General Talking Points and Q&A
InCise™ 2 MLC FDA 510(k) Clearance and CE Mark
EIMEA Region

These talking points are to be used to support introduction and discussion of the InCise™ 2 MLC with current and potential customers following receipt of 510(k) clearance from FDA and CE Mark in the European Union.

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If you are asked a question that isn't listed, please capture the person's contact information and question, and inform them that we will follow-up with a response. Please send the information to:

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Incise™ 2 MLC Talking Points – EIMEA Region
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Background and Status

Product Development

- We continuously evaluate our products in order to meet our customers' needs long-term.
- We conducted a rigorous evaluation of the InCise™ MLC covering a wide range of functionality, performance, reliability and serviceability parameters.
- The InCise MLC successfully met performance criteria and was launched commercially; in the process of evaluation we identified opportunities to enhance the product design, long-term reliability, serviceability and manufacturing scalability.
- We implemented these changes in an updated version of the MLC, which we will refer to as the InCise 2 Multileaf Collimator.
- Because of the design changes we made, we were required to submit a 510(k) to the U.S. Food and Drug Administration (FDA) prior to marketing this product; we received clearance to market the InCise 2 MLC on July 1, 2015.
- Accuray CE marked the InCise 2 MLC in the European Union in June 2015.

Product Availability

- As with the InCise MLC, before we proceed with broad rollout of the InCise 2 MLC we will undertake a rigorous evaluation of the device covering a wide range of functionality and performance parameters with several partner customer sites in the U.S. and Europe.
- Once the evaluation has been completed to Accuray's and the sites' full satisfaction we will make the InCise 2 MLC available to current and potential customers.
  - The InCise 2 MLC is expected to provide improvements in long-term reliability and serviceability compared to the original InCise MLC. Additionally, the InCise 2 MLC includes a number of design enhancements.
  - As a result, it is the intent of Accuray to fulfill our backlog of MLC orders with the InCise 2 MLC.
- Customers who have already received the original InCise MLC will be contacted to discuss upgrading their CyberKnife® M6™ Systems with the InCise 2 MLC.

InCise™ 2 MLC External Talking Points

InCise 2 MLC Program Overview

- Accuray continuously evaluates our products in order to meet our customers' needs long-term.
- Accuray conducted a rigorous evaluation of the InCise™ MLC covering a wide range of functionality, performance, reliability and serviceability parameters.
- The InCise MLC successfully met performance criteria and was launched commercially; in the process of evaluation we identified opportunities to enhance manufacturing scalability and long-term reliability.
- We expedited development and received 510(k) clearance from the FDA on July 1, 2015 to market an updated version of the MLC, the InCise 2 MLC.
- Accuray CE marked the InCise 2 MLC in the European Union in June 2015.
- Before we proceed with a commercial launch of the InCise 2 MLC, we will undertake a rigorous evaluation of the device covering a wide range of functionality and performance parameters.

Product Summary

- Our goal is to provide clinicians with innovative technology that helps them to deliver the best possible care to their patients. The CyberKnife® M6™ System continues to be the only robotic platform with a multileaf collimator, offering distinct advantages to both healthcare professionals and patients.
- As with the InCise MLC, we believe clinicians using the InCise 2 MLC will be able to deliver the same precise radiosurgery treatments they have come to expect with the CyberKnife System, while significantly reducing treatment times, for a wider range of tumor types.
- While delivering extremely precise treatments, the InCise 2 MLC is expected to provide improvements in long-term reliability and serviceability compared to the original InCise MLC. Additionally, the InCise 2 MLC features a number of design enhancements, including (but not limited to):
  - A camera-based secondary leaf position verification system;
  - A simpler, more stable drive train assembly; and
  - Robust ball bearing-based leaf guide tracks.

Product Specifics (Customers who have received the InCise MLC and those with an MLC on backorder)

- The InCise 2 MLC has fewer leaves than the InCise MLC with a similar field size. The change was made to help improve product stability and enhance serviceability, which will further contribute to long-term product quality and performance.
- Accuray internal testing indicates minor differences that are not likely to be clinically significant in terms of treatment plan dosimetry, when comparing the InCise 2 MLC to the original InCise MLC.
- Accuray conducted an internal evaluation of treatment plans generated for the InCise MLC, InCise 2 MLC and Fixed/Iris™ Collimators comparing the conformality index (CI), organ at risk (OAR) dose-volume indices and treatment times.
  - Results indicate:
    - In terms of conformality and avoidance of OARs, the InCise MLC and InCise 2 MLC plans are virtually identical.
    - MLC plans (either InCise or InCise 2) are much more time efficient than Fixed Collimator/Iris plans in all tested clinical cases.
    - The exchangeability of fixed, Iris and MLC collimators is an important feature of the CyberKnife M6 System. This feature gives clinicians the freedom to choose the collimator best suited to a particular clinical situation.

