IMPORTANT INFORMATION – Please Read Before Use

INFORMATIONS IMPORTANTES - À lire attentivement avant d'utiliser

WICHTIGE INFORMATIONEN - Vor Gebrauch bitte lesen

INFORMACIÓN IMPORTANTE - Sírvase leerla antes de emplear

INFORMAZIONI IMPORTANTI - Leggere prima dell'uso

INFORMAÇÃO IMPORTANTE - É favor ler antes de utilizar

BELANGRIJKE INFORMATIE - Vóór gebruik lezen

VIGTIG INFORMATION - Læses før brug

VIKTIGT! - Läs detta innan produkten används

TÄRKEÄÄ - Lue ennen käyttöä

ΣΗΜΑΝΤΙΚΕΣ ΠΛΗΡΟΦΟΡΙΕΣ - Παρακαλούμε διαβάστε πριν από τη χρήση

DULEŽITÉ INFORMACE - Pred použitím si prosím prectete tento leták

FONTOS INFORMÁCIÓ - Használat elott elolvasandó

WAZNE INFORMACJE - Prosimy przeczytac przed uzyciem

DÔLEŽITÉ INFORMÁCIE - Precítajte si láskavo ešte pred použitím

DePuy Synthes
JOINT RECONSTRUCTION
COMPANIES OF Johnson&Johnson

CE 0086 *

IFU-0902-00-836
Rev. E

***Refers to Class IIa products only**

Non-Sterile Surgical Instruments

Contents

ENGLISH

INSTRUCTIONS FOR USE

These instructions apply to reusable non-sterile surgical instruments, supplied by DePuy Orthopaedics, Inc. or DePuy International Ltd., and intended for reprocessing in a health care facility setting.
The instruments used to implant orthopaedic prostheses do not have an indefinite function life. All reusable instruments are subjected to repeated stresses related to bone contact, impaction and routing, cleaning and sterilization process. It is essential that the surgeon and operating theatre staff are fully conversant with the appropriate surgical technique for the instruments and associated implant, if any.

CAUTION: These instructions DO NOT APPLY to single-use devices.

These reprocessing instructions have been validated as being capable of preparing reusable DePuy Orthopaedics, Inc. and DePuy International Ltd. instruments for reuse. It is the responsibility of the re-processor to ensure that the reprocessing is performed using appropriate equipment, materials, and personnel to achieve the desired result. This normally requires validation and routine monitoring of the process. Any deviation from these instructions should be evaluated for effectiveness and potential adverse consequences.

A. Warnings	• Follow the instructions and warnings issued by the suppliers of any cleaning and equipment used. • Do not exceed 284°F (140ºC) during reprocessing steps. • Avoid exposure to hypochlorite solutions and solutions containing iodine or high chlorine content, as these will promote corrosion. • Cleaning agents with a pH between 7 – 9 are recommended. • Highly alkaline conditions (pH > 11) can damage products (esp. aluminum parts). • Manual Cleaning must be performed prior to Automated Cleaning for all instruments complex devices (i.e. lumens, articulating devices, flexible segments, and springs). • Due to the complexity of the Orthopaedic Joint Reconstruction cases, DePuy Orthopaedics, Inc. does not recommend sterilization for immediate use. For further guidance please refer to ST79. • Soiled or used DePuy Orthopaedics, Inc. devices should not be loaded into a case for cleaning in a mechanical washer. Soiled instruments must be processed separate from trays and cases. DePuy Orthopaedics, Inc. cases are designed to be an organization tool for steam sterilization process, a storage tool for all medical devices and an organizational tool for surgery. • The parameters listed are only valid for properly installed, maintained, calibrated and compliant reprocessing equipment in accordance with ISO 15883 and ISO 17665. • Ensure that no instruments or pieces of instruments are left in the surgical site prior to closure, as they may not be detectable using imaging techniques such as X-ray or MRI and patient injury may result.
B. Limitations on Reprocessing	• Repeated processing cycles that include ultrasonic, mechanical washing and sterilization has minimal effects on device life and function. • Carefully inspect devices between uses to verify proper function. • Discard damaged implants. • End of useful instrument life is generally determined by wear or damage in surgical use. • Evidence of damage and wear on a device may include but is not limited to corrosion (i.e. rust, pitting), discoloration, excessive scratches, flaking, wear and cracks. Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and excessively worn devices should not be used. • Return damaged instruments to a DePuy Orthopaedics, Inc. Sales Representative.

