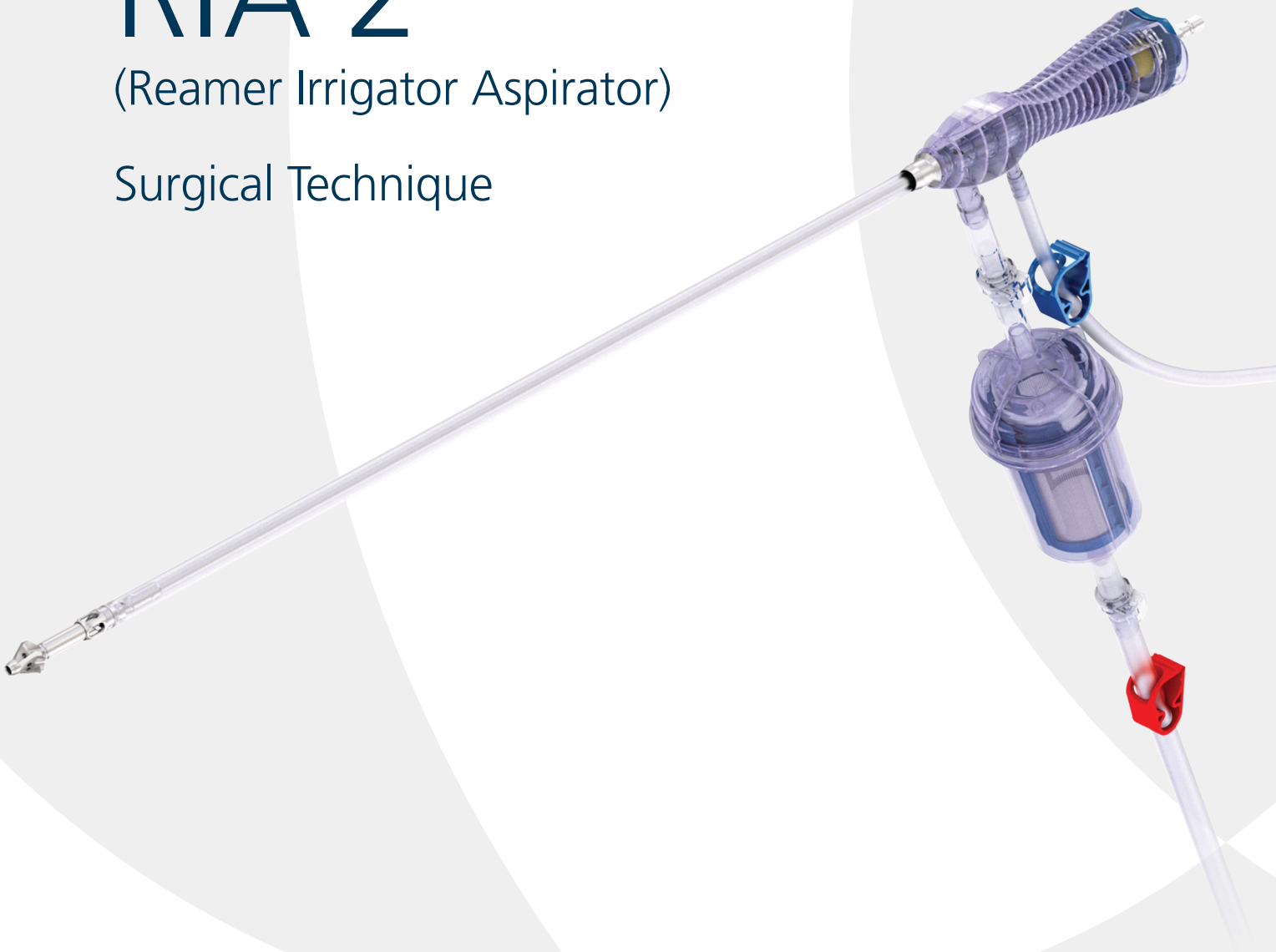
RIA 2

(Reamer Irrigator Aspirator)

