

Request for Extension of AOS 5979 Package

Presentation to the NRC
April 11, 2012

*Human Care Makes
the Future Possible*

Annelie Rosén, Elekta Instrument AB
Bob A. Robnett, Alpha Omega Services



Agenda

1. Attendee introductions
2. Introduction to the Leksell Gamma Knife, Cask, and Loading Machine
3. Cask manufacturing time schedule
4. Loading machine design modifications and time schedule
5. Consequences of time schedule including mitigations
6. Request for time extension to use the 5979 cask

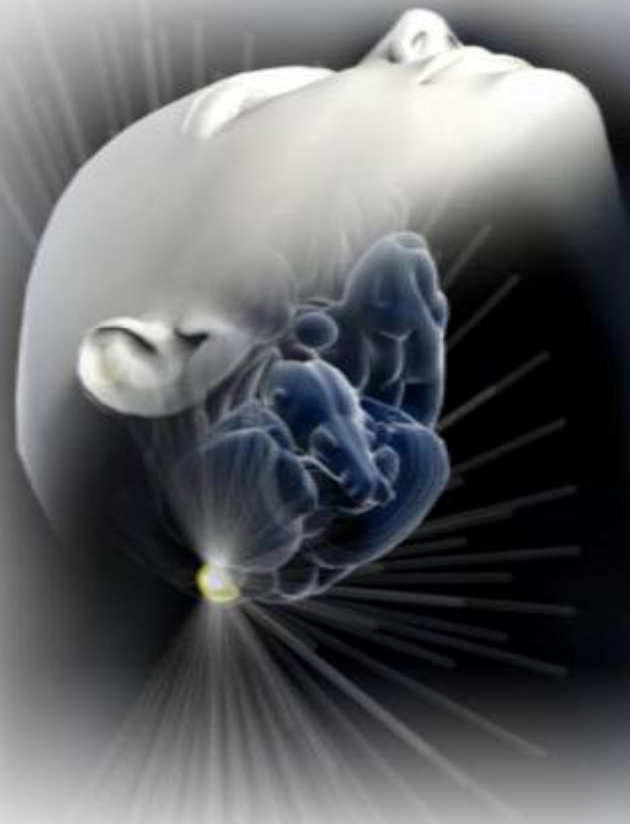
Attendee Introductions

- Annelie Rosén
Purchasing Manager
Elekta Instrument AB
- Jan Wrigfors
Manufacturing Engineer
Elekta Instrument AB
- Bob A. Robnett
Director Regulatory Affairs & Quality
Alpha-Omega Services, Inc.

