

USERS MANUAL OF INSTRUCTION FOR INSTALLATION AND MAINTENANCE

INSIGNIA SPINE

High Speed Surgical Drill System

CAT No. FN10000000

**For any details/ Clarifications please call Customer Care at
+91-9623942932**

FONTIERZ PVT LTD.

2nd floor, Plot No 165 /1 /17
Priyadarshani Industrial Society,
T block , MIDC Bhosari, Pune – 411026

TABLE OF CONTENT

| | | |
|-------------------------------------|--|----|
| Introduction | Insignia Spine (High Speed Surgical Drill System) | 3 |
| | Warnings | 4 |
| | Cautions | 6 |
| | Technical Spécification | 7 |
| | Glossary of Symbol | 8 |
| Assembly and Operating Instructions | Insignia Spine (High Speed Surgical Drill System) | 9 |
| Attachments and Dissection Tools | Universal Angled Attachment | 14 |
| Care and Maintenance | Inspection and Maintenance | 15 |
| | Manual Cleaning | 16 |
| | Mechanical/ Automated Cleaning | 20 |
| | Sterilization | 23 |
| | Trobleshooting | 25 |
| | Ordering Information | 27 |

INTRODUCTION

Insignia Spine is a high-precision, high-speed Surgical Drill system designed to help surgeons operate with greater efficiency and accuracy. Development by India's trusted Fontierz Pvt Ltd. Insignia Spine delivers unmatched performance and reliability at par with the best in the world.

Insignia Spine is intended for cutting and shaping bone including the Spine and cranium.

High Speed Surgical Drill System :

Handpiece operates 20000 to 80,000 rpm. It offers variable speed, minimal sound level. It is a high performance system and highlights minimal vibration performance, thermal energy management, neurologists, skull base surgeons, Spinal surgeons and otologists.

Warning: Before Using any of the Insignia Spine (High Speed Surgical Drill system), it is imperative that all individuals working with the system read the accompanying documentation with the product. The surgeon is responsible for learning the proper techniques in the use of this system, as improper use may cause injury.

WARNING

- The surgeon is responsible for learning the proper techniques in the use of equipment, improper use may cause serious injury to user or patient or damage to system.
- Instrument operator and all operating room personnel must wear eye protection.
- Visually inspect for damage before using; do not use if damage is evident.
- Do not use if the product sterilization barrier or its packaging is compromised.
- Do not use, or discontinue use of powered equipment exhibiting excessive temperatures that can cause patient injury (necrosis) and/or user discomfort.
- Use of damaged or improperly maintained power equipment can result in excessive temperatures.
- Use caution to avoid cutting or tearing gloves while handling dissection tools.
- Dissection tools must be adequately retained within attachment to prevent distal migration, which may cause injury.
- Gently pull on dissection tool shaft to ensure it is fully seated and properly installed.
- Delicate structures in proximity to dissection must be thoroughly protected to prevent injury.
- Maintain firm control of instrument at all times.
- Use a gentle tapping motion or side-to-side motion and let instrument do cutting.
- Do not use excessive force.
- Forceful side loading of dissection tool may cause fracture of dissection tool, which may cause injury.
- Use standard protocol for disposal of sharp instruments.
- Continuous extreme cutting at or near stalling conditions will quickly overheat handpiece.
- Do not operate in an explosive flammable environment.
- Do not modify ground or power cord.
- Do not allow liquid in to console.
- Use of accessories other than provided by Fontierz Pvt Ltd. may result in increased emissions or decreased immunity.

- Medical electrical equipment needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this accompanying documentation.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- Power source should comply with applicable IEC, CEC and NEC requirements. Grounding reliability can only be achieved when this equipment is connected to a receptacle marked "HOSPITAL GRADE."
- Do not use in oxygen rich environment.
- No modification of this equipment is allowed.
- Do not modify. Modifications could result in loss of electrical safety.
- Dispose of items contaminated with body fluids with other bio-hazardous waste.
- At end of life recycle or dispose of device in accordance with local and national regulations.
- To avoid risk of electric shock this equipment must only be connected to a supply main with protective earth. The use of accessories, transducers, and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of this device as replacement parts for internal components, may result in increased emissions or decreased immunity of Insignia Spine.