Incise™ 2 MLC Talking Points – EIMEA Region
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Product Summary and Specifics (Potential MLC customers)

- Our goal is to provide clinicians with innovative technology that helps them to deliver the best possible care to their patients. The CyberKnife® M6™ System continues to be the only robotic platform with a multileaf collimator, offering distinct advantages to both healthcare professionals and patients.
- The InCise™ 2 MLC will enable clinicians to deliver the same precise radiosurgery treatments they have come to expect with the CyberKnife System, while significantly reducing treatment times, for a wider range of tumor types, including larger and different kinds of tumors than were previously treated.
- The InCise 2 MLC has been designed to ensure long-term reliability and serviceability, and the device includes a range of features to help ensure consistency and accuracy of beam delivery.
- Accuray conducted an internal evaluation of treatment plans generated for the InCise 2 MLC and Fixed/Iris™ Collimators comparing the conformality index (CI), organ at risk (OAR) dose-volume indices and treatment times.
    - Results indicate:
        - InCise 2 MLC plans are much more time efficient than Fixed Collimator/Iris plans in all cases.
        - The exchangeability of fixed, Iris and MLC collimators is an important feature of the CyberKnife M6 System. This feature gives clinicians the freedom to choose the collimator best suited to a particular clinical situation.

InCise™ 2 MLC

Q1. Why are you introducing the InCise™ 2 MLC?

A1. While the InCise™ MLC successfully met performance criteria and was launched commercially, in the process of evaluation we identified opportunities to enhance the product design, long-term reliability, serviceability and manufacturing scalability.

Q2. What are the differences between the InCise 2 MLC and the InCise MLC you recently launched?

A2. Our goal is to provide clinicians with an MLC with performance that is comparable to or better than the InCise MLC, along with improved durability, reliability and serviceability, and features that improve manufacturing scalability.

The InCise 2 MLC has fewer leaves than the InCise MLC with a similar field size. This change was made to help improve product stability and enhance serviceability, which will further contribute to long-term product quality and performance. Accuray internal testing indicates minor differences that are not likely to be clinically significant in terms of treatment plan dosimetry, when comparing the InCise 2 MLC to the original InCise MLC.

Accuray conducted an internal evaluation of treatment plans generated for the InCise MLC, InCise 2 MLC and Fixed/Iris™ Collimators comparing the conformality index (CI), organ at risk (OAR) dose-volume indices and treatment times.

- Results indicate:
  - In terms of conformality and avoidance of OARs, the InCise MLC and InCise 2 MLC plans are almost identical.
  - MLC plans (either InCise or InCise 2) are much more time efficient than Fixed Collimator/Iris plans in all tested clinical cases.
  - The exchangeability of fixed, Iris and MLC collimators is an important feature of the CyberKnife M6 System. This feature gives clinicians the freedom to choose the collimator best suited to a particular clinical situation.

Q3. Will the use of the InCise 2 MLC result in any clinical differences compared to the MLC?

A3. Accuray conducted an internal evaluation of treatment plans generated for the InCise MLC, InCise 2 MLC and Fixed/Iris™ Collimators comparing the conformality index (CI), organ at risk (OAR) dose-volume indices and treatment times.

- Results indicate:
  - In terms of conformality and avoidance of OARs, the MLC and InCise 2 MLC plans are virtually identical.
  - MLC plans are much more time efficient than Fixed Collimator/Iris plans in all cases.
  - The exchangeability of fixed, Iris and MLC collimators is an important feature of the CyberKnife M6 System. This feature gives clinicians the freedom to choose the collimator best suited to a particular clinical situation.

As with the InCise MLC, we believe clinicians using the InCise 2 MLC will be able to deliver the same precise radiosurgery treatments they have come to expect with the CyberKnife System, while significantly reducing treatment times, for a wider range of tumor types.

InCise™ 2 MLC (contd.)

Q4. Will Monte Carlo dose calculation be available for InCise 2 MLC treatment plans?

