Ospol's scientific credentials.

Relying on history.

The true biological mechanisms behind osseointegration may still be unknown in part.

Yet, a predictable clinical outcome can be achieved by following a well-documented protocol, covering aspects like surgical and prosthetic procedure, the design of the implant hardware, and the material used to manufacture it. Simply put, the quality of the treatment has come to rely on common and accepted knowledge and science.

Even authorities like the FDA agree. As long as the implant hardware conforms to specific basic requirements, manufacturers can refer to "substantial equivalence" for obtaining registration.

Ospol claims equivalence for several key product features and properties. For these features and properties, we rely on clinical documentation from a number of scientific sources.

The information in these pages describes some of the pertinent features. For further details, please refer to the Ospol White Book, which also contains an extensive list of clinical references.

Responsible innovation.

The challenge of innovating implant dentistry lies largely in the responsible balance between the safety of historical clinical performance and the added benefits of new clinical features.

Another difficulty is finding persuasive, yet ethical, methods to prove that such clinical benefits exist – without adding risk to the equation. For this, most manufacturers rely on extensive pre-clinical and animal data, as well as clinical follow-up after the market introduction of new products.

For dentists, the obvious challenge is to sort through the marketing hype and find real evidence that substantiates the clinical relevance of product innovation.

The Ospol implant surface is such an innovation. The relevance and benefits of its special properties are based both on history and on specific animal studies.

We therefore believe that this is an example of responsible innovation.

Ingeniously simple.

Ospol is implants made easy.

Every single aspect of the Ospol system – implants, packaging, instruments, logistics – aims at maximum simplicity and user-friendliness.

Everything has been conceived and designed from the ground up with those two concepts in mind.

The result is compelling: More efficient implant treatments can be performed in more effective implant clinics.

Ospol is a Swedish implant system – developed and manufactured in the land of safe cars and self-assembly furniture. And just like them, Ospol implants are conquering the world.

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IMPLANTS MADE EASY.

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OSPOL
SMARTER IMPLANT PRACTICE

If you were to simplify implant treatments, where would you start?

Start here.

If your implant clinic is anything like most implant clinics, simplicity and user-friendly are not the first two words that come to mind for characterizing it.

That's because so far, the art of treating patients with implants has been driven first and foremost by product development – rather than process development.

After more than 30 years of evolving implant technology (and successful treatments), you'd think there's little room left for enhancement.

Not so.

Implant systems have indeed become extremely safe and effective for patients. Treatments with titanium implants are currently the most predictable dental therapy of all – with success percentage rates steadily parked in the high 90's.

But today's implant technology has also become extremely complex for dentists.

Most leading systems come with literally thousands of components and tools – plus mountains of accompanying documentation. It makes your work time-consuming, tedious and inefficient. And the clinical, administrative and commercial aspects of your implant practice become a daily uphill battle.

Without fully understanding why, implant clinics are gradually being overwhelmed by the never-ending (and mostly patchy) evolution of the implant systems they use.

This is about to change drastically. All thanks to a clever Swedish idea.

The Ospol implant system is radically different. While offering clinical properties and benefits second to none, it's based on a unique concept of user-friendliness.

It's implants made easy.

All you need is 46 components. (Actually, only 7.)

A more user-friendly implant system.

How many bits and pieces do you really need to perform top-class implant surgery?

A thousand? Two thousand?

The Ospol implant system consists of a single implant screw, three abutments, a cover screw, a healing abutment, one abutment screw and one hexadaptor. That's all.

With a few size variants, you end up with no more than 46 components and instruments. In total.

Nevertheless, you can comfortably meet the clinical needs of at least 80% of all implant patients. And offer them the widest possible choice of prosthetics.

Imagine what such a compact system will do for your practice: The speed of setting up operations. The ease of finding and handling components. And the simplicity of managing supplies.

Implant.

The Ospol implant is a self-tapping screw with a calcium-oxidized titanium surface. Parallel walls facilitate drilling and make handling comfortable and precise. Increased bone fill in the thread of the conical core results in improved primary stability. The implant comes in four lengths, all with a 4.0 mm diameter.

Abutments.

