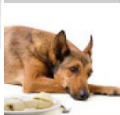




Ingestible Capsule Based Gastrointestinal  
Imaging Systems for Veterinary Use



# INSTRUCTIONS FOR USE ALICAM<sup>®</sup> CAPSULE

**CAUTION: U.S federal law restricts this device to sale by or on the order of a veterinarian.**

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

**CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE: FAILURE TO FOLLOW SPECIFIC INSTRUCTIONS, WARNINGS, AND PRECAUTIONS MAY RESULT IN COMPLICATIONS.**

## **Device Description**

ALICAM® is a single-use, ingestible video capsule that is propelled through the gastrointestinal tract by peristalsis. ALICAM® acquires video images that are stored in on-board memory. Once the capsule is retrieved, images are downloaded on a computer for interpretation. The capsule is typically excreted within 24 to 72 hours after swallowing. In some cases, however, the capsule may be passed in as few as 3 hours or as long as 14 days or more.

## **Storage**

Store in a dry, dark, cool place. ALICAM® should be left in the packaging, and not opened or removed from the package until just prior to use.

## **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

## **Intended Use**

ALICAM® is intended for intraluminal visualization of the GI tract in dogs that are large enough to allow passage of the capsule (11 mm x 31 mm). ALICAM® is

for veterinary use only.

## Contraindications

ALICAM® is contraindicated in patients:

That have known or suspected gastrointestinal obstructions, strictures or fistula

That are pregnant

That have a swallowing disorder

That may be too small to expect the capsule to pass through the GI tract

That are known or suspected to have a surgical abdomen

## Warnings



Laser Radiation— Class 1M Laser

Do not view directly with optical instruments.

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 injury to the animal 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 attempt to modify the capsule.

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.

## Potential Adverse Events

Aspiration of the device may result if ALICAM® is administered to dogs with swallowing dysfunction.

Obstruction may result in patients with strictures or in patients with

gastrointestinal anatomy of insufficient caliber to allow passage of ALICAM®.

Perforation or serious injury may result if patents are administered ALICAM® when the integrity of the clear plastic capsule has been breached.

Mucosal injury and bleeding.

Capsule retention that could require endoscopic or surgical removal.

## **Precautions**

ALICAM® administration has not been attempted in dogs less than 4.3 Kg and should be considered with caution.

ALICAM® administration has not been attempted in species other than dogs and horses and should be considered with caution.

If the ability to pass ALICAM® is questioned due to the size of the patient or suspected stricture or other condition, X-ray contrast studies may be useful in establishing suitable anatomy for use.

Bowel preparation is vital to the acquisition of diagnostic images.

Administration of ALICAM® should be questioned if adherence to proper bowel preparation cannot be verified.

Do not use if package is opened or damaged.

Do not use after expiration date.

Although most dogs will pass the capsule within 72 hours, recovery of the capsule may take as long as 14 days or more in dogs with motility disorders or anatomical lesions.

Do not attempt to autoclave or sterilize.

Do not expose to organic solvents (e.g. alcohol).

## **Product Recommendations**

ALICAM® is intended to be used with ALICAM® Reader and ALICAM® Software.

## **How Supplied**

Supplied in peel-open plastic tray. The product is intended for one-time use. Store in a dark, dry, cool place. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has

occurred. Do not use if product appears damaged.

## Reuse Precaution Statement

ALICAM® is for single patient use only. Do not reuse, reprocess or repurpose. Reuse, reprocessing or repurposing may compromise the structural integrity of the device and/or lead to device failure, which in turn, may result in patient injury, illness, or death. Reuse, reprocessing or repurposing may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

## 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 administered 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. Retrieve the capsule by collecting feces and checking for the presence of the capsule.

## **Preparing Capsule for Download or Return**

The capsule must be cleaned, disinfected, and dried prior to download or return. Infiniti Medical recommends that hospitals/clinics handle the capsules with gloves and recommends cleaning and disinfecting as follows:

1. Clean the capsule using ENZOL<sup>®</sup> 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<sup>™</sup> Resert<sup>®</sup> 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.

## **Limited Warranty**

Infiniti Medical warrants to Buyer that products supplied by Infiniti Medical that are sold to Buyer will be free from defects in material and workmanship for six (6) months after delivery to Buyer. Buyer must inspect and notify Infiniti Medical of any such defects within this six (6) month period. Further, notice of a defective product must be given to Infiniti Medical in writing within ten (10) days following the discovery of such defect prior to the expiration of the warranty period in order to recover under the warranty. All returns are subject to the prior authorization of INFINITI MEDICAL, in its discretion.