Surgical Technique



DePuy Synthes

PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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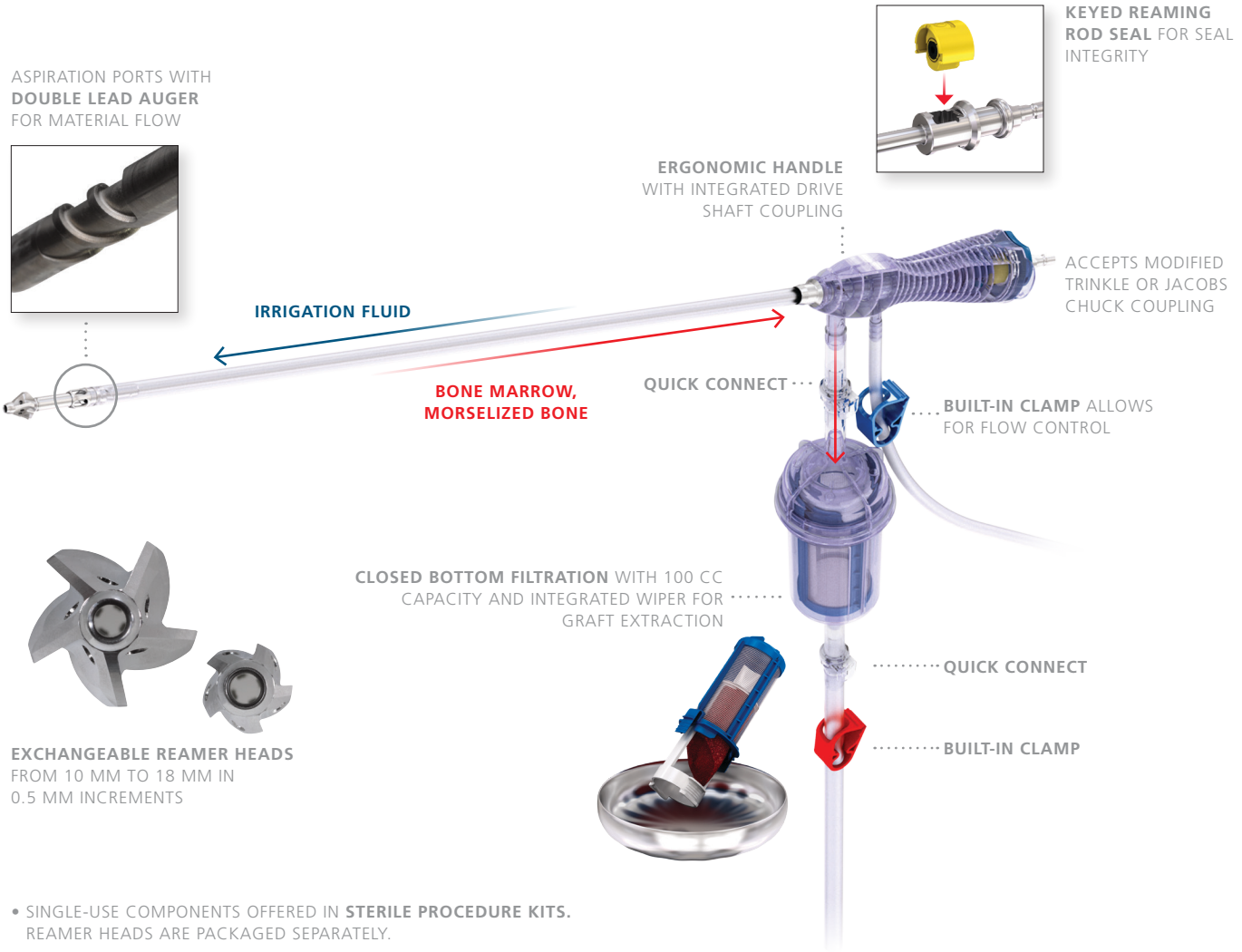
RIA 2 (REAMER IRRIGATOR ASPIRATOR)

Introduction

The RIA 2 System is designed for reaming of the medullary canal for preparation of internal fixation, harvest of bone and bone marrow, and/or clearing of debris. The RIA 2 System consists of disposable Reamer Heads, Tube Assembly, Reaming Rod Seal, Graft Filter, Irrigation and Aspiration Tubes, and reusable Drive Shaft. Ports in the handle of the Tube Assembly allow both irrigation and aspiration through the Tube Assembly during the reaming process. Irrigating fluid is passed through the cannula of the Drive Shaft and the Reamer heads. The aspiration fluid is drawn through the Tube Assembly and out through the Aspiration Tube. The disposables are offered in sterile procedural kits without the Reamer Head. Assorted sizes of the Reamer Head are offered in individual sterile packs.



- SINGLE-USE COMPONENTS OFFERED IN **STERILE PROCEDURE KITS.** REAMER HEADS ARE PACKAGED SEPARATELY.

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 RE-STERILIZE.

The Drive Shaft is offered NONSTERILE only.

Indications

The DePuy Synthes RIA 2 System is intended for use in adults and adolescents (12-21 years)

- 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 finely 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

PREPARATION

1. SELECTION OF THE APPROPRIATE RIA 2 KIT

03.404.000S	RIA 2 Bone Harvesting Kit, 520 mm, sterile
03.404.001S	RIA 2 Reaming Kit, 520 mm, sterile

Select the appropriate RIA 2 kit based on procedure type.

