the Med Supply Line

A publication of ACO Med Supply, Inc. | Volume 3 Issue 4

INSIDE

ACO: An award-winning distributor of orthopaedic and med-surg supplies for over 15 years. Centrally located in Charlotte, NC – proudly servicing the medical community in North and South Carolina, Georgia, Tennessee, Virginia and West Virginia…and growing.

ACO MED SUPPLY

Becoming a Category of One

by Joe Calloway – author, "Becoming a Category of One"

In a business or practice, great performance doesn't happen by chance. Even with all of the cost-cutting initiatives, employee engagement programs and technology upgrades available, you'll find yourself constantly falling short of your goals, unless every resource and employee is intentionally aligned with a compelling vision.

In a world of sameness, we are all just a commodity. Whether you're trying to win a new prospect, or maintain the loyalty of a long time patient or customer, you'd better have tiebreakers. The goal is to make a distinction between you and your competition. If you really differentiate, you can become a "Category of One" – beyond comparison. Here's how market leading companies are winning today:

1. Face to Face. Work to maximize, not minimize, time with patients or customers. This is how you create the most value.
2. Big Picture Perspective. Look at the big picture from your customers' or patients' point of view. Empathy and understanding are important skills.
3. Be Easy. Be the easiest to do business with. Many people rank it as the number one buying and decision-making factor.
4. Win INSIDE the Box. Inside the box are your customers' basic expectations. If you win inside the box - you win. We're talking value, quality, service, consistency. If your customer or a patient has a problem with you, your product, or your company, solve the problem right that second.

THE ULTIMATE TIEBREAKER: Know more about the customer than your competition knows. Use that knowledge in the service of your customer or patient. Awareness of and attention to the needs of the consumer without exception is how you will win and keep loyal customers for life.

I'm proud of my association with "Category of One" organizations like ACO Med Supply. They stay focused on their customers and they truly set themselves apart by creating real value.

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6510 Northpark Blvd.
Charlotte, North Carolina 28216

(704) 921-0116 : Telephone
(800) 351-8006 : Toll Free
(704) 921-0117 : Fax

Stuart Ross, President
James Gray, Vice President
Richard Jacobson, Chief Operations Officer
Greg Harmon, Chief Sales Officer

Sales Representatives

North Carolina
Randy Buck
Tim Van Schaick
David Lindsey
Joe Klun
Ryan Wingrove
Mike Osborne
Craig Deiwert
Kyle Meadows
Courtney Vail
Sandi Caldwell

South Carolina
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Virginia
Jim Reeks
Jeff Turner
Jennifer Lonning
Rod Ferguson
Nicole Holt
Aaron Argenta

Virginia / West Virginia
Aaron Gresham

West Virginia / Kentucky / Ohio
Nick Svingos

The Med Supply Line is an inside look at how orthopedic products are making a positive difference in quality orthopedic care. This publication, produced by ACO Med Supply, is designed to educate and inform orthopedic surgeons, practice administrators, purchasing departments, physical therapists, and athletic trainers. The information contained in this publication is not intended to replace a physician's professional consultation and assessment. Please consult your physician on matters related to your personal health.

15 Years and Counting

In 1995…

- **the San Francisco 49ers won the Super Bowl;**
- **the new $100 bill was released;**
- **Cal Ripkin beat Lou Gehrig's record for most consecutive baseball games;**
- **Forrest Gump won Best Picture; and**
- **ACO Med Supply opened its doors in Charlotte, NC**

Prospects for the U.S. economy may have been bleak, but entrepreneurs like **Stuart Ross** saw a way to stay ahead of the curve when he established ACO Med Supply in June 1995. Initially the distributorship was created to support the DonJoy Sales Rep group in North Carolina and their orthopedic customers. Knowing that modern medical offices wanted quality, accuracy, speed, service and variety, ACO decided to expand the operation to a one-source distribution center of medical-surgical products, focusing on our commitment for the orthopedic market. Through hard work, understanding of their customer base, and the expansion of the orthopedic and sports medicine marketplace, ACO Med Supply experienced rapid growth.

Since then, the company has grown into a $17 million solution provider. A large part of ACO Med Supply's success can be attributed to the strict observance of the company's **Corporate Values,** which sets them apart from other large medical distribution firms. These values are:

- Developing long-term relationships with customers by adhering to shared values.
- Delivering new and innovative solutions to the changing needs of our customers and the market.
- Distributing quality products and services competitively priced.
- Connecting with our customers on a higher level through continual collaboration.

Much of the company's growth and success can be attributed to ACO Med Supply's talented and dedicated leaders and employees. **Jimmy Gray,** VP of Operations, is certainly a perfect example. As the company's co-founder, Jimmy's selfless dedication and personal touch-approach made quite an impact. His focus on servicing the needs of medical offices allows the clinical staff to concentrate on the needs of their patients.

Greg Harmon, ACO's Chief Sales Officer, is another integral spoke in the company's wheel of success. He views the **Corporate Values** that ACO has adopted as the backbone of the company's mission. It has allowed ACO Med Supply to grow from the "home-grown" distributorship, to a multi-state, award-winning supplier of orthopedic and medical/surgical products for customers in the southeast. According to Harmon, "Going over and beyond what our competitors are willing to do for customers, and in many cases, what our customers expect, is what has set us apart."

Going over and beyond proved to pay off and helped the company grow by leaps and bounds. This rapid growth led to a move in July 2009 to a 51,000 square foot warehouse. ACO is now one of the largest distribution centers for orthopedic products in the country and ships products from over 250 manufacturers - providing the latest and most-advanced technologies to our network of physicians and their patients. The service component of ACO Med Supply has also expanded as third-party billing and medical stock-and-bill programs have moved to the forefront. Medicare 2011 DME changes are making procuring and billing durable

ACO Med Supply's Staff (blue) and Sales Team (green)

Easy to apply. Easy to live with.
3M™ Scotchcast™ Wet or Dry Padding.

From now on, you only need one cast padding for either wet or dry use.

3M™ Scotchcast™ Wet or Dry Padding is a hypoallergenic, synthetic cast padding that allows patients to get their cast wet.

Plus, the padding can be applied using the same techniques used for synthetic or cotton cast padding. And, there are no special techniques required for removal of the cast.

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medical equipment, prosthetics and orthotics a business challenge. However, as a DonJoy distributor, ACO offers several stock-and-bill alternatives, customized to fit the specific needs by practice. The most current addition to the "one-source" distribution goal for ACO Med Supply is a recent expansion of PT and Rehabilitation equipment and supplies. "Meeting the needs of our customers with respect to rehabilitation is a natural progression for us," says **Randy Buck,** Rehab Sales Manager. We are routinely reviewing practices' needs to help them achieve cost-effective solutions for the purchasing of equipment and supplies.

