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Instructions for use

PEOPLE HAVE PRIORITY



CE
0297

IDC *Implantology Distance Control*

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Contents

W&H Symbols 4

1. Introduction ..... 5 – 8
2. Before use – Safety notes ..... 9 – 10
3. Product description 11
4. Operation ..... 12 – 14
   To change center drill, Assembly / Removal of the distance gauge,
   Assembly / Removal of the distance sleeve, Test run

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5. Examples of application ..... 15 – 16
6. Hygienic maintenance ..... 17 – 25
Cleaning, Disinfection, Sterilization
7. W&H Accessories ..... 26 – 27
Letter of indemnity 29
Authorized W&H service partner ..... 30 – 31

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W&H Symbols



WARNING!
(Risk of injury)



ATTENTION!
(to prevent
damage occurring)



General
explanations,
without risk to
persons or objects



Thermo washer
disinfection



Sterilizable
up to the stated
temperature

For USA and Canada

Caution! Federal law restricts this device to sale by or on the order of a dentist, 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.

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1. Introduction

Customer satisfaction is the main priority under the W&H quality policy. This W&H product has been developed, manufactured and subjected to final inspection according to legal regulations, quality norms and industry standards.

For your safety and the safety of your patients

Prior to initial use please read the Instructions for use. These explain how to use your W&H product and guarantee a smooth and efficient operation.

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Intended use

Tool for implantologists for placing marker holes, to keep the biological breadth for two or more implants between implants resp. between implant and root.

Misuse can damage the distance gauge, the distance sleeves and the center drill and involves risk and danger to user and third parties.

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CE 0297

Production according to EU directive

The distance gauge and the distance sleeves are medical products according to the EU directive 93/42/EEC, implemented by the Austrian Medical Device Act.

Skilled application

These medical products are intendet only for skilled application in implantology according to their purpose of use in compliance with the valid health and safety at work regulations, the valid accident prevention regulations as well as in compliance with these Instructions for use. These products should be maintained according to the manufacturer's recommendations and in-line with infection control procedures for the safety and well-being of patients.

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Improper use, e.g. poor hygienic maintenance, or non-compliance with our Instructions or the use of accessories and spare parts which are not approved by W&H, invalidates all claims under warranty and anyother claims.

Service

In case of service or repair contact an authorized W&H service partner (see Page 30, 31). Service and maintenance work must only be carried out by an authorized W&H service partner.

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2. Before use – Safety notes



- > The distance gauge, the distance sleeves and the center drill may only be used with the W&H implantology contra-angle WI-75 E/KM.
- > Insert the center drill, the distance gauge or the distance sleeves, only when the contra-angle is stationary.
- > Never touch the inserted distance sleeve during operation! (risk of injury due to center drill)
- > Be careful of contamination due to bone graft during application!

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> Always ensure that sufficient and adequate cooling is delivered and ensure adequate suction. In case of coolant supply failure, the contra-angle must be stopped immediately.

Hygienic maintenance prior to initial use

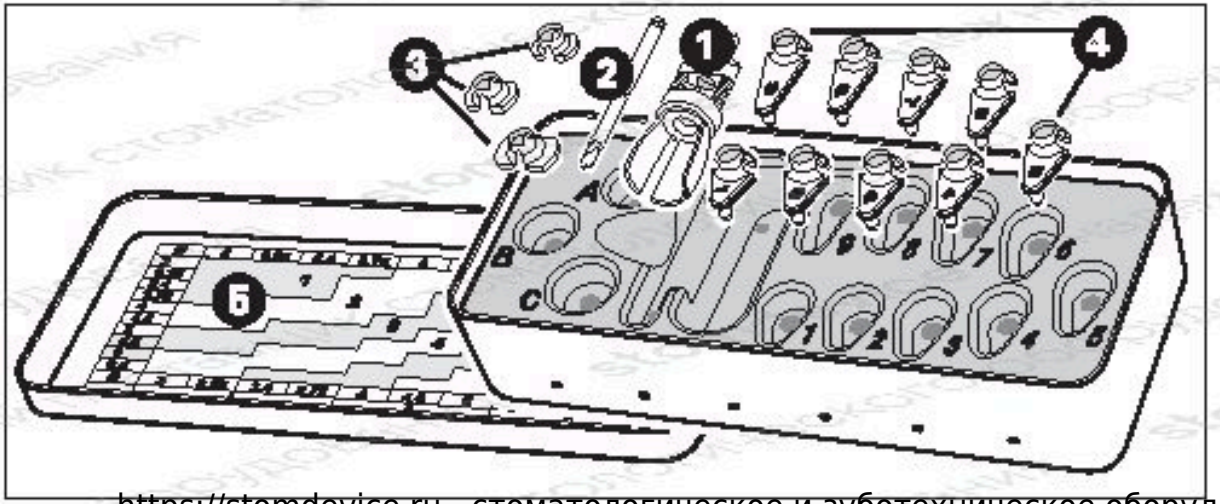
The distance gauge, the distance sleeves, the center drill and the stainless steel box are in a clean condition when delivered. Sterilize the stainless steel box including all parts prior to initial use.