For bone harvesting procedure, use the RIA 2 Bone Harvesting Kit, 03.404.000S

For reaming only procedure, use the RIA 2 Reaming Kit, 03.404.001S

2. REAMER HEAD SIZE SELECTION

Instrument

351.717	Depth Gauge (radiographic ruler)
Or	
03.010.023	Radiographic Canal Width Estimator for IM nails

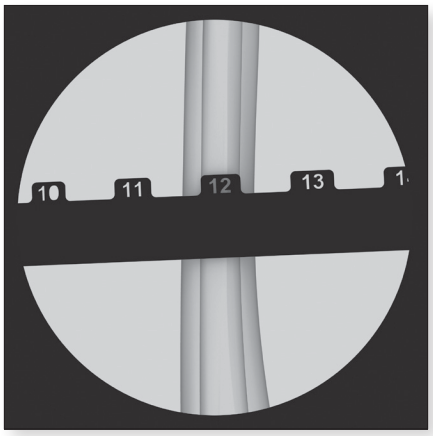
To estimate the canal diameter, position the image intensifier for an AP view of the limb at the level of the isthmus. Hold the radiographic ruler perpendicular to the limb and overlay the diameter tabs over the isthmus. Read the diameter on the tab that fills the canal. Repeat with an ML view.

CAUTION:

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 bone harvesting, select a Reamer Head up to 1.5 mm larger than the canal diameter at the isthmus.

When reaming to prepare the intramedullary canal for an implant, choose the appropriate implant diameter first. Select a Reamer Head based upon the nail manufacturer's recommendation.



NOTE:

Always place the radiographic ruler on the side of the limb closest to the C-arm receiver. Estimate the width as follows:

Distance between radiographic ruler and bone

a. 25 mm = 1 mm larger reading

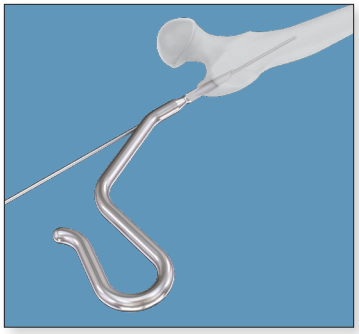
b. 50 mm = 2 mm larger reading

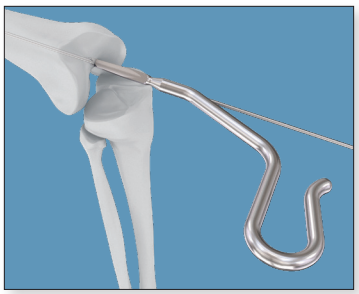
c. 100 mm = 3 mm larger reading

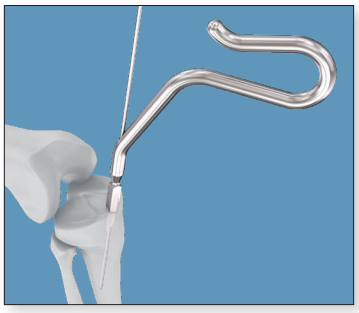
Measure in both AP and ML view.

Pre-operative images can also be used for canal size reference.

3. OPEN CANAL







Instruments

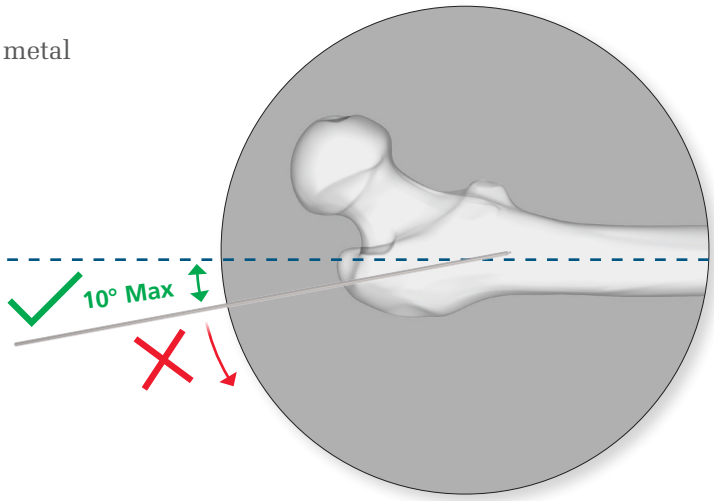
357.399	3.2 mm Guide Wire, 400 mm
03.010.040	12.0 mm Cannulated Awl
Or	
357.399	3.2 mm Guide Wire, 400 mm
357.403	6.0 mm/10.0 mm Stepped Drill Bit - Cannulated/large QC/435 mm
03.010.030	13.0 mm Protection Sleeve
03.010.031	13.0 mm/3.2 mm Wire Guide with trocar tip
Or	
357.399	3.2 mm Guide Wire, 400 mm
03.010.036	12.0 mm Cannulated Drill Bit
357.127	13.0 mm Protection Sleeve
357.128	13.0 mm/3.2 mm Trocar Tip

Open the medullary canal and conduct reaming by following AO reaming techniques for IM nailing and maintain a guide wire entry angle of less than 10° from the axis of the canal.

CAUTION:

If the guide wire entry angle is greater than 10° from the axis of the canal, there is a risk that bowing of the reaming rod will result in:

- Eccentric reaming of the far cortex
- Damage to the reamer head connection, resulting in metal fragments in the canal.