CAUTIONS

- Do not use accessories other than those provided by Fontierz Pvt Ltd. and specified for use with Insignia Spine system.
- To ensure equipment operates as designed, read and follow manufacturer's instructions.
- Do not operate handpiece without an attachment and corresponding dissection tool.
- Only Fontierz Pvt Ltd. dissection tools should be used with Insignia SPINE system.
- Use care to protect hose when handling, cleaning, and during system use.
- Damage to hose can cause leaking, rupture, or other related failures.
- Do not Step on, set equipment on, pinch, kink, clamp, or otherwise occlude handpiece hose during use.
















TECHNICAL SPECIFICATIONS

| Specification | Description |
|---|--|
| Manufacturer Name | Fontierz Pvt Ltd |
| Manufacturer Address | 2nd Floor,Plot No.165/1/17, Priyadarshani Industrial Society,T Block, MIDC,Bhosari,Pune-411026 |
| Product Name | Insignia SPINE |
| Model | Insignia SPINE |
| Sr No | 3 |
| Electric mains connection | 100-250VAC, 50/60Hz |
| Current rating | 2A |
| Power rating | 200VA |
| Dimensions (W X L X H) | 275 X 250 X 110mm |
| Speed | 20000-80000 RPM |
| Recommended Temperature in operating theatre: | + 10° to + 35°C |
| Overload protection | Automatic overload cut out with auto reset |
| Protective Earth | Class I |
| Applied part Type | B |
| Attachment | Universal Angled Attachment-125mm |
| Burr/cutters | 1. Cutting burr 125mm 2. Diamond burr 125mm |
| Display | Touch Screen Display (95 x 55mm) |
| Cable | 3meter cable length for Handpiece and Foot Pedal |

FEATURES

- 1) Light Weight, Portable system.
- 2) High speed, pencil grip drill used to burr/cutter, peerless Precision.
- 3) Ideal for Neuro and Spinal Surgeries.
- 4) No Excessive Heat, vibration and Noise.
- 5) Best-in-class Analog Variable Foot Switch for increased Precision.
- 6) Wide Range of Cutters and burr/cutters for easy compatibility.
- 7) High Performance system, minimal vibration performance and minimal sound level.

GLOSSARY OF SYMBOLS

| | | | |
|---|---|---|--|
|  | Company Logo | rpm | Revolutions per minute |
|  | Company Product Icon |  | Found on Console ON/OFF |
|  | Handpiece connector location |  | Reference number (A.K.A. Item number, catalog number, part number) |
|  | Fuse |  | Lot (A.K.A. Lot number, Batch number, batch code) |
|  | AC Power Source |  | Serial Number |
|  | Consult Operating Instructions |  | Manufacturer |
|  | Keep dry (A.K.A. Protect from moisture) |  | Do not dispose of Household waste. |
|  | Type B Electrical equipment |  | CAUTION: Refer to accompanying documentation |



Identifies equipment is provided with user manual.



Temperature limits



Indicates the item is a medical device

ASSEMBLY AND OPERATING INSTUCTIONS

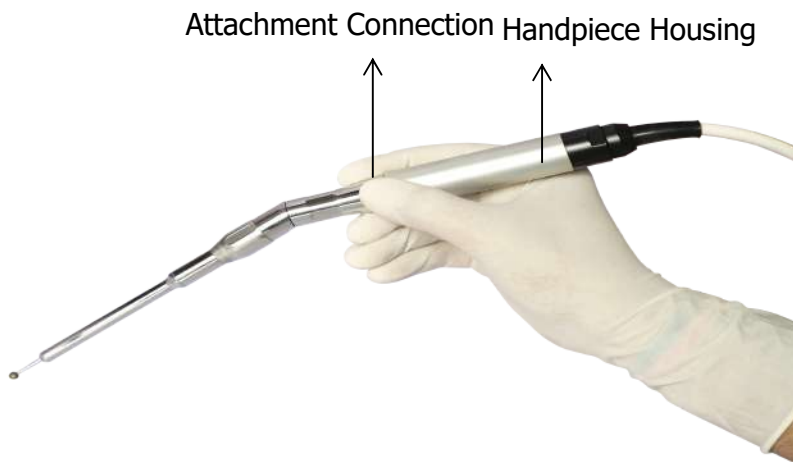
The system console houses the electrical components that provide power, control, and cooling functions to the Insignia Spine handpiece. It provides the user control for all system functions via an integrated touch pad face panel. The system console has connections for the Insignia Spine handpiece, foot controls, AC power inlet and the main power switch.

