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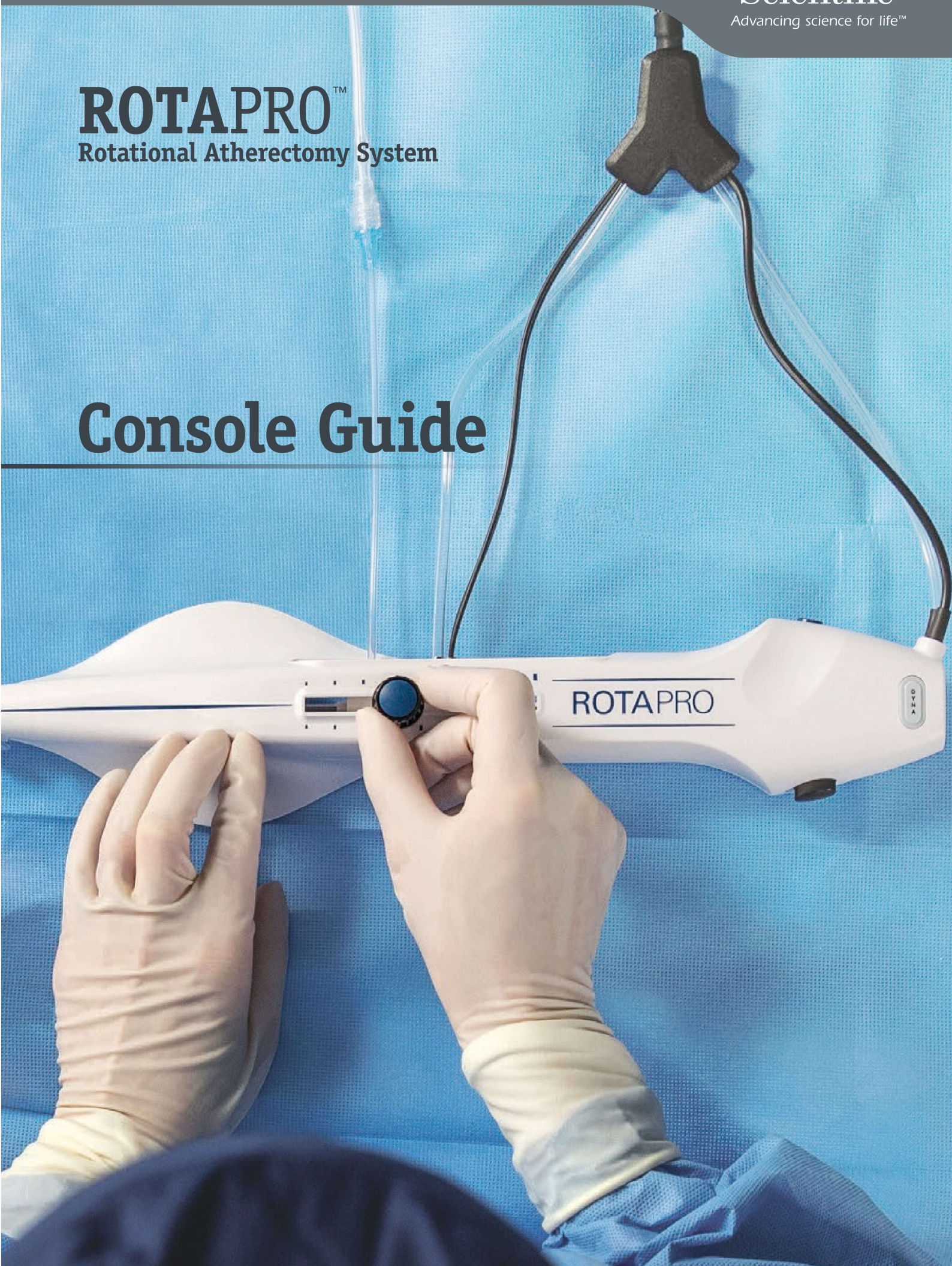
ROTAPRO™
Rotational Atherectomy System

Console Guide



Components

ROTAPRO™ Console

Rotational Speed Display (Tachometer)

Event Timer

Procedure Timer

Reset Button

Turbine Pressure Control Knob (Adjusts RPM)

