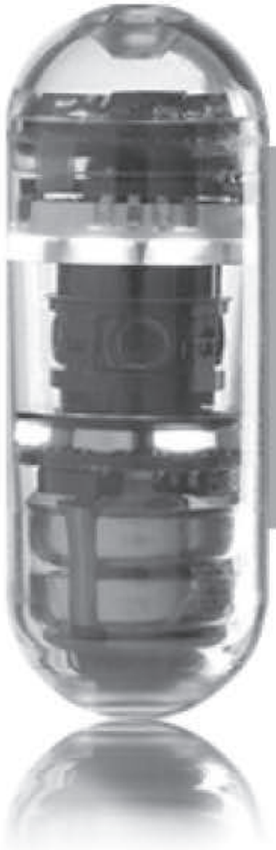
ALICAM™

INFINITI® MEDICAL

Advanced Technology for Vets and Pets



INSTRUCTIONS FOR USE

ALICAM™

English

Device Description

ALICAM™ is a single-use, ingestible capsule for animals that acquires and stores light-based images in on-board memory while moving through the gastrointestinal tract, propelled by natural peristalsis. The animal owner retrieves the capsule, and directs it in the provided collection vial to the veterinarian who downloads and reviews the images on a computer. The capsule is typically excreted between 3 and 30 hours after swallowing.

Ratings

IP68
Type BF applied part
2.7-3.3V DC 20mA
Class IIa

Operation Environment

Device operates *in vivo*. *Ex vivo* it operates within the following environmental ranges—

Temperature: 41°-104° F (5°-40° C)
Humidity: 5% to 95%
Atmospheric Pressure: 59kPa to 105kPa

Indications for Use

The ALICAM™ capsule system is intended for intraluminal visualization of the gastrointestinal tract. It may be used as a tool in the detection of abnormalities of the gastrointestinal tract. The system may be used in hospitals, veterinary clinics, and veterinarians' offices. After the capsule is swallowed, the animal is not restricted to medical supervision and may return home with the provided collection vial.

Contraindications

The ALICAM™ capsule is contraindicated in animals:

- That have known or suspected gastrointestinal obstructions, strictures or fistula
- That are pregnant
- That have a swallowing disorder

The veterinarian should consider performing a small bowel series before utilizing this device in patients who are suspected to have strictures or fistulas or to assess native bowel caliber in small animals to assure that the device will pass.

Preparation for Use

Instruct client regarding desired bowel preparation.

Inspect the foil seal. Do not use if any break in the foil

seal or in the foil itself is observed.

Have ample water available for the patient to drink.

Directions for Use

1. Open the capsule package by peeling back the foil cover.
2. Using gloves, remove the plastic lid covering the capsule.
3. Grasp the capsule carefully and then pull it out and away from the package. Take care not to drop the capsule on the floor.
4. Verify the LEDs within the capsule begin flashing. If they have not begun to flash within about 20 seconds after removing the capsule from the package, place the battery-end of the capsule against the magnet in the package and remove again. If the lights still do not flash, please contact technical support at (650) 327-5000.
5. Once the LED lights begin to flash, the capsule is ready to be swallowed. Administer the capsule using the standard technique used to administer a medication by placing the capsule on the back of the tongue and then holding the mouth shut and tilting the head back until the animal swallows. The capsule must not be coated with food as this will obscure the cameras and encourage the animal to bite the capsule. Care must be taken to prevent biting of the capsule. The capsule should be adminstered within 10 minutes of removing it from the package. If the animal is unable to swallow the capsule within this period, return the capsule to the package with the battery-end of the capsule touching the magnet inside the package, which returns the capsule to the "OFF" state.
6. Instruct the pet owner that the animal may engage in normal daily activities while the capsule moves within the digestive tract. The owner should contact the veterinarian with any questions about the animal engaging in a particular activity.
7. The capsule is typically excreted between 3 and 30 hours after swallowing. Retrieve the capsule by following the ALICAM™ Owner Instructions for Use.

Warnings

Laser Radiation— Class 1M Laser
Do not view directly with optical instruments

CAUTION: This product is intended for veterinary use only. It is not for human use.

Animals should not have an MRI exam performed until

the capsule has been excreted. Possible animal injury and medical complications could occur.

If the capsule is damaged in any way, including by forceful biting, it should not be administered.

If the capsule is not excreted after 72 hours, instruct the client to contact the veterinarian.

Keep out of reach of children.

Keep package, including embedded magnet, at least 5cm (~2.0 inches) away from pacemakers and other active-implant medical devices.

Do not modify the capsule without authorization from the manufacturer.

Used capsules are biologically contaminated and if reused can cause infection from bacteria, viruses, or other agents.

Animals should not board an aircraft until the capsule has been excreted.

Storage

Store the ALICAM™ capsule under normal indoor environmental conditions. Capsules should be left in the packaging and not opened or removed from the package until just prior to use.

