance [companies]; and if [you do], nobody listens to them. Wound management still is healthcare's poor cousin." *Germany*

"I tend not to use vacuum-assisted devices, and the evidence for their benefit is poor." *United Kingdom*

"In our hands, there is no doubt that the V.A.C. has saved many limbs from amputation." *United Kingdom*

On Reimbursement ...

"Insurance coverage is the main factor in the decision of whether to use the V.A.C." *United States*

"Most insurance companies provide coverage for appropriate wounds. In the VA [Veterans Affairs] system, I can obtain this modality whenever I require it." *United States*

"The use of wound-closure systems is more generated by the price that the hospital bears than anything else." *United States*

"If the V.A.C. was reimbursed, and if it was less expensive, I would use it for sure." *France*

"Our budgets are exhausted. But on the other hand, we avoid leg amputations that cause cost of about €100,000." *Germany*

"We have problems discharging patients home with V.A.C. Some of the Primary Care Trusts [PCTs] will pay, others not." *United Kingdom*

"Even big facilities may need to [carefully] select patients eligible for the V.A.C. in order to contain costs. Smaller facilities are, for the time being, cut off from adopting expensive and newer treatments." *Italy*

On KCI's Expanding Sales Force ...

"I don't think the new KCI sales activity will cause V.A.C. use to increase because if there is no pressure to use a medical device – any medical device, you will probably not use it." *United States*

"We've noticed increased sales activity recently. KCI's marketing has improved, and they provide excellent in-service and support." *United States*

"I have not noticed any increased sales activity from KCI. But KCI's services are very good." *France*

"KCI reps already show up very often. Support is excellent. And whenever I had a problem, a rep immediately came." *Germany*

On the Growth of V.A.C. Usage ...

"I am seeing more home use of the V.A.C. system." *United States*

"The indications for V.A.C. use are going up in our hospital because the nurses have to change dressings less frequently with the V.A.C." *United States*

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ADDITIONAL QUOTES

On V.A.C. Treatment Duration ...

"I don't see an increase in V.A.C. usage because I don't get a lot of patients that require the V.A.C." *United States*

"During 2004 and the first half of 2005 we were trying the V.A.C. on everything to see what types of wounds would have the most benefit. Now we are better able to judge when it is best to use the V.A.C., so the increase in usage during the second half of 2005 will be 10% rather than 30%." *United States*

"I don't think our V.A.C. use will change much." *United States*

"We have had a strong increase last year. But since then, we covered most indicated patients." *Germany*

"The treatment is not reimbursed for outpatients. As a consequence of that, nursing and medical costs discourage the private use." *Italy*

"Rather than a real increase, we are consolidating the use of the present resources available." *Italy*

"If insurance once authorized the treatment, I can use it as long as I want. But outpatient treatment with the miniV.A.C. is a big problem." *Germany*

"We get pressure from the insurance [companies]. Sometimes we should use the V.A.C. longer, but insurance does not pay any longer and we have to cancel – or the hospital has to pay." *Germany*

"Patients who used to stay one month or more at the hospital with classical wound treatments only stay nine days thanks to the V.A.C. and its early use." *France*

On V.A.C. Pricing ...

"KCI is able to keep the prices high because they have the monopoly. As soon as a comparable system will be available, the prices will decrease." *Germany*

"The charges this company makes are exorbitant. Despite its effectiveness, KCI still overcharge in my opinion." *United Kingdom*

"I don't understand why KCI is so inflexible and unsupportive. Why produce a super product and then price it out of reach of the NHS? It reflects very poorly on a company that is supposed to be providing products to bring benefits to many patients. It is irresponsible on a corporate level." *United Kingdom*

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1. Are you using Kinetic's V.A.C. system for the treatment of wounds?

	U.S.	FRANCE	GERMANY	ITALY	U.K.	EUROPE
Yes:	29	6	8	6	12	32
No:	5	4	2	1	6	13

2a. If you are using the V.A.C. system, what types of wounds are you treating? (Many sources gave more than one response.)

Diabetic foot ulcers:	19	3	4	3	3	13
Pressure ulcers:	13	3	4	4	8	19
Surgical wounds:	-	2	4	-	6	12
Trauma:	13	4	1	1	4	10
Burns:	2	-	-	1	1	2
Abdominal wounds:	-	-	2	-	5	7
Other:	14	1	2	2	2	7
Not applicable:	5	4	2	-	6	12

2b. If not using the V.A.C. system, do you plan to start using it?

