USERS MANUAL OF INSTRUCTION FOR INSTALLATION AND MAINTENANCE

Insignia Arthro

CAT No. FS 100 00000

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Insignia Arthro is a single powerful system for Arthroscopy Procedures for shaving and drilling of internal tissues during Arthroscopy.

CAUTION

For Your Safety Only!

It is very important that the user of this equipment is fully aware of the functioning of the equipment, the various operations, and safe practices to be followed during the use of equipment.

It is strongly advised that the user should go through the information in the Operating and Maintenance manual carefully and understand the safety aspects, safeguards & follow the safe practices.

A strict adherence to the instructions is recommended for the safety of the operating personnel and the equipment.

In case of any doubt. Please contact,

Customer care Department

Fontierz Pvt Ltd

Cell No. 7045604451

Preface

This application manual with the equipment has been developed for use, by qualified medical personnel trained in their field of special medical techniques and in surgical procedures. This application manual describes the information and procedures, intended to assist healthcare professionals in the use, care, cleaning, autoclavable and long- term maintenance of Insignia Arthro

Date of Issue:

Equipment described in this handbook: Insignia Arthro

Equipment Delivery consists of:

- ☐ 1. Control Unit
- ☐ 2. Insignia Arthro Hand piece
- ☐ 3. Footswitch
- 4. Blade
  - ☐ Full radius Resector.
  - ☐ Aggressive radius.
  - ☐ Meniscus cutter.

- ☐ Round burr.
- ☐ Tapered burr.
- ☐ Oval burr.

☐ 5. Mains Power Cord

☐ 6. User Manual

Inspector: _____	Date : _____	Q. A.: _____

General

- Only medical professionals who are thoroughly familiar with the instrument's function, application and instructions for use should operate the instrument.
- Use of eye and face protection device(s) is recommended while operating powered instruments.
- Applications of excessive force may damage instrument and / or accessory or cause injury to patient and / or operator.
- For optimum result, use new accessory (blade) is required for every procedure.
- Check accessories (blades) for damage before and during use, if accessory seems damaged, discontinue its use.
- Never use a malfunctioning or damaged instrument. Return it to FONTIERZ PVT LTD for prompt service
- Do not drop, throw or hit instrument against any surface
- **To assure safety and optimum results, use only FONTIERZ PVT LTD attachments and accessories**

Important: Do Not Lubricate Powered Surgical Hand piece.

WARNING

- Operate the equipment only if you are authorized to do so. Know it well before you operate.
- Keep the equipment away from open flames/ source of fire.
- Proper work culture & preventive care are important ingredients to ensure safety of the equipment as well as that of the operating personnel.
- Check and ensure that the electrical parameters at the site are fully identical with the data shown on the equipment.
- Do not disturb the setting.
- Only attachments from FONTIERZ PVT LTD are approved. If attachments from other manufacturers are used, **Warranty shall seize to exist. Mixing of components from other manufacturers is not permitted**.
- **Hand piece and attachment must never be immersed in water or cleaning solutions or boiled**. Never apply any acid, corrosive or rubbing cleansing materials. It should only be autoclaved.
- Before operation, check the instrument and attachment are in perfect condition and functioning correctly.
- Insignia Arthro hand piece & attachments must be Cleaned immediately after use.
- Do not open the Front / Rear ends of the equipment. Service only by authorized personnel.

NOTE: All equipment must be cleaned and sterilized before sending for servicing.

Important:

- In order to avoid injuries of personnel or damages to the INSIGNIA ARTHRO do not try to repair the equipment on your own.
- A qualified customer service technician from Fontierz must provide any service or repair of the INSIGNIA ARTHRO only
- The supplier recommends to have the equipment inspected once a year by a qualified customer service technician
- The power supply cord should be checked regularly for any damages on the insulation or on the connections

Function And Intended Application:

- Smart, flexible and easy to operate Insignia Arthro system.
- A reliable power for Arthroscopic procedures.
- Sophisticated tool for effective control and more efficient bone debriment and tissue resection.

