Forté
Pre-Op™ & Post Op™
Science-based, Targeted Nutritional Support for the Surgical Patient
Supporting the Specific Nutritional Needs of Patients Before and After Surgery

Nutritional Status and Surgical Outcomes

The notion that nutritional status can affect outcomes in surgical patients was first reported in 1936 in a study showing that undernourished patients undergoing ulcer surgery had a risk of mortality 10 times higher when compared with well-nourished individuals. More recently, a prospective study of 500 patients, including 200 surgical patients, admitted to a teaching hospital found that 40 percent of patients were undernourished at the time of admission. Poor pre-operative nutritional status has been linked consistently to an increase in post-operative complications, such as infection, slow wound healing and poorer surgical outcomes.

Surgery results in a variety of physiological and metabolic responses, including decreased immunity, increased inflammation, increased levels of stress hormones, increased catabolism and decreased anabolism. All of these stresses contribute to increased protein and energy requirements after surgical intervention, and may increase the risk of poor post-operative nutrition status, which is also linked to poorer surgical outcomes. Pre-loading patients with key nutrients prior to surgery, and supporting their nutrition following surgery, may help patients to prepare for the stress of surgery and to recover more quickly post-operatively.

Need for Nutritional Support Often Overlooked

Elderly patients have an increased risk of malnutrition due to decreased lean body mass and a variety of other factors that may compromise nutrient and fluid intake. For these patients, oral nutritional supplements lead to an increase in energy and nutrient intake, which is particularly important during the peri-operative period. While the elderly are more likely to be malnourished, nutritional deficiencies are common among the general population, as well.

Despite the evidence, physicians often neglect to consider nutritional status or dietary supplementation for facilitating the recovery of patients from surgery. In fact, surgeons routinely advise their patients to stop taking nutritional supplements at least two weeks prior to scheduled surgery. This is due, in part, to the popularity of complementary and alternative medical treatments such as herbal supplements and the potential of many of these products to have serious and potentially harmful side effects when combined with medications commonly prescribed during and after surgery. However, studies in gastrointestinal surgery and other surgical situations have shown the importance and benefits of pre-operative nutritional support.
After surgery, physicians often fail to advise their patients on when or how to apply nutrition to support recovery.

**Key Nutritional Needs for Surgery Patients**

Surgical wound healing is an anticipated drain on a patient’s nutritional stores. Preloading with appropriate vitamins, minerals, amino acids and trace elements can better prepare a patient for—and recover from—the physiologic and metabolic stress of surgery. **Vitamin C**

In addition to acting as an antioxidant to protect cells from damage caused by free radicals, vitamin C is needed for normal immune system function, iron absorption and production of collagen, a critical protein for wound healing. Due to its many biochemical functions, vitamin C is considered not only an essential micronutrient for maintaining health, but also an important therapeutic supplement in a variety of clinical conditions.9

According to the U.S. Centers for Disease Control and Prevention’s most recent National Report on Biochemical Indicators of Diet and Nutrition in the U.S. Population, approximately six percent of Americans are deficient in vitamin C.10 Surgery compounds the problem by lowering blood vitamin C concentration, likely due to increased demand caused by redistribution and increased oxidative stress. In a small study of patients who underwent uncomplicated gastrectomy for gastric cancer, blood concentration of vitamin C decreased post-operatively and the reduction remained significant for seven days following surgery.11 The onset of post-operative complications reduces vitamin C levels even further. As a result, doses much higher than the recommended daily allowance may be needed to normalize plasma and tissue vitamin C concentration in post-operative patients.

