



VYRSA™ General Instruments INSTRUCTIONS FOR USE

NON-STERILE PRODUCT

BEFORE USING THE PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

Reusable instruments are manufactured from a variety of materials commonly used in orthopedic and neurological procedures which meet applicable national and/or international standards.

INDICATIONS FOR USE

These orthopedic manual surgical instruments are intended for use in surgical procedures to manipulate tissue, bone, or for use with other devices in orthopedic surgery. An instrument may incorporate a measuring function which has uses as described on the label and the instrument.

CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

SURGICAL PROCEDURE

Please contact a customer service representative or company representative for the surgical procedure.

PATIENT SELECTION

The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chance of a successful outcome.

WARNINGS

1. Breakage, slippage, misuse, or mishandling of instruments, such as on sharp edges, may cause injury to the patient, or surgical or processing personnel.
2. Improper maintenance, handling, or inadequate cleaning procedures can render the instrument unsuitable for their intended purpose or may even be dangerous to the patient or surgical or processing personnel.
3. The surgeon should use extreme caution when working in close proximity to vital organs, nerves, or vessels. Excessive force should not be used when positioning instruments, since it could cause injury to the patient.

PRECAUTIONS

1. Excessive force applied by instruments to implants can dislodge devices.
2. Exposing instruments to temperatures in excess of 275°F (135°C) may modify the physical characteristics. If instruments are exposed to temperature exceeding 275°F (135°C), perform an additional inspection to ensure they function as intended. See the EXAMINATION section for more information.
3. Extreme care should be taken to ensure instruments remain in good working order. During the procedure, the proper functioning of instruments is extremely important. Instruments should not be bent or damaged.
4. Misuse of instruments, resulting in corrosion, "freezing-up", scratching, loosening, bending, or fracture of components of an instrument may inhibit or prevent proper function.
5. Instruments should be carefully placed on trays, cleaned after each use, and stored in a dry environment.
6. Do not use instruments for any action for which they were not intended.
7. Regularly review the operational state of all instruments and, if necessary, contact VYRSA™ for replacement.

8. To avoid injury, the instrument should be carefully examined for functionality or damage prior to use. A damaged instrument should not be used. Based upon use risk, additional back-up instruments should be available in the set.
9. Preoperative and operating procedures, including knowledge of surgical techniques, are important considerations in the successful use of instruments by the surgeon. The proper selection and the compliance of the patient will greatly affect the results.
10. Proper patient selection and operative care are critical to the success of the surgery and avoidance of injury during surgery. Read and follow all other product information supplied by the manufacturer.
11. Special precautions are needed during pediatric use. Care should be taken when using instruments in pediatric patients, since these patients can be more susceptible to the stresses involved in their use.
12. Ensure instruments with a measuring function are not worn and any surface engravings are clearly visible.

Possible adverse effects include, but are not limited to the following:

- Nerve damage, paralysis, pain, or damage to soft tissue, visceral organs, or joints.
- Infection if instruments are not properly cleaned and sterilized.
- Pain, discomfort, or abnormal sensations resulting from the use of the device.
- Nerve damage due to surgical trauma.
- Dural leak in cases of excessive load application.
- Impingement of close vessels, nerves, and organs by slippage or misplacement of the instrument.
- Bending, loosening or fracture of the implants or instruments
- Vascular damage could result in catastrophic or fatal bleeding.
- Reflex sympathetic dystrophy
- Hemorrhage of the blood vessels and/or hematomas
- Damage due to spontaneous release of clamping devices or spring mechanisms of certain instruments.
- Cutting of skin or gloves of surgical or processing personnel.
- Bony fracture in cases of deformed or weak bone.
- Tissue damage to the patient, physical injury to surgical personnel, and/or increased operating time that may result from the accidental disassembly of multi-component instruments occurring during surgery.
- The methods of use of instruments are determined by the user's experience and training in surgical procedures. A successful result is not always achieved in every surgical case. This fact is especially true in surgery where other patient conditions may compromise the results.

EXAMINATION

Instruments must always be examined by the user pre/post cleaning and prior to surgery. Examination should be thorough and must include a visual and functional inspection of the working surfaces, pivots, racks, spring or torsional operation, cleanliness of location holes or cannulations, and the presence of any cracks, bending, deformation, or distortion, and that all components are complete.

