

INSTRUCTION FOR USE

TECHNICAL NAME: Instrument Kit

TRADE NAME: TRAUMEC Instrument Kit for Column.

ATTENTION: 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

TRAUMEC Instrument Kit for Column - indicated to help the surgeon in surgical procedures in the spine and has as a working principle to fix, model, impact, compress, position, extract, align, move away, insert and introduce the implants during the surgical procedure.

2. MATERIALS USED IN THE MANUFACTURE OF THE ENDOSCOPY TM ACTION KIT

The following materials are used in order to manufacture the **TRAUMEC Instrument Kit for Column**:

Stainless Steel AISI 304, 420 and 440C (NBR 13911)

Stainless Steel UNSS46500 (ASTM F899)

Aluminum (NBR 6834)

Radel (PPSU)

Silicone





The stainless steel used to manufacture the instruments meets the Brazilian standards NBR 13911 (in relation to chemical composition and mechanical properties) and NBR ISO 7153-1 (in relation to steel classes and their uses).







3. Presentation

The following components make up the **TRAUMEC Instrument Kit for Column**:






ITEM	CODE	DESCRIPTION	MATERIAL	ILLUSTRATION
1	PA.02.01.0001	Compressor Tweezers RS	Stainless Steel AISI 420(NBR 13911)	
2	PA.02.01.0002	Distractor Tweezers RS	Stainless Steel AISI 420(NBR 13911)	
3	PA.02.01.0003	Rod Modeler RS	Stainless Steel AISI 420(NBR 13911)	
4	PA.02.01.0004	Torque Wrench RS	Stainless Steel AISI 420(NBR 13911) /Silicone	
5	PA.02.01.0005	Hammer RS	Stainless Steel AISI 304(NBR 13911) /Silicone	
6	PA.02.01.0006	Bone Applicator RS	Stainless Steel AISI 304(NBR 13911)	
7	PA.02.01.0007	Right Rod Twister RS	Stainless Steel AISI 420(NBR 13911)	





8	PA.02.01.0008	Left Rod Twister RS	Stainless Steel AISI 420(NBR 13911)	
9	PA.02.01.0009	Rod Twister RS	Stainless Steel AISI 420(NBR 13911)	
10	PA.02.01.0010	Rod Holder Clamp RS	Stainless Steel AISI 420(NBR 13911)	
11	PA.02.01.0011	Quick T Coupling Cable RS	Stainless Steel AISI 304(NBR 13911) /Silicone	
12	PA.02.01.0012	Straight Quick Coupling Cable RS	Stainless Steel AISI 304(NBR 13911) /Silicone	
13	PA.02.01.0013	Counter-Torque Wrench RS	Stainless Steel AISI 304(NBR 13911) /Silicone	
14	PA.02.01.0014	Straight Probe RS	Stainless Steel AISI 420(NBR 13911) /Silicone	
15	PA.02.01.0015	Hexa Driver 2,5mm RS	Stainless Steel UNS S46500 (ASTM F899)	
16	PA.02.01.0016	Hexa Driver 3,5mm RS	Stainless Steel UNS S46500 (ASTM F899)	
17	PA.02.01.0017	Hexa Driver RS	Stainless Steel UNS S46500 (ASTM F899)	







18	PA.02.01.0018	Initial Guide Driver mono-axial screw RS	Stainless Steel AISI420(NBR 13911) / Stainless Steel AISI 304(NBR 13911)	
19	PA.02.01.0019	Initial Guide Driver Spondylolisthesis screw RS	Stainless Steel AISI420(NBR 13911) / Stainless Steel AISI 304(NBR 13911)	
20	PA.02.01.0020	Initial Guide Driver Poly-axial Screw RS	Stainless Steel AISI420 (NBR 13911) / Stainless Steel AISI 304 (NBR 13911)	
21	PA.02.01.0021	Right Pedicle Marker RS	Stainless Steel AISI 304(NBR 13911)	
22	PA.02.01.0022	Left Pedicle Marker RS	Stainless Steel AISI 304(NBR 13911)	
23	PA.02.01.0023	Bifida Wrench RS	Stainless Steel AISI 420(NBR 13911) /Silicone	
24	PA.02.01.0024	Male Ø4,5mm RS	Stainless Steel AISI 440C (NBR 13911) /	