Sterilization Page 23 – 25

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3. Product description



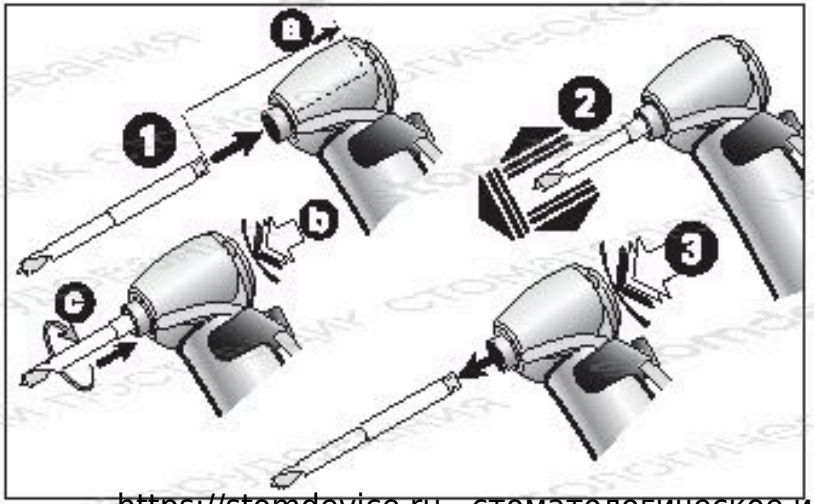
Stainless steel box complete with

1. distance gauge
2. center drill Ø 2.0 mm
3. distance sleeves (A, B, C)
4. distance sleeves (1 – 9)
5. cover with chart

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4. Operation

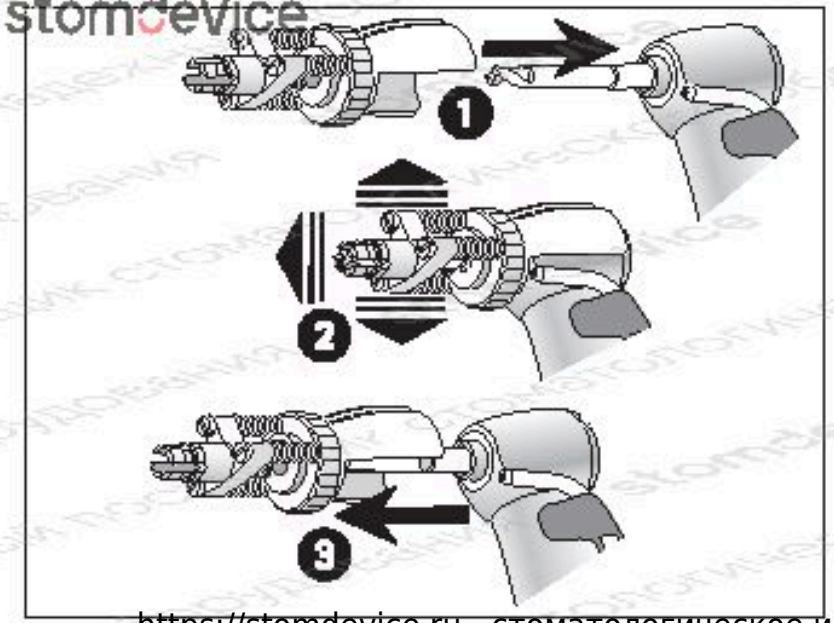


To change the center drill

1. Insert the center drill until back stop (a). Activate press-button (b) and turn the center drill until it engages (c).
2. Check secure location by applying slight axial tension.
3. Remove the center drill by pushing the press-button.

