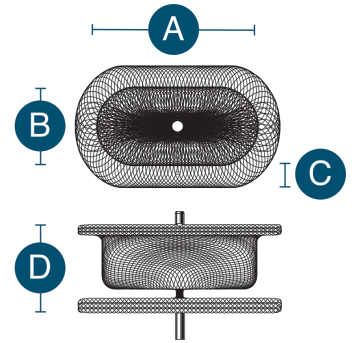


# AMPLATZER™ VALVULAR PLUG III



## SIZING AND DEVICE SELECTION

Note that the device sizes recommended in the sizing chart are greater than 20% larger in area than the corresponding area to be occluded. Select a delivery catheter with the dimensions listed below. French sizes are given as a reference. Refer to the delivery catheter labeling to find the inner diameter (ID) and ensure that it is sufficient to accommodate the device. If preferred, a delivery sheath may be used to deliver the device; make sure that the inner diameter of the sheath can accommodate the device as specified in the chart below.



## MODEL SPECIFICATIONS

Model/Reorder No.	Device Waist Length <b>A</b>	Device Waist Width <b>B</b>	Overhang <b>C</b>	Unconstrained Length <b>D</b>	Minimum Sheath Inner Diameter	Sheath minimum Size	Max Sheath Length
9-APVL3-042	4 mm	2 mm	2 mm	6.5 mm	1.78 mm/0.070 in	6 Fr	120 cm
9-APVL3-063	6 mm	3 mm	2 mm	6.5 mm	1.78 mm/0.070 in	6 Fr	120 cm
9-APVL3-084	8 mm	4 mm	2 mm	6.5 mm	1.83 mm/0.072 in	7 Fr	120 cm
9-APVL3-103	10 mm	3 mm	2 mm	6.5 mm	1.83 mm/0.072 in	7 Fr	120 cm
9-APVL3-105	10 mm	5 mm	2 mm	6.5 mm	1.83 mm/0.072 in	7 Fr	120 cm
9-APVL3-123	12 mm	3 mm	2 mm	6.5 mm	2.54 mm/0.100 in	9 Fr	120 cm
9-APVL3-125	12 mm	5 mm	2 mm	6.5 mm	2.54 mm/0.100 in	9 Fr	120 cm
9-APVL3-143	14 mm	3 mm	2 mm	6.5 mm	2.54 mm/0.100 in	9 Fr	120 cm
9-APVL3-145	14 mm	5 mm	2 mm	6.5 mm	2.54 mm/0.100 in	9 Fr	120 cm

## TEXT

\*The Amplatzer™ Valvular Plug III is delivered using either a sheath or guide catheter meeting the minimum internal diameter requirements.

# TECHNICAL PRODUCT INFORMATION

## MR Conditional

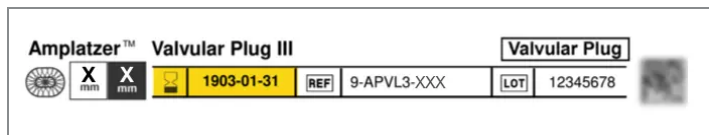
Non-clinical testing has demonstrated that the AVPIII devices implanted in conjunction with the Masters Series valves are MR Conditional. A patient with AVPIII device(s) implanted to address paravalvular leakage, in combination with the referenced valves, can be safely scanned in an MR system under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0-Tesla (3.0T)
- Maximum spatial gradient field of 19 T/m (1900 G/cm)
- Maximum MR system reported, whole-body averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode)

Under the scan conditions defined above, the device is expected to produce a maximum temperature rise of less than or equal to 3°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends radially up to 1.8 cm and 3.6 cm (respectively) from the device when imaged with a gradient echo pulse sequence in a 1.5T MR system and a spin echo pulse sequence in a 3.0T MR system.

## ETIQUETA DEL ENVASE (MUESTRA)



## RECOMMENDED ACCESSORIES

Model/Reorder No.	Sheath Size	Inner Diameter	Outer Diam of Sheath	Sheath Length
9-TV2-05F120	5F	1.82/0.072 mm/in	2.51/0.099 mm/in	120 cm

Model/Reorder No.	Sheath Size	Inner Diameter	Outer Diam of Sheath	Sheath Length
9-TV2-06F120	6F	2.11/0.083 mm/in	2.79/0.110 mm/in	120 cm

App Amplatzer™ Portfolio

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