**Figure 1. Average daily recommended dose of vitamin C**

<table>
<thead>
<tr>
<th>Life Stage</th>
<th>Recommended Amount</th>
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<th>Recommended Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth to 6 mo.</td>
<td>40 mg</td>
<td>Adults (men)</td>
<td>90 mg</td>
</tr>
<tr>
<td>Infants 7-12 mo.</td>
<td>50 mg</td>
<td>Adults (women)</td>
<td>75 mg</td>
</tr>
<tr>
<td>Children 1-3 yrs</td>
<td>15 mg</td>
<td>Pregnant teens</td>
<td>80 mg</td>
</tr>
<tr>
<td>Children 4-8 yrs</td>
<td>25 mg</td>
<td>Pregnant women</td>
<td>85 mg</td>
</tr>
<tr>
<td>Children 9-13 yrs</td>
<td>45 mg</td>
<td>Breastfeeding teens</td>
<td>115 mg</td>
</tr>
<tr>
<td>Teens 14-18 yrs (boys)</td>
<td>75 mg</td>
<td>Breastfeeding women</td>
<td>120 mg</td>
</tr>
<tr>
<td>Teens 14-18 yrs (girls)</td>
<td>65 mg</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

As the body cannot synthesize vitamin C, the main source of vitamin C is from consumption of fruits, vegetables and plant foods.13 Relatively high doses of supplemental vitamin C, combined with other trace elements, have been shown to dramatically accelerate wound healing. Most multivitamin preparations available in the U.S. contain approximately 200 mg of vitamin C. However, in uncomplicated surgery patients, more than 500 milligrams per day of vitamin C supplementation may be required to support wound healing. In cardiac surgery patients, vitamin C supplementation may prevent post-operative atrial fibrillation.14,15 Recently, it was shown that oral vitamin C supplementation, in association with beta-blockers, was more

effective in preventing post-operative atrial fibrillation than beta-blockers alone.\textsuperscript{16}

\textbf{Vitamin D and Calcium}

Vitamin D and calcium are the key nutrients for musculoskeletal development, maintenance and function, which are vital for the success of bone-related surgeries such as spinal fusion. Low vitamin D and poor bone mineral density may be significant factors in instrumentation failure, loss of deformity correction, adjacent fractures and the need for revision surgery.\textsuperscript{17} While the body can produce vitamin D when exposed to sunlight, calcium must be absorbed from food and requires vitamin D for absorption. The Food and Nutrition Board (FNB) recommends a daily Vitamin D requirement of 600 IU, although recent research indicates that the body needs at least 1000 IU per day to support optimal bone health and the Institute of Medicine has determined a safe daily upper limit of 4000 IU.\textsuperscript{18}

Nearly one-third of the general population, and more than 50 percent of general medicine patients, have been found to have vitamin D inadequacy.\textsuperscript{19} Studies demonstrate that the majority of patients undergoing elective orthopedic surgery are deficient in vitamin D.\textsuperscript{20, 21} Restoring vitamin D to appropriate levels may significantly improve outcomes following surgery.

\begin{figure}
\centering
\includegraphics[width=\textwidth]{safe_limits.png}
\caption{Safe limits for vitamin D and calcium intake}
\end{figure}

\textbf{Protein}

The stress response to surgery is characterized by increased secretion of pituitary hormones and activation of the sympathetic nervous system, with secondary effects on hormone secretion from target organs such as the pancreas and adrenal cortex. The overall metabolic effect of the hormonal changes associated with surgery is increased catabolism. Protein catabolism is stimulated by increased cortisol concentrations, resulting in the breakdown of skeletal and visceral muscle to release amino acids, which may be further catabolized for energy or used in the liver to either form acute phase proteins or be converted into glucose, fatty acids, ketone bodies or other substrates.\textsuperscript{22}