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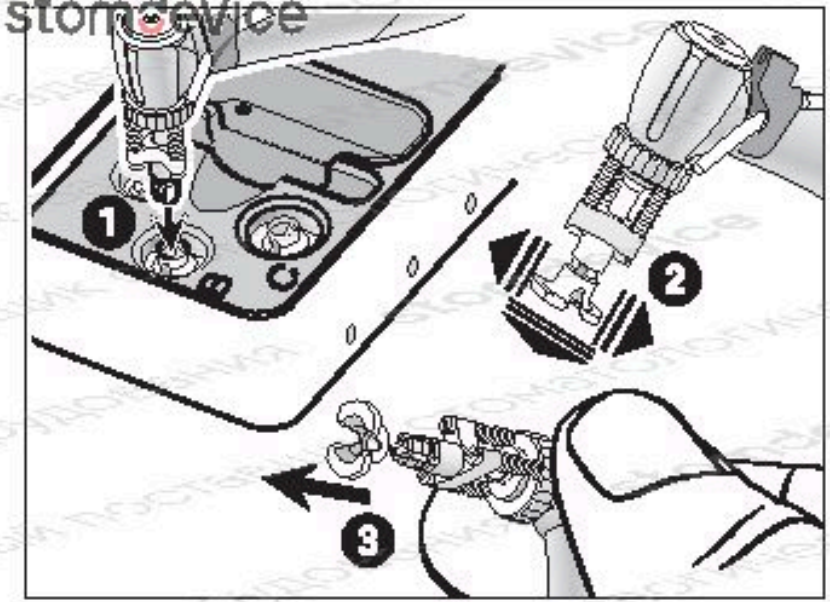


Assembly and removal of the distance gauge

1. Insert the distance gauge over the center drill.
2. Check secure location.
3. Remove the distance gauge by pulling in an axial direction.

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Assembly and removal of the distance sleeve

❶ Take the contra-angle and push the attached distance gauge into the desired distance sleeve.

❷ Check secure location.

❸ Grip the distance gauge firmly and remove the distance sleeve.

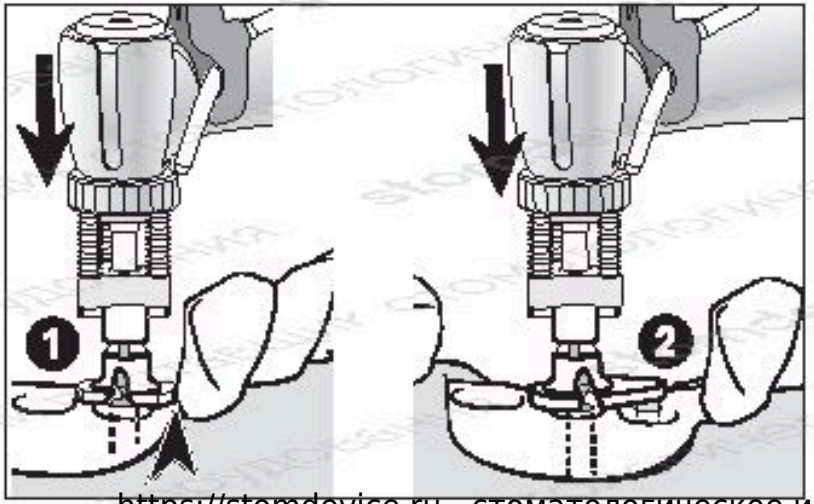
Test run

See Instructions for use of the WI-75 E/KM.

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5. Examples of application



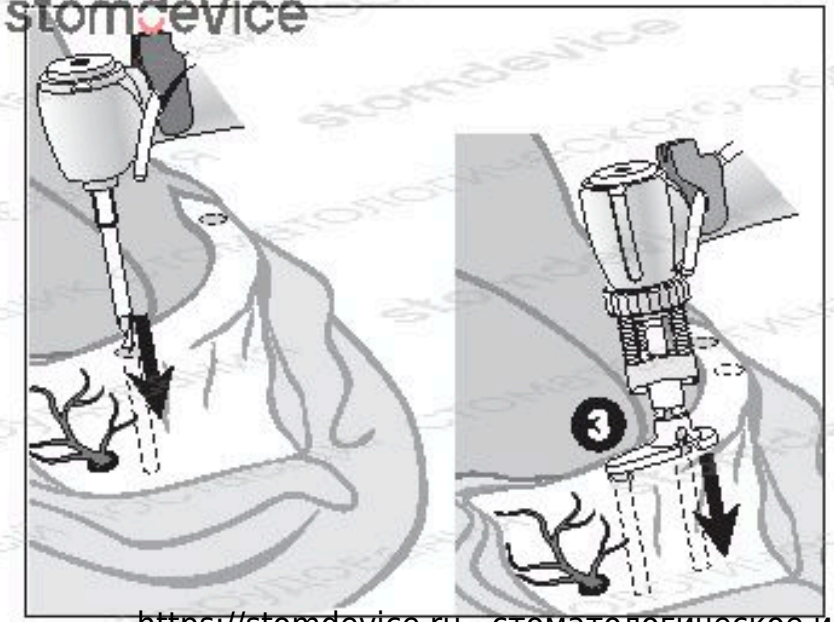
Distance drilling

❶ Tooth to implant (with distance sleeves A, B, C)

❷ Implant to implant (with distance sleeves 1 – 9)

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❸ Implant to implant – Indication:
Lower jaw bar construction on 4 implants
(trapezoidal abutment)

Carry out the two distal holes
with a twist drill Ø 2.0 mm.