Field of Application:

- FONTIERZ PVT LTD's Insignia Arthro a single powerful system for removal of soft and hard tissues during Arthroscopy procedures

SAFETY INSTRUCTION

We are very much concerned about your safety and your team's safety. Therefore, it is imperative for you to comply with the following instructions. Please study this instruction manual carefully before installing the equipment.

- The INSIGNIA ARTHRO must only be used in medical centers those meet all required safety standards.
- Trained and specially instructed personnel may only handle equipment.
- Before placing the equipment 's accessories in use, please read all the warnings and safety instructions attached.
- Before connecting the INSIGNIA ARTHRO to the electric Mains unit, Please check and secure that the electrical parameters at the site are fully identical with the data shown on the equipment.
- Electric components are not explosion free.
- Do not use in the areas where flammable vapours are present.
- Do not open the backside / top of the equipment as Electric Current is present inside the equipment.
- Before operation, check the instrument and attachment are in perfect condition and functioning correctly.

Attention:

- Never–ever operate the equipment in dangerous areas of explosives.
- In case any fluid enters the equipment, turn off the equipment immediately.

- The INSIGNIA ARTHRO may only be connected to equipment's that meet all safety standards and which are proven to be compatible.
- Only operate the equipment in the areas of the air humidity between 30% and 85%. RH
- Install a stabilizer if required to cater to variations in mains supply. Supply voltage variation of 230VAC +/-5%.
- To change the fuse, Switch OFF the equipment and disconnect, electrical cable, replace the damaged fuse with a new fuse of the appropriate type and rating. ***Recommended Line Voltage: 230 V & Fuse Rating: 5 A 250 V***
- The equipment's direct surrounding temperature has to remain in the frame of $+10^0$C to + 40^0C
- Please avoid heavy concussions.
- The INSIGNIA ARTHRO is designed for the indoor use only and not to be used in outdoor areas.
- Avoid jolting the equipment or exposing it to vibrations.
- Always place the equipment in a horizontal area and never put any heavy things on the top of INSIGNIA ARTHRO
- Never apply any acid, corrosive or rubbing cleansing materials. The equipment cannot be completely sterilized.
- The equipment must be clear fully handled strictly in accordance with this application manual.

- Use only FONTIERZ PVT LTD Hand-Piece and attachment supplied with this equipment.
- Use only Foot switch supplied with this equipment

FIRST INSTALLATION STEP OF EQUIPMENT

- After unpacking check the equipment for any outside damages. In case of damages resulting from transportation inform supplier immediately.
- Place the Intelligent Insignia Arthro on a safe base
- Have the unit adjusted to room temperature.

- **Preparing to use:**

  To use Insignia Arthro check for following items

  o Insignia Arthro unit

o Hand piece with 3mtr Cable

o Appropriate blade attachment for planned procedure.

o Foot switch with 3mtr Cable

- **Functional Check:**
  - Before using the Insignia Arthro always test it with the appropriate attachment fitted.
  - Briefly operate Insignia Arthro with attachment and footswitch connected.
  - Ensure that footswitch and Insignia Arthro hand piece is connected and check for forward, reverse and oscillatory motion of the Insignia Arthro attachment.

- **CAUTION :**

  Be sure to connect the AC power cord to a grounded outlet only.