In this time of continued growth and expansion, ACO Med Supply has remained true to its commitment to fulfilling each customer's needs. Twenty-eight sales representatives and a support staff of 20 insure that ACO provides the balance of support, flexibility and service that works best for a customer's individual practice. Whether the needs are for a full-service representative who manages the entire supply closet or an autonomous office whose personnel prefers the ease of using the ACO web-based ordering platform, ACO Med Supply continues to evolve as a market leader. Physicians and patients alike can feel secure knowing they are getting the most advanced orthopedic and medical supplies and rehab equipment available.

Celebrating our 15-year anniversary was quite a milestone and is the daily motivation for ACO Med Supply. We are reminded once more of the company's values: customers, products, collaboration and service. As we strive to become an even more valuable partner in the coming years, we understand that the success of ACO Med Supply is directly attributable to our relationships with our customers and the quality manufacturers we represent. The customers, vendors, and products continue to come together with our hardworking employees and Sales Reps to focus on creating a unique and valued company. Looking to the future, we know our alignment with orthopedic market leaders allows ACO Med Supply to become the key alliance that successfully can identify and adjust to the needs of its customers, thus insuring long-term strategic partnerships.

Congratulations to **Andrea Greer** (SC Sales Rep), **Joe Klun** (NC Sales Rep), and **Ryan Wingrove** (NC Sales Rep) for their induction into the 2010 DJO Global Circle of Excellence. These individuals truly showed how to take their abilities to the next level while delivering to their customers an unparalleled level of service and commitment. You are an example to all others in our field.

Bob Rojahn, Area Vice President, DonJoy Division, DJO Global

Mike Floyd

Corporate Director, Sports Medicine & Events
Carolinas Healthcare Hospital, Charlotte, North Carolina

HEROES IN HEALTH+CARE

Healthcare Hero: An individual or organization dedicated to fighting for a cause, helping others in need and making an impact in the quality of healthcare.

The Med Supply Line is debuting a new segment titled, *Heroes in Healthcare*, where chosen nominees will be recognized for their passion and involvement in advancing the healthcare field in their region.

ACO Med Supply is proud to announce their first Healthcare Hero: **Mike Floyd,** Corporate Director, Sports Medicine/Events of Carolinas Healthcare Hospital in Charlotte, North Carolina. Mike has shown an immense amount of dedication to fundraising cancer research after the passing of his wife, Kathy Floyd, from endometrial cancer in 2010.

"Kathy's Krew" was created by Mike in July, 2010, in hopes of making a small dent in the large process of beating cancer. Compiled of family and friends, the goal of Kathy's Krew is to raise $25,000 for cancer prevention and to empower the community to help fight the battle together.

Here, Mike talks with ACO's Whitney Phillips about his passion for fundraising and commitment to fight cancer:

Whitney Phillips: Congratulations on winning our first Heroes in Healthcare Award! We were very touched by Kathy's story and your drive to rally around cancer research. Tell us a little about yourself and Kathy's Krew:
Mike Floyd: Thank you guys for the nomination and the chance to tell people about our cause to beat cancer through the creation of Kathy's Krew. Kathy's Krew was formed after my wife, Kathy, passed away from a year and a half battle with Stage IV endometrial cancer. Her strength, perseverance and determination to beat the disease fueled my family's desire to continue fighting in her memory.

Mike and Kathy Floyd

WP: Who makes up Kathy's Krew? What is the overall vision and goal?
MF: Kathy's Krew is made up of family and friends and our goal is to make a dent in cancer research in the area of cancer prevention.

WP: How is Kathy's Krew helping the cancer community?
MF: At this early stage, we are putting together a plan to help educate folks in the community about the importance of living healthy (exercise and proper eating habits), going for regular physician checks, and being advocates for themselves if they feel that a second opinion is necessary. We want people to understand that lifestyle choices may help to prevent certain types of cancer.

WP: I was captivated by the Krew's decision to run a marathon in honor of Kathy. Describe the Disney Half Marathon and how you felt once you crossed the finish line.
MF: Disney was one of our family's favorite places to go. And as a matter of fact, a trip to Disney was the last vacation Kathy and I took just before we found out about her cancer diagnosis. So, to do the Disney ½ Marathon in memory of Kathy was a healing process for all of us. Even though we did not finish in record time, we all finished together with our hands linked and hearts held high, which gave us all the comfort and feeling of completion for which we started.

WP: Aside from the marathon, what other fundraising events do you participate in/host?
MF: At this time, Kathy's Krew is planning to participate in other cancer fund raising events, such as 5K's, 10's and half marathons. We are also working with a quilt maker who will make quilts in memory of a love one in exchange for a donation to our cancer research fund. We had quilts made from Kathy's clothing for our family and friends, and gave them as Christmas presents. And I must say that it was, hands down, a heartfelt way of keeping her memory alive!

Wish to make a donation to Kathy's Krew?
Visit www.myteamteal.org
Click on Find a Page and
Select Nancy Katherine Floyd

WP: Do you have a message for others, like yourself, involved in fundraising for cancer research?
MF: No effort or gift is too small to help in the fight against this terrible disease. Keeping the memory of our loved ones alive will help us to always remember what our part is in fighting this disease.

WP: What do you wish to tell the cancer community or readers of this article? Do you have any advice for family members of cancer patients?
MF: Family and friends are so important! Keep them close and continue to nurture those relationships. Being positive is a must. Never ever give up! Kathy's positive attitude and determination were key elements in the fact that she lived ten years after being diagnosed with Stage IV non-hodgkins lymphoma back in 1999 and then a year and a half after her diagnosis of endometrial cancer.

WP: What is your next step to help find a cure?
MF: Our next step will be to discover better ways to help create funds for research and to get feedback on the progress of cancer awareness in the community.

WP: How can others help support Kathy's Krew and your goal?
MF: Of course, donations to Nancy Katherine Floyd's fund through the Blumenthal Cancer Center at Carolinas Medical Center are greatly appreciated. Any suggestions from other teams who want to become part of Keeping the Dream Alive are welcomed!

