

Introduction

Proprietary Notice

Information contained in this document is copyrighted by Integrated Medical Technologies USA, LLC and may not be duplicated in full or part by any person without prior written approval of Integrated Medical Technologies USA, LLC. Its purpose is to provide the user with adequately detailed documentation to efficiently install, operate, maintain and order spare parts 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

Integrated Medical Technologies USA, LLC 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. Integrated Medical Technologies USA, LLC's 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 Integrated Medical Technologies USA, LLC, and seller shall not be liable in any event for incidental or consequential damage.

This warranty is not assignable.

Indications for Use

The Woodpecker is indicated for:

- Health Care professionals trained and licensed in Orthopaedic Surgery.
- Patients undergoing Total Hip Arthroplasty (THA).
- Use in femoral broaching.
- Implantation and removal of I/M Nails.
- Multiple patient use with approved cleaning prior to reuse.

Contraindication

The Woodpecker is not recommended for:

- Implant insertion
- Implant removal

Notes

[illegible]

Notes

[illegible]

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 may result in personal injury or damage to the Woodpecker.

Warnings, Cautions, and Notes (cont.)



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 or Preventive Maintenance Program and will be repaired at the owner's expense.



NOTE: Using less than 100 PSI 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.

The Woodpecker and Accessories

<u>Item Number</u>	<u>Description</u>
929	Woodpecker & Hose Assembly
928	Woodpecker only
931	Woodpecker Hose Assembly with Shrader Quick-Disconnect Fitting
997	Preventive Maintenance Program (3 years from Date of Sale)
935	DePuy Summit™ Compatible Broach Adapter (<i>Tri-Lock Bone Preservation Stem (BPS) and Corial Articulate Taper (AMT)</i>)
937	Stryker Accolade® Compatible Broach Adapter (<i>Exeter V40 and Hipstar</i>)
938	Smith & Nephew Compatible Broach Adapter (<i>All types</i>)
936	DePuy PFC Broach Adapter
939	Zimmer Natural Hip® and APR® Compatible Broach Adapter
809	Modify Customer Supplied Broach Handle to Fit Woodpecker
941	Woodpecker Sterilization Tray
960	Operation Manual

The information above is subject to change. Please contact Integrated Medical Technologies USA, LLC for details at 651.493.9634 or visit us at www.imt-medicalusa.com for the latest in Woodpecker supplies and accessories.

Service Support

Integrated Medical Technologies USA, LLC is the only authorized repair center in North America. If the device needs repair, contact Integrated Medical Technologies USA, LLC. 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 Integrated Medical Technologies USA, LLC unless otherwise specified. The repaired product will be shipped back in the same manner it was shipped to Integrated Medical Technologies USA, LLC.

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Theory of Operation

- 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.
- Pneumatic broaching results in a clear improvement in the quality of prosthesis seating and rotational stability.
- Metaphysical fractures which are caused by excessive radial forces can be avoided.

Specifications

- The Woodpecker**

Effective operating pressure: 100 PSI to 120 PSI; Integrated Medical Technologies USA, LLC recommends starting at 100 PSI.

Air consumption: 275 to 300 liters per minute

Axial Force: 0.8 - 1.0 newton

Total stroke: 10 mm (.3937 inches)

Oscillation frequency: 70 Hz (70 times per second)

Size: Length: 25 cm (9.8 inches)
Height: 19.6 cm (7.7 inches)
Width: 5.9 cm (2.3 inches)

Weight: 2.3 kilograms (5 pounds)

Troubleshooting

If you observe any of the following, contact Integrated Medical Technologies USA, LLC 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
Air leaking from hose, hose fittings or exhaust jacket	Hose damaged
Unit is pressurized but the Woodpecker doesn't start	Piston may be stuck

Maintenance & Service

- Clean the Woodpecker per Instructions for Cleaning (pg. 20).
- It is recommended that the Woodpecker be serviced regularly at Integrated Medical Technologies USA, LLC, a factory authorized service center. The Woodpecker will be completely disassembled, inspected, thoroughly cleaned, worn parts replaced, relubricated, reassembled and tested.
- Recommended service intervals:

Woodpecker Usage	Service Intervals
4 times or less a week	Once a year
5 times or more a week	Every 6 months



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 or Preventive Maintenance Program. Integrated Medical Technologies USA, LLC is the only authorized repair center in North America.

The Woodpecker



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

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

Hose Assembly with Schrader Quick Disconnect Fitting



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

- The Woodpecker is operated with an AO twin-hose (inner-hose \varnothing 18mm and air outlet hose).
- Bent or kinked hoses may prevent the unit from operating satisfactorily.
- Hose assembly can be reused approximately 300 times.



CAUTION: Do not pull on outer-jacket of hose when disconnecting. Separation of the outer-jacket to the hose may happen. **Only grasp the outer-shell of the connector.**

Instructions for Sterilization

Integrated Medical Technologies USA, LLC recommends autoclaving according to standard hospital sterilization procedures and within the guidelines of the autoclave manufacturer to assure a Sterility Assurance Level (SAL) of at least 10^{-6} . Validation method is:

Gravity Displacement Autoclave

With or Without Sterilization Tray ~ 270° F for 10 minutes.^{1,2}

Pre-Vac or Hi-Vac Autoclave

With or Without Sterilization Tray ~ 270° F for at least 4 minutes^{1,2} and a dry time of 30 minutes.