Advancer Connections

Compressed Gas Connector

Electrical Connector

Fiber Optic Connector

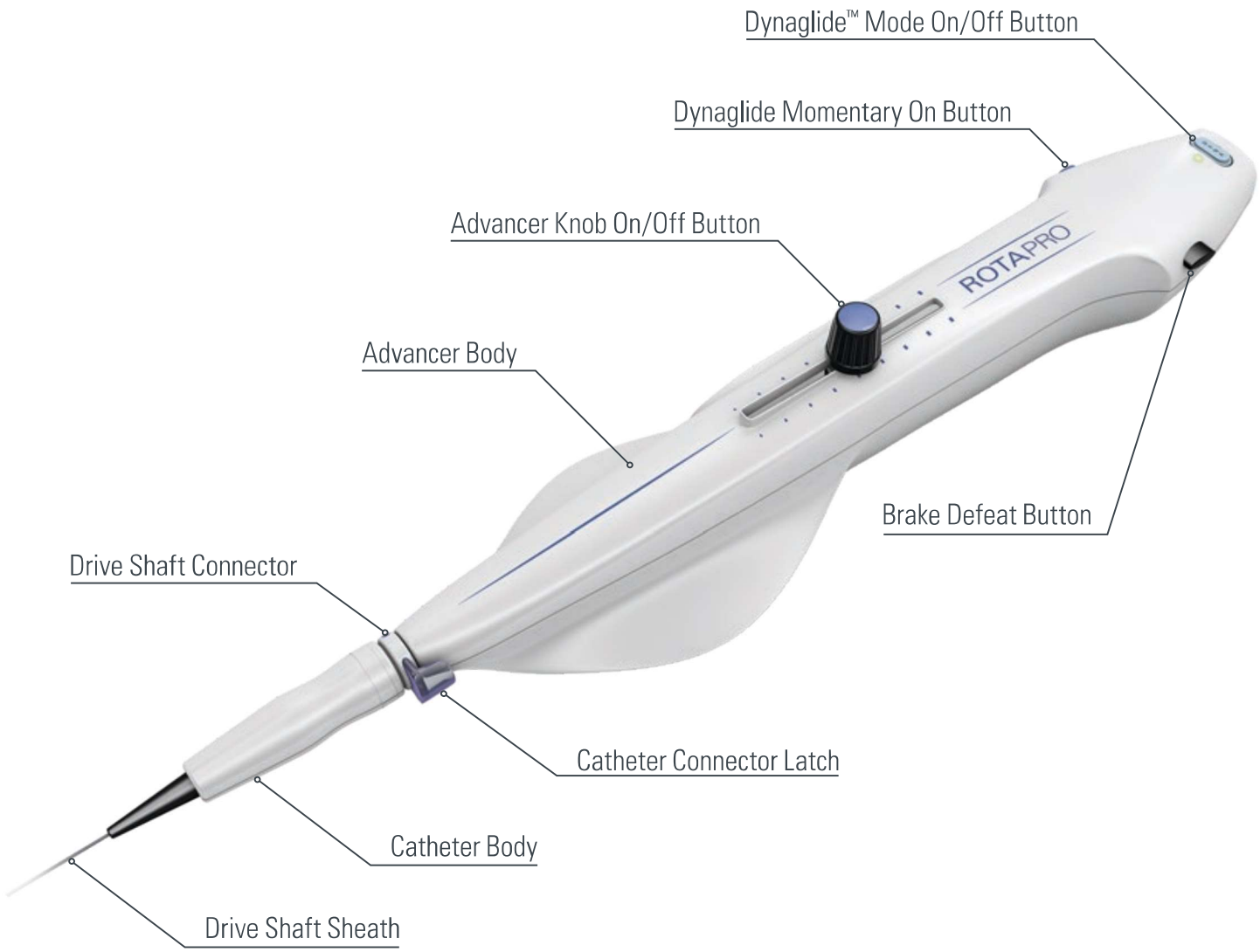
Console Back

Power ON/OFF

Power Cord Connector

Gas Line Connector

ROTAPRO™ Advancer

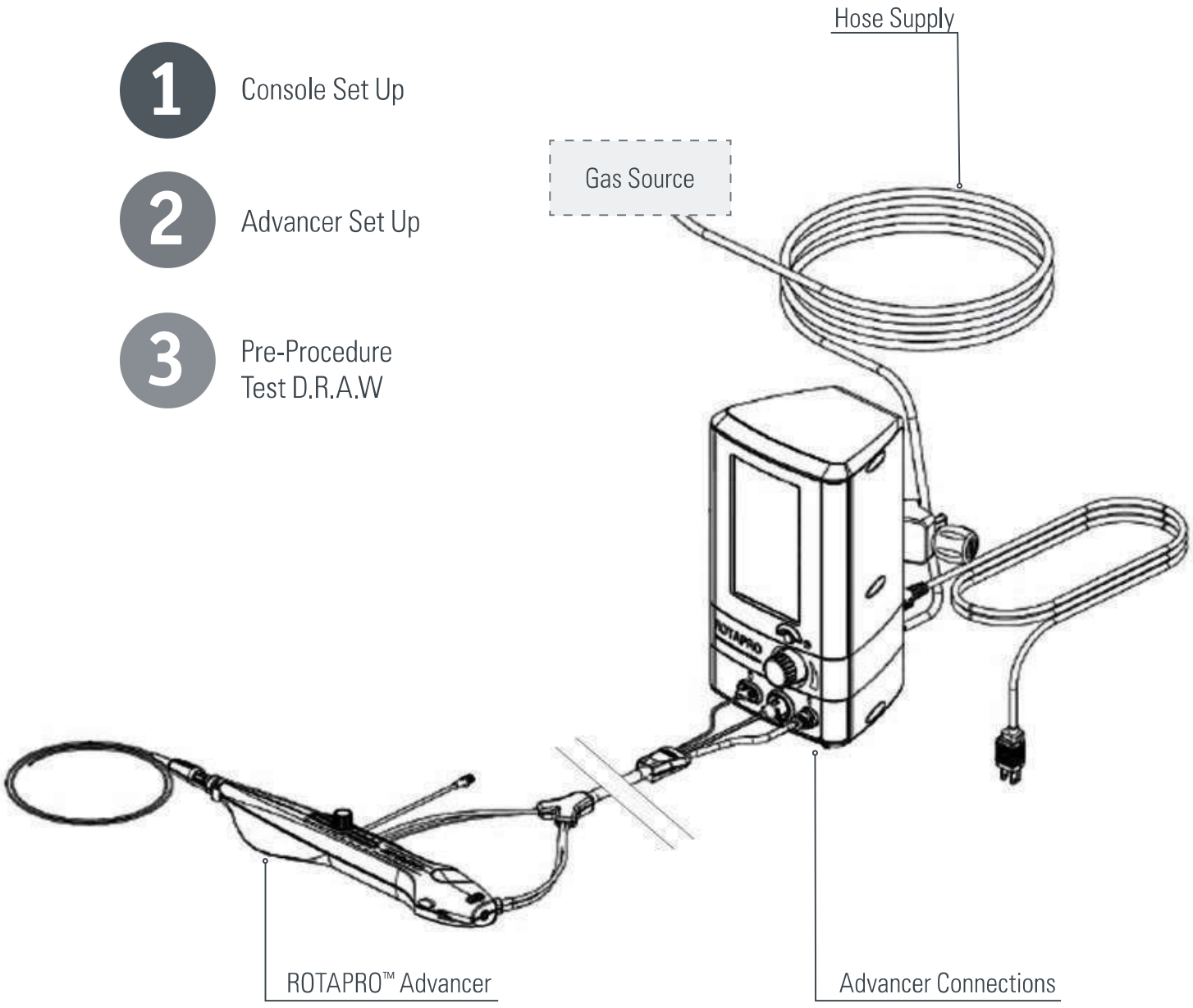


Advancer Controls

Set Up

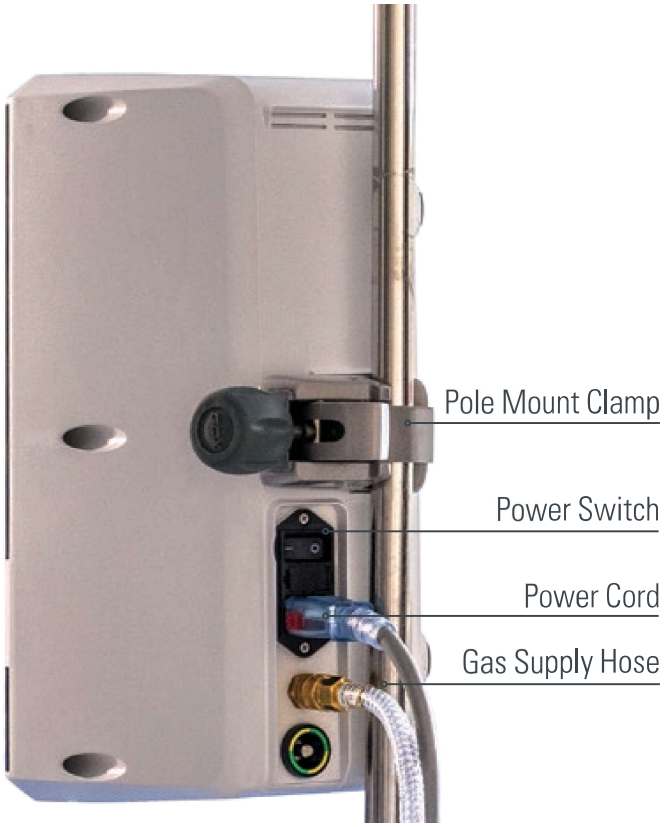
Overview

1. Console Set Up
2. Advancer Set Up
3. Pre-Procedure Test D.R.A.W



Console Set Up

1



1. Connect air hose to air supply and back of the console
2. Connect power cord
3. Open compressed air valve to supply compressed gas to the console
4. Push the console power switch
5. Check gauges to ensure proper system pressure (min 500 PSI / 90–110 PSI to the console)

Dual Stage Regulator

- Monitors gas delivered to console (90–110 PSI)
- Monitors gas contained in tank (minimum 500 PSI per case)

Pole Mounted Orientation

- Standard IV pole (1 in diameter) with five wheels and a 20 in diameter base
- Height not greater than 60 in (153.0 cm) from the floor to the top edge of the console

Advancer Set Up

2

1. Select appropriate burr size and ROTAWIRE™ (Extra Support or Floppy)
2. Load advancer/burr catheter system onto the ROTAWIRE
3. Attach WireClip™ Torquer