			Aluminum (NBR 6834)	
25	PA.02.01.0025	Male Ø5,5mm RS	Stainless Steel AISI 440C (NBR 13911) / Aluminum (NBR 6834)	
26	PA.02.01.0026	Rupture Driver RS	Stainless Steel AISI 304(NBR 13911) /Silicone	
27	PA.02.01.0027	Rod Depressor RS	Stainless Steel AISI 304(NBR 13911) /Silicone	
28	PA.02.01.0028	Space Distractor Rod RS	Stainless Steel AISI 304(NBR 13911)	
29	PA.02.01.0029	Puncture RS	Stainless Steel AISI 420(NBR 13911) /Silicone	
30	PA.02.01.0030	Pedicle Probe RS	Stainless Steel AISI 304(NBR 13911) /Silicone	




31	PA.02.01.0031	Proof Case EP	Radel (PPSU)	
32	PA.02.01.0032	Case for Parallel lumbar intersomatic Spacer EP	Radel (PPSU)	
33	PA.02.01.0033	Case for Inclined lumbar intersomatic spacer EP	Radel (PPSU)	
34	PA.02.01.0034	Base for Grafting Impacting EP	Stainless Steel AISI 304(NBR 13911)	
35	PA.02.01.0035	Lumbar Intersomatic Spacer Introductory Driver EP	Stainless Steel AISI 304(NBR 13911) /Silicone	
36	PA.02.01.0036	Grafting Impactor EP	Stainless Steel AISI 304(NBR 13911)	
37	PA.02.01.0037	Root Flat Retractor EP	Stainless Steel AISI 420(NBR 13911)	
38	PA.02.01.0038	Curved Root Retractor EP	Stainless Steel AISI 420(NBR 13911)	
39	PA.02.01.0039	Lumbar intersomatic spacer impact wrench EP	Stainless Steel AISI 304(NBR 13911) /Silicone	
40	PA.02.01.0040	Spine Spacer 07mm EP	Stainless Steel AISI 304(NBR 13911)	


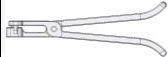

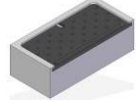
41	PA.02.01.0041	Spine Spacer 08mm EP	Stainless Steel AISI 304(NBR 13911)	
42	PA.02.01.0042	Spine Spacer 09mm EP	Stainless Steel AISI 304(NBR 13911)	
43	PA.02.01.0043	Spine Spacer 10mm EP	Stainless Steel AISI 304(NBR 13911)	
44	PA.02.01.0044	Spine Spacer 11mm EP	Stainless Steel AISI 304(NBR 13911)	
45	PA.02.01.0045	Spine Spacer 12mm EP	Stainless Steel AISI 304(NBR 13911)	
46	PA.02.01.0046	Spine Spacer 13mm EP	Stainless Steel AISI 304(NBR 13911)	
47	PA.02.01.0047	Curette EP	Stainless Steel AISI 420(NBR 13911) /Silicone	
48	PA.02.01.0048	Vertebrae Distracting Tweezers EP	Stainless Steel AISI 420(NBR 13911)	
49	PA.02.01.0049	Articulated Vertebrae Distracting Tweezers EP	Stainless Steel AISI 420(NBR 13911)	
50	PA.02.01.0050	Template 60mm RS	Aluminum (NBR 6834)	
51	PA.02.01.0051	Template 100mm RS	Aluminum (NBR 6834)	

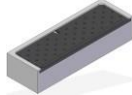
52	PA.02.01.0052	Template 200mm RS	Aluminum (NBR 6834)	
53	PA.02.01.0053	Proof 7mm EP	Stainless Steel AISI 304(NBR 13911)	
54	PA.02.01.0054	Proof 8mm EP	Stainless Steel AISI 304(NBR 13911)	
55	PA.02.01.0055	Proof 9mm EP	Stainless Steel AISI 304(NBR 13911)	
56	PA.02.01.0056	Proof 10mm EP	Stainless Steel AISI 304(NBR 13911)	
57	PA.02.01.0057	Proof 11mm EP	Stainless Steel AISI 304(NBR 13911)	
58	PA.02.01.0058	Proof 12mm EP	Stainless Steel AISI 304(NBR 13911)	
59	PA.02.01.0059	Proof 13mm EP	Stainless Steel AISI 304(NBR 13911)	
60	PA.02.01.0060	Transporter Tweezers EP	Stainless Steel AISI 420(NBR 13911)	
61	PA.02.01.0061	Lumbar Intersomatic Spacer Introductory Driver ET	Stainless Steel AISI 304(NBR 13911) /Silicone	
62	PA.02.01.0062	Base for Grafting Impacting ET	Stainless Steel AISI 304(NBR 13911)	

