

INSTRUCTIONS FOR USE

TECHNICAL NAME: Trocartes

TRADE NAME: Endoscopy Action TM Kit

SINGLE USE PRODUCT - REUSE PROHIBITED **STERILE PRODUCT - REPROCESSING PROHIBITED**

WARNING: Please read carefully all instructions before use. Follow all warnings and precautions mentioned in this instruction. Disregarding these points may lead to occurrence of complications.

1. Product Identification

The Endoscopy Action TM kit is designed to provide surgeons instruments for use in minimally invasive surgical procedures, such as video-assisted procedures (arthroscopy of small joints). Among the surgical examples for using the Endoscopy Action TM kit, we can mention Procedures in the temporomandibular joint (TMJ), knee, shoulder, ankle, elbow, wrist, spine, ophthalmology, ear, nose, throat and cervix, but not limited to these. These are provided sterile devices (method ETO).

2. The following materials are used for the manufacture of the Endoscopy Action TM Kit:

- Stainless steel AISI 304 (NBR 13911)
- Polypropylene (PP)
- Polyethylene (LDPE)

The stainless steel used for the manufacture of tools meet Brazilian NBR standards 13,911 (with respect to chemical composition and mechanical properties) and ISO 7153-1 (with respect to the classes of steels and their use).

3. Presentation

The Endoscopy Action TM Kit code PA.02.03.1581 consists of the following components:

ITEM – CODE – DESCRIPTION - MATERIAL

ITEM	CÓD.	DESCR.	MATERIAL
01	PA.02.03.1582	Cânula Cânula <i>Cannula</i>	Aço Inoxidável AISI 304(NBR 13911)/ Polipropileno (PP) Acero inoxidable AISI 304 (NBR 13911)/ Polipropileno (PP) <i>Stainless steel AISI 304 (NBR 13911) / Polypropylene (PP)</i>
02	PA.02.03.1583	Trocarte Trocarte <i>Trocar</i>	Aço Inoxidável AISI 304(NBR 13911)/ Polipropileno (PP) Acero inoxidable AISI 304 (NBR 13911)/ Polipropileno (PP) <i>Stainless steel AISI 304 (NBR 13911) / Polypropylene (PP)</i>
03	PA.02.03.1584	Obturador Obturador <i>Obturator</i>	Aço Inoxidável AISI 304(NBR 13911)/ Polipropileno (PP) Acero inoxidable AISI 304 (NBR 13911)/ Polipropileno (PP) <i>Stainless steel AISI 304 (NBR 13911) / Polypropylene (PP)</i>
04	PA.02.03.1585	Plugue Conector <i>Plug</i>	Polipropileno (PP) Polipropileno (PP) <i>Polypropylene (PP)</i>
05	PA.02.03.1586	Camisa Camisa <i>Shirt</i>	Poliétileno (PEBD) Poliétileno (PEBD) <i>Polyethylene (LDPE)</i>
06	PA.02.03.1587	Faca Banana Cuchillo Banana <i>Banana Knife</i>	Aço Inoxidável AISI 304(NBR 13911)/ Polipropileno (PP) Acero inoxidable AISI 304 (NBR 13911)/ Polipropileno (PP) <i>Stainless steel AISI 304 (NBR 13911) / Polypropylene (PP)</i>
07	PA.02.03.1588	Minescótomo Meniscótomo <i>Minescótomo</i>	Aço Inoxidável AISI 304(NBR 13911)/ Polipropileno (PP) Acero inoxidable AISI 304 (NBR 13911)/ Polipropileno (PP) <i>Stainless steel AISI 304 (NBR 13911) / Polypropylene (PP)</i>
08	PA.02.03.1589	Aplainador Aplainador <i>Minescótomo</i>	Aço Inoxidável AISI 304(NBR 13911)/ Polipropileno (PP) Acero inoxidable AISI 304 (NBR 13911)/ Polipropileno (PP) <i>Stainless steel AISI 304 (NBR 13911) / Polypropylene (PP)</i>
09	PA.02.03.1590	Gancho Raspador Gancho Raspador <i>Hook Scraper</i>	Aço Inoxidável AISI 304(NBR 13911)/ Polipropileno (PP) Acero inoxidable AISI 304 (NBR 13911)/ Polipropileno (PP) <i>Stainless steel AISI 304 (NBR 13911) / Polypropylene (PP)</i>
10	PA.02.03.1591	Cureta Cureta <i>Curette</i>	Polipropileno (PP) Polipropileno (PP) <i>Polypropylene (PP)</i>
11	PA.02.03.1592	Tampa da Cânula Tapa de la Cânula <i>Cover Cannula</i>	Polipropileno (PP) Polipropileno (PP) <i>Polypropylene (PP)</i>

4. Operation principle

The Endoscopy Action TM Kit is formed by the components cited, and has the function of creating an access route to the inside of joints, without requiring large incisions extension, and through the cannula to insert instruments such as those with according to the manipulation of tissue within the joint.