4. Connect fiber optic, electrical, and gas line cables to console
5. Connect saline infusion bag to infusion port

Advancer Connections:

- A Fiber Optic Connector
- B Electrical Connector
- C Gas Line Connector

Pre-Procedure Test – D.R.A.W.

3

Test system outside body

D **Drip** – Saline drip from bottom of advancer and catheter*

R **Rotate** – Burr is rotating and RPMs are stable**

A **Advancer** – Free movement of advancer knob

W **Wire** – Wire is visible and brake is functioning

ROTAGLIDE™ Lubricant

ROTAGLIDE Lubricant

- Reduces friction and improves tactile feel
- Reduces sudden drops in RPMs caused by lesion feedback
- Reduces heat generation

Instructions:

- Inject one 20 cc vial into 1000 cc saline flush bag
- Contraindicated if patient is allergic to eggs or olive oil
- Does not require refrigeration

* Never operate the ROTAPRO™ Advancer without saline infusion. Flowing saline is essential for cooling and lubricating the working parts of the advancer. Operating the advancer without proper saline infusion may result in permanent damage to the ROTAPRO Advancer.

**Do not allow the burr to remain in one location while rotating at high speeds, as this may lead to wear of the guidewire (for instance, the burr may cut the ROTAWIRE™ when rotating in the same position on the wire for extended periods of time). Gently advance or retract the burr while it is in a high-speed rotary motion.

Troubleshooting

Common Troubleshooting FAQs

- Check Pressure Indicator
- Stall Indicator
- Deceleration Indicator
- Advancer Knob On/Off Advancer Doesn't Respond
- Dynaglide™ Button Doesn't Respond
- Burr Doesn't Stop When On/Off Button is Pressed
- Unable to Reach Desired Speed

Check Pressure Indicator

What is it?

A yellow CHECK PRESSURE indication that appears when pressure is not supplied to the console.

Why is it there?

Troubleshooting feature in the absence of the legacy console gauge to help identify issues with pressure.

What should you do?

- Verify the gas supply hose connection to the console and to the gas supply.
- Verify the gas supply valve is fully open.
- Ensure adequate air supply of at least 500 PSI in tank, 90–110 PSI delivered to console.

NOTE: Console has 30 PSI indicator trigger limit. Indicator is not designed to signal that supplied pressure to the console is within the DFU range of 620.5 kPa to 758.4 kPa (90 PSI to 110 PSI).

