Together, improving life

August 2023

To Whom It May Concern:

We have confirmed with the FDA that iatrogenic Atrial Septal Defect (iASD) closure is included within the current approved indications for GORE® CARDIOFORM Septal Occluder and GORE® CARDIOFORM ASD Occluder.

The relevant approved indications are as follows:
The GORE® CARDIOFORM Septal Occluder and GORE® CARDIOFORM ASD Occluder are permanently implanted devices indicated for the percutaneous, transcatheter closure of ostium secundum atrial septal defects (ASDs).

Please consult the *Instructions for Use* for a full listing of indications, contraindications, warnings and precautions.

Best regards,

Jeff Watson
Product Specialist
Medical Products Division

Consult Instructions for Use
eifu.goremedical.com

INDICATIONS FOR USE: The GORE® CARDIOFORM Septal Occluder is a permanently implanted device indicated for the percutaneous, transcatheter closure of the following defects of the atrial septum: ostium secundum atrial septal defects (ASDs). **CONTRAINDICATIONS:** The GORE® CARDIOFORM Septal Occluder is contraindicated for use in patients: unable to take antiplatelet or anticoagulant medications such as aspirin, heparin or warfarin; with anatomy where the GORE® CARDIOFORM Septal Occluder size or position would interfere with other intracardiac or intravascular structures, such as cardiac valves or pulmonary veins; with active endocarditis, or other infections producing bacteremia, or patients with known sepsis within one month of planned implantation, or any other infection that cannot be treated successfully prior to device placement; with known intracardiac thrombi.

INDICATIONS FOR USE: The GORE® CARDIOFORM ASD Occluder is a permanently implanted device indicated for the percutaneous, transcatheter closure of ostium secundum atrial septal defects (ASDs). **CONTRAINDICATIONS:** The GORE® CARDIOFORM ASD Occluder is contraindicated for use in patients: Unable to take anti-platelet or anticoagulant medications such as aspirin, heparin or warfarin; with anatomy where the GORE® CARDIOFORM ASD Occluder size or position would interfere with other intracardiac or intravascular structures, such as cardiac valves or pulmonary veins; with active endocarditis, or other infections producing bacteremia, or patients with known sepsis within one month of planned implantation, or any other infection that cannot be treated successfully prior to device placement; with known intracardiac thrombi.

Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

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