C. Decontamination Considerations - CJD	Under certain classifications of risk, the World Health Organization (WHO), or local regulatory authorities recommend special CJD (Creutzfeldt-Jakob Disease) inactivation processing procedures. Consult WHO and local regulations for further information.
D. Care at the Point of Use	• Clean instruments as soon as possible after use. If cleaning must be delayed, immerse instruments in a compatible detergent solution, spray with an instrument pre-soak solution, or cover instruments with a towel moistened with purified water to prevent drying and encrustation of surgical soil. • Soiled devices should be separated from non-contaminated devices to avoid contamination of personnel or surroundings. • Flush cannulated devices with sterile or purified water to prevent the drying of soil and/or debris to the inside. • Avoid prolonged exposure to saline to minimize the chance of corrosion.
E. Containment & Transportation	• Process instruments as soon as is reasonably possible after use. It is recommended not to delay cleaning for more than 16 hours. • If desired, place the instrument in its respective position within the instrument tray. The position of the instrument is labelled in its intended position within the tray.
F. Preparation for Cleaning	• For multi-piece or complex instruments, please refer to their disassembly instructions. Disassembly instructions are available per request by contacting DePuy Orthopaedics, Inc. Customer Service at (800) 337-8966. • Additional Technical Information is provided for Disassembly instructions, Lumen size information, and supplemental cleaning instructions for complex devices.
G. Manual Cleaning: All Devices	Equipment: various sized soft-bristled brushes, lint-free cloths, syringes, pipettes and/or water jet, neutral enzymatic cleaner or neutral detergent with a pH between 7 and 9. • Prepare an enzymatic cleaning solution in accordance to the manufacturer's instructions. • Soak soiled devices for a minimum recommended time specified by the enzymatic cleaning solution manufacturer or 5 minutes, whichever is longer. • Prepare a pH neutral (pH 7-9) detergent cleaning solution in accordance to the manufacturer's instructions. • Use a soft non-metallic bristle brush (plastic bristles, like nylon) to thoroughly scrub all traces of blood and debris from the device surfaces for one minute. • Rinse the device with warm, 30°C - 40°C (85°F – 104°F), tap water for a minimum of one minute and until visual evidence of debris, soil, and cleaning solution are gone. • Pay particular attention to thoroughly flush lumens, articulating areas, and flexible segments with warm, 30°C - 40°C (85°F – 104°F), tap water. • Ultrasonically clean the device components for 10 minutes in neutral pH detergent (pH 7-9), prepared in accordance with the manufacturer's instructions. NOTE: Ultrasonic cleaning is only effective if the surface to be cleaned is immersed in the cleaning solution. Air pockets will decrease the efficacy of ultrasonic cleaning. Be sure to minimize air pocket or bubble formation by flushing lumens, cavities, crevices or springs with cleaning solution while the instrument is immersed in the ultrasonic cleaner tank. • Rinse the device components with warm, 30°C - 40°C (85°F – 104°F), tap water for a minimum of one minute and until visual evidence of debris, soil, and cleaning solution are gone. • Perform a final rinse with Reverse Osmosis Deionized (RODI) or Purified (PUR) Water. • Dry the device components immediately after final rinse with a clean towel or clean compressed air until visibly dry.
H. Manual Cleaning – Lumens	Equipment: various sized soft-bristled brushes, lint-free cloths, syringes, pipettes and/or water jet, neutral enzymatic cleaner or neutral