NOTE:

For an antegrade femoral approach, if possible, adduct the limb/hip to facilitate access to entry point. For greater trochanter entry point, target >2cm distal to the lesser trochanter.[1]

For an antegrade tibial approach, the knee will need to be flexed to 90-110° for entry site access. Insert the guide wire aiming down the tibial crest, and thus the center of the medullary canal.[2]

4. INSERT REAMING ROD (REAMING GUIDE WIRE)

Instruments

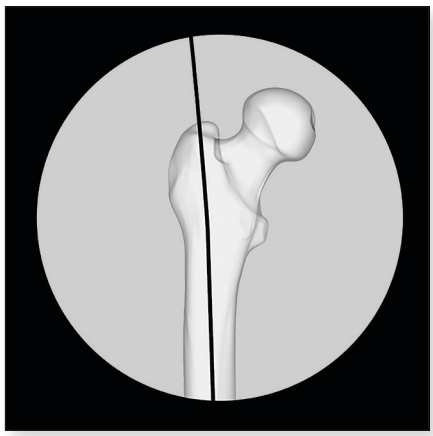
393.10	Universal Chuck with T-Handle
351.706S	2.5 mm Reaming Rod with ball tip, 950 mm, sterile
Or	
351.707S	2.5 mm Reaming Rod with ball tip and extension, 950 mm, sterile

Attach the Universal Chuck with T-handle to the reaming rod. Reduce the fracture (if present). Pass a 2.5 mm reaming rod into the canal and past the fracture site to desired reaming depth. Verify its position with the image intensifier.

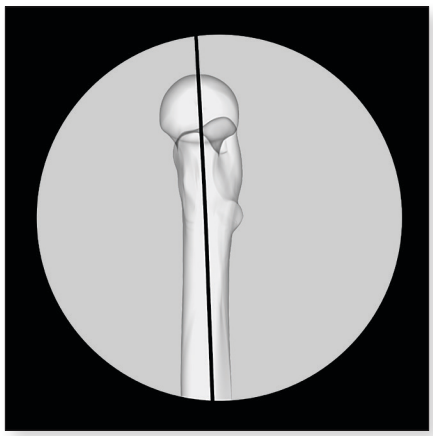
NOTE:

Ensure the reaming rod is centered in the canal in both A-P and Lateral views.

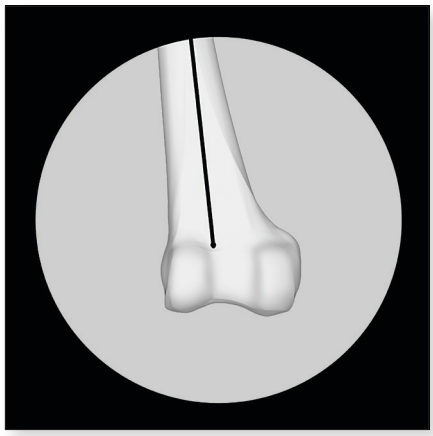
Proximal A-P View



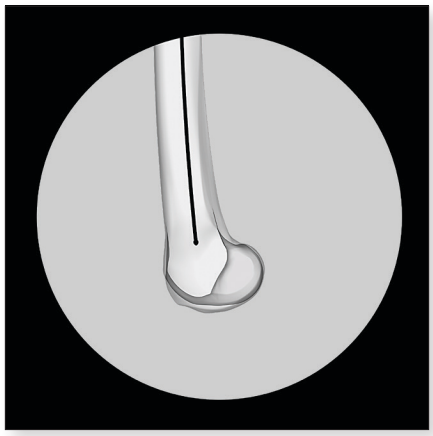
Proximal Lateral View



Distal A-P View



Distal Lateral View



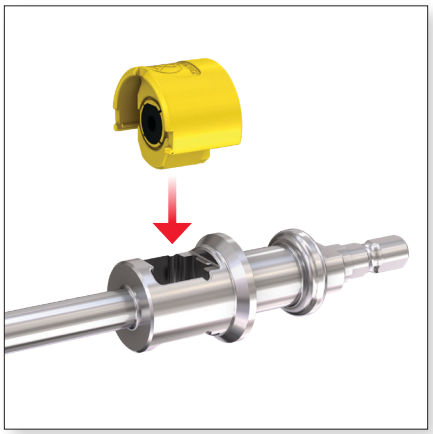
ASSEMBLY

1. INSERT REAMING ROD SEAL

Instrument

03.404.035	Drive Shaft for RIA 2, 520 mm

Ensure the Reaming Rod Seal with the black circle faces the distal end and insert it into the slot on the power driver end of Drive Shaft.