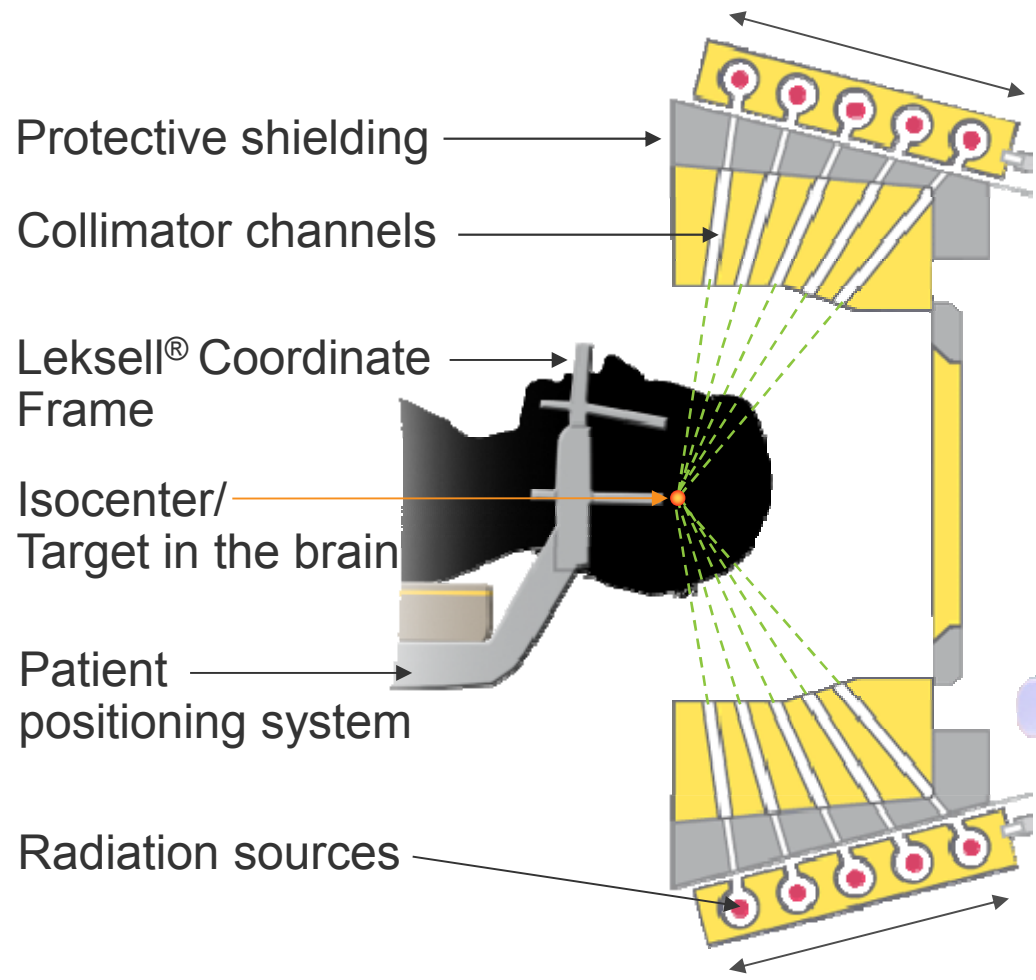
Leksell Gamma Knife®

- the gold standard for intracranial radiosurgery

The delivery of a high dose of irradiation to a small and critically located intracranial volume through the intact skull



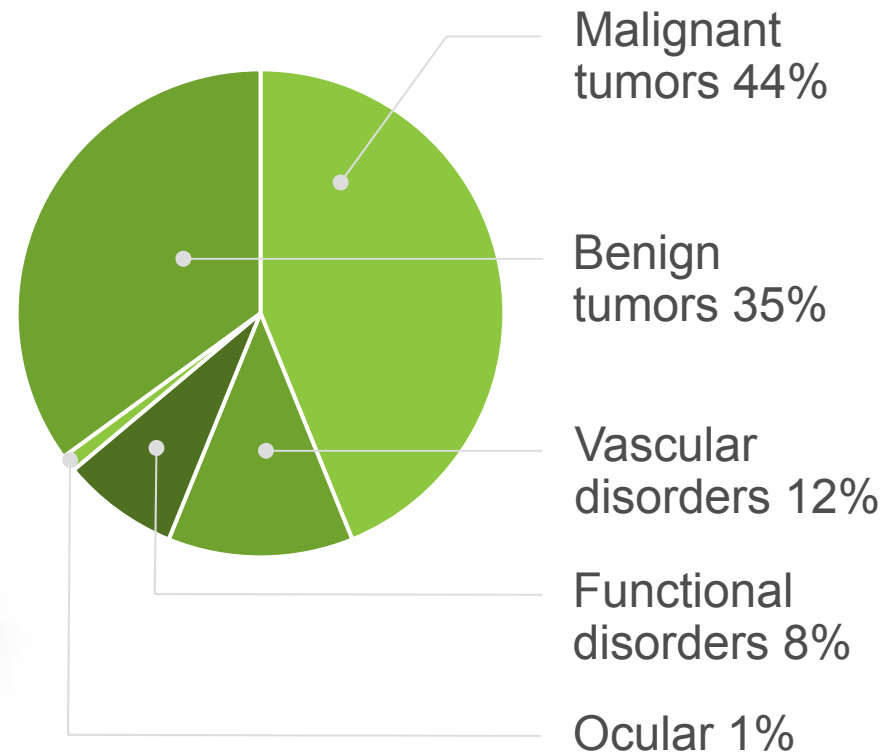
Gamma Knife[®] radiosurgery - principles