Since the stress of surgery creates a hypermetabolic state with increased protein and energy demands, supplemental protein is also beneficial for pre- and post-operative patients.\textsuperscript{23}

\begin{table}
\centering
\begin{tabular}{|c|c|c|c|c|}
\hline
\textbf{Age} & \textbf{Male} & \textbf{Female} & \textbf{Pregnancy} & \textbf{Lactation} \\
\hline
0-6 mo. & 1,000 IU & 1,000 IU & & \\
7-12 mo. & 1,500 IU & 1,500 IU & & \\
1-3 yrs & 2,500 IU & 2,500 IU & & \\
4-8 yrs & 3,000 IU & 3,000 IU & & \\
>9 yrs & 4,000 IU & 4,000 IU & 4,000 IU & 4,000 IU \\
\hline
\end{tabular}
\end{table}

\begin{table}
\centering
\begin{tabular}{|c|c|}
\hline
\textbf{Life Stage} & \textbf{Upper Safe Limit} \\
\hline
Birth to 6 mo. & 1,000 mg \\
Infants 7-12 mo. & 1,500 mg \\
Children 1-8 yrs & 2,500 mg \\
Children 9-18 yrs & 3,000 mg \\
Adults 19-50 yrs & 2,000 mg \\
Adults 51 years and older & 2,500 mg \\
Pregnant and breastfeeding teens & 3,000 mg \\
Pregnant and breastfeeding adults & 2,500 mg \\
\hline
\end{tabular}
\end{table}

\textsuperscript{23} Botella-Carretero JI, et al. Perioperative oral nutritional supplements in normal or mildly undernourished geriatric patients submitted to...
Essential amino acids play a crucial role in protein synthesis and muscle tissue repair. As these amino acids are not produced or stored in the body, they must be obtained through diet or supplementation. Specifically, L-arginine is an amino acid that has been shown to stimulate wound healing, while L-glutamine restores cellular energy stores. In clinical studies, patients given L-arginine supplementation after major surgery benefited from a faster recovery of immunological parameters and fewer infectious complications.24

Randomized clinical trials of patients undergoing surgery for hip fracture demonstrated that providing pre- and post-operative energy-protein supplements resulted in better recovery plasma proteins and fewer post-operative complications, even among patients with normal pre-operative nutritional status.25, 26 In addition, a recent study showed that amino acid supplementation assisted with surgical recovery in patients who had undergone total knee arthroplasty, as demonstrated by attenuated muscle atrophy and accelerated return to functional mobility.27

**Probiotics Aid in Postoperative Recovery**

The use of perioperative broad-spectrum antibiotics has become the standard of care for most major surgeries. Antibiotics are used to reduce postoperative infection risk. This practice has been validated in the literature and is now considered an essential part of the surgical process. While considered essential to surgical success and safety, antibiotic use does contribute to postoperative morbidity. Significant gastrointestinal flora disruption can occur, leading to decreased resistance to pathogens known to cause antibiotic associated diarrhea, such as Clostridium difficile. Studies have shown that the use of antibiotics known to disturb the gastrointestinal flora is associated with clinical symptoms, such as diarrhea, in as many as 30% of patients.28 29 Research has shown that the use of probiotics can help to restore gut microecology through receptor competition, competition for nutrients, inhibition of epithelial and mucosal adherence of pathogens, introduction of lower colonic pH favoring the growth of nonpathogenic species, stimulation of immunity, or production of antimicrobial substances.30 31 Probiotics, when used following surgery, can accelerate recovery through improved immunity, as well as reduce the risk of postoperative infection and antibiotic-associated diarrhea. The existing body of evidence supports the use of Lactobacillus species, either alone or in combination with other genera.32

Probiotics are rendered more effective by the addition of prebiotics. Prebiotics are nondigestible substances that beneficially affect the host by stimulating the growth and activity of one or a limited number of bacteria in the colon, thus improving host health. When combined with probiotics, the mixture is called a symbiotic—a mixture of probiotics and prebiotics that beneficially affect the host, done so by improving the survival and implantation of live microbial dietary supplements in the gastrointestinal tract. This improvement is made by selectively stimulating the growth and by activating the metabolism of one or a limited number of health promoting bacteria, and thus improving host welfare.33