Caution: Do not use handpiece without an attachment and dissection tool properly locked in place. Damage to the burr/cutter lock mechanism could occur.



Front of system console:

- 1) Power Switch:** Push button for turn on control unit.
- 2) Increment touch screen button:** For Increasing RPM
- 3) Decrement touch screen button:** For Decreasing RPM
- 4) Handpiece connector Port:** Handpiece Connector Port
- 5) Footswitch connector Port:** Footswitch Connector Port



Warning: Prior to first use the equipment must be processed as per the included Insignia Spine High Speed System Cleaning and Sterilization instructions.

Note: When following these instructions hold handpiece and attachments with distal end pointing away from user.

System Assembly

1. Place console on a flat sturdy surface.

Warning: Console must be outside sterile field.

2. Plug hospital-grade AC power cord into AC power inlet on back of console. plug opposite end of power cord into standard, hospital-grade grounded wall outlet.

Caution: Connect to supply mains with protective earth only. Position equipment in such a manner that it provides access to the rear of the system in order to disconnect from mains

3. Insert foot control connector into foot control connector port on front of console with red dot on connector facing up.

Warning: Foot control must be outside sterile field.

Caution: Do not push foot control connector into console connector port when out of alignment.

4. Insert handpiece connector into handpiece connector port on front of console with red dot on connector facing up.

Warning: Handpiece must remain inside sterile field with exception of handpiece connector which is connected to console.

Caution: Do not push handpiece connector into console connector port when out of alignment.

5. Activate console by depressing power switch located on front of console. Display will illuminate.
6. Refer to operating instructions.

Warning: Handpiece is fully functional at this time.

Caution: Do not use handpiece without an attachment and dissection tool properly locked in place. Damage to the burr/cutter lock mechanism could occur.

Attachment Assembly

1. Refer to the Insignia Spine Attachment instructions accompanying the specific device.

Dissection Tools

1. Refer to the Insignia Spine dissection tools instructions accompanying the specific device.

System Operation

Warning

1. Do not use a dissection tool without an attachment, injury may occur.
2. Only Use Insignia Spine Dissection Tools. Using other than indicated dissection tools may lead to injury.
3. Use the correct dissection tool and attachment combination or injury may occur.

Caution: Do not use handpiece without an attachment and dissection tool properly locked in place. Damage to the burr/cutter lock mechanism could occur.

Console Default Settings

Direction: Forward (clockwise with distal end pointing away from user)

Speed: 80,000 RPM (maximum)

User Interface: foot control

Console Operation

1. To increase or decrease maximum operational speed of handpiece, depress blue arrows located on front of console. speed increases and decreases in 2,000 RPM increments. Lights on front of console will indicate the maximum revolutions per minute (RPM).

Note: Buttons with hand and foot symbols on front of console are non-operational. Light next to foot symbol is ON indicating console is set to operate in foot control mode. There is no hand control mode for Insignia Spine Handpiece, consoles will always be in foot control mode.

Foot Control Operation

Warning: Handpiece is fully functional at this time.

Caution: Do not use handpiece without an attachment and dissection tool properly locked in place. Damage to the burr/cutter lock mechanism could occur.

1. Press foot control pedal to start handpiece. increase pressure on pedal to increase speed of handpiece and release pressure on pedal to decrease speed of handpiece.

System Operational Assessment

1. Confirm attachment and dissection tools are properly locked in place.
2. Depress foot pedal to assure you have properly functioning device prior to proceeding.
3. Device functions as expected, if device does not function as expected refer to troubleshooting chart.

Prior to Use Inspection

- Visually inspect for any damage to the handpiece, attachment and dissection tool.
- Visually inspect for bent or broken drive shaft and for any damage to the handpiece, attachment and dissection tool.
- Visually inspect for bent or broken foot control.
- Visually inspect for overall damage or missing components.
- Visually inspect for damage to the electrical cord or connector.
- Visually inspect for damage or cracks to the housing or pedal.
- Visually inspect for damage to the silicone hose or to the electrical connector.
- Connect to console and operate.
- The handpiece should operate smoothly.
- Caution: Do not operate without attachment or dissection tool.
- Visually inspect for damage or cracks to the housing. Visually inspect for damage to the electrical power cord.