	detergent with a pH between 7 and 9. • Prepare a new enzymatic or pH neutral (pH 7-9) detergent cleaning solution in accordance to the manufacturer's instructions. • Fully immerse the instrument in freshly prepared enzymatic or cleaning detergent solution to avoid aerosol generation. • Use a minimum 12 inch (305mm) long, tight fitting, soft lumen brush (plastic bristles, like nylon) to thoroughly scrub the lumen or cannula of each device. Minimum brush diameters are specified in Additional Technical Information for each lumen size. • Push the brush through the entire length of the lumen using a twisting motion to remove debris. • Clean the brush in the cleaning solution between each pass of the brush through the lumen by manually immersing the brush in the cleaning solution until no sign of debris can be seen. • Pass the brush through the lumen as described above several times for 1 minute from both ends, cleaning the bristles before retracting until brush comes out clean. • Use a 50ml syringe, or equivalent, filled to capacity with cleaning solution to flush the lumen of each device. • Rinse the device with warm, 30°C - 40°C (85°F – 104°F), tap water for a minimum of one minute and until visual evidence of debris, soil, and cleaning solution are gone. • Pay particular attention to thoroughly flush lumens, articulating areas, and flexible segments with warm, 30°C - 40°C (85°F – 104°F), tap water. • Ultrasonically clean the device components for 10 minutes in neutral pH detergent, prepared in accordance with the manufacturer's instructions. NOTE: Ultrasonic cleaning is only effective if the surface to be cleaned is immersed in the cleaning solution. Air pockets will decrease the efficacy of ultrasonic cleaning. Be sure to minimize air pocket or bubble formation by flushing lumens, cavities, crevices or springs with cleaning solution while the instrument is immersed in the ultrasonic cleaner tank. • Rinse the device components with warm, 30°C - 40°C (85°F – 104°F), tap water for a minimum of one minute and until visual evidence of debris, soil, and cleaning solution are gone. • Perform a final rinse with Reverse Osmosis Deionized (RODI) or Purified (PUR) Water. • Dry the device components immediately after final rinse with a clean towel or clean compressed air until visibly dry.
I. Manual Cleaning – Articulating Instruments (Devices With Movable Parts)	Equipment: various sized soft-bristled brushes, lint-free cloths, syringes, pipettes and/or water jet, neutral enzymatic cleaner or neutral detergent with a pH between 7 and 9. • Fully immerse the instrument in freshly prepared enzymatic or cleaning detergent solution to avoid aerosol generation. • Thoroughly brush with a soft non-metallic bristle brush to remove all traces of blood and debris. • Pay close attention to threads, crevices, seams, and any hard to reach areas. • Actuate any moveable mechanisms, such as hinged joints, box locks, or spring-loaded features, to free trapped blood and debris. • If the components of the instrument can be retracted, retract or open the part while cleaning the exposed area. • Use a 50ml syringe, or equivalent, filled to capacity with enzymatic cleaning solution to flush the threads, crevices, seams, and any hard to reach areas. • Rinse the device with warm, 30°C - 40°C (85°F – 104°F), tap water for a minimum of one minute and until visual evidence of debris, soil, and cleaning solution are gone. • Pay particular attention to thoroughly flush lumens, articulating areas, and flexible segments with warm, 30°C - 40°C (85°F – 104°F), tap water. • Ultrasonically clean the device components for 10 minutes in