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27– Dreyer HC, et al. Essential amino acid supplementation assisted with surgical recovery in patients who had undergone total knee arthroplasty, as demonstrated by attenuated muscle atrophy and accelerated return to functional mobility.
30– Rolfe RD. The role of probiotic cultures in the control of gastrointestinal health. _J Nutr_. 2000;130(25 suppl) 396-4025
### Supplement Facts

**Serving Size:** 1 Pack (6.6 Grams)
**Servings Per Container:** 14

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Amount Per Serving</th>
<th>% Daily Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A (Beta-Carotene &amp; Ascorbate)</td>
<td>8.000 IU</td>
<td>140%</td>
</tr>
<tr>
<td>Vitamin C (Ascorbate)</td>
<td>580 mg</td>
<td>125%</td>
</tr>
<tr>
<td>Vitamin D (Cholecalciferol)</td>
<td>1000 IU</td>
<td>125%</td>
</tr>
<tr>
<td>Vitamin K (Phylloquinone)</td>
<td>64 mcg</td>
<td>50%</td>
</tr>
<tr>
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<td>600 mcg</td>
<td>250%</td>
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<tr>
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<tr>
<td>Vitamin B6 (Pyridoxine)</td>
<td>100 mcg</td>
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<td>20 mg</td>
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<tr>
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<tr>
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<tr>
<td>Selenium</td>
<td>200 mcg</td>
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<tr>
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<td>20%</td>
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<tr>
<td>Manganese (Gluconate)</td>
<td>5 mg</td>
<td>200%</td>
</tr>
<tr>
<td>Chromium (Picolinate)</td>
<td>50 mcg</td>
<td>42%</td>
</tr>
<tr>
<td>Potassium (Phosphate)</td>
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**Proprietary Blend**

- L-Cystine, L-Glutamine, L-Taurine, L-Carnitine

**Other Ingredients:** Citric Acid, Lemon-Lime Flavor and Stevia (Soybean Extract)

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**WARNING:** ACCIDENTAL CONSUMPTION OF NON-COMMERCIAL PRODUCTS IS A POTENTIAL CAUSE OF HEART ATTACK. PERSONAL AND FAMILY HISTORY OF HEART ATTACK ARE IMPORTANT FACTORS TO CONSIDER. CALL 0-0-0 IF YOU SUSPECT A HEART ATTACK OR CALL 9-1-1. CALL 0-0-0 IF YOU SUSPECT A HEART ATTACK OR CALL 9-1-1.

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**Proprietary Blend**

- L-Cystine, L-Glutamine, L-Taurine, L-Carnitine

**Other Ingredients:** Propylparaben, Butylparaben, Glycerin, Propylene Glycol, Natural and Artificial Flavors, Antioxidants, Vitamin C (Sodium Ascorbate) and Sorbic Acid

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125 1401 – 1412
Other Nutrients

Other vitamins, trace elements and compounds are also important for surgery patients:

- Vitamin A supports immune system function and contributes to collagen strength, a necessary component of tissue repair.
- The complement of B vitamins are needed for cellular metabolism, tissue repair and immune support.
- Zinc is an essential trace mineral used in enzymatic reactions and biochemical pathways involved in wound healing and tissue regeneration.34
- Copper and selenium are antioxidant minerals that support cell damage repair.
- Following surgery, bromelain (a pineapple enzyme with anti-inflammatory properties) and quercetin (a plant flavonoid with anti-oxidant and anti-inflammatory properties) may help reduce bruising, swelling and scarring.35, 36

Access to Quality, Pharmaceutical-Grade Nutritional Supplements

The abundance of clinical research validating the role of nutritional elements in preparing for, or recovering from, surgery is counterbalanced by the lack of high-quality, pharmaceutical-grade nutritional supplements specifically designed to support the nutritional needs of pre- and post-op patients. Mediceutical supplements address this significant unmet need by tailoring nutritional products to address specific clinical and medical conditions, using elements and dosages that have been validated by evidence-based research.