System Shutdown

1. There are no special procedures for system shutdown. Depress power switch on front of console to shut down system for approximately 2–3 seconds.

2. To disconnect power cord from mains, grasp ridged portion of connector between thumb and forefinger of one hand. Gently pull connector away from console. connector should remove easily. If not, ensure only ridged portion of connector is pulled. do not pull on smooth part of connector, as connector will not disengage from console.

Additional Information

To isolate the device from the mains supply, remove the power cord. All specifications are subject to change.

The Insignia Spine system operates continuously without a duty cycle under normal operating conditions.

After completing the procedure perform the inspection and maintenance steps provided. If the alert does not clear, return the system for repair to Fontierz Pvt Ltd. .

End of Life

Return all equipment for proper disposal.

Recommended Manufacturer Inspection Interval

It is recommended that the equipment be returned to Fontierz Pvt Ltd. at a minimum every 12 months to perform a full product inspection.

ATTACHMENT AND DISSECTION TOOL IDENTIFICATION

Warning: All dissection tools are packaged sterile and are single use.

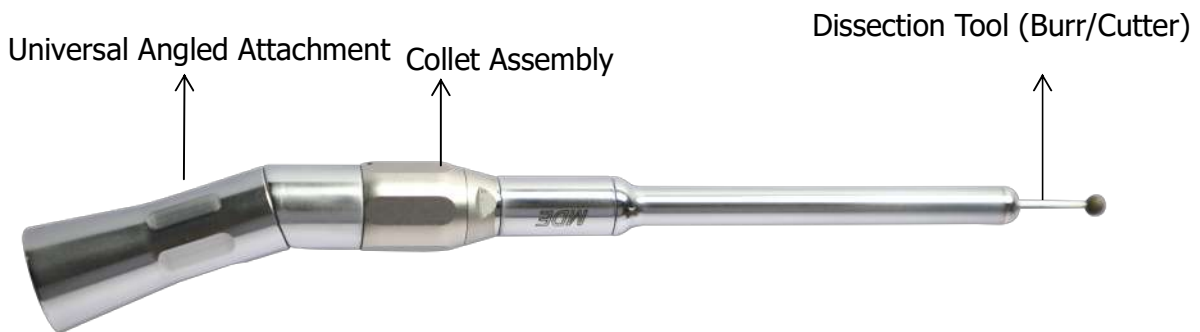
Cleaning and Sterilization

1. Prior to first use the equipment must be processed as per the instructions Fontierz Pvt Ltd. Insignia Spine High Speed Surgical Drill System/cutter System system cleaning and sterilization instructions.
2. At the point of use the device must be cleaned as soon as possible after use to prevent drying of blood, tissue, other biological debris and contaminants on the device.
3. Refer to the Insignia Spine high speed system cleaning and sterilization instructions accompanying this device.

Attachment and Dissection Tool Selection

To assist in identifying the correct attachment and dissection tool combination.

UNIVERSAL ANGLED ATTACHMENT :



Note: When following these instructions hold handpiece and attachments with distal end pointing away from user.

Caution: Do not use handpiece without an attachment and dissection tool properly locked in place. Damage to the burr/cutter/cutter lock mechanism could occur.

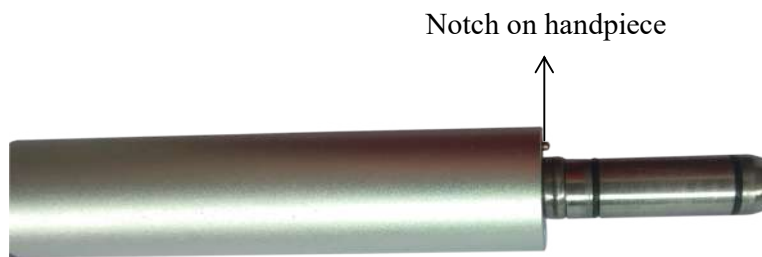


Fig: Closed view of Handpiece

1. Confirm alignment of notch on handpiece matching with attachment notch. If not aligned properly, hold handpiece housing firmly with one hand and with other hand attachment, insert attachment in handpiece match the notch gently push attachment until click sound heard.
2. Insert dissection tool into end of attachment, hold attachment housing firmly with one hand and collet assembly from other hand, rotate collet assembly upward or clockwise for 2steps.
3. Gently pull on dissection tool to ensure proper engagement.