If you would like to make a nomination for future Heroes In Healthcare articles, please visit the ACO website for more details!
www.acomedsupply.com

Introducing the NEW DonJoy® REACTION™ Knee Brace

The REACTION knee brace is a responsive, webbed approach to anterior knee pain that gives a distinct alternative to the basic knee sleeve. This new innovative knee brace is one of the first braces that disperses knee pain. The elastomeric web design absorbs shock and shifts the peak loads away from the painful area of the knee. This dispersion of energy helps reduce the anterior knee pain you suffer from. Another advantage of the elastomeric web is that it dynamically stabilizes the patella on all sides, bringing the patella into proper tracking position to reduce pain caused by patellofemoral instabilities.

The REACTION knee brace was developed by an orthopedic surgeon who specializes in patellofemoral disorders. The objective of the device is to control contact stresses within the knee. The brace achieves this in two ways; 1) it absorbs and disperses energy that enters the knee, much the same as muscles do upon foot impact, and 2) it controls and stabilizes subtle laxity within the joint. This stabilization function is based on the principle that a joint will always take the "path of least resistance." The form-fit of the REACTION elastomeric web helps to maintain the knee joint in a neutral position whereby the contact stresses are distributed more uniformly, minimizing peak loading of a given area. Peak loading is particularly detrimental to articular cartilage surfaces.

The Reaction has the advantage of being lightweight and comfortable. It can be worn for activities of daily living as well as sporting activities. Its fit and tensionability gives the device a broad range of potential users. The older patient who needs stabilization and kinetic assist will find the brace user-friendly and effective. The younger, athletic individual will find the REACTION to be responsive and comfortable. The REACTION has been successful in controlling pain even in the heavier, hard-to-fit patients.

As compared to the conventional knee sleeve, the REACTION has distinct functional properties, yet is equally comfortable. The REACTION can be released for resting activities and re-tensioned according to the user's desired activity level and functional demands. The Reaction affords some of the characteristics of a rigid brace without the bulk. The REACTION tends to have minimal migration, seen in many other brace designs.

The DonJoy REACTION knee brace is used to treat or prevent the following injuries:

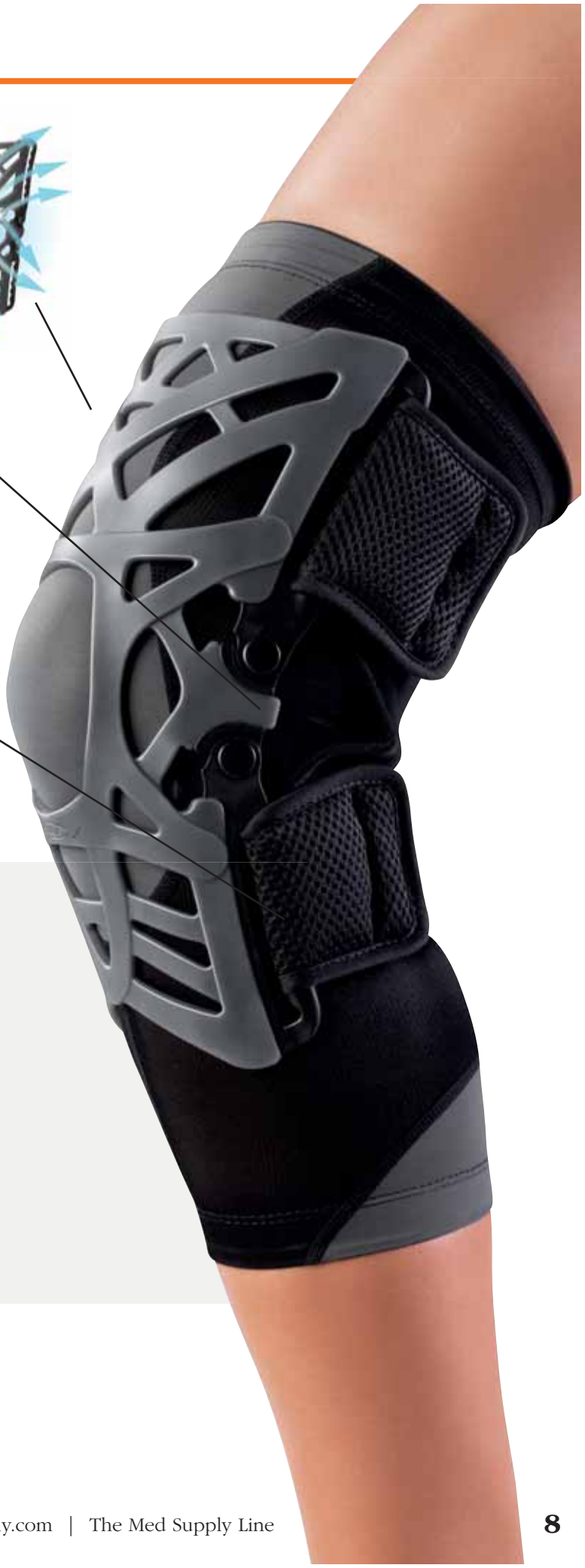
- Chondromalacia patella
- Quadriceps or patellar tendonitis/tendinosis
- Osgood-Schlatter disease
- General patellofemoral tracking issues
- Mild OA

Product Features and Benefits

Progressive Pain Relief: The web absorbs shock and shifts the peak loads away from the painful area of the knee and stabilizes the patella on all sides to ensure proper tracking position.

Reimbursable Solution: PDAC approved for L1810, the Dual-axis hinges are flexible, creating synergy with the elastomeric web for optimal fit and support, and providing energy dispersion to the knee.

Sustained Comfort: The lightweight and open framework in combination with the mesh backing create a very comfortable and breathable solution for anterior knee pain.

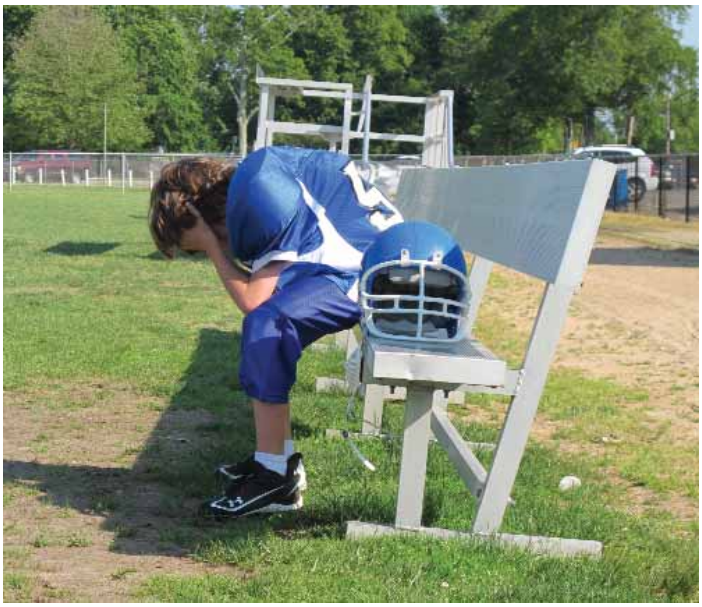


EVERY PAINFUL ACTION REQUIRES A COMFORTABLE REACTION

DONJOY® DJO™

Concussions Continue to Command Center Stage in Sports

From global-reaching professional sports to our local school teams, clinicians, athletic directors, athletic trainers, coaches and team physicians have long struggled with the challenge of accurately diagnosing concussions and determining an appropriate recovery timeframe before an athlete can be cleared to safely return-to-play.



