

December 20, 2018

Re: **Use of CERTAS™ Plus Programmable Valve System in Magnetic Resonance (MR) environment**

Dear Customer:

Integra has received clearance from the Food and Drug Administration via K152152 and K182265 to market the Integra CERTAS™ Plus Valve System with MR Conditional Labeling. The devices listed in Table 1 can be safely scanned in an MR system that meets the conditions outlined in the "Magnetic Resonance Imaging (MRI) Safety Information" section below.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

MR Conditional



CERTAS™ Plus Valve System Conditions for Safe Use: Non-clinical testing demonstrated that the CERTAS Plus Programmable Valve is MR Conditional. A patient with this device can be scanned safely, immediately after placement under the following conditions:

- A horizontal cylindrical-bore MRI scanner
- Static magnetic field of 1.5 and 3 T
- Maximum spatial field gradient of 2,000 Gauss/cm (20 T/m).
- Maximum console reported SAR corresponding to first level controlled operating mode (WB SAR of 4 W/kg, Head SAR of 3.2 W/kg and partial body SAR of 4-10 W/kg)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg in the First Level Controlled Operating Mode of operation for the MR system.
- **WARNING:** Do not use Transmit / Receive RF Head coils. Only use Transmit / Receive RF Body coil or Transmit RF Body coil / Receive-only RF Head coil.
- **WARNING:** Do not use Transmit / Receive local coils that are placed directly over the location of valve.

In non-clinical testing, under the scan conditions defined above, the Codman® CERTAS™ Plus Programmable Valve is expected to produce a maximum Temperature rise of 3.4°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 25 mm from the CERTAS™ Plus Valve when imaged with a gradient echo pulse sequence and a 3T MRI System.

MRI ADDITIONAL INFORMATION

The highest spatial gradient magnetic field is commonly located off-axis, at a side wall, and near the opening of the bore of the scanner. Please refer to MRI manufacturers published value and location of the peak SG that is accessible to the patient.

SPECIFIC GUIDELINES

The valve setting should be verified after the MRI procedure.

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Table 1: List of SKU numbers that are MR Conditional

SKU	Product Name
828801PL	Codman® CERTAS™ Plus In-Line Valve with catheters & accessories
828802PL	Codman® CERTAS™ Plus In-Line Valve with unitized catheter & accessories
828803PL	Codman® CERTAS™ Plus In-Line Valve with unitized BACTISEAL® Antimicrobial Catheter & accessories
828804PL	Codman® CERTAS™ Plus In-Line Valve-only with SIPHONGUARD® Anti-Siphon Device
828805PL	Codman® CERTAS™ Plus In-Line Valve with SIPHONGUARD® Anti-Siphon Device catheters & accessories
828806PL	Codman® CERTAS™ Plus In-Line Valve with SIPHONGUARD® Anti-Siphon Device, unitized catheter & accessories
828807PL	Codman® CERTAS™ Plus In-Line Valve with SIPHONGUARD® Anti-Siphon Device, unitized BACTISEAL® Antimicrobial Catheter & accessories
828810PL	Codman® CERTAS™ Plus In-Line Small Valve only
828811PL	Codman® CERTAS™ Plus In-Line Small Valve with catheters & accessories
828813PL	Codman® CERTAS™ Plus In-Line Small Valve with unitized BACTISEAL® Antimicrobial Catheter & accessories
828814PL	Codman® CERTAS™ Plus In-Line Small Valve-only with SIPHONGUARD® Anti-Siphon Device
828815PL	Codman® CERTAS™ Plus In-Line Small Valve with SIPHONGUARD® Anti-Siphon Device catheters & accessories
828817PL	Codman® CERTAS™ Plus In-Line Small Valve with SIPHONGUARD® Anti-Siphon Device, unitized BACTISEAL® Antimicrobial Catheter & accessories
828820PL	Codman® CERTAS™ Plus Right Angle Valve only
828821PL	Codman® CERTAS™ Plus Right Angle Valve with catheters & accessories
828823PL	Codman® CERTAS™ Plus Right Angle Valve with unitized BACTISEAL® Antimicrobial Catheter & accessories
828824PL	Codman® CERTAS™ Plus Right Angle Valve-only with SIPHONGUARD® Anti-Siphon Device
828825PL	Codman® CERTAS™ Plus Right Angle Valve with SIPHONGUARD® Anti-Siphon Device catheters & accessories
828827PL	Codman® CERTAS™ Plus Right Angle Valve with SIPHONGUARD® Anti-Siphon Device, unitized BACTISEAL® Antimicrobial Catheter & accessories

We sincerely appreciate your business. If you have any further questions, please contact your local sales representative or customer service at 1-800-654-2873.

Sincerely,

V Phutane

Vijaya Phutane
Global Product Manager
Codman Specialty Surgical

This communication is intended for distribution in the US only.

- Always refer to the appropriate instructions for use for complete clinical instructions.
- Non-contractual document. The manufacturer reserves the right, without prior notice, to modify the products to improve quality.

Indications

The CERTAS Plus Programmable Valve is an implantable device that provides constant intraventricular pressure and drainage of CSF for the management of hydrocephalus.

Contraindications

These devices are contraindicated in patients receiving anticoagulants or known to have a bleeding diathesis.

Avoid shunt implantation if infection is present within the body. Delay the shunt procedure when infections such as meningitis, ventriculitis, peritonitis, bacteremia, and septicemia are present.

The BACTISEAL Catheters are contraindicated in patients with known hypersensitivity to rifampin or clindamycin hydrochloride.

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