INSIGNIA ARTHRO AND ATTACHMENTS

Control Unit

Part No. FS 10000000

Power ON/OFF

Handpiece Plugin

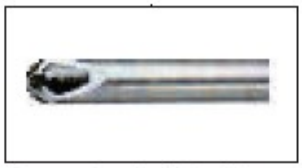
Insignia Arthro Hand piece

Part No. FS 100 20000

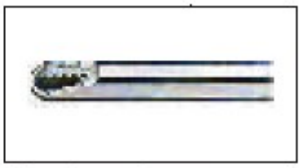
Nozzle

Attachments

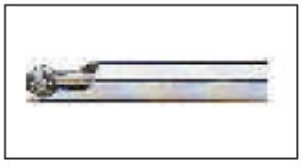
Full Radius Resector
Part No : LS 10050001



Agressive Full Radius
Part No : LS 10050002

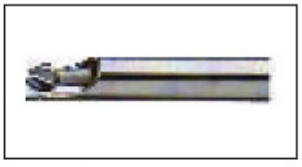


Meniscus Cutter
Part No : LS 10050003



Round Burr
Part No : LS 10050004

Tapered Burr
Part No : LS 10050005



Oval Burr
Part No : LS 10050006

TECHNICAL DATA

Electric mains Connections	230 VAC 50 Hz, + / -5%
Power Consumption	200 VA
Frequency	50 /60 Hz
Fuses	2 x 5 Amp 250V IEC 127
Mode of operation	Continuous Operation
Dimensions	281(W) X 216(L) X 92(H) mm
User Interface	Touch screen
Display	4.3” Colour TFT Display
Weight	4 kg
Oscillation Mode	900 RPM to 3000 RPM (Increment / Decrement in the step of 300 RPM)

Linear Mode	1. Low Operation: - 900 RPM to 2700 RPM (Increment / Decrement in the step of 300 RPM) 2. High Operation: - 3000 RPM to 6300 RPM (Increment/ Decrement in the step of 300 RPM)
Operating environment	10^0 C - 40^0 C ambient temperature 30% - 70% relative humidity
Storage & transportation environment	-40^0 C - $+70^0$ C ambient temperature 10% - 90% relative humidity.
Maximum relative air humidity	85%
Protection, Apparatus grade	Class I
Classification	Type BF
Control	Micro computerized Control
Accuracy	Max. ± 5%
Sterilization	Hand piece –Autoclavable Footswitch –water proof

*** Equipment not suitable for use in presence of FLAMMABLE ANAESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE.**

GLOSSARY OF SYMBOLS

Fontierz	Company Logo	rpm	Revolutions per minute
	Manufacturer		Found on Console ON/OFF
	Handpiece connector location		Connection for foot pedal
	Fuse	LOT	Lot (A.K.A. Lot number, Batch number, batch code)
	AC Power Source	SN	Serial Number

	Consult Operating Instructions		Reference number (A.K.A. Item number, catalog number, part number)
	Keep dry (A.K.A. Protect from moisture)		Do not dispose of Household waste.
	Type BF Electrical equipment		CAUTION: Refer to accompanying documentation
	Identifies equipment is provided with user manual.		Caution! Federal law restricts this device to sale by or on the order of a physician or any other practitioner licensed by the law of the state in which he or she practices to use or order the use of the device.
	Indicates the item is a medical device		Latex-free
	Single-Use only		Temperature limits
	Zone M Anaesthetic agent inspection under Class AP		Class II
	Can be placed in an autoclave < 135°C		Top
	Fragile		Date of manufacture
	Expiry date		Non-sterile
	Only use if packaging is undamaged		Thermo washer disinfectable

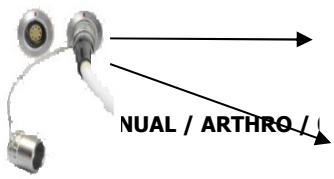
FEATURES

- Incorporated the State- of – Art high performance 3 Phase BLDC motor.
- Ergonomically designed Foot Switch dedicated soft touch pedals that stays clean & is fully immersible.
- Oscillation speed from 600 rpm up to 3500 rpm
- Complete autoclavable system

CONNECTION & DISCONNECTION OF DETACHABLE PARTS & ACCESSORIES

Control Unit:

- Insert main cord in main socket carefully.
- To connect Insignia Arthro Handpiece, check the symbol of handpiece. Match the red dots at both ends (Male & Female Connector). Verify with a click sound. The Handpiece is secured in



place.