Returning to play before giving the brain an adequate amount of time to heal can leave athletes susceptible to second-impact syndrome, which results in severe brain swelling and potential damage. Sometimes the hit that causes second-impact syndrome isn't a hard one.

An estimated ten percent of all athletes participating in contact sports suffer a concussion each season. According to the Centers for Disease Control and Prevention, the most common brain injury in sports is a concussion. In fact, approximately 300,000 sports-related concussions occur in the United States each year, with only a fraction of them receiving proper treatment.

Concussion in Former Athletes Can Carry Long-Term Affects

Researchers have found evidence that athletes who were concussed during their earlier sporting lives can show a decline in their mental and physical processes more than 30 years later.

The research compared 19 healthy, former athletes who had sustained mTBI (mild traumatic brain injury) more than 30 years ago with 21 healthy, former athletes with no history of concussion. The study found that those who had suffered a concussion only once or twice in their early adulthood showed a decline in their attention and memory and a slowing of some of their movements compared to athletes who had no history of concussion.

Professional Football Is Taking Concussion Seriously

Concussions in professional football have recently become a hot topic: In October 2010, the National Football League announced it would begin suspending players for illegal and dangerous hits that could result in head injuries.

A new 12-year study of NFL data suggests that in recent years, players have been sidelined significantly longer after concussions than they were in the late 1990s and early 2000s.

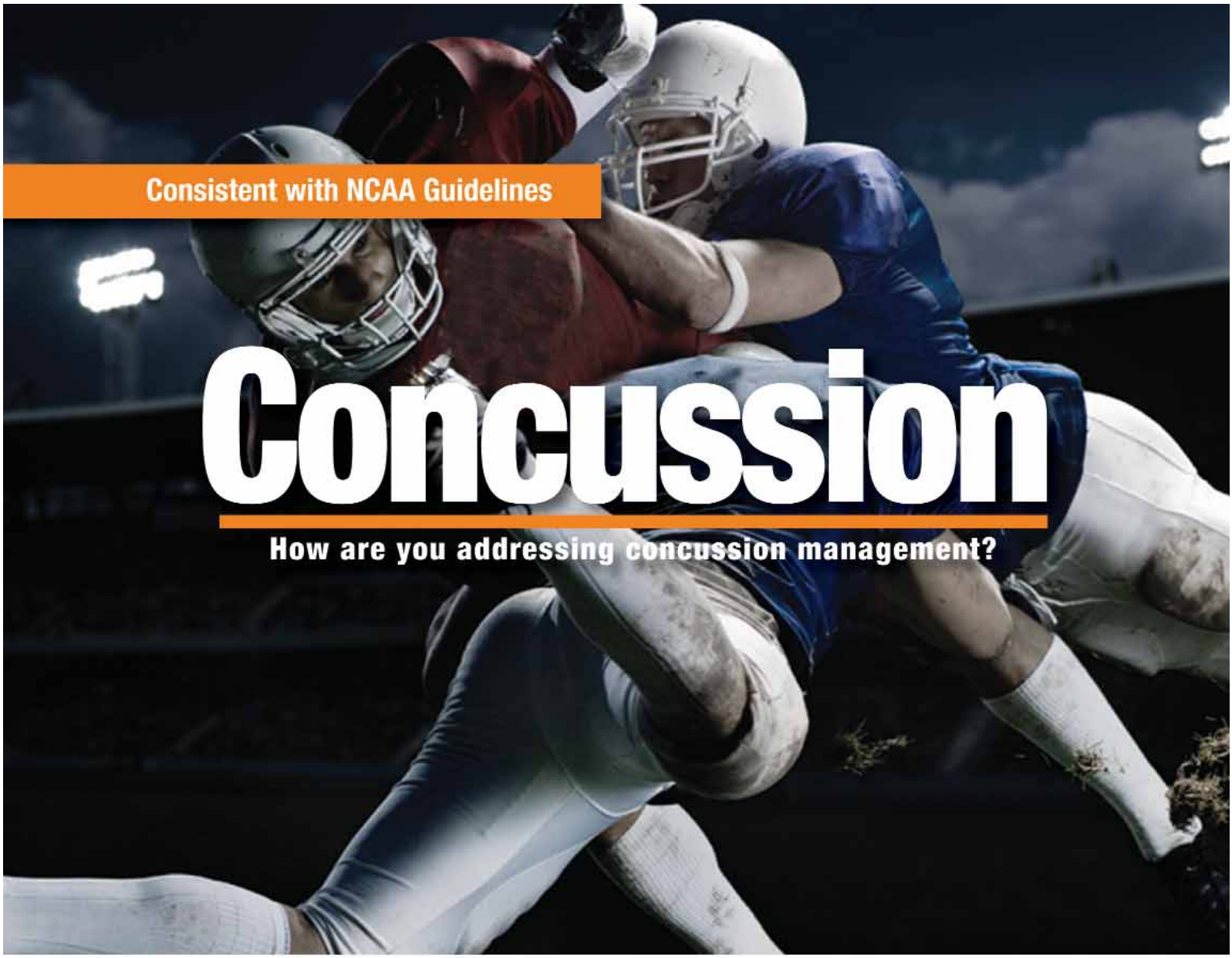
The study, by former members of the NFL's Mild Traumatic Brain Injury Committee, compared injury and treatment statistics from two consecutive six-year periods (1996 to 2001, and 2002 to 2007) and found the average number of days that players were sidelined after a concussion more than doubled.

In the 2010-2011 season alone, the NFL has seen reported concussions increase 21 percent from last season. The league believes this dramatic increase in reported cases is evidence that players and teams are taking head injuries more seriously.

In recognition of the growing issue, the NFL has launched a website, called NFLHealthandSafety.com, to spread information about the relationship between football and concussions.