	neutral pH detergent, prepared in accordance with the manufacturer's instructions. NOTE: Ultrasonic cleaning is only effective if the surface to be cleaned is immersed in the cleaning solution. Air pockets will decrease the efficacy of ultrasonic cleaning. Be sure to minimize air pocket or bubble formation by flushing lumens, cavities, crevices or springs with cleaning solution while the instrument is immersed in the ultrasonic cleaner tank. • Rinse the device components with warm, 30°C - 40°C (85°F – 104°F), tap water for a minimum of one minute and until visual evidence of debris, soil, and cleaning solution are gone. • Perform a final rinse with Reverse Osmosis Deionized (RODI) or Purified (PUR) Water. • Dry the device components immediately after final rinse with a clean towel or clean compressed air until visibly dry.
J. Manual Cleaning: Flexible Shafts And Springs	• Fully immerse the instrument in freshly prepared enzymatic or cleaning detergent solution to avoid aerosol generation. • Thoroughly brush with a soft non-metallic bristle brush to remove all traces of blood and debris. • Flex and relax the instrument under the cleaning solution while brushing. • Use a 50ml syringe, or equivalent, filled to capacity with enzymatic cleaning solution to flush the flexible segments and springs of each device. • Rinse the device with warm, 30°C - 40°C (85°F – 104°F), tap water for a minimum of one minute and until visual evidence of debris, soil, and cleaning solution are gone. • Pay particular attention to thoroughly flush lumens, articulating areas, and flexible segments with warm, 30°C - 40°C (85°F – 104°F), tap water. • Ultrasonically clean the device components for 10 minutes in neutral pH detergent, prepared in accordance with the manufacturer's instructions. NOTE: Ultrasonic cleaning is only effective if the surface to be cleaned is immersed in the cleaning solution. Air pockets will decrease the efficacy of ultrasonic cleaning. Be sure to minimize air pocket or bubble formation by flushing lumens, cavities, crevices or springs with cleaning solution while the instrument is immersed in the ultrasonic cleaner tank. • Rinse the device components with warm, 30°C - 40°C (85°F – 104°F), tap water for a minimum of one minute and until visual evidence of debris, soil, and cleaning solution are gone. • Perform a final rinse with Reverse Osmosis Deionized (RODI) or Purified (PUR) Water. • Dry the device components immediately after final rinse with a clean towel or clean compressed air until visibly dry.
K. Manual Thermal Decontamination	• Thermal decontamination may be performed to render the devices safe for handling. • Thermal decontamination does not render the devices safe for patient use. • Place devices with lumens and holes at an angle to prevent the formation of air pockets. • Thermally decontaminate the devices by immersing in a heated water bath at 93°C (199.4°F) for 10 minutes.
-OR-	
L. Automated Cleaning	• Prepare an enzymatic cleaning solution in accordance to the manufacturer's instructions. • Soak devices for a minimum recommended time specified by the enzymatic cleaning solution manufacturer or 5 minutes, whichever is longer. • Complex devices should be pre-cleaned in accordance with the appropriate Manual Cleaning Instructions section. • Rinse the device with warm, 30°C - 40°C (85°F – 104°F), tap water for a minimum of one minute and until visual evidence of debris, soil, and cleaning solution are gone.

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Pay particular attention to thoroughly flush lumens, articulating areas, and flexible segments with warm, 30°C - 40°C (85°F – 104°F), tap water for a minimum of one minute and until visual evidence of debris, soil, and cleaning solution are gone.
Load the device components so that the lumens can drain.
Clean, using the “INSTRUMENTS” cycle in a validated washer disinfector and a pH neutral cleaning agent intended for use in automated cleaning using the minimum cycle parameter set points below:

<table>
<tr><th>Phase</th><th>Time (Minutes)</th><th>Temperature</th><th>Detergent Type</th></tr>
<tr><td>Pre Wash</td><td>2:00</td><td>Cold Tap Water</td><td>N/A</td></tr>
<tr><td>Enzyme wash</td><td>1:00</td><td>< 40°C</td><td>Enzymatic Cleaner</td></tr>
<tr><td>Wash</td><td>2:00</td><td>66°C</td><td>Neutral pH Detergent</td></tr>
<tr><td>Rinse</td><td>0:15</td><td>> 40°C</td><td>N/A</td></tr>
<tr><td>Thermal Decontamination*</td><td>5:00</td><td>> 93°C</td><td>N/A</td></tr>
<tr><td>Dry</td><td>7:00</td><td>115.5°C</td><td>N/A</td></tr>
</table>
* Reverse Osmosis Deionized (RODI) or Purified (PUR) Water
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<tr><td>M. Cleaning Inspection</td><td>

Inspect all devices before sterilization or storage to ensure the complete removal of soil from surfaces, lumens, holes, and moveable parts.
If areas are difficult to inspect visually, check for blood by immersing or flushing the instrument in a 3% hydrogen peroxide solution. If bubbling is observed, blood is present. Rinse instruments for a minimum of 1 minute with warm, 30°C - 40°C (85°F – 104°F), tap water after using hydrogen peroxide solution. If soil is still present, re-clean the instrument.

