



I n t e g r a l M e d i z i n t e c h n i k A G

Operation Manual

*Woodpecker*TM

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Introduction

Proprietary Notice

Information contained in this document is copyrighted by IMT Integral Medizintechnik AG and may not be duplicated in full or part by any person without prior written approval of IMT Integral Medizintechnik AG. Its purpose is to provide the user with adequately detailed documentation to efficiently install, operate, maintain for the device supplied. Every effort has been made to keep the information contained in this document current and accurate as of the date of publication or revision. However, no guarantee is given or implied that the document is error free or that it is accurate with regard to any specification.

Limited Warranty

IMT Integral Medizintechnik AG warrants each new Woodpecker and accessories to be free from defects in workmanship and materials under normal use and service for a period of one (1) year from the date of shipment. IMT Integral Medizintechnik AG sole obligation under this warranty will be to repair or replace, at its option, products that prove to be defective during the warranty period. The foregoing shall be the sole warranty remedy. Except as set forth herein, seller makes no other warranties, either expressed or implied, including the implied warranties of merchantability and fitness for a particular purpose. No warranty is provided if the products are modified without the express written consent of IMT Integral Medizintechnik AG and seller shall not be liable in any event for incidental or consequential damage. This warranty is not assignable.

Service Support

If the device needs repair, contact an authorized IMT service center. When calling, have the Woodpecker(s) serial number(s) ready. If you need to ship the device, pack the device in its original packing materials, if possible, to prevent shipping damage. You are responsible for all shipping and insurance costs to and from IMT unless otherwise specified.

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Indications for use

The Woodpecker is indicated for:

- Health Care professionals trained and licensed in Orthopaedic Surgery
- Patients undergoing Total Hip Anthroplasty (THA).
- Use in femoral broaching
- This device is intended for multiple patient uses with approved cleaning and sterilization prior to reuse.

Warnings, Cautions and Notes

A **warning** indicates something that could hurt the patient/operator.

A **caution** indicates something that could damage the device.

A **note** indicates other important information.



WARNING: Always start with the smallest broach.



WARNING: Rotation during insertion of the broach is not recommended. If done, this could cause axial or rotational pressure and fracture of the femur.



WARNING: Do not attempt to completely broach the intramedullary canal in one pass. Forward pressure must be exerted for cutting; pull back while running to clear bone debris.



WARNING: Forceful insertion of the final broach using a mallet or other instrument is not recommended. If done, this could cause axial pressure and fracture.



WARNING: Operating at pressures higher than 120 PSI (8 bar) may result in personal injury or damage to the Woodpecker.

Warnings, Cautions and Notes



WARNING: There are no user serviceable components on the Woodpecker. Any attempt at making repairs by a non-authorized service center may result in personal injury or damage to the Woodpecker.



CAUTION: Use nitrogen or clean, filtered compressed air to power this instrument.



CAUTION: Immersion or power washing is considered abuse; any resulting damage is NOT covered under the manufacturer's warranty and will be repaired at the owner's expense.



NOTE: Using less than 100 PSI (7 bar) of air pressure may cause unsatisfactory broaching results



NOTE: Remove all watches and jewelry when operating the Woodpecker. 70 Hz frequency may cause damage to watches or jewelry.

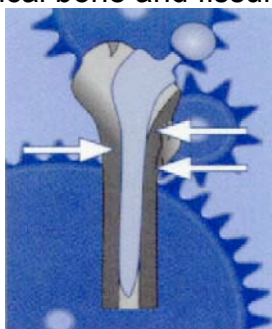
Theory of Operation

Theory

- The Woodpecker is a pneumatically powered device. The linear motion of the Woodpecker has a total travel of 10 mm (.3937 inches) and operates at 70 Hz (70 times per second). This linear back and forth motion of the Woodpecker creates an efficient cutting movement on the forward stroke and clearing of bone chips on the backward stroke, preventing the broach from wedging/jamming in the cortical bone. The Woodpecker exerts no more than 1.0 newton of axial force on the femoral bone.

What's great about pneumatic broaching with the Woodpecker

- Accurate shaping of the femoral canal provides improved fit. Gaps between the bone and the prosthesis are avoided. Non-physiological dilation of the femur, damage to the cortical bone and fissures are minimized substantially.



