Instructions for Use
RIA 2 (Reamer Irrigator Aspirator)

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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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Instructions for Use

RIA 2 (Reamer Irrigator Aspirator)

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The RIA 2 System is designed for reaming of the medullary canal for preparation of internal fixation and/or harvest of bone and bone marrow. The RIA 2 System consists of disposable Reamer Heads, Tube Assembly, Reaming Rod Seal, Graft Filter, Irrigation and Aspiration Tubes, and reusable Drive Shaft.

The DePuy Synthes RIA 2 Tube Assembly, Reamer Heads, Drive Shaft Seal, Graft Filter, and Irrigation and Aspiration Tubes are provided sterile for single-use only. The Drive Shaft is offered non-sterile only.

Important note for medical professionals and OR staff: These instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use, the DePuy Synthes brochure "Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical technique.

Device(s)	Material(s)	Standard(s)
Reamer heads	440A Stainless Steel	ASTM F899
Bone Harvest and Reaming Kits	Polycarbonate	ISO 7391-2
	ABS (Acrylonitrile butadiene styrene)	ISO 19062-1
	PVC (Polyvinyl chloride)	ISO 21306-2
	Liquid Silicone Rubber	ISO 14949
	HDPE (High Density Polyethylene)	ASTM F755
	FEP (Fluorinated ethylene propylene)	ASTM D4000
	304 Stainless Steel	ASTM F899
Graft Filter	Polycarbonate	ISO 7391-2
	ABS (Acrylonitrile butadiene styrene)	ISO 19062-1
	PVC (Polyvinyl chloride)	ISO 21306-2
	Liquid Silicone Rubber	ISO 14949
	PES (Polyethersulfone)	ISO 25137-1
Drive Shaft	Nitinol	ASTM F2063
	17-4 Stainless Steel	ASTM F 899

Intended Use
The RIA 2 System is intended for reaming of the medullary canal for preparation of internal fixation, harvest of bone and bone marrow, and/or clearing of debris.

Indications
The DePuy Synthes RIA 2 System is intended for use in adults and adolescents (12 to 21 years) with closed physes.
- To clear the medullary canal of the bone marrow and debris
- To effectively size the medullary canal for the acceptance of an intramedullary implant or prosthesis
- To harvest morselized autogenous bone and bone marrow for any surgical procedures requiring bone graft to facilitate fusion and/or fill bone defects
- To remove infected and necrotic bone and tissue from the medullary canal in the treatment of osteomyelitis

Contraindications
No specific contraindications.

Patient Target Group
There are no known restrictions of patient population, when the product is used in respect to the intended use, indications, contraindications and in consideration of the anatomy and health condition of the patient.

Intended User
This IFU alone does not provide sufficient background for direct use of the Device or System. Instruction by a surgeon experienced in handling these devices is highly recommended.

This device is intended to be used by qualified health care professionals e.g. surgeons, physicians, radiologists, OR Staff, and professionals involved in preparation of the device. All personnel handling the device should be fully aware of the intended use of the products, the applicable surgical techniques and the DePuy Synthes "Important Information" brochure.

Expected Clinical Benefits
Expected clinical benefits of the RIA 2 System when used according to instructions for use and recommended technique are:
- Harvest morselized autologous bone graft
- Debridement of the infected medullary canal
- One-pass ream for intramedullary implant acceptance

Performance Characteristics of the Device
DePuy Synthes has established the performance and safety of RIA 2 and that it represents a state of the art medical device and performs as intended for reaming of the medullary canal for preparation of internal fixation, harvest of bone and bone marrow, and/or clearing of debris when used according to the instructions for use and labeling.

Potential adverse Events, undesirable Side Effects and residual Risks
- Adverse Tissue Reaction
- Infection
- Damage to Surrounding Structures
- Embolism
- Neuro-vascular Damage
- Surgical Delay
- Bone Damage
- Bone Fracture Intra-operatively
- Bone Fracture Post-operatively
- Injury to User
- User Dissatisfaction

Sterile Device

STERILE R Sterilized using irradiation

Store sterile implants in their original protective packaging, and do not remove them from the packaging until immediately before use.

Do not use when packaging is damaged

Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use, if the package is damaged or date of expiration has passed.

Do not resterilize

Resterilization of RIA 2 can result in product not being sterile, and/or not meeting performance specifications and/or altered material properties.

Single-Use Device


Do not re-use

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Re-use or clinical reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.

Furthermore, re-use or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Warnings and Precautions
- Before each use, carefully inspect the drive shaft for corrosion, nicks, bents, broken, or scratched. Do not use if any of these conditions are observed.
- The distance of the radiographic ruler from the bone and the position of the C-arm receiver affect the image magnification and thus the diameter measurement.
- For Antegrade femur approach: if the trochanteric entry is angled too far away from the femoral axis, there is a risk that bowing of the guide wire will result in eccentric reaming of the medial femoral cortex.
- Do not use drill with torque greater than 6 Nm
- Do not use a reduction drive
- Do not use power driver designed for reaming
- Reamer Heads are extremely sharp. Use the provided protective sleeve to handle the Reamer Head.
- Never ream when there is no irrigation/aspiration. The irrigation/aspiration fluid cools the Reamer Head and removes bone marrow and morselized bone from the medullary canal. Fluid flow is crucial for proper system performance.
- Periodically check the reaming aspirate is flowing through the tube and into the suction canister. If there is no material flow, stop reaming, turn off suction and retract the reamer head outside the patient to evaluate for obstructions in the flow path.
- Stop suction if the reaming is paused with reamer in the canal. Extended reaming under suction may result in excessive blood loss. Clamps on the suction tube can be used to stop suction.
- Reamer Heads are extremely sharp. Use the provided protective sleeve to handle the Reamer Head.

Combination of Medical Devices
DePuy Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Treatment before Device is Used
The DePuy Synthes RIA 2 Tube Assembly, Reamer Heads, Reaming Rod Seal, Graft Filter, and Irrigation and Aspiration Tubes are provided sterile for single-use only. Do not resterilize.

The Drive Shaft is supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the DePuy Synthes brochure "Important Information".

Store sterile items in their original protective packaging, and do not remove them from the packaging until immediately before use. Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use, if the package is damaged.

Troubleshooting
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Clinical Processing of the Device
Detailed instructions for processing of implants and reprocessing of reusable devices, instrument trays and cases are described in the DePuy Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" are available on the website.

Disposal
Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

Not all products are currently available in all markets.

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