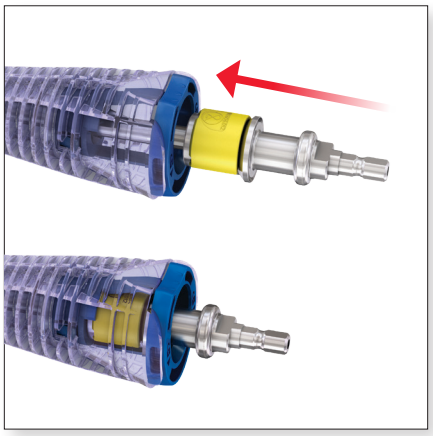
NOTE:

The Reaming Rod Seal is designed to be fully inserted into the slot of the Drive Shaft.

2. INSERT DRIVE SHAFT INTO THE TUBE ASSEMBLY

Take the Tube Assembly and insert the Drive Shaft with seal into the back of the Tube Assembly handle until it is fully seated.

Ensure the Drive Shaft is fully seated into the handle and cannot be pulled out.



3. ATTACH DRIVE UNIT TO THE END OF THE DRIVE SHAFT

Instrument

03.404.035	Drive Shaft for RIA 2, 520 mm

Attach the assembled Tube Assembly with Drive Shaft to a Modified Trinkle drill adapter.

Select a power drive unit that will deliver 3.5 Nm to 6.0 Nm of torque and 700 rpm to 900 rpm (standard drill speed).

Ensure drill setting is selected for the power driver.

CAUTION:

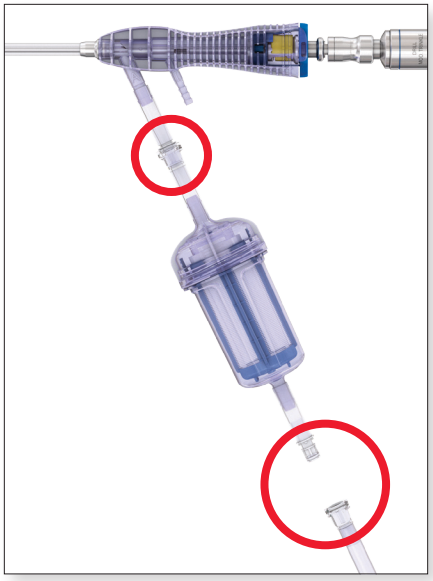
Do not use drill with torque greater than 6 Nm. Do not use a reduction drive. Do not use power driver designed for reaming.

Alternatively, a Jacobs chuck can be used to attach the Drive Shaft to the drive unit.

NOTE:

Do not turn the power on when the Drive Shaft is disengaged from the Tube Assembly.

4. ATTACHING GRAFT FILTER FOR BONE HARVESTING OR SPECIMEN COLLECTION (SKIP FOR REAM ONLY)



Check to ensure the lid of the Graft Filter is closed and secured.

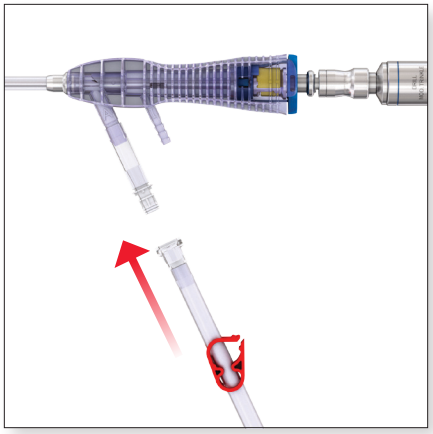
Connect the female end of quick coupling on the Graft Filter to the male end of the quick coupling attached to the aspiration port on the handle.

NOTE:

The aspiration port is the larger port with the quick connect coupling and indicated with a letter "A".

Connect the female end of the quick coupling on the suction tubing to the male end of the quick coupling at the bottom of the Graft Filter.

5. CONNECT ASPIRATION TUBE



When using the RIA 2 System for reaming only, connect the Aspiration Tube directly to the aspiration port on the Tube Assembly handle, bypassing the instructions for connecting the Graft Filter in Step 4.

With or without the Graft Filter, connect the remaining end of the Aspiration Tube to a single suction canister with vacuum source.

NOTE:

Connect the Aspiration Tube directly to the suction canister to avoid a reduction in suction. Never connect several suction canisters in series.

Start the vacuum source.

NOTE:

Recommended operating vacuum pressure range is between 200 and 350 mmHg

6. CONNECT IRRIGATION TUBE

Materials

- 1-2 liter container of irrigation fluid (Not provided by DePuy Synthes)
- Irrigation Tube

Suspend a one (1) or two (2) liter container of irrigation fluid approximately one meter above the level of the patient.

Connect the end of the Irrigation Tube to the irrigation port on the tube assembly handle.

NOTE:

The irrigation port is the smaller of the two ports and is indicated by the letter "I".

Ensure that one of the irrigation clamps is closed.

Attach spike end of tubing set to the irrigation container.

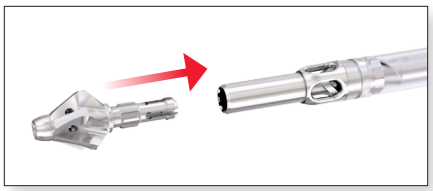
NOTE:

At least one of the clamps on the Irrigation Tube should be closed until reaming begins.