A4. Monte Carlo dose calculation for the InCise 2 MLC is not part of the initial product release. It is planned as part of a future purchasable upgrade to the CyberKnife® Treatment Planning System. We will inform you of timing, availability and pricing this upgrade when that information is available.

Evaluation Program

Q5. Why are you initiating an evaluation of the InCise 2 MLC?

A5. We continuously evaluate our products in order to meet our customers' needs long-term. In particular, when introducing new or significantly updated technology, we complete a rigorous evaluation of that technology with clinical partners to ensure optimum product quality and performance. In addition, the evaluation will enable us to verify our operational and logistical processes in support of the InCise 2 MLC.

Q6. How many evaluation sites do you plan to work with?

A6. Our plan calls for several partner sites located in the U.S. and Europe. Feedback and working experience from the sites will guide our next steps.

Q7. Which customer sites are testing the InCise 2 MLC?

A7. Both Accuray and the customers involved have signed non-disclosure agreements specifying we will not disclose their location or confirm their involvement, so we will NOT be divulging this information.

Q8. How were the sites selected to participate in the evaluation?

A8. Participating sites were selected based on several criteria including that the sites:

- Have a CyberKnife® M6™ system and experience using it (preferably >6 months including previous CyberKnife System experience);
- Have strong physics support (experience and bandwidth); and
- Have a patient load that predicts substantial MLC usage soon after the physics tests conclude (either high absolute patient volume or a high percentage of patients that are candidates for treatment with the MLC).

We also considered the following:

- Accuray history of working with the site (predictability of compliance with a tight timeline), if possible.

Q9. How long will it take to complete the evaluation?

A9. Overall timing will depend on a variety of factors including resource availability and physics staff workflow capacity. We anticipate that it will take each site approximately three months to complete the evaluation.

Q10. When will clinical data on the InCise 2 MLC be available?

A10. We expect to obtain clinical data later this calendar year. Availability of clinical data depends on treatment schedules and the ability of InCise 2 MLC sites to share clinical information.

Q11. When will the InCise™ 2 MLC be available for other customers?

A11. The availability of the InCise 2 MLC will depend on the result of the field evaluations; it is premature to speculate on an exact date, though we anticipate availability in the fall of 2015.

Availability and Pricing

Q12. What will happen with customers who already received the original InCise MLC?

A12. Customers who have already received the original InCise MLC will be contacted to discuss upgrading their CyberKnife® M6™ System with the InCise 2 MLC.

Q13. Will sites that have an MLC on order receive the InCise MLC or the InCise 2 MLC?

A13. The InCise 2 MLC is expected to provide improvements in long-term reliability and serviceability compared to the original InCise MLC. Additionally, the InCise 2 MLC includes a number of design enhancements.

Q14. What happens if a site that has an MLC on order doesn't want an InCise 2 MLC?

A14. The InCise 2 MLC provides a number of improvements as compared to the original InCise MLC and we will transition to selling only the InCise 2 MLC.

Q15. Will sites that ordered an MLC need to cancel their order to receive an InCise2 MLC?

A15. No, a new purchase order will not be required. MLC orders in backlog will automatically be fulfilled with the InCise 2 MLC.

Q16. When the InCise 2 is commercially available, will you sell both this product and the InCise MLC?

A16. The InCise 2 MLC provides a number of improvements as compared to the original InCise MLC and we will focus on selling the InCise 2 MLC going forward.

Q17. What would happen to the global commercial launch if there is an unexpected technical outcome from an evaluation site using the InCise 2 MLC?

A17. Per Accuray standard operating procedure, we would thoroughly investigate, perform a detailed risk analysis and take appropriate action as necessary. Next steps would be determined based on the nature of the unexpected outcome.

Q18. How will the InCise 2 MLC shipment schedule be determined?

A18. We will generally fulfill MLC orders in the same order they were received, based on customer readiness and resource availability.

The commercial release timing for the InCise 2 MLC will depend on the result of the field evaluations. We will provide information on availability and shipment schedules once the evaluation program has been completed.

Q19. What is the cost of the InCise 2 MLC?

A19. Pricing information is available through the normal Accuray sales quote process. There is no change in price between the InCise MLC and InCise 2 MLC.

Marketing Support

Q20. What sales tools are available to educate clinicians about the InCise™ 2 MLC?

A20. When the InCise 2 is launched we will provide a variety of materials to support sales efforts. These materials will be uploaded to a folder located in the Marketing Communications section of SharePoint and will be launched through the normal channels (WebEx etc).

Please contact your regional marketing team for more specifics:

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Misc.