"When it comes to concussion, don't believe me when I tell you that I am okay."

– NFL Player 2010



Consistent with NCAA Guidelines

Concussion

How are you addressing concussion management?

The **Play It S.A.F.E.®** Concussion Management Program

▲ *Biodex Balance System SD™*

Biodex introduces the NEW **Play It S.A.F.E.® Concussion Management Program**, an objective, database solution that includes both cognitive and functional assessment. This best practices concussion management program can be applied to Junior High, High School, Collegiate and Professional levels.

Play It S.A.F.E.® starts with baseline testing on the Biodex Balance System SD or Portable BioSway using objective neuro-physical balance testing to complement the neuro-cognitive testing tool of your choice. The program's clinical algorithm for a sideline assessment and follow-up evaluation provides insight into the question "Can this athlete return to play?"

▲ *Biodex BioSway shown with optional Printer and Printer Stand.*

Play It S.A.F.E.® Concussion Management Program developed by 360° BALANCE We care and we can help

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Contact Biodex to establish your Concussion Management Program

New Merger for ACO Med Supply:
SelectCare, Inc. and JAS Splints!

SelectCare, Inc.

JAS®
DIFFERENT BY DESIGN.™

Some things in this world are meant to be. The same could be said for ACO Med Supply and their new affiliate, SelectCare, Inc. Continuous paths have been crossed in the Rehab industry between the two entities and the decision to merge has been made! ACO Med Supply is excited to announce their new business partner SelectCare and introduce JAS splints into their expanding product lines.

SelectCare, Inc. specializes in state-of-the-art home care rehabilitation equipment. They work with physicians, therapists, home-care providers and insurance companies to provide the most effective product for the patient's needs. This includes all pre-certifications to secure coverage, billings and collections of claims, obtaining documentation from physicians, renewing Prescriptions and appealing disputed claims. SelectCare, Inc. will set up and provide training on equipment, instruct on Patient Care Plans and continue follow up as long as the patient is using the products!

Along with superb customer care from trained healthcare professionals, the addition of JAS splinting will help ACO Med Supply provide a full range of products and services to patients. Joint Active Systems (JAS) is the innovator and market leader for adjunctive stress relaxation and low-load stretch therapy, the proven approach for fast and effective joint range of motion (ROM) restoration. With unequaled design technology and two complete product lines to choose from, JAS moves beyond convention to assure the best results for patients challenged with range of motion loss.

The JAS and JAS EZ ROM systems comfortably stretch your patients beyond what's possible with the competition. The key to success is in product design. With patented Motion Tower and Motion Arm technology, JAS and JAS EZ are the only product lines that "unload the joint"- reducing painful joint surface loading during use. JAS geometry applies soft tissue distraction, enabling ROM increase without pain during 30 minute sessions, three times a day. Success is measured through accreditation companies and is at a 98% patient compliance!

We encourage you to move beyond the competition and see the proven outcomes achievable with JAS and JAS EZ! Products and services are currently available in North and South Carolina. Contact your local ACO Med Supply/SelectCare sales representative for more information!

JAS EZ Shoulder

JAS EZ Pro/Sup

Betamethasone Sodium Phosphate and Betamethasone Acetate
Injectable Suspension, USP
6 mg per mL

Rx Only

BRIEF SUMMARY (For full prescribing information, including Dosage and Administration, see package insert at www.americanregent.com.)

DESCRIPTION Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, USP is a sterile aqueous suspension containing betamethasone 3 mg per milliliter as betamethasone sodium phosphate, and betamethasone acetate 3 mg per milliliter. Inactive ingredients per mL: dibasic sodium phosphate 7.1 mg; monobasic sodium phosphate 3.4 mg; edetate disodium 0.1 mg; and benzalkonium chloride 0.2 mg as a preservative. The pH is adjusted to between 6.8 and 7.2.

INDICATIONS AND USAGE When oral therapy is not feasible, the **intramuscular use** of Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension is indicated as follows:

Allergic States Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in asthma, atopic dermatitis, contact dermatitis, drug hypersensitivity reactions, perennial or seasonal allergic rhinitis, serum sickness, transfusion reactions.

Dermatologic Diseases Bullous dermatitis herpetiformis, exfoliative erythroderma, mycosis fungoides, pemphigus, severe erythema multiforme (Stevens-Johnson syndrome).

Endocrine Disorders Congenital adrenal hyperplasia, hypercalcemia associated with cancer, nonsuppurative thyroiditis. Hydrocortisone or cortisone is the drug of choice in primary or secondary adrenocortical insufficiency. Synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy mineralocorticoid supplementation is of particular importance.

Gastrointestinal Diseases To tide the patient over a critical period of the disease in regional enteritis and ulcerative colitis.

Hematologic Disorders Acquired (autoimmune) hemolytic anemia, Diamond-Blackfan anemia, pure red cell aplasia, selected cases of secondary thrombocytopenia.

Miscellaneous Trichinosis with neurologic or myocardial involvement, tuberculous meningitis with subarachnoid block or impending block when used with appropriate antituberculous chemotherapy.

Neoplastic Diseases For palliative management of leukemias and lymphomas.

Nervous System Acute exacerbations of multiple sclerosis; cerebral edema associated with primary or metastatic brain tumor or craniotomy.

Ophthalmic Diseases Sympathetic ophthalmia, temporal arteritis, uveitis and ocular inflammatory conditions unresponsive to topical corticosteroids.

Renal Diseases To induce diuresis or remission of proteinuria in idiopathic nephrotic syndrome or that due to lupus erythematosus.

Respiratory Diseases Berylliosis, fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy, idiopathic eosinophilic pneumonias, symptomatic sarcoidosis.

Rheumatic Disorders As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in acute gouty arthritis; acute rheumatic carditis; ankylosing spondylitis; psoriatic arthritis; rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy). For the treatment of dermatomyositis, polymyositis, and systemic lupus erythematosus.

The **intra-articular or soft tissue administration** of Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension is indicated as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in acute gouty arthritis, acute and subacute bursitis, acute nonspecific tenosynovitis, epicondylitis, rheumatoid arthritis, synovitis of osteoarthritis.

The **intralesional administration** of Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension is indicated for alopecia areata; discoid lupus erythematosus; keloids; localized hypertrophic, infiltrated, inflammatory lesions of granuloma annulare, lichen planus, lichen simplex chronicus (neurodermatitis), and psoriatic plaques; necrobiosis lipoidica diabeticorum. Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, may also be useful in cystic tumors of an aponeurosis or tendon (ganglia).