- To connect Insignia Arthro foot switch place, check the symbol of Footswitch. Match the red dots at both ends (Male & Female Connector). Verify with a click sound. The Footswitch is secured in place.
- Ensure that, the connector is aligned with the red mark.
- To Detach the Insignia Arthro console and foot switch, pull the Knurled portion of the connector of cord toward back end and softly pull out the cord

Insignia Arthro Blade :

- **To connect Blade:** Place the rear end of the blade to Insignia Arthro's front end ensuring that the notch of the blade fits into the Insignia Arthros groove firmly.
- **To detach Blade:** Push the knob at the locking groove softly and pull out the blade .

OPERATING PROCEDURE

Caution: The adapter provided with the instrument has the facility to accept different Insignia Arthro blades supplied/recommended by *FONTIERZ PVT LTD.* The Hand piece shall not be operative for any other type of blades.

Full Radius Resector

Agressive Full Radius

Operating speed :1800 to 3600 RPM

Use: Partial, subtotal synovectomy, removal of degenerative meniscus Tissue and adhesion strands removal.

Meniscus Cutter

Operating speed:1800 to 3300 RPM

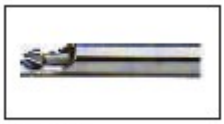
Use: Removal of degenerative meniscus tissue, cicatricle and synovial strands removal cartilage

Round Burr

Operating speed:3000 to 5600 RPM

Use: Removal of physical or functionally interfering outgrowth, smoothing Bone irregularities milling of subchondral abrasion for the induction of fibrous cartilage

Tapered Burr



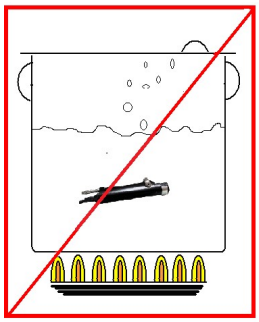
Oval Burr

Operating speed :3300 to 5600

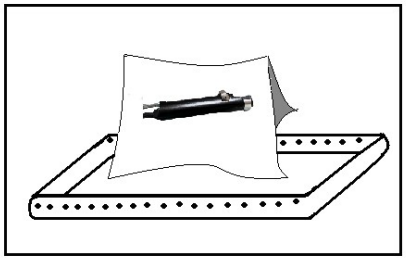
Use: Extensive ablation with acromial decompression at the shoulder extensive cartilage removal with acromial decompression

DIRECTIONS FOR CLEANING PROCEDURE

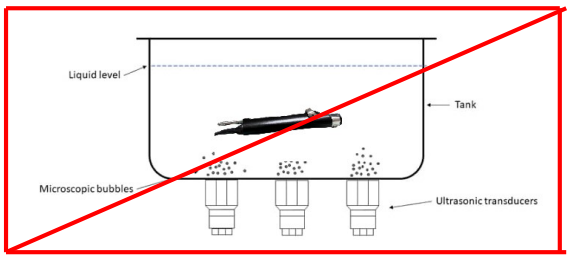
Improper way of cleaning.



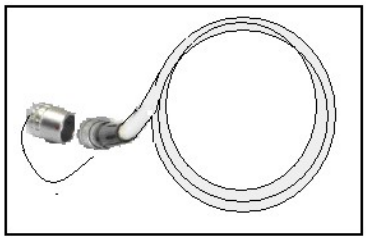
Do not immerse and boil



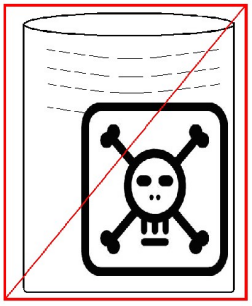
Wrap in cloth during sterilization.