Mediceutical supplements like Forté Elements Pre-Op and Forté Elements Post-Op were developed by physicians specifically to support patients preparing for, and recovering from, surgery. Mediceuticals are an emerging category of nutritional products that have been specifically formulated to support specific health conditions or situations. Unlike nutritional supplements or nutraceuticals that lack regulatory oversight or a rigorous testing, mediceuticals are produced using pharmaceutical-grade ingredients and manufacturing practices, and undergo a scientific, transparent testing process. Both Forté Elements Pre-Op and Forté Elements Post-Op contain vitamins A, B, C and D, as well as key trace elements and proprietary blends of amino acids, at the high supplemental doses that clinical research indicates will be beneficial in surgical patients. For example, while Forté Elements Pre-Op contains 500 mg of vitamin C, the amount considered to be well-absorbed in healthy patients, Forté Elements Post-Op contains 1500 mg of vitamin C to address the deficiency related to oxidative stress and surgery.

Mediceuticals: An Emerging Category

A pioneer in developing condition-specific combinations of vitamins, minerals, amino acids and other nutrients, Forté Elements is the leader in providing nutritional support for surgery and other common clinical conditions in which nutritional status has been shown to have an impact on outcomes. To ensure that each nutritional support system meets rigorous standards for quality and evidence-based research, Forté Elements has defined and developed strict criteria for the emerging mediceutical category.

Formulated in conjunction with licensed physicians, a mediceutical is a pharmaceutical-grade nutritional support system designed for a specific medical condition using clinically-proven ingredients that are based on published science.

In order to qualify as a mediceutical, a supplement must:

1. Be formulated to support a specific health condition or situation
2. Contain only non-synthetic, pharmaceutical-grade ingredients that are Generally Recognized as Safe (GRAS)
3. Contain elements that have been validated by clinical research for the specific health condition or situation, as published in peer-reviewed journals
4. Conform to pharmaceutical-grade dosage standards for the specific health condition or situation
5. Be produced in FDA-compliant manufacturing facilities using pharmaceutical-grade manufacturing practices
6. Be accompanied by a Certificate of Analysis confirming that product ingredients meet the mediceutical standard and are as listed on the product label

Meeting the Medical Need for Clinical Nutrition

Poor nutrition status has long been linked to increases in post-operative complication and adverse outcomes for patients undergoing elective surgery. Optimal planning for nutrition therapy should be comprehensive, spanning the entire perioperative period. In fact, recent advances in nutrition have emphasized the concept of “prehabilitation” – providing pre-operative nutritional support to best prepare the patient prior to surgery. Research has shown that adding immune/metabolic modulating formulas with carbohydrate drinks during the week of surgery optimizes glycogen deposition immediately prior to surgery, enhancing recovery and return to baseline function.37

A significant body of clinical research supports the relationship between nutritional status, quality of patient care, and physicians need high-quality, pharmaceutical-grade nutritional support solutions to offer their patients. In the case of surgery, improved attention to nutritional status and dietary intake in pre- and post-operative patients may affect clinical outcomes. The nutritional density of conventional hospital food is often poor, and not well-targeted for specific clinical situations. Even among patients who are given nutritional support and dietary supplementation, studies have shown that conventional approaches still provide most patients with an inadequate diet.38

Mediceuticals help to bridge the gap between traditional pharmaceuticals and unproven nutraceuticals by providing clinical nutrition to support repair, recovery and restoration of the body from surgery, trauma or other stress. Since mediceuticals are specifically designed for a particular health condition or situation, they provide patients with nutritional support that is appropriate for their unique health needs and delivered in a simple-to-follow protocol. Pre- and post-op mediceuticals such as the Forté Elements Pre-Op and Post-Op system contain specific blends of vital nutrients that have been carefully selected to reduce surgical stress and support the immune system, while promoting the wound healing and tissue repair processes.

A fusion of science and practical medical experience unlike anything that has come before.