The Ospol abutments have a conical connection – the strongest way of joining metal to metal. The result is a very tight seal with minimal micro-leakage. Three basic versions (each in two heights) are available for cemented prosthetics: standard, anatomic straight and anatomic angled. All are equipped with an octagon for precise indexing – thus facilitating single-tooth restorations.

Abutment screw.

A single one-size abutment screw fits all abutment versions and heights. It's designed with a short thread and long neck to improve the pre-load "rubber-band" effect – with as little as 20 Ncm of torque. In the unlikely event of a breakage, the screw has been designed to snap just below the head, making retrieval of the damaged screw simple.

Hexadaptor.

The Ospol hexadaptor for screw-retained prosthetics links the Ospol implant to a world of prosthetic choices – from straightforward prefab abutments to customized CAD crowns and bridges made in metal or ceramics.

One size fits all. (It's true.)

A more user-friendly instrument kit.

With fewer implant components, you obviously need fewer tools to mount them.

The Ospol instrument kit contains nine tools: a single all-purpose screwdriver, four drills, one implant inserter, one torque wrench, one abutment remover and one hexadaptor remover.

They all fit comfortably on two small custom trays – one for surgery, one for prosthetics – together with the implant components relevant to each.

You get an excellent overview of the entire system. And can instantly determine which component and which instrument to use next.

Drill sequence.

The three main drills are packed in a single sterile kit. There is a special reamer for drilling in high-density bone. Thanks to the parallel walls of the implant, drills are cylindrical and easier to use. The guide drill makes it easy to mark the implant site with precision – and provides a first impression of the bone quality.

Implant inserter.

A unique metal locking ring makes it easy and safe to pick up the implants from their protective casings. The tip of the inserter is shaped to fit cover screws and healing abutments as well – reducing tool changes to a minimum.

Torque wrench.

The user-friendly Ospol torque wrench is turned until the desired torque value is displayed. It clicks onto the manual screwdriver to facilitate handling. And few moving parts make the wrench easy to clean and sterilize.

Abutment remover.

Whenever a change of abutment is required, this instrument makes removal remarkably easy. Ospol abutments have a unique internal thread that the remover uses for leverage. This makes separation from the implant effortless.

Trays.

The two clinical trays are very compact – only A5 (8"x 6"). Stainless steel, aluminum liner and titanium bowls give the trays optimum weight and stability, and make them easy to clean. Both trays have custom slots for instruments and implants.

Unexpectedly awarded simplicity.

A more user-friendly packaging system.

Ospol's award-winning packaging system looks like nothing you've ever seen before. Nor does it handle like anything you've ever handled before.

But it will dramatically simplify your clinical work and make your practice a more organized place.

From the oval shape and slanted top of the component container to the size and opening angle of the storage binder – everything has been meticulously designed for maximum simplicity, comfort and efficiency.

One type of container for all components. One type of storage binder. One type of ID label (easy-to-read, needless to say). You'll be amazed at how well it all fits together.

Container.

The same basic Ospol container is used for all implants, abutments, drills, cover screws and healing abutments. The exact content is clearly described on the top cover. Inside is a metal casing that protects the implants and allows no-touch pickup and transfer to the surgical tray. This keeps them protected until the very last moment before insertion.

Identification.

Each container is marked with text and a few symbols on the top cover, clearly identifying the content. On the side is a barcode automating the same task by being scannable.

Binder.

The containers are kept in the Ospol product binder. Executed in standard A4 size (8"x11.5"), each binder holds up to 42 products. This means that a normal inventory for an average implant practice fits in four binders.

Storage.

The binders are easily stored, like any other binder, in any standard bookcase. As a result, the entire four-binder inventory uses less than 200 mm (7.5") of shelf space in all.

The barcode miracle.

A more user-friendly logistics system.

The Ospol implant system comes with a handheld scanner that plugs into your computer.

It reads barcodes – a rather indispensable asset for every implant surgeon.

You'll find barcodes on every component container you receive from Ospol.

They are the core of the Ospol Business Platform, an easy-to-use Internet-based logistics system. It monitors your inventory, tells you what and when to order, keeps an eye on incurrency dates – and provides many other useful services.

