

TECHNICAL SHEET



PRMEDICAL

PROMOTING INNOVATION

Detecto

Distal cap

Illustration



Description

Detecto is a disposable distal attachment made of medical silicon, featuring a main body and a spacer cap. The main body consists of an elastic ring connected to the endoscope from which four equally spaced arms branch out, each of which splits into a double arm. During insertion and advancement through the colon, each of these protruding elements bends, flattening around the instrument to minimise the profile of the device and so facilitate its progress. During this phase, the protruding elements also act as pins at the tip of the colonoscope, increasing its stability as it advances. By contrast, during the withdrawal of the instrument, the main arms hold the double arms in the open position. As the double arms come into contact with the walls of the colon, they gently stretch the folds, facilitating vision. The spacer cap on the tip makes it possible to maintain adequate depth of the field of vision at all times and facilitates the advancement of the instrument.

PRM01 Compatible with distal endoscopes diameter 12.5 – 13.5 mm

PRM02 Compatible with distal endoscopes diameter 11.5 – 12.5 mm

Intended Use

Detecto is intended for attachment to the distal end of the endoscope in order to facilitate endoscopic therapy, specifically improving visibility during colonoscopy screening procedures. Detect can also be used to maintain adequate depth of the visual field of the endoscopy, gently stretch the internal folds of the




colon, facilitate the advancement of the instrument through the gastrointestinal tract, stabilise the tip of the instrument inside the colon to offer more stable vision.

Code	Commercial Name	Compatible with distal endoscopes diameter
PRM01	DETECTO	12.5 – 13.5 mm
PRM02	DETECTO	11.5 – 12.5 mm

Raw Material

Non-toxic medical silicone

Safety of Materials

Disposable	YES	
Latex Free	YES	
Phtalate Free	YES	

Packaging

Primary packaging	Single polypropylene (PP) pouch
Secondary packaging	50 pieces in corrugated cardboard box

Sterilization

Non-sterile

Standards e Certifications

CE Marking	CE Conformity Declaration according to Regulation 2017/745/UE
Classification	Class I Medical Device

Instructions For Use

The device is accompanied by an instruction manual containing all precautions, usage information, and warnings to avoid risks associated with the use of the device, as required by current regulations.

Labelling

The information necessary for device recognition, in compliance with current regulations, is provided and described within the Instructions For Use.

Storage Condition

It is recommended to store the device in a clean and dry place, away from sunlight and heat sources, and to avoid extreme temperatures.

Disposal

After use, the product poses a potential biological risk and presents a risk of cross-contamination. Handle and dispose of it in accordance with approved medical practice and local, regional, and national laws and regulations in force.

Manufacturer

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