

Instructions for Use Instrapac MantaProp® Intraoral Mouth Prop For Animal Use Only

Caution: Federal law restricts this device to use by or on the order of a licensed veterinarian.

- READ AND UNDERSTAND THE INSTRUCTIONS DETAILED IN THIS DOCUMENT AND ON THE PRODUCT PACKAGING.
- PAY PARTICULAR ATTENTION TO VETERINARY WARNINGS.
- WARNING FOR VETERINARY PROFESSIONAL USE ONLY.
- Instrapac MantaProp Intraoral Mouth Props are intended for use by suitably qualified veterinary professionals only.
- The veterinary professional is responsible for determining device suitability for use with dogs and cats and for any intended clinical application.
- MantaProp Intraoral Mouth Props must be handled with care to avoid injury to animal patients.
- In the event of a serious product related incident, contact Midmark Corporation in the first instance, details below.
- WARNING THIS DEVICE MUST NOT BE RE-USED OR REPROCESSED UNDER ANY CIRCUMSTANCES.
 - This is a single use device and is supplied sterile.
 - Midmark Corporation will accept no responsibility for harm caused to animal patients or veterinary clinicians if this device is re-used.
 - This device is not designed to be decontaminated as organisms from a previous patient may be retained in the micro structure of the material.
 - This device is not designed for repeat sterilization, as this can affect the structure, integrity and strength of the material.
- WARNING DO NOT USE IF THE PACKAGING OR PRODUCT IS DAMAGED OR DEFECTIVE.

INDICATIONS FOR USE

- MantaProp Intraoral Mouth Props are sterile, single use medical devices intended for use by appropriately qualified veterinary professionals only.
- The veterinary professional is entirely responsible for determining the suitability of its use for any intended clinical application
- This device is indicated for use during veterinary intraoral radiography performed under general anesthesia.

CONTRAINDICATIONS

- MantaProp Intraoral Mouth Props are contraindicated in the following clinical circumstances:
 - Animal patients with craniofacial disorders with compromised dentitions or skeletal anomalies.
 - MantaProp Intraoral Mouth Props are not intended for non-professional, domestic or recreational use.
 - Where their use is not deemed to be appropriate by the responsible veterinary clinician.
 - WARNING; MantaProp Intraoral Mouth Props are contraindicated for use with larger dogs where the maximum interocclusal bite force is likely to exceed 1000 N (225 pound-force). A large sized dog may have a bite force that exceeds 225 pound-force; therefore, it is important to take extra care and closely monitor large dogs when using the Mouth Prop.

INSTRUCTIONS FOR USE

- Before treating patients under general anesthesia, it is recommended that they are confirmed to be at Stage III surgical anesthesia prior to and during obtaining dental radio graphs. The MantaProp Intraoral Mouth Prop is not a substitute for appropriate anesthesia and vital signs monitoring. The MantaProp Intraoral Mouth Prop offers added protection to a digital dental sensor should an animal patient attains a lighter stage of anesthesia and regains a bite reflex:
 - Ensure that the MantaProp Intraoral Mouth Prop is appropriate for the safe and effective completion of the intended procedure.
 - The veteninary clinician should select the appropriate size of mouth prop to suit the anatomy of the animal patient:
 - Small/medium animal patients: The PURPLE ('small') size MantaProp Intraoral Mouth Props should be used.
 - Large/extra-large animal patients: The GREEN ('medium') size MantaProp Intraoral Mouth Props should be used.
- Examine the product packaging before use. Do not use if the wrapper or seal is damaged or broken.
- Open the sterile pack by peeling back the paper and dispense into the operative field, observing appropriate aseptic technique.
- Hold the mouth prop by the white colored end with the serrated bite platforms positioned vertically, ensuring that the single-color curved tether hangs naturally downwards. whether you are working on the left or right side of the animal patient, the Instrapac MantaProp tether will be rostral to the white MantaProp Intraoral Mouth Prop body when it is positioned in the patient's mouth.
- MantaProp Intraoral Mouth Prop body when it is positioned in the patient's mouth.
- Gently insert the MantaProp Intraoral Mouth Prop into the side contralateral to the intended procedure.
- Place the MantaProp Intraoral Mouth Prop between the upper and lower dentitions, ensuring that the occlusal surfaces of the teeth locate fully with the serrated bite
- Take care to avoid potential damage to the supporting dentition or intraoral soft tissues.
- Locate the device to achieve adequate, but not excessive, mouth opening during the procedure to avoid inadvertent subluxation or dislocation of the temporomandibular joints.
- Maxillary and Mandibular Radiographs:
- Whether animal patients are in sternal/dorsal, lateral, or ventral recumbency, the MantaProp Intraoral Mouth Prop should be placed on the contralateral working on the left side of a patient's mouth, the MantaProp Intraoral Mouth Propwill be placed between the maxillary and mandibular molars on the patient's right side (it is likely you will include the upper fourth premolar crown on the serrated bite platform).
- When working on the right side of the patient's mouth, the MantaProp Intraoral Mouth Prop will be placed between the maxillary and mandibular molars on the left (it is likely you will include the upper fourth premolar crown on the serrated bite platform).
- Once the MantaProp Intraoral Mouth Prop is in position, it is safe to begin acquiring images on the opposite side of the patient's mouth, including the patient's incisors.
- Once radiographs are completed for the caudal maxilla/mandible and incisors, position the MantaProp Intraoral Mouth Prop on the opposite side of the mouth and begin acquiring the remaining radiographs.
- At the end of the procedure, gently withdraw the MantaProp Intraoral Mouth Prop by holding the integral tether, taking care not to damage the supporting dentition or intraoral soft tissues and to avoid inadvertent subluxation or dislocation of the temporomandibular joints.
- Since the MantaProp Intraoral Mouth Prop will prop an animal patient mouth open, using gauze or other material to stabilize the sensor may be beneficial.

When treating patients under general anesthesia

In emergency situations, or when opening the mouth is not possible, the MantaProp Intraoral Mouth Prop can be removed by pulling on the tether. It is extremely strong and should not break under normal conditions, though it may extend a little. The white, serrated bite platform area will flex to release it from the dentition.

STORAGE, HANDLING & DISPOSAL

- Store in a clean, dry environment.
- After use, MantaProp Intraoral Mouth Props must be placed safely into an appropriate clinical waste container, and disposed of PERh local policies and procedures.
- THIS DEVICE MUST NOT BE RE-STERILIZED OR RE-USED UNDER ANY CIRCUMSTANCES.

To request paper copies of the manuals, please contact Customer Experience Midmark Corporation: Phone: 1-800-MIDMARK +1 847-415-9800 Fax: 847-415-9810 animalhealth@midmark.com To obtain technical support, please contact Technical Support Group: Phone: 1-800-MIDMARK (800-643-6275) Fax: 847-415-9801 imagingtechsupport@midmark.com For instructional video, please visit midmark.com/MouthProp