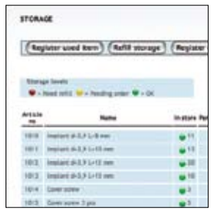
The every-day impact on your practice should not be underestimated.

Inventory manager.

An individual login code provides instant access to a personal inventory manager in the Ospol Business Platform. In addition to viewing the current inventory status, minimum and maximum stock levels can be set to match actual treatment volumes.

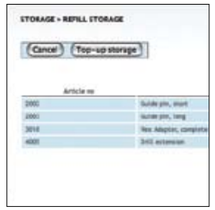
Overview.

The inventory is exact and always up-to-date. Products running low are signaled, along with products on order and their scheduled delivery dates. In-depth product descriptions are also provided at the click of a key.



Stock updates.

After treatment, all empty containers are scanned into the system. This instantly updates the inventory by subtracting the components used.



Order entry.

When a component reaches its minimum stock level, a refill suggestion is displayed, bringing the stock up to the preset max level. If the suggestion is accepted, a replacement order is sent to Ospol, for delivery within 48 hours. (Naturally, you can also place individual ad-hoc orders anytime.)

Simplicity in practice.

A day in the life of an Ospol user.

The following takes place in an implant clinic in central Sweden – probably not too different from yours.

Two implant dentists (performing both surgery and prosthetics). Three dental assistants. Together they treat some 50 patients every year, who receive a total of around 150 implants. The patient base is primarily their own.

The clinic has used several leading implant systems in the past. In 2007, it decided to try Ospol.

And all of a sudden, this clinic became quite different from yours.

Preparation.

Ulla, the OR assistant, preps the patient and pulls out the Ospol binder. She also prepares the Ospol tray by setting up the relevant instruments.

Operation.

Anders, the dentist, undertakes the operation. Using the Ospol drill sequence, he drills down to the mark that matches the pre-determined implant length, according to x-rays.

Selection.

Lena, the circulating assistant, now picks the relevant implants (in this case two 10 mm and two 12 mm) from the binder. Because this treatment involves one-stage surgery, she also finds four low-profile healing abutments in the binder. She opens the eight containers and places the protective casings on the tray.

Insertion.

As the operation proceeds, Anders picks up implants and healing abutments with the same instrument – the Ospol implant inserter.

Wrap-up.

Anders then uses the one-size Ospol screwdriver to perform the final tightening of the healing abutments. (He uses the same instrument for cover screws, abutment screws and impression copings).

Inventory update.

When surgery is completed, Lena returns to collect all empty containers (including the drill container). She logs into the Ospol Business Platform to update the inventory with the products used. She also makes a printout of the products to include in the patient file, for future reference and tracking.

Replacement order.

Lena notices a red dot on the screen, signaling that the stock of 12-mm implants is now low. After checking with Anders, she places a refill order with a single click. Within 48 hours, the package arrives from Ospol by post. Lena keys in the package number, which automatically updates the inventory.

Substantial equivalence...

Clinical reports on implant technology, published in major scientific journals, mostly revolve around screw-shaped titanium implants – essentially similar to the Ospol implants.

Systems preceding Ospol's have proven in study after study to be at least as successful as the original Brånemark® System.

This collective empirical platform is the foundation to Ospol's claims of substantial equivalence (in FDA terms) for several major system properties.

Implant design.

The Ospol implant is screw-shaped – by far the most common macro-shape for dental implants. The core is slightly tapered, while the outer threaded profile is cylindrical. This design combines the comfortable placement of a cylindrical implant body with the greater stability of a tapered implant.

The Ospol implant is also self-tapping, which preserves bone mass and optimizes bone fill through the thread. The thread continues all the way up, to provide additional stability in the crucial cortical bone.

Cylindrical thread, conical core.

Conical abutment connection.

The Ospol abutments have a conical connection design with a separate center screw. This creates a mechanically stable and sealed connection between the implant body and the abutment.

The cone shape provides the most stable mechanical joint between two metal parts. It also creates a tight seal and minimizes stress in the marginal bone, by distributing the functional load.

Conical connection for maximum strength.