CONTRAINDICATIONS Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension is contraindicated in patients who are hypersensitive to any components of this product. Intramuscular corticosteroid preparations are contraindicated for idiopathic thrombocytopenic purpura.

WARNINGS General Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension should not be administered intravenously. Rare instances of anaphylactoid reactions have occurred in patients receiving corticosteroid therapy. (See **ADVERSE REACTIONS**). In patientson corticosteroid therapy subjected to any unusual stress, hydrocortisone or cortisone is the drug of choice as a supplement during and after the event.

Cardio-renal Average and large doses of corticosteroids can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium. These effects are less likely to occur with the synthetic derivatives except when used in large doses. Dietary salt restriction and potassium supplementation may be necessary. All corticosteroids increase calcium excretion. Literature reports suggest an apparent association between use of corticosteroids and left ventricular free wall rupture after a recent myocardial infarction; therefore, therapy with corticosteroids should be used with great caution in these patients.

Endocrine Corticosteroids can produce reversible hypothalamic-pituitary adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment.

Metabolic clearance of corticosteroids is decreased in hypothyroid patients and increased in hyperthyroid patients. Changes in thyroid status of the patient may necessitate adjustment in dosage.

Infections General: Patients who are on corticosteroids are more susceptible to infections than are healthy individuals. There may be decreased resistance and inability to localize infection when corticosteroids are used. Infection with any pathogen (viral, bacterial, fungal, protozoan, or helminthic) in any location of the body may be associated with the use of corticosteroids alone or in combination with other immunosuppressive agents. These infections may be mild to severe. With increasing doses of corticosteroids, the rate of occurrence of infectious complications increases. Corticosteroids may also mask some signs of current infection.

Fungal Infections: Corticosteroids may exacerbate systemic fungal infections and therefore should not be used in the presence of such infections unless they are needed to control drug reactions. There have been cases reported in which concomitant use of amphotericin B and hydrocortisone was followed by cardiac enlargement and congestive heart failure (see **PRECAUTIONS, Drug Interactions,** Amphotericin B Injection and Potassium-Depleting Agents section).

Special Pathogens: Latent disease may be activated or there may be an exacerbation of intercurrent infections due to pathogens, including those caused by Amoeba, Candida, Cryptococcus, Mycobacterium, Nocardia, Pneumocystis, and Toxoplasma. It is recommended that latent amebiasis or active amebiasis be ruled out before initiating corticosteroid therapy in any patient who has spent time in the tropics or in any patient with unexplained diarrhea. Similarly, corticosteroids should be used with great care in patients with known or suspected Strongyloides (threadworm) infestation. In such patients, corticosteroid-induced immunosuppression may lead to Strongyloides hyperinfection and dissemination with widespread larval migration, often accompanied by severe enterocolitis and potentially fatal gram-negative septicemia. Corticosteroids should not be used in cerebral malaria.

Tuberculosis: The use of corticosteroids in active tuberculosis should be restricted to those cases of fulminating or disseminated tuberculosis in which the corticosteroid is used for the management of the disease in conjunction with an appropriate antituberculous regimen. If corticosteroids are indicated in patients with latent tuberculosis or tuberculin reactivity, close observation is necessary as reactivation of the disease may occur. During prolonged corticosteroid therapy, these patients should receive chemoprophylaxis.

Vaccination: **Administration of live or live, attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of corticosteroids. Killed or inactivated vaccines may be administered. However, the response to such vaccines cannot be predicted.** Immunization procedures may be undertaken in patients who are receiving corticosteroids as replacement therapy, eg, for Addison's disease.

Viral Infections: Chickenpox and measles can have a more serious or even fatal course in pediatric and adult patients on corticosteroids. In pediatric and adult patients who have not had these diseases, particular care should be taken to avoid exposure. If exposed to chickenpox, prophylaxis with varicella zoster immune globulin (VZIG) may be indicated. If exposed to measles, prophylaxis with immunoglobulin (IG) may be indicated. (See the respective package inserts for complete VZIG and IG prescribing information.) If chicken pox develops, treatment with antiviral agents should be considered.

Neurologic Reports of severe medical events have been associated with the intrathecal route of administration (see **ADVERSE REACTIONS, Gastrointestinal** and **Neurologic/Psychiatric** sections). Results from one multicenter, randomized, placebo controlled study with methylprednisolone hemisuccinate, an IV corticosteroid, showed an increase in early mortality (at 2 weeks) and late mortality (at 6 months) in patients with cranial trauma who were determined not to have other clear indications for corticosteroid treatment.

High doses of corticosteroids, including Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, should not be used for the treatment of traumatic brain injury.

Ophthalmic Use of corticosteroids may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves, and may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses. The use of oral corticosteroids is not recommended in the treatment of optic neuritis and may lead to an increase in the risk of new episodes. Corticosteroids should not be used in active ocular herpes simplex.

PRECAUTIONS General This product, like many other steroid formulations, is sensitive to heat. Therefore, it should not be autoclaved when it is desirable to sterilize the exterior of the vial. The lowest possible dose of corticosteroid should be used to control the condition under treatment. When reduction in dosage is possible, the reduction should be gradual. Since complications of treatment with glucocorticoids are dependent on the size of the dose and the duration of treatment, a risk/benefit decision must be made in each individual case as to dose and duration of treatment and as to whether daily or intermittent therapy should be used. Kaposi's sarcoma has been reported to occur in patients receiving corticosteroid therapy, most often for chronic conditions. Discontinuation of corticosteroids may result in clinical improvement.

Cardio-renal As sodium retention with resultant edema and potassium loss may occur in patients receiving corticosteroids, these agents should be used with caution in patients with congestive heart failure, hypertension, or renal insufficiency.

Endocrine Drug-induced secondary adrenocortical insufficiency may be minimized by gradual reduction of dosage. This type of relative insufficiency may persist for months after discontinuation of therapy. Therefore, in any situation of stress occurring during that period, naturally occurring glucocorticoids (hydrocortisone cortisone), which also have salt-retaining properties, rather than betamethasone, are the appropriate choices as replacement therapy in adrenocortical deficiency states.

Gastrointestinal Steroids should be used with caution in active or latent peptic ulcers, diverticulitis, fresh intestinal anastomoses, and nonspecific ulcerative colitis, since they may increase the risk of a perforation. Signs of peritoneal irritation following gastrointestinal perforation in patients receiving corticosteroids may be minimal or absent. There is an enhanced effect of corticosteroids in patients with cirrhosis.