Note: Handpiece is now fully functional.

Disassembly

1. Rotate collet assembly downward or anticlockwise.
2. Remove dissection tool from attachment.
3. Remove attachment from handpiece by gently pulling out from handpiece.

Note: When following these instructions hold handpiece and attachments with distal end pointing away from user. Universal angled Attachment is compatible with multiple burr/cutter configurations. Instructions are the same for all burr/cutter configurations.

Inspection and Maintenance

Perform these activities regularly as per institution policy.

Warning: Do not use any damaged equipment. Return to Fontierz Pvt Ltd. repair facility.

| | |
|-------------------------------|--|
| Universal Straight Attachment | <ol style="list-style-type: none">1. Visually inspect for any damage to attachment.2. Visually inspect for bent or broken drive shaft and for any damage to the attachment. |
|-------------------------------|--|

| | |
|--------------|---|
| Foot Control | <ol style="list-style-type: none">1. Visually inspect for damaged electrical cord or connector.2. Visually inspect for damage or cracks to the housing or pedal. |
|--------------|---|

| | |
|-----------|---|
| Handpiece | <ol style="list-style-type: none">1. Visually inspect for damage to the silicone hose or to the electrical connector.2. Connect to console and operate. The handpiece should operate smoothly. |
|-----------|---|

Caution: Do not operate the handpiece without an attachment and dissection tool. Damage to the burr lock mechanism could occur.

| | |
|----------|---|
| Consoles | <ol style="list-style-type: none">1. Visually inspect for damage or cracks to the housing.2. Visually inspect for damage to the electrical power cord. |
|----------|---|

MANUAL CLEANING

Warnings:

- Cannulations must be cleaned with appropriate brushes as described in cleaning instructions.
- At the point of use the device must be cleaned as soon as possible after use to prevent drying of blood, tissue, other biological debris and contaminants on the device.
- National regulations must be observed.
- You must follow standard hospital procedures.
- You must follow manufacturer's recommendations for any detergents, disinfectants and washing equipment used.

- Dispose of all non – reusable consumables as per local regulations / Guidelines of Health Care Facilities.

Cautions:

- Do not use any alkaline detergent with a pH greater than 7. Alkaline detergents with higher pH attack grease and seals which can increase wear and cause device to malfunction.
- Do not use ultrasonic equipment.
- Do not use hypochlorite solution (i.e. bleach).
- Handpieces must not be immersed in cleaning solution but may be sprayed with it.
- Fully demineralized (deionized, distilled, or purified) water must be used during final rinse to prevent corrosion and spots.

Note: Use of alkaline detergents can cause device color to fade but this does not impair function.

Operating Room (OR) Personnel Instructions

1. After completion of procedure, remove external debris by wiping attachments and handpiece.
2. Dispose of open or used dissections tools.

Reprocessing Personal Instruction

Handpiece



Note: The instructions in this section are specific to the Insignia Spine Electric Handpiece.

1. Preparation

- Assemble all necessary supplies including the attachment cleaning brush (ACB), sponge, lint-free cloth and soft bristle brush.
- Remove attachment and dissection tool from handpiece.

2. Rinse

- Use a sponge, soft lint-free cloth or soft bristle brush to assist in removing gross soil.

Caution: Do not immerse. Do not use high pressure water or air. Do not allow running water to enter distal end of handpiece or console connector (end of cable).

3. Clean

- Prepare cleaning solution using alkaline detergent or neutral pH enzymatic detergent per manufacturer's directions for correct temperature, water quality (i.e. pH, hardness) and product concentration/dilution.
- With distal end pointing down spray and wipe using cleaning solution for a minimum of 2 minutes.
- Use a sponge, soft lint-free cloth or soft bristle brush to remove all visible soil.
- Hold handpiece with distal end pointing down and clean handpiece with mild solution into distal end of handpiece.

Caution: Do not immerse. Do not allow running water to enter distal end of handpiece or console connector. Do not use pipe cleaners.

4. Inspect

- Visually inspect handpiece. repeat steps 2 thru 5 if visible soil remains.
- Go to sterilization section for further instructions.

Attachment

Note: The instructions in this section are specific to the Insignia Spine Attachments.

1. Preparation
 - Assemble all necessary supplies including burr/cutter.
 - Remove attachment and dissection tool from handpiece.