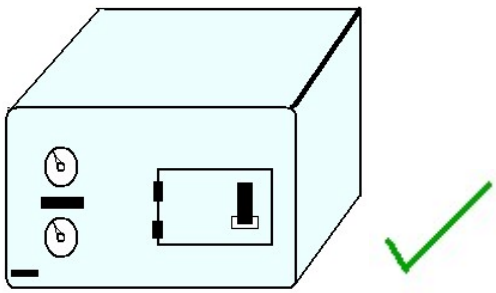
Do not clean with ultra-sonic cleaner



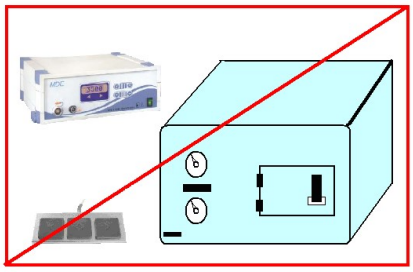
Attach the Dust preventive cap to the cord and coil the cable to a circle of 30-40 cm during sterilization



Do not clean with acid



Sterilization max 121 ° C



Do not Sterilize Control Unit OR Foot Switch

CLEANING AND STERILIZATION

Control unit and foot pedal:

Use enzymatic detergent with a neutral pH (6 to 8). Spray the outside to clean the residues. Soak a clean cloth and carefully clean the surfaces.

Do not Sterilize Control Unit OR Foot Switch

Hand piece:

- ✓ Hand piece should be cleaned as soon as possible after the surgical procedure.
- ✓ Follow general precautions for protective apparel when handling and cleaning infected instrument.
- ✓ Dispose of all non – reusable blades and bits properly after each use.
- ✓ Before cleaning and sterilizing remove attachment and accessory from the hand piece.
- ✓ Do not lubricate hand piece and attachment.
- ✓ Clean hand piece and attachments immediately after using.
- ✓ Never submerge Hand piece or attachments in disinfection solution.
- ✓ Never clean hand piece or attachment in an automatic washer or ultrasonic cleaner
- ✓ Use a mild, neutral pH cleaning solution to clean the hand piece and attachment using soft brush or cloth.
- ✓ Wipe or spray hand piece and attachment with antiseptic.
- ✓ Rinse Accessory (tools/ blades) under running water, using soft brush or cloth.
- ✓ Dry hand piece and attachment with a soft cloth.
- ✓ Place hand piece and attachment in autoclave for sterilization.
- ✓ Hand piece with end cap can be sterilized at up to 5 bar at 132°C in the stream sterilizer. It is advisable to place the equipment on a cloth or wrap it in a cloth to prevent external and internal damage.
- ✓ Avoid the use of strong cleaning agents such as Benzene or Alcohol.

Cleaning of equipment interior

Depending upon the surrounding conditions of the equipment, the Insignia Arthro interior has to be cleaned by removing the dust. This can be done for example with a vacuum cleaner carrying a small nozzle. Especially the ventilator blades absorb a lot of dust. This area should be cleaned with a smooth cloth using a little bit of spirit.

Caution:

1) Dry cycles are required to ensure evaporation of moisture from sterilizing. Equipment should be dry prior to surgical use. If devices are not dry, wipe all surfaces with sterile cloth prior to use.

2) Detach the cord from the control unit close the Dust Preventive cap of cord before sterilization. Foil the cable to a circle of 30-40 Cm during sterilization.

IMPORTANT NOTICE:

Never ever pour any cleansing/ disinfectant liquids directly into the equipment. Never use any gas purifier or diluents and a cloth that carries any chemicals. If equipment gets cleaned by way of liquids that are inflammable, the equipment has to dry-off for at least one hour before putting it back to use.

STERILIZATION:

Sterilization by steam/moist heat is the recommended method for the hand piece and its cable. Following are the sterilization parameters, using a B type cycle

Temperature	132°C
Time	40 minutes.

MAINTENANCE

Hand piece:

The FONTIERZ PVT LTD Insignia Arthro, itself requires no maintenance. Nevertheless, we recommend annual inspection. This must only be entrusted to the manufacturer or qualified persons authorized by the manufacturer. The Maintenance interval depends on frequency of sterilization of the equipment.