Intra-Articular and Soft Tissue Administration Intra-articular injected corticosteroids may be systematically absorbed. Appropriate examination of any joint fluid present is necessary to exclude a septic process. A marked increase in pain accompanied by local swelling, further restriction of joint motion, fever, and malaise are suggestive of septic arthritis. If this complication occurs and the diagnosis of sepsis is confirmed, appropriate antimicrobial therapy should be instituted.Injection of a steroid into an infected site is to be avoided. Local injection of a steroid into a previously injected joint is not usually recommended. Corticosteroid injection into unstable joints is generally not recommended. Intra-articular injection may result in damage to joint tissues (see **ADVERSE REACTIONS, Musculoskeletal** section).

Musculoskeletal Corticosteroids decrease bone formation and increase bone resorption both through their effect on calcium regulation (ie, decreasing absorption and increasing excretion) and inhibition of osteoblast function. This, together with a decrease in the protein matrix of the bone secondary to an increase in protein catabolism, and reduced sex hormone production, may lead to inhibition of bone growth in pediatric patients and the development of osteoporosis at any age. Special consideration should be given to patients at increased risk of osteoporosis (ie, postmenopausal women) before initiating corticosteroid therapy.

Neuro-psychiatric Although controlled clinical trials have shown corticosteroids to be effective in speeding the resolution of acute exacerbations of multiple sclerosis, they do not show that they affect the ultimate outcome or natural history of the disease. The studies do show that relatively high doses of corticosteroids are necessary to demonstrate a significant effect (see **DOSAGE AND ADMINISTRATION**). An acute myopathy has been observed with the use of high doses of corticosteroids, most often occurring in patients with disorders of neuromuscular transmission (eg, myasthenia gravis), or in patients receiving concomitant therapy with neuromuscular blocking drugs (eg, pancuronium). This acute myopathy is generalized, may involve ocular and respiratory muscles, and may result in quadriparesis. Elevation of creatinine kinase may occur. Clinical improvement or recovery after stopping corticosteroids may require weeks to years. Psychic derangements may appear when corticosteroids are used, ranging from euphoria, insomnia, mood swings, personality changes, and severe depression to frank psychotic manifestations. Also, existing emotional instability or psychotic tendencies may be aggravated by corticosteroids.

Ophthalmic Intraocular pressure may become elevated in some individuals. If steroid therapy is continued for more than 6 weeks, intraocular pressure should be monitored.

Information for Patients Patients should be warned not to discontinue the use of corticosteroids abruptly or without medical supervision, to advise any medical attendants that they are taking corticosteroids and to seek medical advice at once should they develop fever or other signs of infection. Persons who are on corticosteroids should be warned to avoid exposure to chicken pox or measles. Patients should also be advised that if they are exposed, medical advice should be sought without delay.

Drug Interactions Aminoglutethimide: Aminoglutethimide may lead to a loss of corticosteroid-induced adrenal suppression.Amphotericin B Injection and Potassium-Depleting Agents. When corticosteroids are administered concomitantly with potassium-depleting agents (ie, amphotericin B, diuretics), patients should be observed closely for development of hypokalemia. There have been cases reported in which concomitant use of amphotericin B and hydrocortisone was followed by cardiac enlargement and congestive heart failure.

Antibiotics: Macrolide antibiotics have been reported to cause a significant decrease in corticosteroid clearance.

Anticholinesterases: Concomitant use of anticholinesterase agents and corticosteroids may produce severe weakness in patients with myasthenia gravis. If possible, anticholinesterase agents should be withdrawn at least 24 hours before initiating corticosteroid therapy.

Anticoagulants, Oral: Coadministration of corticosteroids and warfarin usually results in inhibition of response to warfarin, although there have been some conflicting reports. Therefore, coagulation indices should be monitored frequently to maintain the desired anticoagulant effect.

Antidiabetics: Because corticosteroids may increase blood glucose concentrations, dosage adjustments of antidiabetic agents may be required.

Antitubercular Drugs: Serum concentrations of isoniazid may be decreased.

Cholestyramine: Cholestyramine may increase the clearance of corticosteroids.

Cyclosporine: Increased activity of both cyclosporine and corticosteroids may occur when the two are used concurrently. Convulsions have been reported with this concurrent use.

Digitalis Glycosides: Patients on digitalis glycosides may be at increased risk of arrhythmias due to hypokalemia.

Estrogens, Including Oral Contraceptives: Estrogens may decrease the hepatic metabolism of certain corticosteroids, thereby increasing their effect.

Hepatic Enzyme Inducers (eg, barbiturates, phenytoin, carbamazepine, rifampin): Drugs which induce hepatic microsomal drug-metabolizing enzyme activity may enhance the metabolism of corticosteroids and require that the dosage of the corticosteroid be increased.

Ketoconazole: Ketoconazole has been reported to decrease the metabolism of certain corticosteroids by up to 60%, leading to an increased risk of corticosteroid side effects.

Nonsteroidal Anti-inflammatory Agents (NSAIDS): Concomitant use of aspirin (or other nonsteroidal anti-inflammatory agents) and corticosteroids increases the risk of gastrointestinal side effects. Aspirin should be used cautiously in conjunction with corticosteroids in hypoprothrombinemia. The clearance of salicylates may be increased with concurrent use of corticosteroids.

Skin Tests Corticosteroids may suppress reactions to skin tests.

Vaccines Patients on prolonged corticosteroid therapy may exhibit a diminished response to toxoids and live or inactivated vaccines due to inhibition of antibody response. Corticosteroids may also potentiate the replication of some organisms contained in live attenuated vaccines. Route administration of vaccines or toxoids should be deferred until corticosteroid therapy is discontinued if possible (see **WARNINGS, Infections, Vaccination** section).

Carcinogenesis, Mutagenesis, Impairment of Fertility No adequate studies have been conducted in animals to determine whether corticosteroids have a potential for carcinogenesis or mutagenesis. Steroids may increase or decrease motility and number of spermatozoa in some patients.

Pregnancy Teratogenic Effects: *Pregnancy Category C*: Corticosteroids have been shown to be teratogenic in many species when given in doses equivalent to the human dose. Animal studies in which corticosteroids have been given to pregnant mice, rats, and rabbits have yielded an increased incidence of cleft palate in the offspring. There are no adequate and well-controlled studies in pregnant women. Corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Infants born to mothers who have received corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism.

Nursing Mothers Systematically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when corticosteroids are administered to a nursing woman.