Visual Inspection

As applicable, ensure the following:

- All laser markings and other markings are legible.
- No cracks are present in instrument handles or any part of the instrument.
- Discoloration, corrosion, stains, or rust does not exist. If present, follow the instructions in the Limitations on Processing section of this document.
- There is no handle/shaft separation, and the handle-to-shaft connection is secure.
- No cuts or gouges in the surface are present.
- There is no damage to the working ends or tips. The working end should be free of cracks, sharp edged gouges, and other damage. When applicable, the working end should be sharp.
- There is no damage to threads.
- All parts are present and free of damage and deterioration. Examples of parts that may be missing, loose, or damaged include set screws, springs, curved springs, pins, and prongs.

- Mating ends are free of damage (nicks, gouges, bends, etc.) that would interfere with the mating function.
- Cannulated instruments are inspected for cleanliness.

Functional Inspection

As applicable, ensure the following:

Instruments:

- Any moving parts move freely, without sticking, binding, or grinding.
- Springs return the handle of the instrument to its original position.
- Retention tabs hold appropriate mating parts and are not damaged.
- The instrument will function as intended with the appropriate mating parts.
- Ball detents will hold mating parts and are free from damage.
- Sharp edges are sharp to the touch and are not dull, have no nicks, or any other damage.
- Tips meet when appropriate.
- Ratcheting mechanisms are functional. This includes handles, latches, and other mechanisms. All teeth should be present and functional.
- Driver tips are not worn beyond functional use. If necessary, mate the instrument with the appropriate part.

CLEANING OF REUSABLE INSTRUMENTS

MANUAL CLEANING OF INSTRUMENTS AFTER USE

1. Use utility/tap water to rinse instrument(s) for a minimum of 1.5 minutes to remove gross debris. Do not use hot water.
2. Continue to rinse with the utility/tap water until gross debris is removed.
3. Open, disassemble and/or flush instrument(s) if applicable, so cleaning solution can reach all instrument surfaces.
4. Mix enzymatic cleaning solution per the manufacturer's label instructions.
5. Tube (lumen) portion of instrument(s) must be filled with cleaning solution during soak.
6. Soak in cleaning solution for a minimum of 4 minutes.
7. Mix a separate detergent bath using enzymatic cleaning solution per the manufacturer's label instructions in an ultrasonic unit.
8. Fully immerse the instrument(s), in an open position/disassembled, under the surface of the cleaning solution ensuring the cleaning solution can be reached to all instrument(s) surfaces.
9. Sonicate the instrument(s) for a minimum of 5 minutes.
10. Prepare a separate (3rd) detergent bath using enzymatic cleaning solution per the manufacturer's label instructions.
11. Fully immerse the devices into cleaning solution and using a soft-bristled or medium non-metal bristle brush, remove all visible soil and debris from the surfaces.
12. Brush difficult to reach areas such as lumens/cannula, hidden surfaces, and actuate device, if applicable, 4x (back and forth=1x).
13. If all debris is not removed, repeat brushing and flushing.
14. Flush device with deionized water, or equivalent, by placing the device under the water flow for a minimum of 3x.
15. Actuate parts, if applicable 3x, under running deionized water, or equivalent.
16. Rinse lumens, tubes, or cannula under running deionized water, or equivalent, 4x.
17. Use heat or lint-free cloth to dry devices following final rinse.

AUTOMATED CLEANING FOR INSTRUMENTS AFTER USE

1. Use utility/tap water to rinse instrument(s) for a minimum of 1.5 minutes to remove gross debris. Do not use hot water.
2. Continue to rinse with the utility/tap water until gross debris is removed.
3. Open, disassemble and/or flush instrument(s) if applicable, so cleaning solution can reach all instrument surfaces.
4. Mix enzymatic cleaning solution per the manufacturer's label instructions.
5. Tube (lumen) portion of instrument(s) must be filled with cleaning solution during soak.
6. Soak in cleaning solution for a minimum of 4 minutes.
7. Mix a separate detergent bath using enzymatic cleaning solution per the manufacturer's label instructions in an ultrasonic unit.