7. ATTACH REAMER HEAD

Materials

03.404.016S - 03.404.032S	Reamer Heads for RIA 2, 10.0 mm - 18.0 mm, sterile



Using the protective sleeve, insert the selected Reamer Head (determined in step 2) into the distal end of the drive shaft until it is fully seated.

NOTE:

The gear of the Reamer Head needs to be aligned with the spline in the Drive Shaft to be fully seated.

CAUTION:

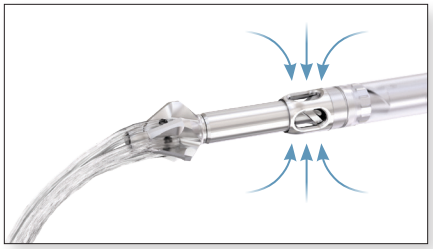
Reamer Heads are extremely sharp. Use the provided protective sleeve to handle the Reamer Head.

REAMING

1. INTRODUCE RIA 2 SYSTEM INTO MEDULLARY CANAL

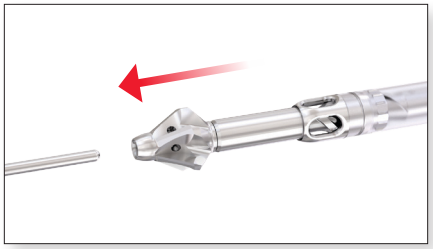
Ensure the clamps on Irrigation and Aspiration Tubes are open.

Guide the Reamer Head over the 2.5 mm reaming rod and into the prepared canal opening of the bone.



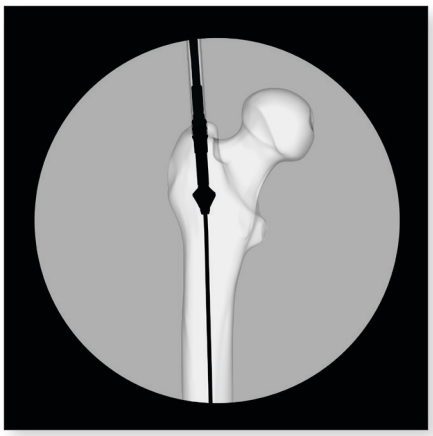
NOTE:

Prior to insertion into patient's limb, ensure irrigate is flowing and suction is present at the aspiration holes at the tip of the assembly.



Advance the RIA 2 System, without power, over the reaming rod until the Reamer Head is inserted into the entry point of the canal.

Check position on the image intensifier.



NOTE:

Flow of aspiration begins when aspiration holes are fully immersed in the bone.

CAUTION:

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.

2. REAM

Minimize direct soft tissue contact with suction holes to prevent potential clogging.

Using the power driver in drill setting, begin reaming under power, slowly advancing the Reamer Head 20–30 mm and then retracting 50–80 mm, allowing the irrigation fluid to flow in front of the Reamer Head. Advance the RIA 2 System until resistance is felt, then repeat the advance and retraction technique to continue reaming.

Use intermittent image intensification to monitor the Reamer Head position during reaming.

NOTE:

An insufficient irrigation volume may lead to clogging. To prevent clogging, avoid rapid advancement of the assembly.

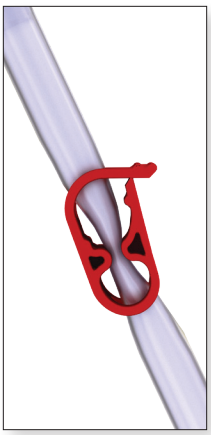
CAUTION:

- Periodically check that 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 also be used to stop suction.

After the Reamer Head reaches the desired depth, withdraw the RIA 2 System with power on until the Reamer Head is at the canal entry site.

3. TURN OFF IRRIGATION AND ASPIRATION

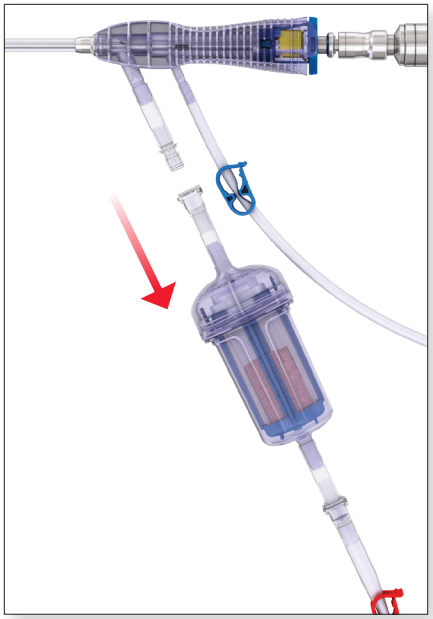
When reaming is completed, retract the RIA 2 System and turn off the irrigation and suction.