Yes, by mid-2005:	2	-	-	-	1	1
Do not plan to use V.A.C.:	2	3	2	1	5	11
Don't know:	1	1	-	-	-	1
Not applicable:	29	7	8	6	12	33

3. How many patients are you starting on Kinetic's V.A.C. system weekly?

9 or more:	-	-	-	2	-	2
6-8:	-	-	2	1	4	7
3-5:	3	2	3	2	3	10
1-2:	10	2	2	1	4	9
Fewer than 1:	11	2	-	-	-	2
Not applicable:	5	4	3	1	6	14
Don't know:	3	-	-	-	-	-
No response:	2	-	-	-	1	1
Weighted average:	0-3	0-3	3-6	5-8	4-7	3-6

4. What is the average time period of V.A.C. use per patient?

Less than 1 week:	1	-	-	-	1	1
1-2 weeks:	1	4	4	1	3	12
3-4 weeks/1 month:	18	-	3	5	2	10
6 weeks:	1	-	-	-	-	-
2 months:	2	1	1	1	5	8
3-5 months:	2	1	-	-	2	3
Don't know:	4	-	-	-	-	-
Not applicable:	5	4	2	-	4	10
No response:	-	-	-	-	1	1

5. What effect is reimbursement having on your usage of Kinetic's V.A.C. system?

Major:	5	2	1	5	7	15
Moderate:	1	-	3	1	-	4
Minor:	2	-	-	-	-	-
None:	14	6	3	1	4	14
Don't know:	3	-	1	-	-	1
No response:	4	2	2	-	7	11
Not applicable:	5	-	-	-	-	-

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6. Has there been increased sales activity because of Kinetic's sales reps?

	U.S.	FRANCE	GERMANY	ITALY	U.K.	EUROPE
Yes:	7	-	-	2	3	5
No:	20	10	10	3	10	33
Don't know:	2	-	-	2	-	2
No response:	1	-	-	-	3	3
Not applicable:	4	-	-	-	2	2

7. Have you noticed any pricing flexibility or discount deals with the V.A.C. or associated dressings?

Yes:	-	-	-	2	1	3
No:	28	7	8	1	11	27
Don't know:	-	-	-	3	1	4
No response:	1	-	-	1	2	3
Not applicable:	5	3	2	-	3	8

8. If the option were available, would you prefer to rent or purchase the V.A.C. in the future?

Rent:	6	2	3	2	11	18
Purchase:	6	-	-	-	-	-
Combination:	2	2	5	3	3	13
Don't know:	5	2	-	2	-	4
No response:	5	-	-	-	-	-
Not applicable:	10	4	2	-	4	10

9. Do you expect your total usage of Kinetic's V.A.C. system to increase, decrease or remain the same during 1H05 compared with year-end 2004?

Up 41%-50%:	1	-	-	-	-	-
Up 31%-35%:	-	-	1	-	-	1
Up 26%-30%:	2	-	-	-	-	-
Up 21%-25%:	-	-	1	-	-	1
Up 11%-15%:	1	-	-	-	-	-
Up 6%-10%:	1	-	-	-	2	2
Up 1%-5%:	7	-	1	4	2	7
Up less than 1%:	1	-	-	-	-	-
Up:	-	-	-	-	2	2
Flat:	16	6	3	2	4	15
Down:	-	-	1	-	-	1
Down 1%-5%:	-	-	1	-	-	1
Don't know:	4	-	-	-	2	2
Not applicable:	1	4	2	1	6	13
Weighted average:	4%-7%	0%	9%-12%	0%-3%	1%-4%	2%-5%

10. Do you expect V.A.C. usage to increase, decrease or remain the same during 2Q05 qq?

Up 16%-20%:	1	-	-	-	-	-
Up 6%-10%:	1	-	2	-	4	6
Up 1%-5%:	9	2	1	-	2	5
Up:	1	-	-	-	2	2
Flat:	14	4	4	6	4	18
Down:	-	-	1	-	-	1
Don't know:	3	-	-	-	-	-
No response:	2	-	-	-	-	-
Not applicable:	3	4	2	1	6	13
Weighted average:	1%-4%	0%-2%	3%-6%	0%	2%-5%	1%-4%

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11. Do you expect your usage of Kinetic's V.A.C. system to increase, decrease or remain the same during 2H05 compared with 1H05?

	U.S.	FRANCE	GERMANY	ITALY	U.K.	EUROPE
Up 11%-20%:	-	-	1	-	-	1
Up 6%-10%:	3	-	-	-	4	4
Up 1%-5%:	9	-	-	4	2	6
Up:	-	-	-	-	2	2
Flat:	16	6	5	3	2	16
Down:	-	-	1	-	-	1
Down 11%-15%:	-	-	1	-	-	1
Don't know:	3	-	-	-	2	2
No response:	2	-	-	-	-	-
Not applicable:	1	4	2	-	6	12
Weighted average:	1%-4%	0%	2%-5%	0%-3%	4%-7%	3%-6%

United States Only

12. How familiar are you with Blue Sky Medical's wound vacuum assisted closure system?

Very familiar:	4
Somewhat familiar:	9
Not familiar:	20
No response:	1

13. Do you plan to use Blue Sky Medical's wound vacuum assisted closure system during 1H05?

Yes:	2
No:	28
Maybe:	3
No response:	1