- The high-frequency axial impulses of the Woodpecker reduce operation time.
- Like thousands of other Surgeons have already discovered, you too will agree that the Woodpecker gives you precise control, yielding consistent results; every time.
- The extremely low-level impulses of the Woodpecker
 - Minimizes Hoop stresses and decreases the bone marrow emboli risk.
 - Lower the risk of femoral fractures caused by excessive radial forces
- Broaches or Adapters can be orientated in 90° increments to accommodate Surgeon preference or approach

Instructions for use

The Woodpecker



1. Upgrade Nosepiece
2. Lock/Release Push Button
3. Trigger Button
4. Force Control Knob
5. Trigger Bar
6. Quick Connect for Hose Assembly
7. Housing

Instructions for use (cont.)

- Power

The Woodpecker is a pneumatically powered device and must be operated at a pressure of 100-120 PSI (7-8 bar). Use nitrogen or clean, filtered compressed air to power this device.

- Air Hose

The Woodpecker is operated with a twin-hose (inner-hose \approx 18m and air outlet hose).

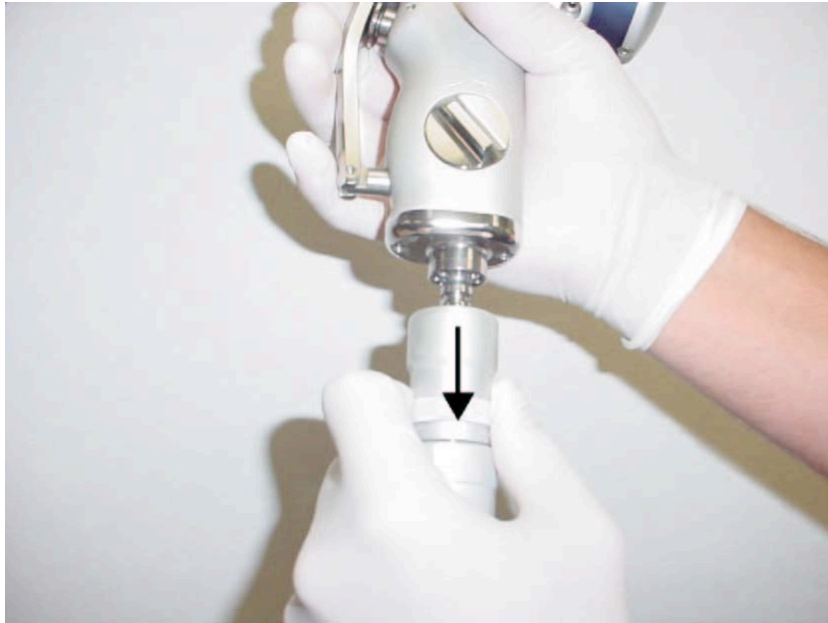
Bent or kinked hoses may prevent the unit from operating satisfactorily.



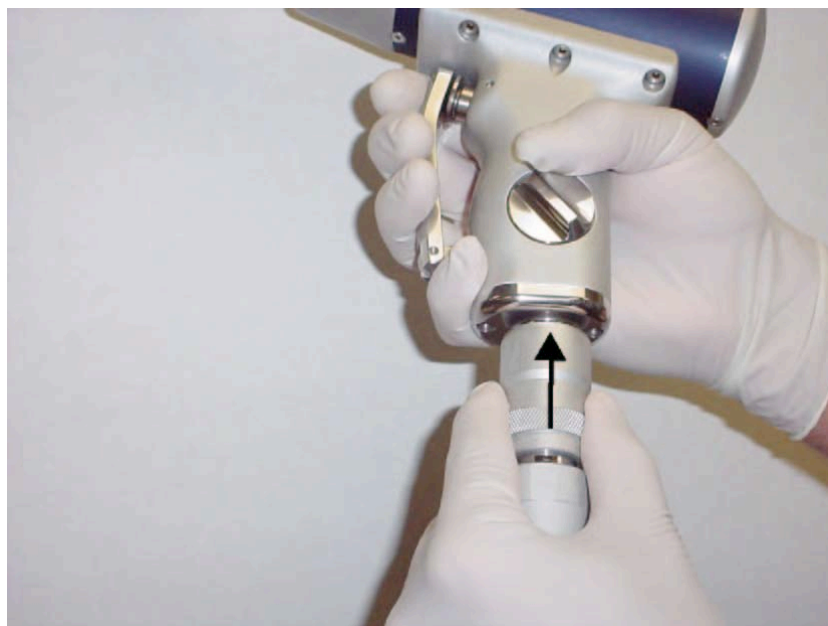
1. Quick disconnect fitting (on the left) to the Woodpecker (female)
2. Connection (on the right) to air supply (male)