EXTRACTING BONE GRAFT

1. DISCONNECT THE GRAFT FILTER

Disconnect the Graft Filter by disconnecting the quick coupling at the top of the filter.



2. OPEN GRAFT FILTER

Unscrew and open the lid of the Graft Filter.

NOTE:

If the suction has not been turned off or clamped, it may be difficult to remove the Graft Filter lid.

3. REMOVE FILTER ELEMENT (OPTIONAL)

Disconnect the Aspiration Tube and over a sterile container (bowl or basin), press the blue tabs on the filter and pull the filter out of the canister.

4. REMOVE EXCESS FLUID (OPTIONAL)

Instrument

03.404.037	Graft Compressor for RIA 2 Graft Filter

Lift white inner sleeve out by 2 cm and seat the Graft Compressor into the filter.

With Graft Compressor held down, pull white inner sleeve to remove excess fluid.

5. EXTRACT GRAFT MATERIAL (IF APPLICABLE)

Pull the white inner sleeve out slowly, extracting the graft material over a sterile container.

REAMER HEAD EXCHANGE

EXCHANGE REAMER HEAD

Instrument

03.404.038	Reamer Head Removal Tool for RIA 2

Remove RIA 2 System completely from the reaming rod. Place the Reamer Head into the Removal Tool and pull the Reamer Head away from the Drive Shaft. Insert the new Reamer Head as instructed in step 7 of the Assembly section.

CAUTION:

Reamer Heads are extremely sharp. Use the provided protective sleeve to handle the Reamer Head.

DISASSEMBLY

Ensure that the reaming rod has been removed from the Drive Shaft.

Place the Reamer Head into the Removal Tool and pull the Reamer Head away from the Drive Shaft.

CAUTION:

Reamer Heads are extremely sharp. Use the provided protective sleeve to handle the Reamer Head.

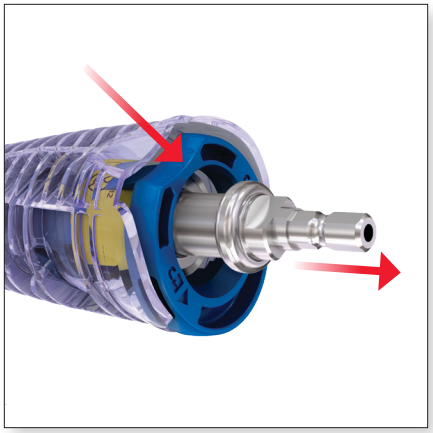
Disconnect and dispose of the Irrigation/Aspiration tubes.

Remove the Drive Shaft from the Tube Assembly by pressing and holding the blue tab at the end of the handle then pull the Drive Shaft out.

Remove and dispose of the Reaming Rod Seal from the Drive Shaft.

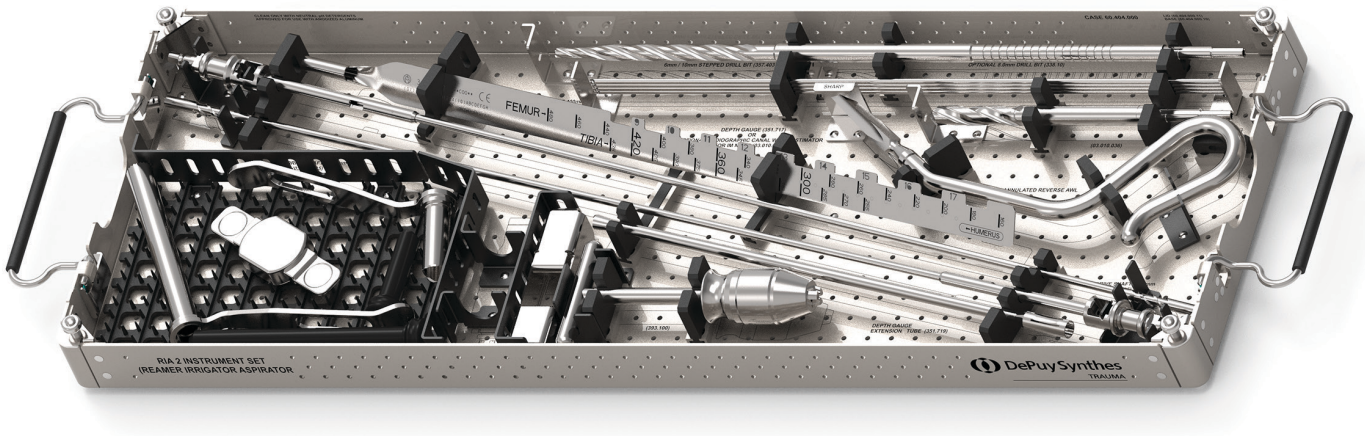
NOTE:

Dispose of the Tube Assembly, Reamer Head, and Reaming Rod Seal. These are single-use items.