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6. Hygienic maintenance



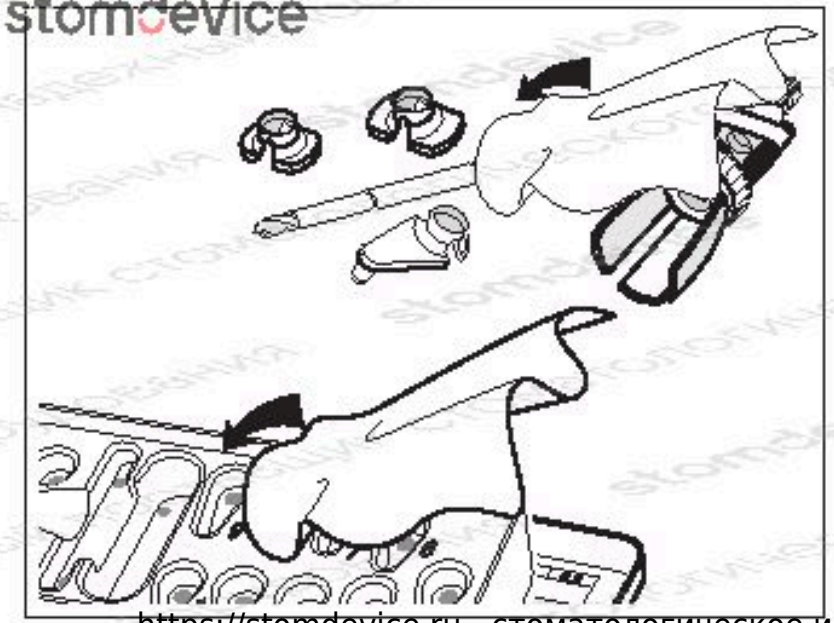
> Follow your country-specific directives, standards and guidelines for cleaning, disinfection and sterilization.
> You can process the distance gauge, the distance sleeves and the center drill in the stainless steel box manually or mechanically.



> Wear protective clothing.
> Clean and disinfect the distance gauge, the distance sleeves and the center drill **immediately after every treatment.**
> Sterilize the distance gauge, the distance sleeves and the center drill following manual or mechanical cleaning and disinfection.

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Pre-disinfection

> If heavily soiled: Clean first with disinfectant cloths.

Only use disinfectants that have no protein-fixing effects.

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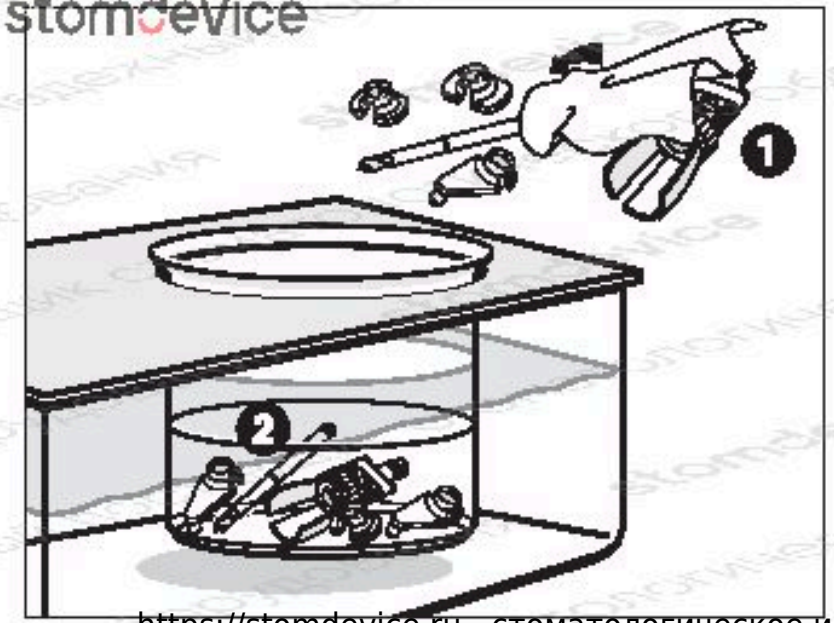
Manual cleaning internal and external

❶ Rinse under demineralized water (< 38 °C / < 100 °F) with the aid of a brush (brush is not recommended in U.K.)