Instructions for use (cont.)

- Pull hose quick-disconnect outer-shell back and attach the hose to the Woodpecker

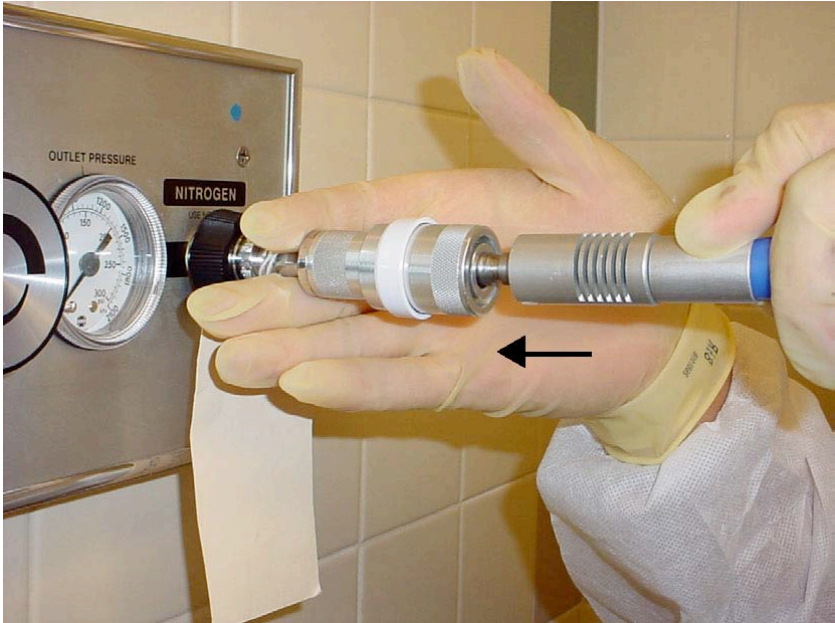


- Slide quick-disconnect outer-shell in direction shown to secure hose to the Woodpecker.



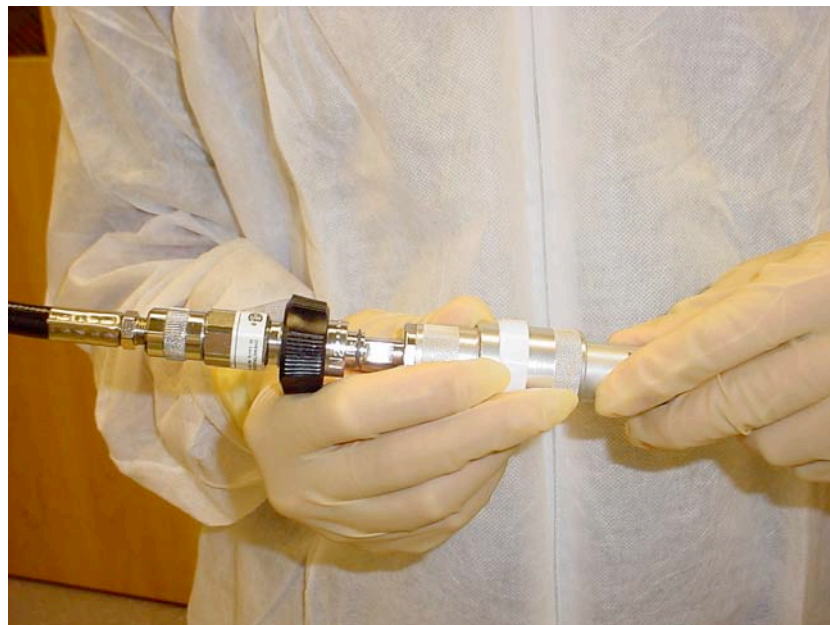
Instructions for use (cont.)