63	PA.02.01.0063	Grafting Impactor ET	Stainless Steel AISI 304(NBR 13911)	
64	PA.02.01.0064	Lumbar intersomatic spacer impact wrench 01 ET	Stainless Steel AISI 304(NBR 13911) /Silicone	
65	PA.02.01.0065	Lumbar intersomatic spacer impact wrench 02 ET	Stainless Steel AISI 304(NBR 13911) /Silicone	
66	PA.02.01.0066	Lumbar intersomatic spacer impact wrench 03 ET	Stainless Steel AISI 304(NBR 13911) /Silicone	
67	PA.02.01.0067	Lumbar intersomatic spacer impact wrench 04 ET	Stainless Steel AISI 304(NBR 13911) /Silicone	
68	PA.02.01.0068	Proof 7mm ET	Stainless Steel AISI 304(NBR 13911)	
69	PA.02.01.0069	Proof 8mm ET	Stainless Steel AISI 304(NBR 13911)	
70	PA.02.01.0070	Proof 9mm ET	Stainless Steel AISI 304(NBR 13911)	

71	PA.02.01.0071	Proof 10mm ET	Stainless Steel AISI 304(NBR 13911)	
72	PA.02.01.0072	Proof 11mm ET	Stainless Steel AISI 304(NBR 13911)	
73	PA.02.01.0073	Proof 12mm ET	Stainless Steel AISI 304(NBR 13911)	
74	PA.02.01.0074	Proof 13mm ET	Stainless Steel AISI 304(NBR 13911)	
75	PA.02.01.0075	Grafting Impact Plier ET	Stainless Steel AISI 420(NBR 13911)	
76	PA.02.01.0076	Proof Case ET	Radel (PPSU)	
77	PA.02.01.0077	Case for Parallel lumbar intersomatic Spacer ET	Radel (PPSU)	
78	PA.02.01.0078	Case for inclined lumbar intersomatic Spacer ET	Radel (PPSU)	
79	PA.02.01.0079	Curved Probe RS	Stainless Steel AISI 420(NBR 13911) /Silicone	
80	PA.02.01.0080	Male Ø6,5mm RS	Stainless Steel AISI 440C (NBR 13911) / Aluminum (NBR 6834)	

81	PA.02.01.0081	Male Ø7,5mm RS	Stainless Steel AISI 440C (NBR 13911) / Aluminum (NBR 6834)	
82	PA.02.01.0082	Hexa 3mm RS	Stainless Steel UNS S46500 (ASTM F899)	
83	PA.02.01.0083	Instrument Case RS	Stainless Steel AISI 304(NBR 13911)	
84	PA.02.01.0084	Instrument Case RS	Stainless Steel AISI 304(NBR 13911)	
85	PA.02.01.0085	Tray 01 RS	Stainless Steel AISI 304(NBR 13911)	
86	PA.02.01.0086	Tray 02 RS	Stainless Steel AISI 304(NBR 13911)	
87	PA.02.01.0087	Tray 03 RS	Stainless Steel AISI 304(NBR 13911)	
88	PA.02.01.0088	Tray 04 RS	Stainless Steel AISI 304(NBR 13911)	
89	PA.02.01.0089	Tray 05 RS	Stainless Steel AISI 304(NBR 13911)	
90	PA.02.01.0090	Tray 06 RS	Stainless Steel AISI 304(NBR 13911)	

91	PA.02.01.0091	Tray 01 EP	Stainless Steel AISI 304(NBR 13911)	
92	PA.02.01.0092	Tray 02 EP	Stainless Steel AISI 304(NBR 13911)	
93	PA.02.01.0093	Tray 03 ET	Stainless Steel AISI 304(NBR 13911)	
94	PA.02.01.0094	Tray 04 ET	Stainless Steel AISI 304(NBR 13911)	
95	PA.02.01.0095	Template 140mm RS	Aluminum (NBR 6834)	
96	PA.02.01.0096	Template 180mm RS	Aluminum (NBR 6834)	
97	PA.02.01.0097	Template 240mm RS	Aluminum (NBR 6834)	
98	PA.02.01.0098	Vertebral Retractor RS	Stainless Steel AISI 304(NBR 13911)	
99	PA.02.01.0099	Grafting Impactor Pliers EP	Stainless Steel AISI 420(NBR 13911)	
100	PA.02.01.0100	Instrument Case EP	Stainless Steel AISI 304(NBR 13911)	
101	PA.02.01.0101	Instrument Case ET	Stainless Steel AISI 304(NBR 13911)	
102	PA.02.01.0102	Case for counter screw and transverse connector RS	Radel (PPSU)	