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<tr><td>N. Disinfection</td><td>

Thermal decontamination may be performed as an additional step to render the devices safe for handling.
Devices must be terminally sterilized prior to surgical use. See Sterilization instructions

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<tr><td>O. Maintenance</td><td>

Carefully inspect instruments between uses to verify proper functioning. Return damaged instruments to a DePuy Orthopaedics, Inc. Sales Representative.

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<tr><td>P. Inspection And Functional Testing</td><td>

DePuy Orthopaedics, Inc. devices should be inspected after processing prior to sterilization for:

Cleanliness
Damage, including but not limited to, corrosion (rust, pitting) discoloration, excessive scratches, flaking, cracks, and wear
Proper function, including but not limited to cutting tools should be sharp and free from nicks, long thin instruments should be checked for bending and distortion, movement of hinges/joints/box locks and moveable features such as handles, ratchets and couplings, jaws and teeth should align properly and locking mechanisms should fasten.
Missing or removed (buffed off) part numbers
Wear

Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and worn devices should not be used.
Disassembled devices should be reassembled prior to sterilization unless otherwise noted.
Lubricate moving parts with water soluble lubricant per the manufactures instructions. Lubricate after cleaning and prior to sterilization.

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<tr><td>Q. Packaging</td><td>Sterilization Wraps:</td></tr>
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Use instrument trays to contain instruments that are provided in sets.
Wrap instruments in accordance with local procedures, using standard wrapping techniques such as those described in the current revision of ANSI/AAMI ST79. In the United States (US), use an FDA-cleared Sterilization Wrap.

Only legally marketed, FDA cleared sterilization wrap, pouches, or DePuy Orthopaedics, Inc. Reusable Sterilization Containers should be used by the end-user for packaging terminally sterilized devices. The manufacturer's instructions for use for the sterilization wrap, pouches, or DePuy Orthopaedics, Inc. Reusable Sterilization Containers are to be followed. The use of DePuy Orthopaedics, Inc. Reusable Sterilization Containers are limited to use in the United States only, and are not approved for use outside of the United States.

Label the contents of the wrapped instruments using an indelible marker or other sterilization compatible label system.

Aesculap Rigid Sterilization Container – Models JN442 through JN446:

Aesculap Rigid Sterilization Container used as packaging for DePuy Orthopaedics, Inc. instrument sets must include two vents on the lid and two vents on the base.
Refer to Aesculap instructions for use for care and handling of information including cleaning, filter assembly, assembly for use, preparation of, and loading the rigid sterilization container in the sterilizer.
Leave 1 inch (26 mm) of free space between the instrument tray and the inside of the container lid for effective processing.

QUAD-LOCK™ Sterilization Container System1:

Refer to QUAD-LOCK Sterilization Container System Instructions for Use for care and handling information, including; inspection, cleaning, assembly for use, sterilization, and storage.
For effective sterilization and drying of any sized QUAD-LOCK Sterilization Container, the recommended maximum combined weight of the single container, lid, basket, and basket contents is 25 lb (11.3 kg).
Leave a minimum of 2 inches (51 mm) of free space between the instruments and the inside of the container lid for effective processing.

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<td>R. Sterilization (United States)</td>
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Use a validated, properly maintained and calibrated steam sterilizer.
Effective steam sterilization can be achieved using the following cycle

<table>
<tr><th>Cycle Type</th><th>Minimum Temperature</th><th>Minimum Exposure Time / Dry Time</th></tr>
<tr><td>Pre-Vacuum</td><td>270°F (132°C)</td><td>4 minutes / 30 minutes dry time</td></tr>
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Contact DePuy Orthopaedics, Inc. Customer Service for Additional Technical Information
For further guidance for Sterilization, refer to: ANSI/AAMI ST79 “Comprehensive guide to steam sterilization and sterility assurance in health care facilities.”