Caution: Do not use high Pressure water or air. Do not rinse attachment with saline solution.

2. Rinse
 - Rinse attachment under running cold deionized, distilled, or purified water.
 - Use a sponge, soft lint-free cloth or soft bristle brush to assist in removing gross soil.

Caution: Do not immerse. Do not use high pressure water or air. Do not rinse attachment with saline solution.

3. Clean
 - Prepare cleaning solution using alkaline detergent or neutral pH enzymatic detergent as per manufacturer's directions for correct temperature, water quality (i.e. pH, hardness) and product concentration/dilution.
 - Fully immerse attachment in cleaning solution in a suitable container and manually agitate for 2 minutes.
 - Use a sponge, soft lint-free cloth or soft bristle brush to remove all visible soil.
 - Gently use a brush to clean cannulations of attachment while immersed in cleaning solution. use the small-diameter cleaning brush (SDCB) for Attachment burr/cutter. If attachment has a release sleeve, move sleeve and brush exposed area.

Note: Brushes may be inserted from distal or proximal end of attachments and bearing sleeves.

Caution: Do not use high pressure water or air. Do not rinse attachment with saline solution.

4. Rinse Thoroughly
 - Rinse attachment thoroughly using running hot deionised, distilled, or purified water.

Caution: Do not use high pressure water or air. Do not rinse attachment with saline solution.

5. Inspect
 - Visually inspect handpiece. repeat steps 2 thru 5 if visible soil remains.
 - Go to sterilization section for further instructions.
6. Lubricate.

Caution: This step is for attachments only. Do not lubricate handpieces.

Lubrication for Universal Angled Attachment

- Apply lubrispray to attachment from proximal end and from distal end.
- Allow it to drain completely until no visible droplets are coming from it.
- Return attachments to basket for further processing.

Caution: Do not rinse out instrument milk. Do not apply mineral oil or other lubricants, which may cause attachment to overheat.

7. Go to sterilization section for further instructions.

Console

Caution: Do not immerse or sterilize. Do not allow liquid to enter console.

Note: Consoles are non-sterile capital equipment and shall always be maintained outside the operating room sterile field.

1. Disconnect all power from console.
2. Clean console by wiping with non-abrasive cloth and neutral pH detergent and deionized, distilled, or purified water after each case.
3. Dry thoroughly with non-abrasive cloth.

Foot Pedal

Caution: Do not immerse or sterilize. Do not allow liquid to enter foot pedal.

Note: Foot pedals are non-sterile capital equipment and shall always be maintained outside the operating room sterile field.

1. Disconnect from console.
2. Clean foot pedal by wiping with non-abrasive cloth and neutral pH detergent and deionized, distilled, or purified water after each case.
3. Dry thoroughly with non-abrasive cloth.

Dissection Tool

Warning: Dissection tools are for multiple use.

1. Clean dissection tool by wiping with non-abrasive cloth and neutral pH detergent and deionized, distilled, or purified water after each case.
2. Dry thoroughly with non-abrasive cloth.
3. Go to sterilization section for further instructions.

MECHANICAL/ AUTOMATED CLEANING

Warnings:

- Manual precleaning must be completed prior to mechanical cleaning.
- Manual precleaning must be followed by mechanical cleaning.
- Cannulations must be precleaned with appropriate brushes as described in precleaning instructions.
- At the point of use the device must be cleaned as soon as possible after use to prevent drying of blood, tissue, other biological debris and contaminants on the device.
- National regulations must be observed.
- You must follow standard hospital procedures.
- You must follow manufacturer's recommendations for any detergents, disinfectants, and washing equipment used.

Cautions:

- Do not use any alkaline detergent with a pH greater than 7. Alkaline detergents with higher pH attack grease and seals which can increase wear and cause device to malfunction.
- Do not use ultrasonic equipment.
- Do not use hypochlorite solution (i.e. bleach).
- Handpieces must not be immersed in cleaning solution but may be sprayed with it.
- Fully demineralized (deionized, distilled, or purified) water must be used during final rinse to prevent corrosion and spots.

Note: Use of alkaline detergents can cause color to fade but this does not impair function of device.

Operating Room (OR) Personnel Instructions

1. After completion of procedure, remove external debris by wiping attachments and handpiece.
2. Properly dispose of open or used dissections tools.