Treated with Leksell Gamma Knife®



**Over 600,000 patients treated
- expanding by 60,000 annually**



Installed base Leksell Gamma Knife – May 2011

117 units in the US and 282 units world-wide



Introduction to the Leksell Gamma Knife, Cask, and Loading Machine

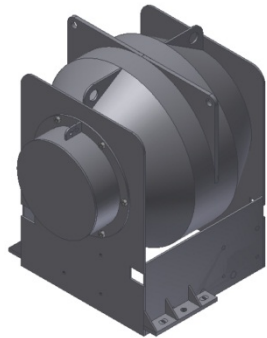
- There are several types of Leksell Gamma Knife units
 - LGK U – one site in the US remaining
 - LGK B, LGK C and LGK Perfexion – 120 sites in operation in the US
- The LGK U makes use of a temporarily built hotcell for loading/unloading, whereas the LGK B, C and Perfexion are loaded/unloaded using a loading machine
- The loading machine is docked to the Leksell Gamma Knife, the cask is inserted under the loading machine and the sources are taken from the cask and inserted into the LGK via use of manipulators

Introduction to the Leksell Gamma Knife, Cask, and Loading Machine

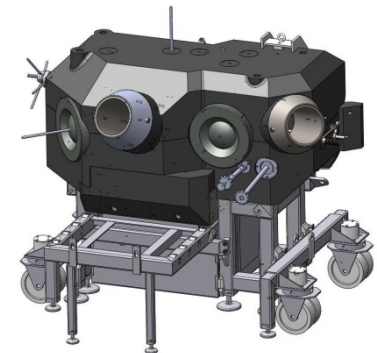
The Leksell Gamma Knife, the AOS 5979 Cask and the Loading Machine must all be on site simultaneously