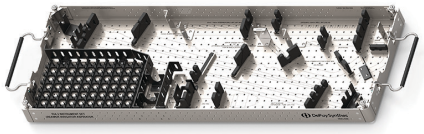


PRODUCT INFORMATION

RIA 2 INSTRUMENT SET – 01.404.000



PART NUMBER	DESCRIPTION	QUANTITY	
03.404.035	Drive Shaft for RIA 2 - 520 mm	2	
357.399	3.2 mm Guide Wire 400 mm	4	
393.10	Universal Chuck with T-handle	1	
351.717	Depth Gauge (radiographic ruler)	1	
351.719	Depth Gauge Extension Tube	1	
357.403	6.0 mm/10.0 mm Stepped Drill Bit - Cannulated/large QC/435 mm	1	
03.010.030	13.0 mm Protection Sleeve	1	
03.010.031	13.0 mm/3.2 mm Wire Guide, with trocar tip	1	

PART NUMBER	DESCRIPTION	QUANTITY	
357.127	13.0 mm Protection Sleeve	1	
03.010.036	12.0 mm Cannulated Drill Bit, Large QC/190 mm	1	
357.128	13.0 mm/3.2 mm Trocar Tip	1	
03.010.040	12.0 mm Cannulated Awl	1	
03.404.037	Graft Compressor for RIA 2 Graft Filter	1	
03.404.038	Reamer Head Removal Tool for RIA 2	1	
60.404.000	Graphic Case with Lid for RIA 2 Instrument Set	1	

PROCEDURE KITS:

PART NUMBER	DESCRIPTION
03.404.000S	RIA 2 Bone Harvesting Kit, 520 mm, Sterile
03.404.001S	RIA 2 Reaming Kit, 520 mm, Sterile

REAMER HEADS:

PART NUMBER	DESCRIPTION
03.404.016S	10.0 mm Reamer Head for RIA 2, Sterile
03.404.017S	10.5 mm Reamer Head for RIA 2, Sterile
03.404.018S	11.0 mm Reamer Head for RIA 2, Sterile
03.404.019S	11.5 mm Reamer Head for RIA 2, Sterile
03.404.020S	12.0 mm Reamer Head for RIA 2, Sterile
03.404.021S	12.5 mm Reamer Head for RIA 2, Sterile
03.404.022S	13.0 mm Reamer Head for RIA 2, Sterile
03.404.023S	13.5 mm Reamer Head for RIA 2, Sterile
03.404.024S	14.0 mm Reamer Head for RIA 2, Sterile
03.404.025S	14.5 mm Reamer Head for RIA 2, Sterile
03.404.026S	15.0 mm Reamer Head for RIA 2, Sterile
03.404.027S	15.5 mm Reamer Head for RIA 2, Sterile
03.404.028S	16.0 mm Reamer Head for RIA 2, Sterile
03.404.029S	16.5 mm Reamer Head for RIA 2, Sterile
03.404.030S	17.0 mm Reamer Head for RIA 2, Sterile
03.404.031S	17.5 mm Reamer Head for RIA 2, Sterile
03.404.032S	18.0 mm Reamer Head for RIA 2, Sterile

ADDITIONALLY AVAILABLE ITEMS:

PART NUMBER	DESCRIPTION	
530.793	Modified Trinkle Drilling Attachment for Battery Power Line	
03.010.023	Radiographic Canal Width Estimator for IM nails	
338.10	8.0 mm Drill Bit for DHS/DCS Triple Reamer	
351.05	Tissue Protector	
351.706S **351.708S**	2.5 mm Reaming Rod with ball tip, 950 mm, sterile 2.5 mm Reaming Rod with ball tip, 1150 mm, sterile	
351.707S	2.5 mm Reaming Rod with ball tip and extension, 950 mm, sterile	

Note: For additional information, please refer to the package insert or www.e-ifu.com.

For detailed cleaning and sterilization instructions, please refer to www.depuysynthes.com/hcp/cleaning-sterilization or sterilization instructions, if provided in the instructions for use.

REFERENCES

1. Paulo Barbosa and Clifford Turen. (2012). AO teaching video: Femur—Shaft fracture 32-B2 Intramedullary nailing with the Expert Lateral Femoral Nail (LFN). Retrieved from https://surgeryreference.aofoundation.org/orthopedic-trauma/adult-trauma/femoral-shaft/simple-oblique-middle-1-3-fractures/antegrade-nailing#antegrade-nailing-approaches
2. Matthias Hansen, Dankward Höntzsch. (2006). AO teaching video: Tibia Fractures - Intramedullary Nailing with the Expert Tibial Nail (with reaming). Retrieved from https://surgeryreference.aofoundation.org/orthopedic-trauma/adult-trauma/tibial-shaft/simple-fracture-transverse/intramedullary-nailing#patient-preparation-and-approach

Please refer to the package insert for a complete list of indications, contraindications, precautions and warnings.

For further information on DePuy Synthes Companies products, please contact your local DePuy Synthes representative.

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