Pediatric Use The efficacy and safety of corticosteroids in the pediatric population are based on the well-established course of effect of corticosteroids, which is similar in pediatric and adult populations. Published studies provide evidence of efficacy and safety in pediatric patients for the treatment of nephrotic syndrome (>2 years of age), and aggressive lymphomas and leukemias (>1 month of age). Other indications for pediatric use of corticosteroids, eg, severe asthma and wheezing, are based on adequate and well-controlled trials conducted in adults, on the premises that the course of the diseases and their pathophysiology are considered to be substantially similar in both populations.

The adverse effects of corticosteroids in pediatric patients are similar to those in adults (see **ADVERSE REACTIONS**). Like adults, pediatric patients should be carefully observed with frequent measurements of blood pressure, weight, height, intraocular pressure, and clinical evaluation for the presence of infection, psychosocial disturbances, thromboembolism, peptic ulcers, cataracts, and osteoporosis. Pediatric patients who are treated with corticosteroids by any route, including systematically administered corticosteroids, may experience a decrease in their growth velocity. This negative impact of corticosteroids on growth has been observed at low systemic doses and in the absence of laboratory evidence of HPA axis suppression (ie, cosyntropin stimulation and basal cortisol plasma levels). Growth velocity may therefore be a more sensitive indicator of systemic corticosteroid exposure in pediatric patients than some commonly used tests of HPA axis function. The linear growth of pediatric patients treated with corticosteroids should be monitored, and the potential growth effects of prolonged treatment should be weighed against clinical benefits obtained and the availability of treatment alternatives. In order to minimize the potential growth effects of corticosteroids, pediatric patients should be titrated to the lowest effective dose.

Geriatric Use No overall differences in safety or effectiveness were observed between elderly subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and young patients, but greater sensitivity of some older individuals cannot be ruled out.

ADVERSE REACTIONS (listed alphabetically, under each subsection)

Allergic Reactions Anaphylactoid reaction, anaphylaxis, angioedema.

Cardiovascular Bradycardia, cardiac arrest, cardiac arrhythmias, cardiac enlargement, circulatory collapse, congestive heart failure, fat embolism, hypertension, hypertrophic cardiomyopathy in premature infants, myocardial rupture following recent myocardial infarction (see **WARNINGS**), pulmonary edema, syncope, tachycardia, thromboembolism, thrombophlebitis, vasculitis.

Dermatologic Acne, allergic dermatitis, cutaneous and subcutaneous atrophy, dry scaly skin, ecchymoses and petechiae, edema, erythema, hyperpigmentation, hypopigmentation, impaired wound healing, increased sweating, rash, sterile abscess, striae, suppressed reactions to skin tests, thin fragile skin, thinning scalp hair, urticaria.

Endocrine Decreased carbohydrate and glucose tolerance, development of cushingoid state, glucosuria, hirsutism, hypertrichosis, increased requirements for insulin or oral hypoglycemic adrenocortical and pituitary unresponsiveness (particularly in times of stress, as in trauma, surgery, or illness), suppression of growth in pediatric patients.

Fluid and Electrolyte Disturbances Congestive heart failure in susceptible patients, fluid retention, hypokalemic alkalosis, potassium loss, sodium retention.

Gastrointestinal Abdominal distention, bowel/bladder dysfunction (after intrathecal administration), elevation in serum liver enzyme levels (usually reversible upon discontinuation), hepatomegaly, increased appetite, nausea, pancreatitis, peptic ulcer with possible perforation and hemorrhage, perforation of the small and large intestine (particularly in patients with inflammatory bowel disease), ulcerative esophagitis.

Metabolic Negative nitrogen balance due to protein catabolism.

Musculoskeletal Aseptic necrosis of femoral and humeral heads, calcinosis (following intra-articular or intralesional use), Charcot-like arthropathy, loss of muscle mass, muscle weakness, osteoporosis, pathologic fracture of long bones, postinjection flare (following intra-articular use), steroid myopathy, tendon rupture, vertebral compression fractures.

Neurologic/Psychiatric Convulsions, depression, emotional instability, euphoria, headache, increased intracranial pressure with papilledema (pseudotumor cerebri) usually following discontinuation of treatment, insomnia, mood swings, neuritis, neuropathy, paresthesia, personality changes, psychic disorders, vertigo. Arachnoiditis, meningitis, paraparesis/paraplegia, and sensory disturbances have occurred after intrathecal administration (see **WARNINGS, Neurologic** section).

Ophthalmic Exophthalmos, glaucoma, increased intraocular pressure, posterior subcapsular cataracts, rare instances of blindness associated with periocular injections.

Other Abnormal fat deposits, decreased resistance to infection, hiccups, increased or decreased motility and number of spermatozoa, malaise, moon face, weight gain.

OVERDOSAGE Treatment of acute overdose is by supportive and symptomatic therapy. For chronic overdosage in the face of severe disease requiring continuous steroid therapy, the dosage of the corticosteroid may be reduced only temporarily, or alternate day treatment may be introduced.

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American Regent, Inc.
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DUAL AGENT Formulation: Fast Acting & Long Lasting

*Betamethasone 6 mg/mL as 3 mg/mL Betamethasone Sodium Phosphate and 3 mg/mL Betamethasone Acetate.

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The intra-articular or soft tissue administration of Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension is indicated as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in acute gouty arthritis, acute and subacute bursitis, acute nonspecific tenosynovitis, epicondylitis, rheumatoid arthritis, synovitis of osteoarthritis.

Important Safety Information: As with any potent corticosteroid, adverse events have been associated with Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, USP, including fluid and electrolyte disturbances, as well as adverse reactions involving the following systems: allergic reactions, cardiovascular, dermatologic, endocrine, gastrointestinal, metabolic, musculoskeletal, neurological/psychiatric, and ophthalmic. Corticosteroids may also affect immune response. Rare instances of anaphylactoid reactions have occurred in patients receiving corticosteroid therapy. **Betamethasone Sodium Phosphate and Betamethasone Acetate Injectable Suspension, USP should not be administered intravenously or used in systemic fungal infections. Vaccination administration of live or live, attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of corticosteroids.** Patients should be warned not to discontinue the use of corticosteroids abruptly or without medical supervision, to advise any medical attendants that they are taking corticosteroids and to seek medical advice at once should they develop fever or other signs of infections. Persons who are on corticosteroids should be warned to avoid exposure to chicken pox or measles and to seek medical advice without delay if exposed.

Please see next page for brief summary of full prescribing information

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ONE LUITPOLD DRIVE | PO BOX 9001 | SHIRLEY, NY 11967 | 800-645-1706 | **www.americanregent.com**

ACO Med Supply
6510 Northpark Blvd.
Charlotte, NC 28216