DR. HOLT: Good Afternoon. Welcome to the 2007 Xoft Electronic Brachytherapy Symposium. My name's Randy Holt. I'm pleased to be here today. With me, we're pleased to have three fine speakers who are going to talk to us about breast brachytherapy and about electronic brachytherapy using the Axxent Electronic Brachytherapy System. Just as a quick note, I am a consultant with Xoft and a few others, so I need to disclose that up front. I'm really enjoying myself in Minnesota. It's kind of fun because I've learned a few things. I don't know if you all know that this punctuation mark actually has a pronunciation. Up here it's pronounced "a." These punctuation marks - we all know what it's really called, ellipsis, also has a pronunciation. It's "ya ya ya." Let me talk about Xoft a little bit. Xoft is a privately held company, venture-funded in Fremont, California. It was founded almost nine years ago to utilize a miniaturized x-ray tube for medical purposes. Initially it was designed for use in intravascular brachytherapy, but accelerated partial breast irradiation was chosen five years ago for the first clinical applications. It received FDA clearance two years ago - almost two years ago. And as of March this year, our first human patient was treated. We're currently doing a roll out study, a post-market evaluation with an initial nine clinical sites. There are currently three centers that are treating. Two more centers are very close to ready for treating, just looking for the right patients. And there are seven patients that have been treated to date. The idea of this study is to collect and review the results and experience of the initial 40 patients, taking the surgeons' experiences and opinions, along with the oncologists and especially the medical physicists, so that we can combine and share innovative new techniques for measurement, as well as applications. Let me describe to - the Xoft Axxent APBI System. The main components are a controller with a very user-friendly interface. The controller has an armature where the source, which is a disposable applicator, falls. Unfortunately, one of the slides fell off that was showing the balloon, which I'll show in a moment. The source is a disposable high dose rate x-ray source. It emulates iridium-192 at the prescription point. The balloon, which I mentioned, is also a key component of breast brachytherapy. Multiple balloon sizes and shapes are available. One of the key issues with this balloon that's different than any other is that it does have a drainage port valve. Along with the balloon inflation and the source lumen, it also has drainage holes so that seroma or other non-conforming tissue can be drained and hence improve the wall attachment to the PTV - the wall conformants to the PTV. The balloon itself has imbedded in the wall of the balloon barium sulfate, a radiolucent, so that it's a radiolucent balloon wall; shows up very nicely on kV diagnostic images, as well as the CT. The controller is pretty much a kilovoltage controlling system; delivers power to the brachytherapy source. It also - the armature steps the dwell positions back from the distal to the proximal end. It's pretty much responsible for the overall system operation. The dwell times are loaded in and the source positions are loaded in. That output can be brought in from conventional brachytherapy systems. The source is characterized by the TG-43 parameter formalism, which has been published by the Rivard group. The source itself is really one of the exciting aspects of this. It has tremendous potential, I think, 2.2 ml in diameter. You can see the length of it, as well. Completely - it's fully disposable, intended for one source per patient; can be operated at various kilovoltages, so we're able to tune that. Currently, we're just looking at 50 kV for this initial study. It's not a radioactive source, which is very exciting because, as we know, the nuclear regulatory issues are becoming pretty heavy for everyone, yet it almost completely mimics iridium dose rate, although it does fall off a little bit faster. The RBE with 50 kV is very similar to iodine-125 down in a mean energy range of 28 to 30 kV. Treatment times are very comparable to a fresh iridium source, so that there's - there are no length decay times as the source gets older and older by the end of three or four months. The source itself has anode-cathode and then is - the high voltage cable that comes down, it's surrounded by a cooling tube that, as you can see here, the high voltage connection, then you also have the cooling connections, it is important to keep this source fairly well cooled so that - because there's a tremendous power output there. As I mentioned, there's a TG-43 dose rate. This is the shape of that dose rate of the Xoft 700 source at 50 kVp. Of course, inverse squares, a linear - a line model inverse squares, two-dimensional attenuation in the polar angle with azimuthal symmetry. One of the interesting things about this shape you'll notice is that there is no tip anisotropy, there's no dimple at the tip, which is what you would see with an iridium source. The dark region, of course, is somewhere where we can't adequately or reasonably measure, but that's okay because it's only 0.5 cm away and we aren't typically treating in that region. Our balloons are much bigger than that. Brachytherapy system - one of the major advantages, as it is in the 50 kV region, is a limited shielding requirements. This means that we don't have to tie up a vault. The operator can be very close to the patient with some adequate shielding and convert - pretty much be used either in the CT room, the kV sim room, and simply operates off of a standard electrical outlet. The treatment planning is really quite straight forward. It's - we're currently validated clinically on both PLATO and BrachyVision. Treatment plans come straight from CT images. Of course, we - the APBI twice daily conformation balloon integrity is part of the regimen and we're currently recommending the same - this is recommended for the same fractionation that other APBI regimens are, 3.4 Gy X 10 fractions.