Reprocessing Personnel Instructions

Manual Precleaning of Handpiece

Note: The instructions in this section are specific to the Insignia Spine Electric Handpiece.

1. Preparation

- Assemble all necessary supplies including sponge, lint-free cloth, and soft bristle brush.
- Remove attachment and dissection tool from handpiece.

2. Rinse

- Use a sponge, soft lint-free cloth, or soft bristle brush to assist in removing gross soil.

Caution: Do not immerse. Do not use high pressure water or air. Do not allow running water to enter distal end of handpiece or console connector.

3. Clean

- Prepare cleaning solution using alkaline detergent or neutral pH enzymatic detergent per manufacturer's directions for correct temperature, water quality (i.e. pH, hardness), and product concentration/dilution.
- With distal end pointing down spray and wipe using cleaning solution for a minimum of 2 minutes.
- Use a sponge, soft lint-free cloth, or soft bristle brush to remove all visible soil.

Caution: Do not immerse. Do not allow running water to enter distal end of handpiece or console connector. Do not use pipe cleaners.

4. Inspect

- Visually inspect handpiece for visible soil. repeat steps 2 thru 5 if visible soil remains.
- Go to mechanical/Automated cleaning section for further instructions.

Warning: Manual precleaning must be followed by mechanical/automated cleaning.

Manual Precleaning of Attachment

Note: The instructions in this section are specific to the Insignia Spine Attachment.

1. Preparation

- Assemble all necessary supplies.
- Remove attachment and dissection tool from handpiece.

2. Rinse

- Rinse attachment under running cold deionized, distilled, or purified water.
- Use a sponge, soft lint-free cloth, or soft bristle brush to assist in removing gross soil.

Caution: Do not use high pressure water or air. Do not rinse attachment with saline solution.

3. Clean

- Prepare cleaning solution using alkaline or neutral pH enzymatic detergent per manufacturer's directions for correct temperature, water quality (i.e. pH, hardness), and product concentration/dilution.
- Use a sponge, soft lint-free cloth, or soft bristle brush to remove all visible soil.
- Gently use a brush to clean cannulations of attachment.

Note: Brushes may be inserted from distal or proximal end of attachment.

Caution: Do not use pipe cleaners.

4. Rinse thoroughly

- With distilled end pointing down rinse device thoroughly using running hot dionized, distilled, purified water.
- Use a syringe or pipette filled with hot deionized, distilled, or purified water to flush lumens or channels.

Caution: Do not use high pressure water or air. Do not rinse attachment with saline water.

5. Inspect

- Visually inspect attachment for soil. repeat steps 2 thru 5 if visible soil remains.
- Go to mechanical/Automated cleaning section for further instructions.

Warning: Manual precleaning must be followed by mechanical/automated cleaning.

STERILIZATION

Before sterilizing

- Ensure sterilization equipment is in proper working order as specified by manufacturer.
- Assure equipment manufacturer's instructions are properly employed by trained and qualified personnel.
- Assure actual cycle employed has been properly validated for the device(s)/load configuration being processed and appropriate sterilization indicator devices are included for each process and cycle.

Warning:

- Devices must be cleaned prior to sterilization using the validated cleaning method outlined in these instructions.
- Must follow manufacturer's instructions for any wraps used.
- Do not use any other sterilization method or cycle than those listed below.

Autoclave Instructions

| Option | Exposure Temperature | Exposure Time | Minimum Dry Time |
|--------------------------------------|----------------------|---------------|------------------|
| 1. Pre-Vacuum (Wrapped) | 132°C | 4 minutes | 40 minute |
| 2 Gravity Air displacement (wrapped) | 132°C | 15 minutes | 40 minute |

Caution: A drying cycle is required to avoid possible adverse effects caused by exposure to condensation.

Notes:

- Metal devices, tools and equipment are constructed of materials unaffected by normal environmental conditions of current standard sterilization means, when proper operational techniques are employed.
- Effectiveness of sterilization equipment or sterilization processes are directly dependent upon numerous factors beyond Fontierz Pvt Ltd. control including among other things; sterilization means, processes and wrapping techniques employed, brand, model and condition of sterilization equipment, care and maintenance techniques employed, and operator knowledge and experience.
- Cannot anticipate all possible equipment, processes, and/or conditions that may be encountered. The suggested operation conditions are to be considered as a starting point for determination of the overall process capability, without regard for type or condition of equipment used or methods, techniques or practices employed by user. Use of proper sterilization indicator devices is strongly recommended. It is recommended that a

drying cycle be included to avoid possible adverse effects caused by exposure to condensation.