❷ Remove any liquid residues (absorbent cloth, blow dry with compressed air).

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❶ Manual disinfection

> Wiping disinfection with disinfectants.

or

❷ Manual disinfection in an ultrasonic bath

> Disinfection with disinfectants.

> Use only disinfectants which do not contain chlorine and which are certified by officially recognized institutes. **For USA and Canada:** Use EPA registered surface disinfectants.

> Note the manufacturer's specifications for the use of the disinfectants.

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After manual cleaning, disinfection and lubrication you must carry out a final sterilization (wrapped) in the class B or S steam sterilizer (according to EN 13060).

For USA and Canada: Hospital grade sterilization with pre and post vacuum cycle.

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Mechanical cleaning and disinfection internal and external



The stainless steel box, the distance gauge, the distance sleeves and the center drill can be cleaned and disinfected in a thermo washer disinfector.



W&H recommends processing with thermo washer disinfector.

> Note the manufacturer's specifications on equipment, cleaning agents and detergents.

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Sterilization and storage

W&H recommends sterilization according to EN 13060, class B.
For USA and Canada: Hospital grade sterilization with pre and post vacuum cycle.

- > Note the instructions of the unit manufacturer.
- > Clean and disinfect before sterilizing.
- > Wrap the stainless steel box and the accessory in sterile goods packaging according to EN 868-5.
  For USA and Canada: Place the stainless steel box and the accessory in a standard sterilization pouch.
- > Make sure, that you only remove dry sterile goods.
- > Store sterile goods dust-free and dry.

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Approved sterilization procedures



Follow your country-specific directives, standards and guidelines.

> Steam sterilization class B (pre and post vacuum) with sterilizers in accordance with EN 13060.
Sterilization holding time a minimum of 3 minutes at 134 °C (273.2 °F).

or

> Steam sterilization class S with sterilizers in accordance with EN 13060.
Sterilization holding time a minimum of 3 minutes at 134 °C (273.2 °F).

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For USA and Canada

- Steam vacuum sterilization (hospital grade sterilization), 4 minutes at 134 ±2 °C (273.2 ±1.1 °F) or
- Gravity displacement sterilization, 6 minutes at 134 ±2 °C (273.2 ±1.1 °F)
- All other sterilization methods are not approved and must not be used.

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7. W&H Accessories

Use only original W&H accessories and spare parts!
Suppliers: W&H partners

04825100	Distance gauge
04726400	Center drill Ø 2.0 mm
04830500	Distance sleeve A, distance 3.8 mm
04830600	Distance sleeve B, distance 4.3 mm
04867900	Distance sleeve C, distance 5.1 mm

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04824900	Distance sleeve No. 1, distance 6.1 mm
04825000	Distance sleeve No. 2, distance 6.6 mm
04830100	Distance sleeve No. 3, distance 7.1 mm
04830200	Distance sleeve No. 4, distance 7.6 mm
04830300	Distance sleeve No. 5, distance 8 mm
04830400	Distance sleeve No. 6, distance 8.6 mm
04903700	Distance sleeve No. 7, distance 9.1 mm
04929500	Distance sleeve No. 8, distance 9.6 mm
04929600	Distance sleeve No. 9, distance 11.5 mm
10207550	Implantology contra-angle WI-75 E/KM, 20:1

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Letter of indemnity

This W&H product has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantee faultless operation. Please note that claims under warranty can only be validated when all the directions in the instructions for use have been followed.

As manufacturer, W&H is liable for material or manufacturing defects within a warranty period of 12 months from the date of purchase.

We accept no responsibility for damage caused by incorrect handling or by repairs carried out by third parties not authorized to do so by W&H!

Claims under warranty – accompanied by proof of purchase – must be sent to the vendor or to an authorized W&H service partner. The provision of service under warranty extends neither the warranty period nor any other guarantee period.

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12 months warranty

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Authorized W&H service partner

Find you nearest W&H service partner at http://wh.com
Simply go to the menu option »Service« for full details. Alternatively please contact:

W&H (UK) Limited, Unit 6, Stroud Wood Business Centre, Park Street, St Albans, Herts AL2 2NJ Hertfordshire
t + 44 1727 874990, **f** + 44 1727 874628, E-Mail: technical.uk@wh.com

W&H Impex Inc., 6490 Hawthorne Drive, Windsor, Ontario, N8T 1J9, Canada
t + 1 519 9446739, **f** + 1 519 9746121, E-Mail: service.ca@wh.com

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