103	PA.02.01.0103	Cross hanger case RS	Radel (PPSU)	
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4. Operating Principle

The **TRAUMEC Instrument Kit for Column** consists of the components mentioned above and has as a working principle to fix, model, impact, compress, position, extract, align, move away, insert and introduce the implants during the surgical procedure.

5. Directions for use

Preoperative: The selection of instruments is an integral part of surgical planning and must be carried out by means of a formal medical request that indicates the intended technique, as well as the characteristics of the implant to be used, and the specifications of the component parts of the instrument system. It is very important to perform a thorough inspection in each component, taking into account the conditions of use and cleaning. Sterilization is mandatory and must have its proven efficiency. The revision of the surgical instrumentation technique before actual use makes the procedure more efficient.

Intraoperative: The instruments are exclusively for medical aid, and will never be an integral part of the implants as to the permanence in the body after the procedure. They must be selected and matched only for the device to be implanted, aiming at the adequacy of the orthopedic implant with the implantation site. Instrumentation from different manufacturers can be used in association only when the compatibility and suitability among them is previously assessed.

PROCEDURES FOR USE AND REUSE OF MEDICAL PRODUCT

The use of surgical instruments should always be done under technical guidance and restricted to clinical and hospital environments, with the following precautions: Handling and moving: the instruments shall be transported and handled in such a way as to prevent any damage or changing in their characteristics. They must be handled carefully, in small

batches, avoiding beats or falls. Any instrument that has fallen or been improperly handled, or with suspected damage, must be separated and forwarded to the institution's authorized technician responsible for inspection, even if it has already passed through this step.

Inspections: Only instruments submitted to a previous technical inspection can be used.

Technical Inspection: The Instruments, including assembly of the kit, must undergo the technical inspection performed by authorized person, before being made available for use.

Disapproved parts must be separated for revision and maintenance by the supplier, or intended for disposal. The inspection shall verify the characteristics associated with the conservation and the functionality of the instrument, including surface features such as blemishes, oxidation and damage, besides characteristics pertinent to each instrument, such as ease of articulation, capacity for seizure, cutting capacity and tip alignment.

Sterilization: The instruments should be sterilized prior to use. The appropriate parameters of the sterilization process for each equipment and volume should be analyzed and conducted by people trained and specialized in sterilization processes, assuring the complete efficiency of this procedure.

Reuse: The process for reuse of surgical instruments involves, at least, five basic steps: previous cleaning, decontamination, washing, and rinse and drying. It is recommended that all instruments be cleaned immediately after the surgical procedure in which they were used, avoiding the hardening of dirt from this procedure. The cleaning should have a standardization, avoiding the spread of contamination and damage to the instrument. Every manual cleaning procedure must be carried out using appropriate personal protective equipment. In automatic equipment cleaning operations, the manufacturers' instructions must be strictly followed, in particular with regard to products and the quality of the water to be used.

Whenever applicable, introduce the instruments open or disassembled in the equipment.

Under no circumstances, make use of metal brushes, steel wools or other abrasive products, even the scouring products to remove any remaining dirt from any stage of the cleaning process. Do not use aggressive cleaning agents such as mineral and acidic agents (sulfuric, nitric). It shall be ensured that the instrument and its components, where relevant, are free from any preservation products, as well as from any dirt arising from storage or from the repair procedure. The presence of non-hydro-soluble products can lead to the formation of physical barriers, protecting microorganisms from the action of germicides, as well as providing retention of undesirable dirt to later use of the instruments. Water quality is a fundamental factor both for the cleaning process and for the conservation of the instruments. The presence of particulate elements, the concentration of elements or chemicals, and the pH imbalance can deteriorate the instrument during the cleaning process. The combination of some of these parameters can lead to the incrustation of mineral precipitates, which cannot be removed during the phase of removing organic matter, as well as to induce the corrosion process of Stainless Steel, as in the case of excessive presence of chlorides. It is recommended that the water used to wash the instruments be in accordance with the quality requirements established in the sterilization process.