- Wall manifold connection



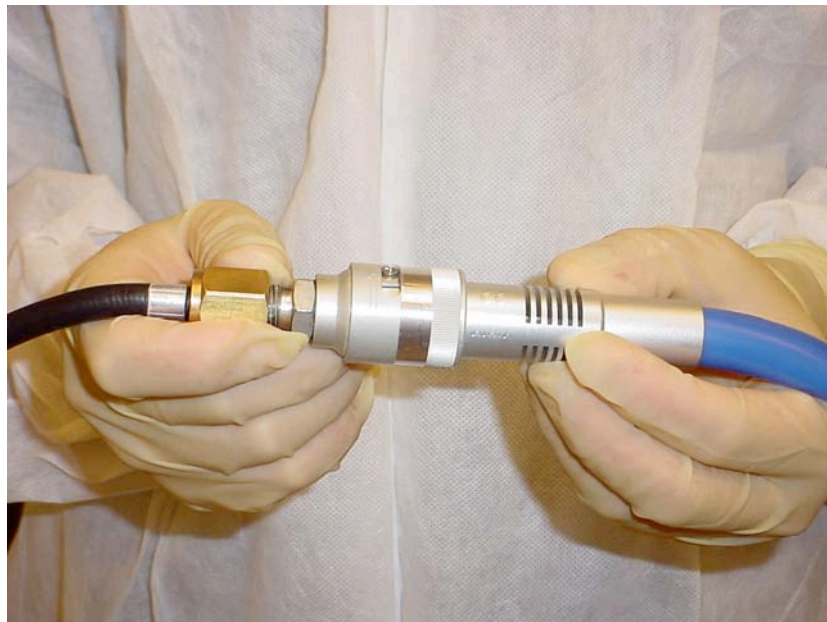
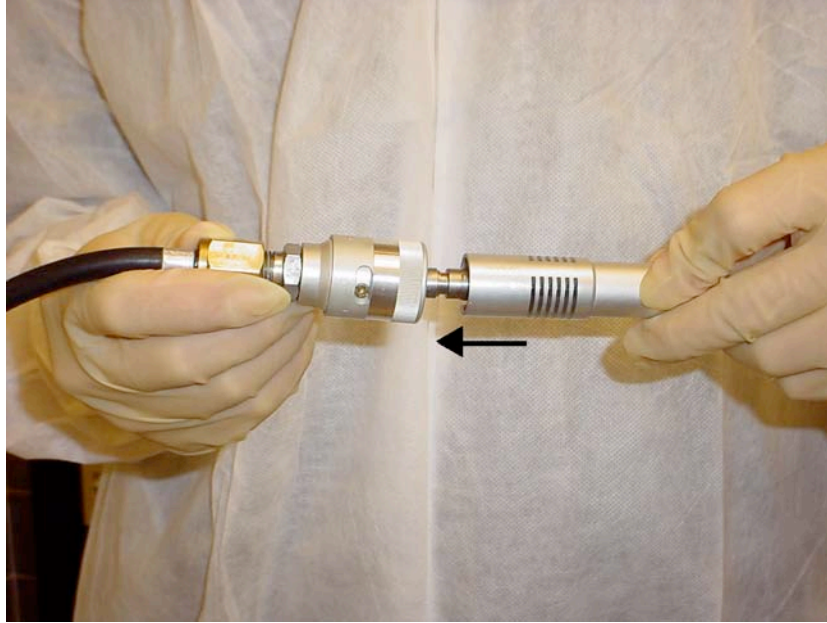
Instructions for use (cont.)

- Filter connection



Instructions for use (cont.)

- Extension connection



Instructions for use (cont.)

- IMT AG recommends starting at 100 PSI (7 bar). Effective pressure range is 100 to 120 PSI (7-8 bar).



WARNING: Operating at pressures higher than 120 PSI (8 bar) may result in personal injury or damage to the Woodpecker.