- Packaged and sterilized products should be stored in a dry, clean environment, protected from direct sunlight, pests, and extremes of temperature and humidity. Use products in the order in which they are received ("first-in, first-out principle").

TROUBLE SHOOTING

| Problem | Problem Cause | Possible Solution |
|--|---|--|
| Unit does not power on when on/ off button at console is pressed. | 1. Not enough time for console to detect signal. | 1. Keep the on/off button pressed for at least 1 second. |
| Unit does not power off when on/ off button at console is pressed. | 1. Not enough time for console to detect signal. | 1. Keep the on/off button pressed for at least 2 seconds. |
| Excessive handpiece noise. | 1. faulty internal component. | 1. Return attachment to Fontierz Pvt Ltd. . |
| Lack of power to console. | 1. Plug is not fully inserted/power switch not turn ON. 2. Outlet is not functional. | 1. Verify plugs to wall and back of console are pushed in completely. 2. Verify another piece of electrical equipment can receive power from outlet. |
| Handpiece vibration or extremely hot. | 1. Faulty internal component. 2. Internal motor overheats due to continuous extreme cutting at near stalling conditions. 3. Handpiece out of balance. | 1. Return to Fontierz Pvt Ltd. for service. 2. Decrease cutting force, allow motor to cool. 3. Return to Fontierz Pvt Ltd. for service. 4. Return to Fontierz Pvt Ltd. for service. |
| Excessive vibration of dissection tool. | 1. Dissection tool may be bent. 2. Dissection tool may not be fully seated. 3. Improper attachment and dissection tool combination. 4. possible attachment bearing damage. | 1. Replace with new dissection tool. 2. Reassemble dissection tool and attachment. 3. Only use correct dissection tool with appropriate attachment. 4. Return to Fontierz Pvt Ltd. for service. |

| Problem | Problem Cause | Possible Solution |
|------------------------------------|---|---|
| Unable to place or lock attachment | <ol style="list-style-type: none">1. The indicator bar in the handpiece is not aligned with the unlock (load) symbol.2. Misalignment of Angled Attachment with Handpiece Shaft | <ol style="list-style-type: none">1. Check alignment of notch with attachment and gently push attachment until click sound heard.2. Manually Rotate collet assembly downward or anticlockwise. |
| Unable to remove attachment. | <ol style="list-style-type: none">1. Attachment has safely locking mechanism.2. Attachment is captured by dissection tool. | <ol style="list-style-type: none">1. Follow Instruction carefully to remove the attachment.2. Manually rotate the collet assembly upward or clockwise. |
| Attachment is hot | <ol style="list-style-type: none">1. Debris lodged inside attachment.2. Possible bearing damages. | <ol style="list-style-type: none">1. Clean attachment using attachment cleaning instructions.2. Return attachment to Fontierz Pvt Ltd. for service. |
| Inoperative foot control | <ol style="list-style-type: none">1. Connector may not be fully inserted. | <ol style="list-style-type: none">1. Verify plugs for handpiece and foot control are fully inserted. Plug will latch in place once fully inserted. |

ORDERING INFORMATION

| Description | Catalog Nos. | Sterilization Conditions |
|-----------------------------|---------------------|---------------------------------|
| Insignia Spine | FN10000000 | Non- Sterile |
| Console Insignia Spine | FN10010000 | Non- Sterile |
| Foot Pedal | FN10020000 | Non- Sterile |
| Handpiece with cable | FN10030000 | Non- Sterile |
| Universal angled attachment | FN10040000 | Non- Sterile |

| Dimension (mm) | Cutting burr 125mm | Diamond burr 125mm | Sterilization Conditions |
|-----------------------|---------------------------|---------------------------|---------------------------------|
| 3.1 | FN10051031 | FN10052031 | Non- Sterile |
| 3.5 | FN10051035 | FN10052035 | Non- Sterile |
| 4 | FN10051040 | FN10052040 | Non- Sterile |
| 4.5 | FN10051045 | FN10052045 | Non- Sterile |
| 5 | FN10051050 | FN10052050 | Non- Sterile |