5. Directions

Initially we defined the points of insertion of the trocarte near the joint, where the instruments are inserted through the cannula. A small incision is made with a scalpel, and then with the aid of the shutter, the cannula is introduced to the outside of the joint, and from this point, the stopper is replaced by the trocarte, which together with the cannula are inserted into the interior of the joint. From this point on, the trocarte is withdrawn leaving the cannula in use position, thus permitting the use of optics and instruments through it. Below we describe the function of the components alone.

Cannula - Device cast which allows the passage of instruments that allow for percutaneous introduction of it to the desired location.

Obturator - Device with the sharp end that is inserted into the cannulated tube segment. This device serves for piercing the tissue for atraumatic introduction of the cannula.

Plug - A device for sealing the front entrance of the cannula.

Trocarte - A device for facilitating and guiding the entry of the cannula.

Cannula Cover - A device for sealing the fluid inlet hole of the cannula.

Minescotome - Instrument used to make small incisions in the joint structures with the cutting part, performing minor repairs of the structure of the disc.

Planer - Instrument used to flatten the irregularities of the articular fossa, formed after wear the same, and removal of adhesions that holds the disc to the fossa.

Hook Scraper - Instrument used for scraping of the articular surfaces aiming to release the adhesions.

Curette - Instrument used for the scraping of the articular surfaces, for removing bone spurs that greater resistance than the articular adhesions, not only are removed using the gain scraper.

Banana Knife - Instrument used for the larger incisions meniscotomy as to discopexia procedures.

6. Storage Conditions

The Endoscopy Action TM Kit should be stored in clean, dry place away from heat and protected from direct light and in their original packaging, in Temperature: +10 ° to +40 ° C - Relative Humidity: 30 to 85%. The special conditions of storage, handling and storage of the product should be followed in order to ensure that the components remain intact for the procedure. Care of the receipt, storage, transportation, cleaning and maintenance of the lot of the references should be adopted in conjunction with good storage and distribution of medical products.

7. Conditions of Transport and Handling

The Endoscopy Action TM Kit must be transported and handled in a clean, dry place away from heat and direct light under and in its original packaging, in Temperature: +10 ° to +40 ° C - Relative Humidity: 30 to 85 % in order to prevent any damage or alteration of their characteristics.

Note: Any product that has been dropped or improperly handled, or suspected to have suffered damage, should be separated and segregated.

8. Contraindications

The Endoscopy Action TM Kit should not be used in regions of active infection.

9. Warnings

- * Do not use if package is opened or damaged.
- * Product single-use, reprocessing prohibited.
- * Product to be used only by a qualified professional.
- * Before starting the procedure, anatomical structures of the patient should be identified to ensure that the insertion point of The Endoscopy Action TM Kit is far from blood vessels and other anatomical structures of interest.
- * Do not use excessive force when handling the kit Endoscopy Action TM, because excessive pressure can cause damage to anatomical structures and tissues near the site of insertion of the trocar and the instruments.

10. Precautions

- The minimally invasive procedures should be performed only by competent personnel who are familiar with these procedures.
- Properly position the patient in order to obtain the best position for the introduction and manipulation of Kit Endoscopy Action TM, for facilitating the surgical procedure.
- When using The Endoscopy Action TM Kit resort to additional stabilization devices.
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Batch Number, Manufacturing Date, Expiration Date: See Product Label.

Manufacturing Date Do Not Use if Package is Ruined Expiration Date
See Use Instructions Single Use Product Keep Dry
Do Not Reuse
Reprocessing Prohibited
Keep Away from Sunlight Fragile, Handle with care

Tabela - Simbologia, conforme NBRISO 15223

 Data de Fabricação	 Não utilizar se a embalagem estiver danificada	 Validade
 "Ver instruções de uso"	 Produto de uso único Não reutilizar Proibido reprocessar"	 Manter seco
 Manter ao abrigo do sol	 Frágil, manusear com cuidado	

Registro ANVISA n. ° 80455639001

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