Reference:

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

2.) Association for the Advancement of Medical Instrumentation. Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers. AAMI TIR 12-1994. Arlington (VA): AAMI, 1995. AAMI Technical Information Report.



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 or Preventive Maintenance Program and will be repaired at owner's expense.

Instructions for Cleaning

The Woodpecker and accessories are supplied non-sterile. To clean them prior to first use or after surgery, Integrated Medical Technologies USA, LLC recommends a neutral PH or slightly alkaline detergent according to the recommendations of the detergent manufacturer. All instruments should then be thoroughly rinsed and dried prior to steam sterilization.



CAUTION: Do not immerse (Bucket Soak) or power wash the Woodpecker. Damage to the Woodpecker will occur. Immersion damage is **NOT** covered under manufacturer's warranty or Preventive Maintenance Program and will be repaired at owner's expense.

Instructions for Use

- 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



Quick Reminders for Instructional Use

- 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. Integrated Medical Technologies USA, LLC recommends starting at 100 PSI.
- 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 Use (cont.)

- Press trigger bar to test.



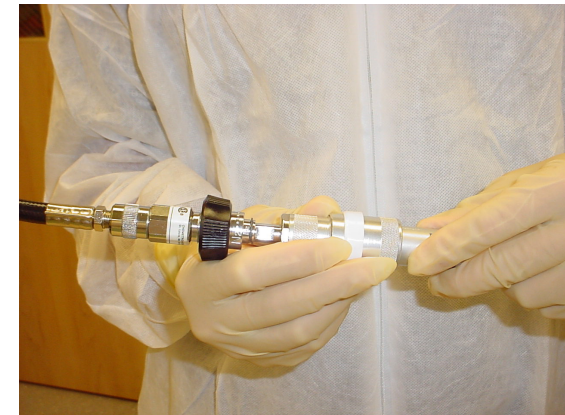
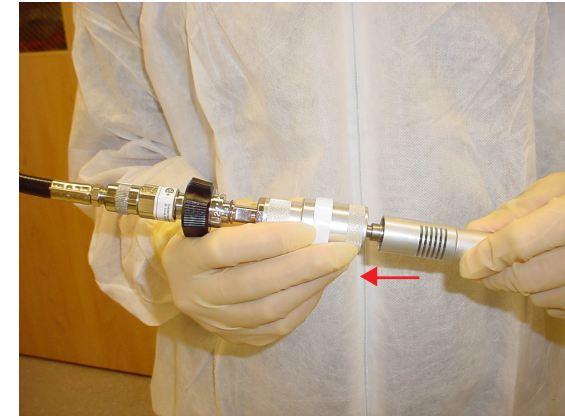
CAUTION

Running the Woodpecker without an adapter installed may damage the Woodpecker.



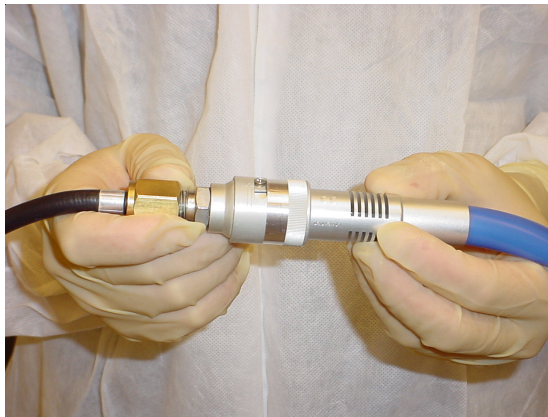
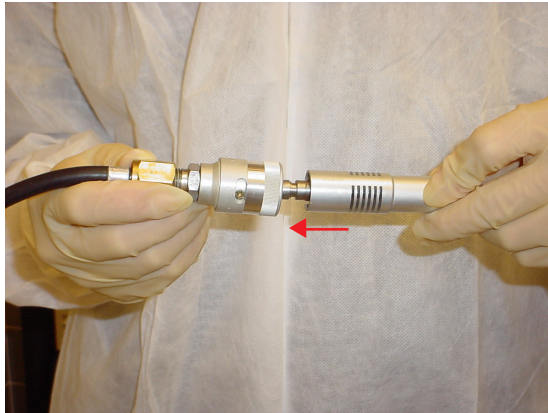
Instructions for Use (cont.)

- Drop connection



Instructions for Use (cont.)

- Extension connection



Instructions for Use (cont.)

- 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.)

- Determine the adapter orientation. All compatible broach adapters have the ability to be orientated in 90° increments.



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



Instructions for Use (cont.)

Integrated Medical Technologies USA, LLC recommends starting at 100 PSI. Effective pressure range is 100 to 120 PSI.



WARNING

Operating at pressures higher than 120 PSI may result in personal injury or damage to the Woodpecker.



Instructions for Use (cont.)

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



- Set force control knob to the minus setting.



Integrated Medical Technologies USA, LLC recommends beginning the procedure at the minus (-) position (0.8 newton). This allows the Orthopaedic Surgeon to work efficiently in Type C cortical bone. Moving the dial toward the plus (+) position (1.0 newton) increases the force required to broach Type A cortical bone.

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.