Stall Indicator

What is it?

A safety feature that automatically stops burr rotation when the speed drops below 15,000 RPM for a ½ second or more.

Why is it there?

Signal that user is engaging the lesion with too much force and ensure the burr is not lodged.

What should you do?

- Pull back and re-platform proximal to the lesion. Actuating the advancer start/stop button should regain the RPM display.

If system still displays a STALL condition:

- If the advancer was running prior to stall, ensure saline flow. If there is no flow then advancer "burn out" may have occurred, which happens quickly.
- Ensure ALL connections are secure: electrical, fiber optic, and air.
- Ensure air supply is adequate.

If system still displays a STALL condition:

- Replace advancer and burr catheter
- Resistance is likely in the advancer/ burr catheter

Deceleration Indicator

What is it?

Safety feature that warns user of significant drops in burr rotational speed.

Why is it there?

Ensure proper procedural technique is used.

What should you do?

- Before starting ablation, **allow approximately 1 second of rotation** in the free lumen to set platform speed for each instance rotation is activated or the speed control knob is adjusted.
- **Failure to wait 1 second** before engaging lesion may result in an incorrect baseline of speed. Therefore, the deceleration feature may remain on during the procedure.
- **To reset deceleration indicators,** retract to the free lumen and deactivate rotation. Reactivate rotation and allow 1 second before engaging the lesion to baseline speed.

Issue: Advancer Knob On/Off Button Doesn't Respond

What should you do?

Test button to ensure it is functioning properly:

- Activation/Deactivation of rotation is achieved upon release of the button.
- Holding button down for 4 seconds voids activation.
- ½ second minimum press is required to protect against unintentional activation.

Check for possible causes:

- Check if Dynaglide™ mode is engaged. On/Off button is inactive in Dynaglide mode.
- Verify there is no stall or low pressure indicator on console.
- Ensure ALL connections are secure: electrical, fiber optic, and air.
- Ensure air supply is adequate.

If button still doesn't respond:

- Replace advancer and burr catheter

Issue: Dynaglide™ Momentary Button Doesn't Respond

What should you do?

Test button to ensure it is functioning properly:

- Press Dynaglide On/Off button and ensure Dynaglide mode is activated on the console and the green LED light on the advancer is on.
- Press and hold down the Dynaglide momentary button. Rotation is deactivated upon release.

Check for possible causes:

- Check if Dynaglide mode is engaged. Momentary button is inactive in normal mode.
- Verify there is no stall or low pressure indicator on console.
- Ensure ALL connections are secure: electrical, fiber optic, and air.
- Ensure air supply is adequate.

If button still doesn't respond:

- Replace advancer and burr catheter

Issue: Burr Doesn't Stop When On/Off Button is Pressed

What should you do?

- Turn speed down to Dyna speeds (60–80K) and retract the burr from the artery using the same technique as the burr exchange procedure.
- If the RPM adjustment knob does not decrease burr rotational speed, power down the console using the power switch on the back of the console. Remove the burr catheter without rotation.
- Unplugging any of the connections will also stop rotation.

Issue: Unable to Reach Desired Speed

What should you do?