Leksell Gamma Knife



AOS 5979 Cask



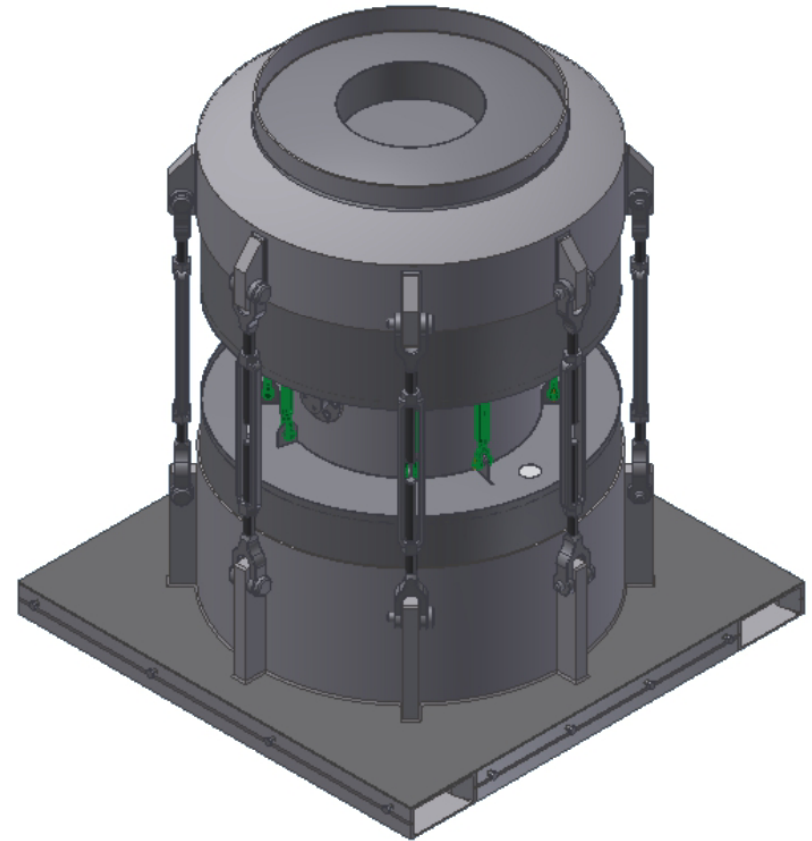
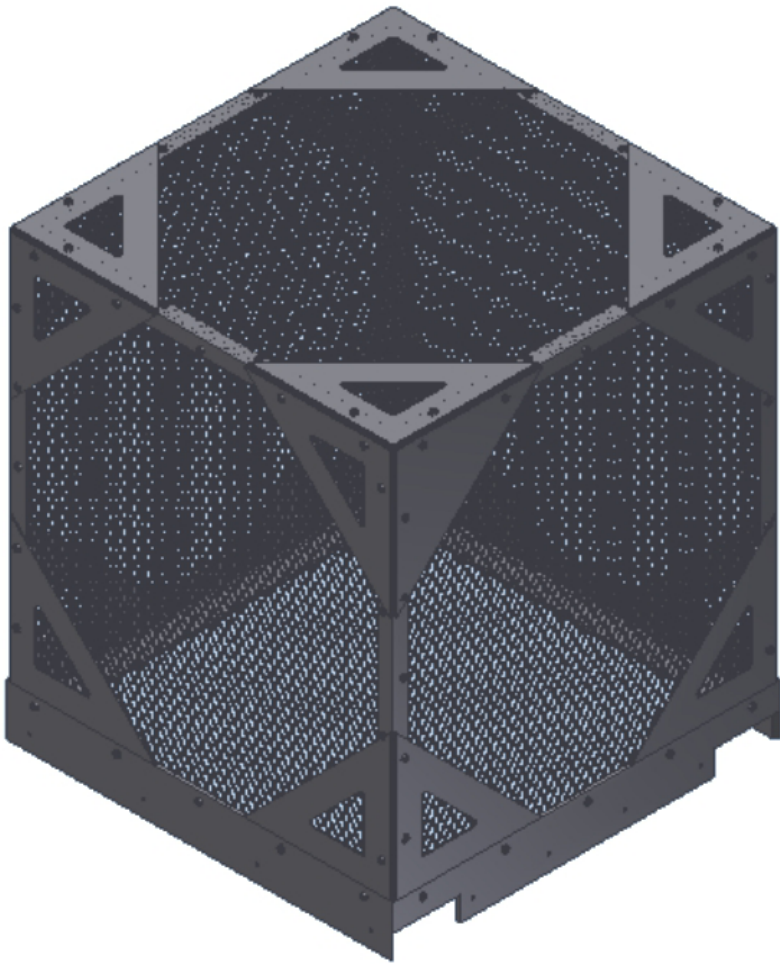
Loading Machine

AOS-100 Cask Manufacturing Schedule

AOS-100 Schedule										
Activity	2012									
	Q1		Q2			Q3		Q4		
Receive License		■								
Casks & Impact Limiters Manufacturing			■	■	■	■				
Pallet, Cage, & Tie Down System Manufacturing				■	■	■	■			
Leak Testing							■			
Thermal Testing							■			
Training								■		