Note: All instruments must be cleaned as soon as the surgical procedure ends, thus avoiding the hardening of liquids originating from the surgical work. Every cleaning process should be done with maximum care, avoiding falls or knocks that could compromise the instruments.

Pre-cleaning: The instruments should be dipped, open or disassembled, where applicable, in a suitable container with water and detergent, preferably enzymatic, at room temperature. Next, they should go thoroughly rinsed under running water, preferably lukewarm. This phase should always be performed with water at temperatures below 45 ° C, because higher temperatures cause the coagulation of proteins, making it difficult to remove encrustations from the instruments.

Decontamination: It is made by immersing the instruments, open or disassembled, where applicable, in a suitable container with disinfectant solution in water, at room temperature (chemical disinfection), or in a heated bath (thermochemical disinfection). The soaking time of the instrument depends on both the operating temperature and the dilution, and the type of disinfectant used.

Washing: It is recommended to thoroughly brush the parts using a soft bristled brush, giving special attention to joints, serrations and racks. The instruments, where applicable, must be disassembled and each component washed separately. Special attention should be paid to areas of difficult access, where retention of organic tissues can occur and deposition of secretions or disinfectant solutions.

Rinse: The instruments should be thoroughly rinsed under running water, and the articulated instruments must be opened and closed a few times during rinsing. It is recommended to use heated water for instrument rinsing.

Drying: Make sure that the drying processes do not introduce moisture, particles or fluff on the surface of the instrument. Special care should be given to joints, serrations and racks. It is recommended that the fabric be absorbent, soft, and that each component of a detachable instrument is insulated dry; if there are cavities or depths, they must be completely dried up.

Disposal: Disposal of disapproved parts should be done under evaluation and technical guidance. After the replacement, destroy damaged components avoiding undue use.

When it is necessary to discard the instruments, it must be immediately, in order to prevent inadvertent use. Disposal of the instruments must comply with the regulations regarding the disposal of contaminating hospital waste, discarded in suitable containers and with clear identification that it is contaminant waste.

We highly recommend that the parts be cut, warped or sanded for its destruction. In order to discard the instruments, follow local legal procedures in the country, touched upon to the correct disposal of potentially contaminating products.

6. Storage Conditions

Instruments should be stored in a clean, dry, ventilated place at room temperature and away from light. Special conditions for storage, handling and conservation of the product must be followed in order to ensure that the components remain intact for the surgical procedure. Care of receiving, storing, transporting, cleaning and storing batch references should be adopted in conjunction with good practices for storage and distribution of medical products.

7. Transporting and Handling Conditions

The Instruments must be transported and handled in a way to prevent any damage or change in its characteristics.

Articulated Instruments should be handled carefully, in small batches, avoiding beats or falls. Any instrument that has fallen or been improperly handled, or with suspected damage, must be separated and forwarded to the institution's authorized technician responsible for inspection, even if it has already passed through this step.

8. Contraindications

None.

9. Warnings

There are surgical instruments appropriate for each stage of surgery. The usual wear, the exercise of excessive forces and the use of instruments for the unadvised ends of the project may impair the evolution of the surgical procedure and damage to the implant. The use of separate instruments may entail risks of improper and other technical complications. The instruments are metallic components that are subject to important mechanical stresses during continued use for variable and indefinite duration so it is necessary the inspection and revision of the conditions of use of the instruments or parts thereof. If there are variations

of performance, loss of accuracy, instability or lack of cutting, the part needs immediate replacement.

10. Precautions

The Instruments must be kept in their original packaging until their sterilization and use. After each use, perform a correct cleaning to avoid encrustations and corrosion.

Only specialized professionals trained in the corresponding surgical technique can use these instruments.

Check, at each use, if the instruments have not suffered any damage.

Always use the appropriate instruments for each type of implant, and never try to replace some element with another that is not appropriate to the intended use.

Instruments should not be stored together with chemicals, whose corrosive evaporations can cause eventual damage to them.

ANVISA Registration: 80455630005

Technician Responsible: José Luiz Caritá - CREA-SP – 0685038754

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