Titanium in bone.

The Ospol implant is made of Cp titanium Grade IV – the strongest grade of pure titanium. The surface is anodized to provide increased roughness, as this has been proven to improve osseointegration, compared with machined surfaces.

Bone tissue growing onto a titanium surface.

...with a rather nice twist.

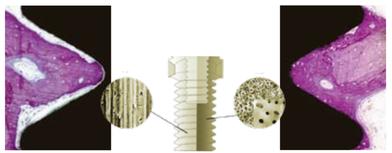
The Ospol implant system introduces several new, innovative (sometimes proprietary) features and properties. The most far-reaching of these is a new implant surface, which in consistent pre-clinical studies has induced an acceleration of early bone apposition.

A new Ospol surface.

Oxidizing the implant surface is currently a common method for achieving surface enlargement, in order to improve the mechanical interlocking between bone and implant. Several manufacturers use this modification technique, among them Nobel Biocare with its TiUnite surface.

Other attempts have also been made at increasing the bio-activity of the surface, in order to increase the speed and quality of bone apposition to the implant. Examples include Straumann's SLActive surface, AstraTech's Osseospeed surface (with fluoride incorporated), and 3i´s Nanotite with particles of calcium phosphate added.

Decades of research at the University of Gothenburg, Sweden, has been conducted in pursuit of an implant surface with controlled chemical and physical properties.



Histology has showed that a machined implant (left) has significantly less close contact with the bone than the calcium-oxidized Ospol implant (right) after six weeks.

Theory and research.

Dr. Young Taeg Sul, Department of Biomaterial Sciences at the University of Gothenburg, Sweden, has focused his research and thesis on methods to optimize the mechanical and chemical properties of implant surfaces.

Research and clinical evidence have shown that the mechanical properties of an oxidized surface improve osseointegration compared to machined surfaces – especially

in compromised bone. Dr. Sul has shown in animal studies that bone response can be further enhanced by incorporating calcium ions in the outermost surface layer.

The Ospol implant surface is oxidized with calcium ions present in the electrolyte. The end result is a well-defined titanium-oxide surface, whose1-2 µm thick coat contains 11% calcium ions in the outermost layer.

Documented results.

Experiences from various research laboratories have shown that the femur and tibia of rabbits constitute a model that most appropriately replicates bone healing in man. This model is therefore routinely used for studying bone reactions to implantable materials and devices. The model is standardized, allowing data to be compared between laboratories and over time.

The following are major pre-clinical and animal studies involving the Ospol implant surface:

Sul YT. The significance of the surface properties of oxidized titanium to the bone response: special emphasis on the potential biochemical bonding of oxidized titanium implants. Biomaterials 2003;24:3893-3907.

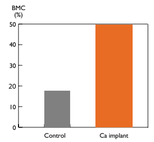
Sul YT, Byon ES, Jeong Y. Biomechanical measurements of calcium-incorporated oxidized implants in rabbit bone: effect of calcium surface chemistry of a novel implant. Clin Implant Dent Rel Res. 2004;6(2):101-110.

Fröjd V, Franke-Stenport V, Meirelles L, Wennerberg A. Increased bone contact to a calcium reinforced oxidized c.p. titanium implant: an in vivo study in rabbit. In manus

Sul YT, Johansson CB, Albrektsson T. Oxidized titanium screws coated with calcium ions and their performance in rabbit bone. Int J Maxillofac Implants A 2002;17(5):625-634.

Sul YT, Johansson CB, Jeong Y, Wennerberg A, Albrektsson T. Resonance frequency and removal torque analysis of implants with turned and anodized surface oxides. Clin Oral Implants Res. B. 2002;13(3):252-259.

Sul YT, Johansson CB, Kang Y, Jeong DG, Albrektsson T. Bone reactions to oxidized titanium implants with electrochemical anion sulphuric acid and phosphoric acid incorporation. Clin Implant Dent Relat Res. C 2002;4(2):78-87.



Implants with a calcium-oxidized surface have showed significantly improved early stability compared with machine-surfaced control implants.

The bone-to-metal contact value (BMC) more than doubled (above), while the removal torque increased by one-third (below).