Data Download at Clinic

Prior to downloading data from the used capsule, it must be cleaned, disinfected, and dried. Infiniti Medical recommends that hospitals/clinics handle the capsules with gloves and recommends cleaning and disinfecting as follows:

1. Clean the capsule using ENZOL® Enzymatic Cleaner or equivalent, according to the manufacturer's instructions, thoroughly rubbing the capsule with a soft bristle brush as necessary to remove all debris.
2. Disinfect the capsule using Revital-OX™ Resert® High Level Disinfectant or equivalent and rinse thoroughly, according to the manufacturer's instructions.
3. Dry capsule completely.

Disposal

Dispose of packaging as per local ordinances. Disposal of capsule after use should be handled by the health care organization in accordance with accepted medical practice and applicable national, local and institutional requirements.

Warranty

Limited Warranty. Infiniti Medical warrants solely that this product is free from defects in materials and workmanship for a limited period of time. Infiniti Medical shall, at no charge, replace any product that fails due to a defect in material or workmanship that is discovered and reported to Infiniti Medical by the user prior to the expiration date listed on the product package. All product returns for product replacement under this warranty must have prior authorization from Infiniti Medical. If you believe that you have received a defective product, please contact your Infiniti Medical representative for information. If your representative determines that the product is defective and such defect is covered under this warranty, your representative will make arrangements to replace the product under this warranty at no charge. The replacement product shall have the same limited warranty as the original product. Infiniti Medical makes no warranty or representation concerning the suitability of the product for any procedure. The veterinarian who has selected the product for use shall be solely responsible for determining the suitability of the product for any procedure. THERE ARE NO REPRESENTATIONS OR WARRANTIES OTHER THAN THE REPRESENTATIONS AND WARRANTIES IN THIS SECTION APPLICABLE TO THE PRODUCT, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL INFINITI MEDICAL OR ITS SUPPLIERS BE LIABLE FOR ANY CONSEQUENTIAL, INDIRECT, EXEMPLARY, SPECIAL, OR INCIDENTAL DAMAGES (INCLUDING WITHOUT LIMITATION, DAMAGES FOR LOSS OF BUSINESS PROFITS, BUSINESS INTERRUPTION, OR ANY OTHER PECUNIARY LOSS) ARISING FROM OR RELATING TO THE PRODUCT, EVEN IF INFINITI MEDICAL OR ITS SUPPLIERS HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. THE PROVISIONS CONTAINTED IN THIS PARAGRAPH LIMITING WARRANTIES AND LIMITING INFINITI MEDICAL'S AND ITS SUPPLIERS' LIABILITY SHALL APPLY TO THE FULL EXTENT PERMITTED BY LAW AND REGARDLESS OF FAULT.

Adverse Events

Potential adverse events associated with the use of this device may include bowel obstruction or perforation, and mucosal injury or bleeding.

Applicable Standards

EN 60601-1
EN-60601-1-2
EN ISO-10993

Federal Communication Commission (FCC) Compliance

The ALICAM™ capsule complies with Part 15 of the United States FCC rules and with international standards for electromagnetic compatibility regarding its use.

(Table 1)

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The ALICAM™ capsule is intended for use in the electromagnetic environment specified below. The customer or the user of the ALICAM™ capsule should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The ALICAM™ capsule uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ALICAM™ capsule is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage Fluctuations/ Flicker emissions IEC 61000-3-3	Not Applicable	

(Table 2)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The ALICAM™ capsule is intended for use in the electromagnetic environment specified below. The customer or the user of the ALICAM™ capsule should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not Applicable	Mains power quality should be that of a typical domestic, commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not Applicable	Mains power quality should be that of a typical domestic, commercial or hospital environment.

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(Table 2 continued)

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	Not Applicable	Mains power quality should be that of a typical domestic, commercial or hospital environment. If the user of the EQUIPMENT requires continued operation during power mains interruptions, it is recommended that the EQUIPMENT be powered from an uninterruptible power supply or a battery.
(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment.
NOTE UT is the A.C. mains voltage prior to application of the test level.			

(Table 3)

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The ALICAM™ capsule is intended for use in the electromagnetic environment specified below. The customer or the user of the ALICAM™ capsule should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	Not Applicable	Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol: 

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(Table 3 continued)

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ALICAM™ capsule is used exceeds the applicable RF compliance level above, the ALICAM™ capsule should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ALICAM™ capsule. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

(Table 4)

Recommended Separation Distances Between Portable and Mobile Rf Communications Equipment and The ALICAM™ capsule

The ALICAM™ capsule is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ALICAM™ capsule can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ALICAM™ capsule as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter W	**Separation Distance According to Frequency of Transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

If you have any questions, please contact Infiniti Medical Customer Care at (650) 327-5000

Symbol	Meaning	Symbol	Meaning
REF	Manufacturer's catalog designation or number		Do not re-use this product.
	Use caution		Use by date (With accompanying date)
	Instructions are included and must be followed	SN	Item serial number (with accompanying number)
	Special disposal for electronic waste required.		Manufacturer
LOT	Item lot number (with accompanying number)	QTY	Quantity
℞ Only	Prescription only		Type BF applied part
104°F (40°C) 41°F (5°C)	Temperature limitation		Laser Radiation—Class 1M Laser Product Do not view directly with optical instruments

Contact Information

ALICAM™

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