Q21. What type of results are clinicians seeing with the InCise MLC?

A21. Actual treatment times reported by customers, by case type are below. These real-world examples are consistent with the MLC technical evaluation site experience.

Case Type	Treatment Type	MLC Treatment Times	Fixed/Iris™ Collimator Treatment Times
Intracranial	SRS	22 min	~ 51 min
	SRS	30 min	~ 90 min
Prostate	SBRT	25 min	~ 40 min
	SBRT	18 min	~ 26 min
	IMRT	29 min	~ 49 min
Lung	SBRT	19 min	

Additionally, the MLC treatment plan quality was reported as showing a reduction in integral dose due to the conformity per beam and in all cases the customer locations reported “rock solid” device performance.

Misc. (contd.)

Q22. Can customers continue to visit a reference site to see demonstrations of the MLC?

A22. Yes, they can. In fact we encourage customers to visit a site for a demonstration. As with the InCise™ MLC, we expect clinicians who purchase the InCise™ 2 MLC will be able to deliver the same precise radiosurgery treatments they have come to expect with the CyberKnife® System, while significantly reducing treatment times, for a wider range of tumor types, including larger and different kinds of tumors than were previously treated.

UPMC in Pittsburgh, Pennsylvania and Mercy Hospital in Grand Rapids, Michigan are reference sites for customers interested in viewing a demonstration of the MLC.

Q23. Can customers continue to have visits to Accuray's Madison and Sunnyvale offices for MLC demonstrations?

A23. MLCs are installed on the M6 systems in the Sunnyvale and Madison training centers and are available for customer demonstrations with advanced notice. Please coordinate with Jen Talbot in the Madison office to arrange VIP visits. Jen can be reached by phone at 1-608-824-2935 or e-mail at jtalbot@accuray.com.

Q24. When will customers be able to have visits to Accuray's Madison and Sunnyvale offices for InCise™ 2 MLC demonstrations?

A24. Once the evaluations have been completed and the product is commercially available we will provide you with information on the opportunity for Accuray office visits.

Additional Product and Internal Evaluation Details

Attribute/Spec	MLC	InCise™ 2 MLC
Number of leaves/bank	41	26
Leaf thickness (@800mm SAD)	2.5 mm	3.85 mm
Open field size	120mm x 102.5mm	120mm x 100mm
Max usable field size	110mm x 97.5mm	115mm x 100mm
Secondary check for leaf position check	Not equipped	Internal optical camera (Live camera images available on UI during use)
Leaf guides	Lubricated tracks	Ball bearing tracks
Penumbra	3.5mm X and Y (10mm x 10mm field) 12mm X and 20mm Y (100mm x 100mm field)	
Leakage (mean/max)	0.3% / 0.5%	
Leaf bank tilt	0.5°	
Leaf height	90mm nominal	
Leaf over-travel	Full travel range	
Leaf position reference and pre-fraction check	Cross bank in the back and front of very leaf bank	

- Further results of the internal evaluation of treatment plans generated for the InCise™ MLC, InCise 2 MLC and Fixed/Iris™ Collimator comparing the conformality index (CI), organ at risk (OAR) dose-volume indices and treatment times.
  - PTV dimension <20 mm – 5 cases
    - The exchangeability of fixed, Iris and MLC collimators is an important feature of the CyberKnife® M6™ System.
    - Results depended on several factors including the size and relationship of the tumor to OARs.
    - **For some small lesions, the plans for Iris, InCise MLC, InCise 2 MLC are substantially equivalent; for others, a fixed or Iris Collimator may be a better choice than an MLC.**
      - The exchangeability of fixed, Iris and MLC collimators is an important feature of the CyberKnife M6 System. This feature gives clinicians the freedom to choose the collimator best suited to a particular clinical situation.
  - PTV dimension >20 mm – 17 cases
    - **Treatment plans for the InCise MLC and InCise 2 MLC were substantially equivalent for all cases.**
    - There were no Iris plans for many of the larger cases. Previous data indicates that MLC plans are often better than Iris plans for larger cases.
  - InCise 2 MLC plans are much more time efficient than Fixed Collimator/Iris plans in all cases.

Case Type	Approx. Target Size	InCise 2 MLC Treatment Times	Fixed/Iris Treatment Times
Spine C1	13 mm	10 min	18 min
Pituitary	19 mm	15 min	21 min
Brain metastasis	28 mm	24 min	42 min
Prostate SBRT	53 mm	11 min	28 min