- Set force control knob to the minus setting.



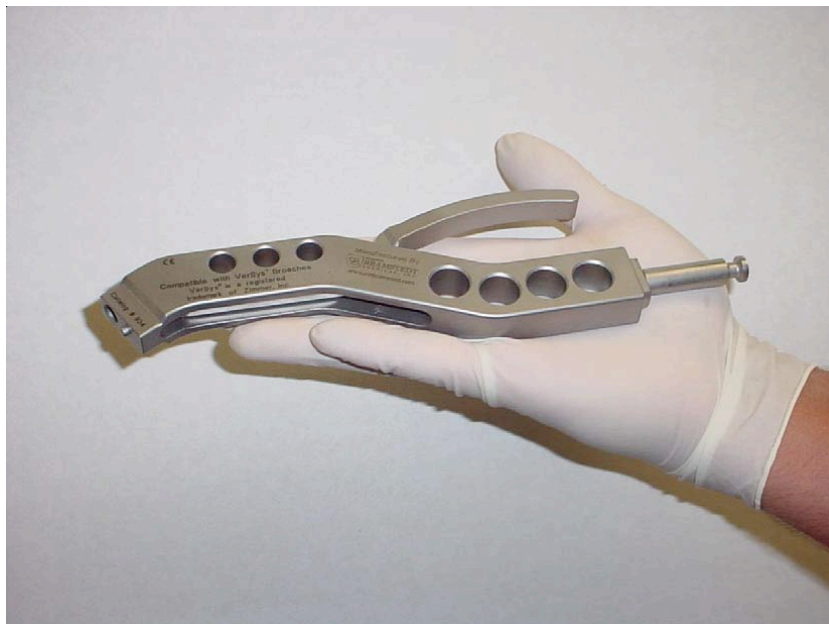
IMT AG recommends beginning the procedure at the minus (-) position. This allows the Orthopaedic Surgeon to work efficiently in Type C cortical bone. Moving the dial toward the plus (+) position increases the force required to broach Type A cortical bone.

Instructions for use (cont.)

- Press trigger bar to test

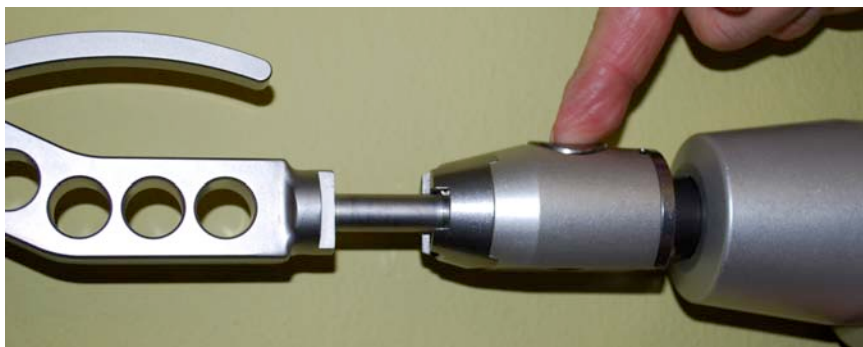
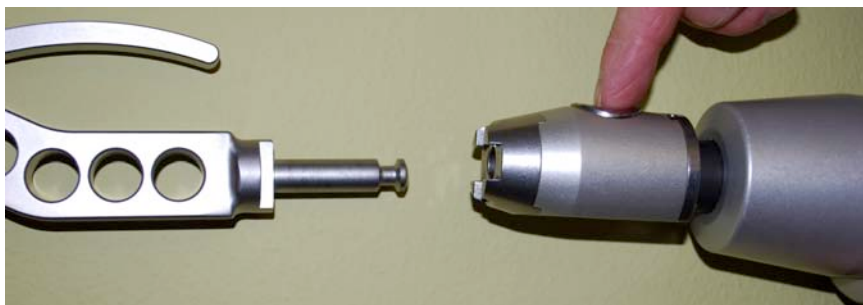


- Select broach adapter compatible with the femoral hip system to be implanted. This may vary depending on the hip system being used.



Instructions for use (cont.)

- Press down and hold button on upgrade nose piece. Insert adapter to preferred orientation.