Never disassemble the hand piece or its cable

Caution: Prior to changing fuses, set power unit main switch OFF and disconnect power cord

SERVICING

We recommend sending the Insignia Arthro to FONTIERZ PVT LTD for servicing after one in a Year.

REPAIRS

FONTIERZ PVT LTD only accepts responsibility for the safety, reliability and performance of the Insignia Arthro. The Insignia Arthro is used in compliance with the instruction in the User's Manual

- Installation, Additions, Adjustments, Modifications are Repairs are carried out by **FONTIERZ PVT LTD** or by Qualified persons expressly authorized by **FONTIERZ PVT LTD**
- Only original spare parts from **FONTIERZ PVT LTD** may be used for repairs

Warning: All equipment must be cleaned and sterilized before sending for servicing

TROUBLE SHOOTING

Control Unit:

SR. NO.	TROUBLE	CAUSE	REMEDY
1.	The control unit does not turn on.	a) Power Cord is not connected. b) Main fuse has burnt.	a) Check Power cord connection. b) Replace the main fuse.

Insignia Arthro:

2.	Insignia Arthro controller not operating	Loosely fitted Insignia Arthro mains cord	Check for Insignia Arthro connection
3.	Error Message ` HAND PIECE NOT CONNECTED` appears on alphanumeric display	Hand piece is not connected properly	Check the Hand Piece connection to the control unit. Match the Red dots and gently push the connector till to hear a click sound
4.	The Cutter/ burr keeps 'jumping' out of the Hand piece.	The cutter/ burr is not locked.	Lock the cutter / burr using the locking ring at the Hand Piece.
5.	Insignia Arthro motor is not rotating.	a) Insignia Arthro hand piece is not connected to the control unit. b) Foot-Switch is not connected.	a) Connect the Insignia Arthro hand piece connector to the control unit. b) Connect the foot switch and Press the Footswitch.
6.	Fluid from nozzle does not come out	a) Blockage in the nozzle b) Suction pump not working	a) Clear blockage b) Connect suction pump properly.

PRODUCT CATALOG NUMBERING

Sr.No.	Part	Catalog No.
1.	Control Unit	FS10010000
2.	Insignia Arthro Hand piece with 3mtr cable	FS10020000
3.	Foot switch with 3mtr cable	FS10030000
4.	Power cable 3mtrs	FS 10040000

5.	Insignia Arthro Blades	
	a) Full Radius Resector	FS10050001
	b) Aggressive Radius	FS10050002
	c) Meniscus Cutter	FS10050003
	d) Round Burr	FS10050004
	e) Tapered Burr	FS10050005
	f) Oval Burr	FS10050006

Fontierz

FONTIERZ PVT LTD

Date:

WARRANTY

Name of the Customer	**:**	
Address	**:**	
Booked By	**:**	
Sr. No. of Insignia Arthro Control Unit/Insignia Spine Control Unit	**:**	
Sr. No. of Insignia Arthro Hand-piece /Insignia Spine Hand-piece Unit	**:**	

We hereby offer the warranty to **Insignia Arthro/ Insignia Spine** supplied with above-mentioned **Sr. No.** for the period of **ONE Years.** warrants, the Hardware, free from defective workmanship and Material for the period of **12 months** from the warranty date.

Fontierz Pvt. Ltd. will at its option repair or replace products, which will prove to be defective during the warranty period. The above warranty shall not apply to defects resulting from:

1. Improper or inadequate maintenance by buyer.
2. Unauthorized modifications or misuse.
3. Attempt by unauthorized service agents.
4. Operations outside of the environmental specifications.
5. Improper installation through unauthorized service agents.

For **Fontierz Pvt. Ltd.**

Authorized Signatory

NOTE: Warranty is applicable only for manufacturing defects & does not cover physical damage or any consumable items.

FON/QA/F/10

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