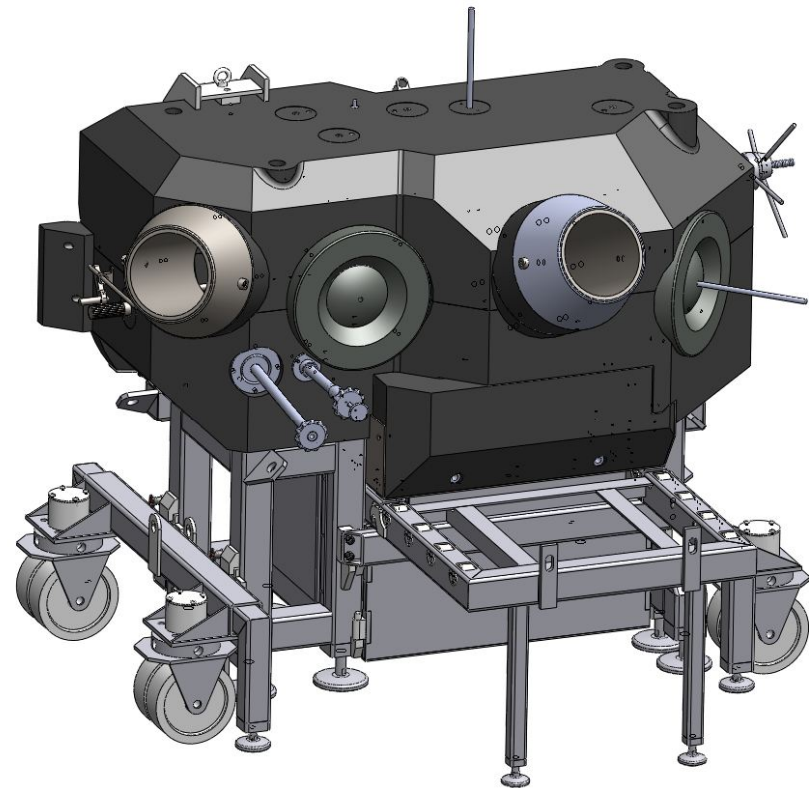
NOTE: The Pallet, Cage, & Tie Down System manufacturing has been delayed due to issues resulting from welding of the specified materials. In the original design it was to be constructed of aluminum, which would not retain its strength in the weld zone. The system is being quoted using stainless steel.

AOS-100 Cask Pallet, Cage, & Tie Down System



Loading Machine Design Modifications And Time Schedule

- Loading machine design modifications include:
 - Compatibility with a wider and higher cask
 - Compatibility with a longer lid



Design of modified loading machine

Loading machine design modifications and time schedule

The modified loading machine is expected to be ready in mid November 2012. Transportation from Sweden to the US takes approx. one additional month.

Activity		2011				2012			
		Q3	Q4	Q1	Q2	Q3	Q4		
	Project Go Ahead/AOS-100 license issued	▼		▼					
	Design Phase								
	Concept / Preliminary Design	■		▼					
	Systems Req. Spec. established				■				
	Detailed Design				■				
	Freeze Long Lead Time Item (casting, lead parts)			▼					
	Freeze Long Lead Time Item (machining, lead parts)				▼				
	Manufacturing								
	Long Lead Time Item (casting, lead parts)				■				
	Long Lead Time Item (machining, lead parts)					■			
	Assembly (Loading Machine Complete)							■	
	Verification and Validation								▼

Consequences and mitigations

With the current license expiry of June 30, 2012, the following consequences and mitigations are likely:

- Gamma Knife loading/unloading disrupted or stopped
- Delays and/or suspension of life saving procedures
- Partial mitigation by importing foreign sources
- Limitations in site approvals regarding foreign Co-60 vendors
- Use of foreign sources will cause delays and/or suspension of international life-saving procedures

Request for extension to use the 5979 cask

- Current Authorization of Limited Shipments allows for 42 shipments between 1NOV11 and 30JUN12.
- 22 of the 42 authorized shipments will have taken place by 30JUN12.
- AOS requests a time extension until 31DEC12 to allow for the remaining 20 shipments.
- The following 13 jobs consists of 21 shipments (13 new sources sets and 8 spent source sets).

Gamma Knife Loads/Unloads 1JUL12 – 31DEC12	
Cleveland Clinic Foundation: Cleveland, OH Akron General Medical Center: Akron, OH University of Minnesota: Fairview, MN Barrow Neurological Institute St. Joseph: Phoenix, AZ West Houston Medical Center: Houston, TX Sacred Heart: Pensacola, FL Jewish Hospital: Cincinnati, OH	UCSF: San Francisco, CA Florida Hospital: Orlando, FL Piedmont Hospital: Atlanta, GA Louisiana State University: Shreveport, LA William Beaumont Hospital: Royal Oak, MI Legacy Good Samaritan: Portland, OR

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