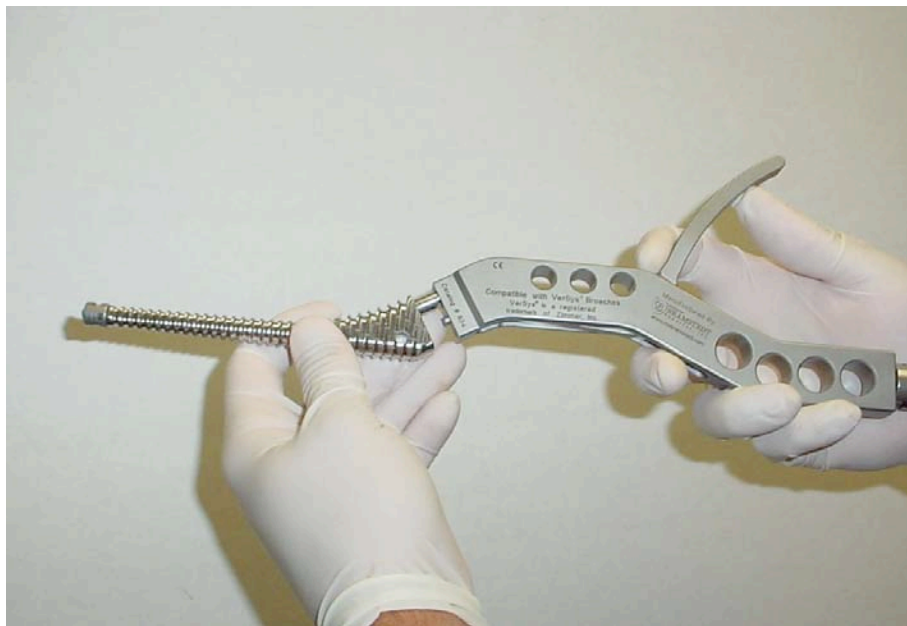
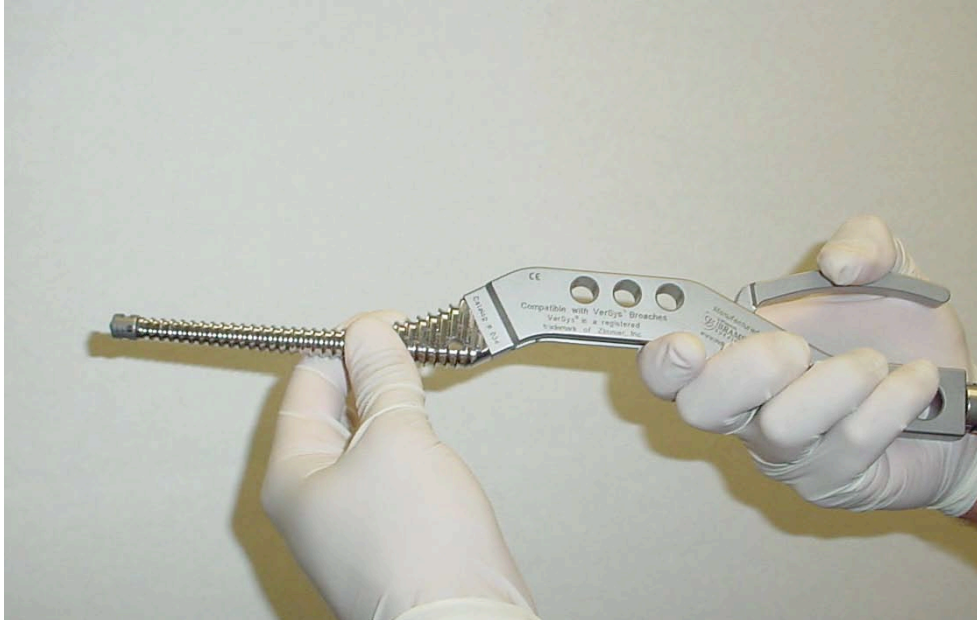


- Press lock/release push button to lock adapter into place.
- To remove or change orientation of adapter, press and hold lock/release push button and remove or readjust adapter.



Instructions for use (cont.)

- Insert broach into broach adapter. Lock into place.