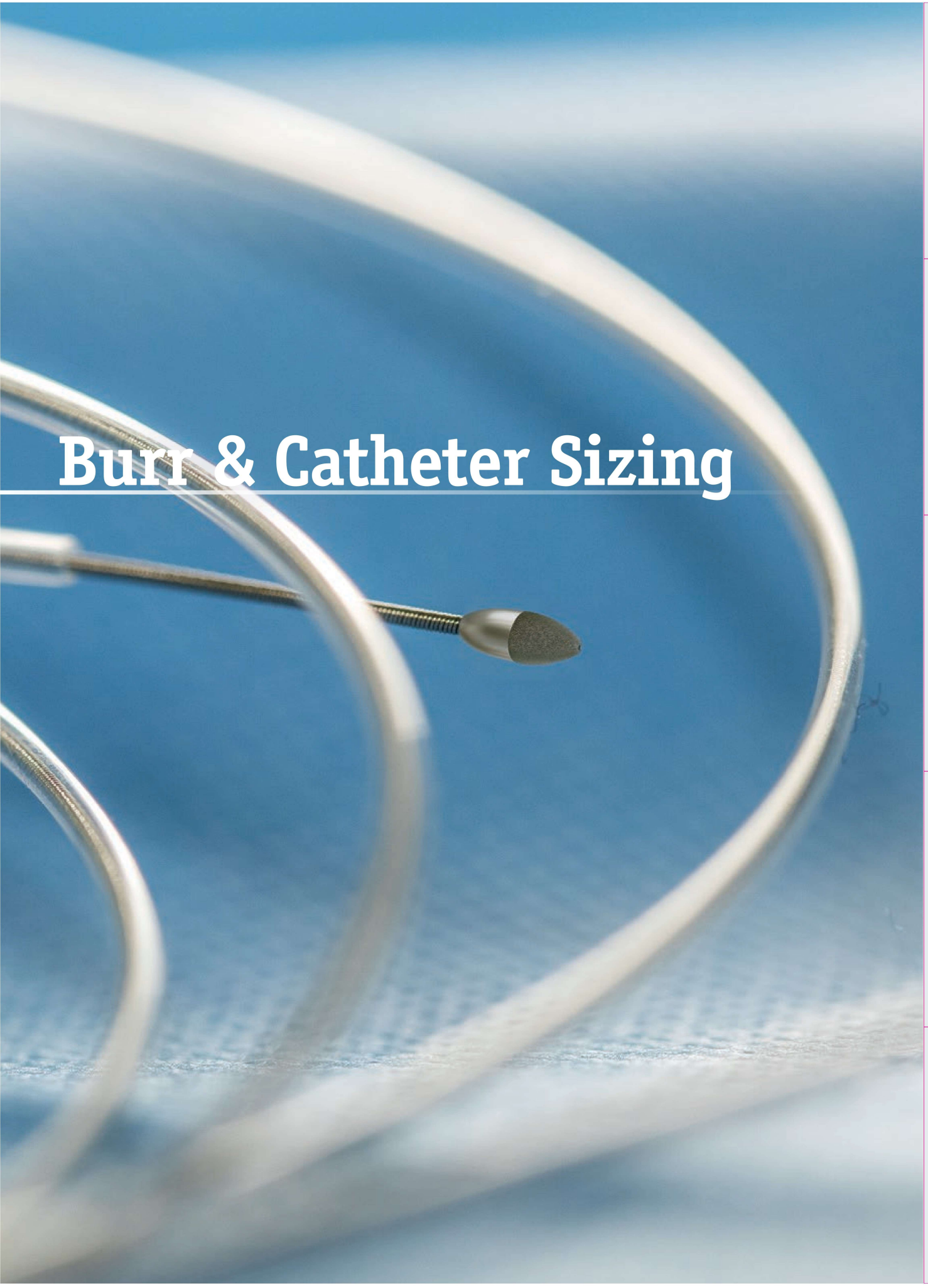
- Platform speed is automatically set at approximately 160K RPM (±15K RPM).

Check for potential causes:

- Low initial speeds are often a sign of excess resistance in the advancer, burr, or wire.

Common causes include:

- Kink in wire or burr catheter
- Tortuous anatomy
- Wire friction
- Hemostasis valve too tight
- Incorrect handshake connection
- Check air source, ensure it is on and delivering 90–110 PSI
- Check for kinks in air hoses



Burr & Catheter Sizing

Burr & Catheter Sizing

Guide sizes are based on larger lumen catheters.

Burr (mm)	Diameter (Inches)	Minimum Recommended Guide Catheter Internal Diameter (Inches)*	Recommended Guide Catheter†,‡	Recommended Burr Speed
1.25	0.049	0.060	6F	160,000–180,000
1.50	0.059	0.063	6F	160,000–180,000
1.75	0.069	0.073	7F	160,000–180,000
2.00	0.079	0.083	8F	160,000–180,000
2.15	0.085	0.089	8F	140,000–160,000
2.25	0.089	0.093	9F	140,000–160,000
2.38	0.094	0.098	9F	140,000–160,000
2.50	0.098	0.102	10F	140,000–160,000

* Add 0.004" to burr diameter to calculate minimum ID needed.
† Inside guide catheter diameter and French size may differ among manufacturers. Ensure guide is compatible with the largest burr intended to be used.
‡ Sheath size is the determinant of the minimum ID on the 1.25 mm burr.

Recommended Guide Catheter Curves

Right: FR4, Multipurpose **Left:** Q-CURVE™, CLS™, Left Back-Up

(Guide catheters with side holes can help to improve flow.)