8. Fully immerse the instruments, in an open position/disassembled, under the surface of the cleaning solution ensuring the cleaning solution can be reached to all instrument(s) surfaces.
9. Sonicate the instruments for a minimum of 5 minutes.
10. Prepare a separate (3rd) detergent bath using enzymatic cleaning solution per the manufacturer's label instructions.
11. Fully immerse the devices into cleaning solution and using a soft-bristled or medium non-metal bristle brush, remove all visible soil and debris from the surfaces.
12. Brush difficult to reach areas such as lumens/cannula, hidden surfaces, and actuate device, if applicable, 4x (back and forth=1x).
13. If all debris is not removed, repeat brushing and flushing.
14. Load the instrument(s) into the appropriate washer-disinfector.
15. Select the cycle which reflects the following parameters:

AUTOMATIC WASHER

Phase	Recirculation Time (min)	Temperature	Detergent Type & Concentration
Pre-wash 1	01:00	Cold tap water	N/A
Wash 1	05:00	43°C tap water (Set point)	Enzymatic detergent per washer instructions
Rinse 1	01:00	Warm tap water	N/A
Pure Water Rinse	01:00	43°C deionized water	N/A
Dry Time	10:00	90°C	N/A

STERILIZATION FOR INSTRUMENTS

Warning: VYRSA™ Technologies does not recommend that the instruments be sterilized by Flash, EtO or Chemical sterilization. When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.

To achieve a sterility assurance level of SAL 10⁻⁶, VYRSA™ recommends the following parameters:

Method	Steam	Steam
Cycle	Gravity Displacement (Wrapped)	Pre-vacuum (Wrapped)
Preconditioning Pulses	N/A	4
Temperature	132°C (270°F)	132°C (270°F)
Exposure Time	15 minutes	4 minutes
Drying Time	45 minutes	45 minutes
Open Door Drying Time	15 minutes	15 minutes

Note: An FDA Cleared Wrap must be used.

*VYRSA™ Technologies has validations for the above sterilization cycles and has the data on file. The validated sterilization parameters are compliant with the full cycle validation approach per ANSI/AAMI/ISO 17665-1, Annex D. Other sterilization cycles may also be suitable; however individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques.

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.









Limitations on Processing

- Repeated processing has minimal effect on these instruments.
- End of life is determined by excessive wear and damage from normal use.
- See the EXAMINATION section of this document including the Visual and Function inspection subsections to determine if the device is at the end of its useful life.

MRI Information

The VYRSA General Instruments have not been evaluated for safety in the MR (Magnetic Resonance) environment. The VYRSA General Instruments are not intended for implantation.

SYMBOLS

Symbol	Definition	Reference
	Catalogue Number-Indicates the manufacturer's catalogue number to that the medical device can be identified	ISO 15223-1:2021 Symbol 5.1.6
	Batch code-Indicates the manufacturer's batch code so that the batch or log can be identified	ISO 15223-1:2021 Symbol 5.1.5
	Non-sterile-Indicates a medical device that has not been subjected to a sterilization process	ISO 15223-1:2021 Symbol 5.2.7
	Prescription Only-Caution: Federal law restricts this device to sale by or on the order of a physician	FDA 801.15(c)(1)(i)(F)
	Consult Instructions for Use-Indicates the need for the user to consult the instructions for use	ISO 15223-1:2021 Symbol 5.4.3
	Manufacturer-Indicates the medical device manufacturer	ISO 15223-1:2021 Symbol 5.1.1
	Unique Device Identifier (UDI)-Indicates a carrier that contains unique device identifier information	ISO 15223-1:2021 Symbol 5.7.10
	Date of Manufacture-Indicates the date when the medical device was manufactured	ISO 15223-1:2021 Symbol 5.1.3

FOR FURTHER INFORMATION

If further information on this product or the Surgical Technique Guide is needed, please contact VYRSA™ Technologies at the number listed below:

MANUFACTURED BY:

VYRSA™ Technologies
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
USA

Customer Service:

Phone 1-866-GLOBUS1 (OR)
1-866-456-2871
Fax 1-866-GLOBUS3 (OR)
1-866-456-2873