The warranty does not cover and Infiniti Medical will have no warranty obligation whatsoever with respect to any damage to a product caused by or associated with: (i) usage not in accordance with product instructions or usage for a purpose not indicated on the labeling; (ii) abuse, misuse, neglect, improper maintenance or storage,

accident, vandalism, or the negligence of any party other than Infiniti Medical; (iii) external causes, including (but not limited to) natural disasters, acts of God, power failure, cosmetic damage or damage to product packaging; or (iv) use of unauthorized consumables and/or accessories with the product. Infiniti Medical's sole liability under this warranty will be, at Infiniti Medical's sole option, to a) replace; b) repair; or c) refund the purchase price of the defective product(s). This will be Buyer's exclusive remedy for a covered defect. Any oral or written statement concerning the products inconsistent with the limited warranty set forth herein will be of no force or effect.

INFINITI MEDICAL EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES AND CONDITIONS, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, WARRANTIES OR CONDITIONS OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AS WELL AS ANY WARRANTIES ARISING FROM COURSE OF DEALING AND USAGE OF TRADE, AND INFINITI MEDICAL DOES

NOT REPRESENT OR WARRANT THAT ANY PRODUCT WILL MEET BUYER'S REQUIREMENTS.

## **RETURNS**

Buyer must notify Infiniti Medical within seven (7) calendar days of delivery regarding any products delivered to Buyer that were shipped in error, were damaged in shipping, or were in a shipping package that was damaged in shipping and such damage to the shipping package may have affected the quality of the products inside the shipping package.

Any products which Buyer wishes to return due to a) being shipped in error or damaged in shipping or b) a defect subject to the warranty provisions will be subject to receiving a Return Material Authorization (RMA) from Infiniti Medical. All returns are subject to the prior authorization of Infiniti Medical in its discretion. Only items appearing on an approved RMA are acceptable for return. Product returns will only be accepted from the original Buyer. Product returns will not be

accepted from any third parties. Unauthorized returns will be destroyed and no credit issued. All authorized returned products must be shipped freight prepaid to the Infiniti Medical location indicated on the RMA, except Infiniti Medical will pay freight costs for product shipped-in-error or damaged in shipping.

## **LIMITATIONS OF LIABILITY**

In no event shall Infiniti Medical be liable to Buyer for any unforeseen, indirect, incidental, special, punitive or consequential damages (including any loss of use, loss of revenue or damage for lost or anticipated profits), or otherwise arising out of or in connection with furnishing of products or service hereunder, or the performance, use of, or inability to use any products or service, or otherwise, whether based in contract, warranty, tort, including without limitation, negligence and strict liability, or any other legal or equitable theory. Infiniti Medical's total liability for any claim or action, whether based in contract,



warranty, tort, including without limitation, negligence and strict liability, or any other legal or equitable theory shall not exceed the purchase price of the product or products out of which such claim or action arose, or Ten Thousand Dollars (\$10,000.00), whichever is less.

## **Applicable Standards**

ANSI/AAMI-60601-1

EN-60601-1-2

EN ISO-10993

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## Federal Communication Commission (FCC) Compliance

ALICAM® 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)

<p>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</p>	<p>&lt;5 % UT (&gt;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 &lt;5 % UT (&gt;95 % dip in UT) for 5 sec</p>	<p>Not Applicable</p>	<p>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.</p>
<p>(50/60 Hz) magnetic field IEC 61000-4-8</p>	<p>3 A/m</p>	<p>3 A/m</p>	<p>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment.</p>
<p>NOTE UT is the A.C. mains voltage prior to application of the test level.</p>			

(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 <sub>rms</sub> 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:  

(continues on next page)

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
	Manufacturer's catalog designation or number		Single Use
	Keep away from sunlight		Store in cool, dry place
	Use caution		Use by date (With accompanying date)
	Consult Instructions for Use		Item serial number (with accompanying number)
	Special disposal for electronic waste required		Manufacturer
	Item lot number (with accompanying number)		Quantity
	Federal law restricts this device to sale by or on the order of a veterinarian.		Laser Radiation—Class 1M Laser Product Do not view directly with optical instruments
	Temperature limitation		Type BF applied part
	Do not use if package is damaged.		Conformity with health and safety requirements in European Market

## Contact Information

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