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<td>S. Sterilization (Outside the United States)</td>
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Use a validated, properly maintained and calibrated steam sterilizer.
Effective steam sterilization can be achieved using the following cycle

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[1] The third-party trademarks used herein are trademarks of their respective owners.

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<table>
<tr><th>Cycle Type</th><th>Minimum Temperature</th><th>Minimum Exposure Time / Dry Time</th></tr>
<tr><td>Pre-Vacuum</td><td>273°F (134°C)*</td><td>3 minutes / 30 minute dry time</td></tr>
</table>
*NOTE: Effectiveness of the 134°C cycle for the sterilization of DePuy Surgical Instruments in the QUAD-LOCK Sterilization Container System has not been established.
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<tr><td>T. Storage</td><td>Store sterile packaged instruments protected from dust, moisture, insects, vermin, and extremes of temperature and humidity.</td></tr>
<tr><td>U. Additional Information</td><td>

Cleaning Agent Information: DePuy Orthopaedics, Inc. used the following cleaning agents during validation of these reprocessing recommendations. These cleaning agents are not listed in preference to other available cleaning agents which may perform satisfactorily – Terg-A-Zyme™, Nph-Klenz®, and Enzol.
The cleaning and sterilization information is provided in accordance with ANSI/AAMIST81, EN ISO 17664, AAMI TIR 12, EN/ISO 17665-1 and AAMI ST77.
The recommendations provided above have been validated by the medical device manufacturer as being capable of preparing a non-sterile DePuy Orthopaedics, Inc. medical devices. It remains the responsibility of the processor to ensure that the processing is actually performed using equipment, materials and personnel in the reprocessing facility, and achieves the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the recommendations provided should be properly evaluated for effectiveness and potential adverse consequences.
All users should be qualified personnel with documented expertise, competency and training. Users should be trained on hospital policies and procedures along with current applicable guidelines and standards.
Users should utilize appropriate personal protective equipment (PPE) when processing devices in accordance with the Department of Environmental and Occupational Health and Safety's (OSHA) bloodborne pathogen guidelines.

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<tr><td>V. Manufacturer Contact</td><td>

DePuy Orthopaedics, Inc. Customer Service 1-800-337-8966

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</table>

Where further information is desired, please contact your local DePuy sales representative. For instruments produced by another manufacturer, reference the manufacturer's instructions for use.

Symbol to be Included in IFU	Interpretation	Symbol(s)
✓	DEPUY, INC.	D/DP
✓	QUANTITY	QTY
✓	MANUFACTURED BY:	MFG and MFG/MANUFACTURED BY:
✓	MADE IN	MADE IN
✓	SIZE / SIZE / DIAMETER / INCHES / FEET / DEGREES / GROUP / POUNDS / OUTER DIAMETER / INNER DIAMETER	SIZE / SZ / DIA / IN / FT / DEG / GRP / LB / OD / ID
✓	NON-STERILE	
✓	DO NOT DISASSEMBLE	
✓	FORWARD	FORWARD
✓	LOCK	LOCK
✓	REVERSE	REVERSE
✓	Rasps for use with T-Handle Only	Rasps for use with T-Handle Only
✓	Stella-Lube Prior to Use	Stella-Lube Prior to Use
✓	APEX	APEX
✓	NOT FOR USE WITH IMPLANT	NOT FOR USE WITH IMPLANT
✓	PRELIMINARY ASSEMBLY INSTRUMENT	PRELIMINARY ASSEMBLY INSTRUMENT
✓	RESET TO GREEN	RESET TO GREEN
✓	MUST USE WITH GUIDE SHAFT	MUST USE WITH GUIDE SHAFT

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*** For recognized manufacturer and model designation, refer to product label.**

US REP

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COMPANIES OF Johnson&Johnson