NOTE: Broach and adapter shown are for illustration purposes only. Broach and adapter types, shapes, mounting and clamping methods may vary from manufacturer to manufacturer.

Instructions for use (cont.)

- Always begin with the force control set to the minus (-) setting.
- Always start with the smallest broach.
- Do not attempt to broach the intermedullary canal in one pass.
- The linear back and forth motion of the Woodpecker creates an efficient cutting movement on the forward stroke and clearing of bone chips on the backward stroke, preventing the broach from wedging/jamming in the cortical bone.
- When using the Woodpecker run the unit continuously while broaching. Do not start and stop the unit while broaching.
- The Woodpecker is a pneumatically powered device and must be operated at a pressure of 100-120 PSI (7-8 bar).
- To obtain a precise, prosthesis seating over a large surface, it is sufficient to continue broaching until the instrument can not insert the broach any further due to resistance from the cortical bone.
- Forceful insertion of the final broach using a mallet or other instrument is not recommended. If done, this could cause axial pressure and fracture.

Instructions for cleaning

The Woodpecker and accessories are supplied non-sterile.

° Washing

This is done in the usual fashion by autoclaving

All implants and instruments, which are supplied non-sterile, are packaged individually in shipping/storage boxes or plastic bags.

To clean them prior to their first use or after surgery, we recommend a neutral PH (or slightly alkaline detergent according to the recommendations of the detergent manufacturer. **Put the stericup on for washing.**

All instruments should then be thoroughly rinsed and dried prior to steam sterilization.

° Sterilization

The stericup must be removed before sterilization.

We recommend autoclaving according to standard hospital sterilization procedures and within the guidelines of the autoclave manufacturer, to assume a Sterility Assurance Level (SAL) <of 10^{-6} according to the ANSI/AAMI ST33-1990* validation method which is:

Pre Vacuum and hold at 270°F for at least 4 minutes.

*Reference:

American National Standard; Good Hospital Practice: Guidelines for the Selection and Use of Reusable Rigid Sterilization Container Systems. ANSI/AAMI ST33-1990.

Literatur:

- 1.) American National Standard; Good Hospital Practice: Guidelines for the Selection and Use of Reusable Rigid Sterilization Container Systems. ANSI/AAMI ST33-1990.



CAUTION: Do not sterilize the Woodpecker with Ethylene Oxide (ETO). Damage to the O-Rings and seals will occur. ETO sterilization is NOT covered under the manufacturer's warranty and will be repaired at owner's expense.

Maintenance and Service

- It is recommended that the Woodpecker be serviced regularly at an authorized IMT service center. The Woodpecker will be completely disassembled, inspected, thoroughly cleaned, relubricated, reassembled and tested.



CAUTION: There are no user serviceable components. Any attempt at making repairs by a non-authorized service center may result in personal injury or damage to the Woodpecker and will void the manufacturer's warranty

Troubleshooting

If you observe any of the following, contact IMT AG for service.

Problem	Possible Cause
Broach adapter sticks in upgrade nosepiece	Nosepiece is damaged or dirty
Trigger button sticking	Damaged O-rings
Air leaking from Woodpecker	Damaged O-rings
Unit is pressurized but the Woodpecker doesn't start	Piston may be stuck
Air leaking from hose, hose fittings or exhaust jacket	Hose damaged

Specifications

- **Woodpecker**

Effective operating pressure: 100 PSI to 120 PSI (7 to 8 bar)

Total Stroke: 10 mm (0,3937 Zoll/Inches)

Oscillation frequency: 70 Hz (70 times per second)

Air consumption: 275 to 300 liters per minute

Size: Length: 25 cm (9,8 Zoll/Inches)
Height: 19,6 cm (7,7 Zoll/Inches)
Width: 5,9 cm (2,3 Zoll/Inches)

Weight: 2,3 kilograms (5 pounds)

Air Consumption: 250 – 300 liters per minute

- **Air hose**

Twin-hose (inner-hose \varnothing 18 mm and air outlet hose).

The information above is subject to change. Please contact IMT AG for details or visit us at www.imt-medical.com for the latest in Woodpecker supplies and accessories.

Notes