

Head Holder for MR-Guided Drug Delivery Testing (head_holder) Product Design Specifications

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Function: Convection enhanced drug delivery (CED) monitored through real time MRI requires immobilization of the subject's head. Our client, Professor Wally Block, requests a head holder device that is compatible with his experimental setup for in vivo studies on beagles and rhesus monkeys. The head holder must not include ferrous materials or parts that will conflict with the MRI antenna array. Due to the high degree of accuracy required, the device must restrict translational movement to less than 1 mm.

Client Requirements:

Our client wants a head holder that:

- Is compatible with MRI and experimental setup
- Restricts translation motion to less than 1 mm
- Allows reproducible positioning
- Works with beagles and rhesus monkeys

Design Requirements:

1. Physical and Operational characteristics

- Performance requirements:* The device should be reusable, easily sanitized, compatible with MRI, and prevent unnecessary damage to tissue.
- Safety:* Device cannot harm animal, including inhibiting breathing or swallowing.
- Accuracy and Reliability:* Immobilization should prevent translational movement from exceeding 1 mm. Animal must be able to be removed from the head holder completely and then returned to the same position.
- Life of Service:* Device must be reusable and last 5 years.
- Shelf Life:* Device should be stored at room temperature and atmospheric pressure.
- Operating Environment:* Device will be exposed to high magnetic fields at room temperature.
- Ergonomics:* Device must be easily used by one person including maneuvering and placement. Device must also conform to both species of subjects.
- Size:* Device must fit within the MRI bore (60 cm across) with other experimental instruments (brain port and ear coils) for real time MRI infusions and animal monitoring.
- Weight:* Maximum weight of device should be no more than 9 kg.
- Materials:* Device should contain materials that are compatible with MRI. It should not contain ferrous materials. Materials must be easily sanitized. Materials must also be sufficiently rigid to withstand forces necessary for immobilization.
- Aesthetics, Appearance, and Finish:* Finish should be conducive for gripping and have no ill effects on animals.

2. Production Characteristics

- Quantity:* One functional device is needed.
- Target Product Cost:* Total production cost should be less than \$1,000.

3. **Miscellaneous**

a. Standards and Specifications: IRB/IACUC approval is needed to test on live animals.

b. Customer: Client is environmentally conscious and would prefer a reusable or semi-reusable device. A reusable device is also the most practical. Functionality, however, is main priority to the client.

c. Patient-related concerns: Device cannot be harmful to animal and therefore must immobilize head without harming the animal. Device will be sterilized between uses.

d. Competition: All other head holder devices are not compatible with experimental setup (ie use ear bars) or MRI. Current devices (although incompatible) cost approximately \$2,000. A cheaper device is requested by the client.